

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services**

42 CFR Parts 414, 416, 419, 482, 486, 488, and 495

[CMS–1656–FC and IFC]

RIN 0938–AS82

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Nonexcepted Off-Campus Provider-Based Department of a Hospital; Hospital Value-Based Purchasing (VBP) Program; Establishment of Payment Rates Under the Medicare Physician Fee Schedule for Nonexcepted Items and Services Furnished by an Off-Campus Provider-Based Department of a Hospital**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final rule with comment period and interim final rule with comment period.

SUMMARY: This final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2017 to implement applicable statutory requirements and changes arising from our continuing experience with these systems. In this final rule with comment period, we describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. In addition, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

Further, in this final rule with comment period, we are making changes to tolerance thresholds for clinical outcomes for solid organ transplant programs; to Organ Procurement Organizations (OPOs) definitions, outcome measures, and organ transport documentation; and to the Medicare and Medicaid Electronic Health Record Incentive Programs. We also are removing the HCAHPS Pain

Management dimension from the Hospital Value-Based Purchasing (VBP) Program.

In addition, we are implementing section 603 of the Bipartisan Budget Act of 2015 relating to payment for certain items and services furnished by certain off-campus provider-based departments of a provider. In this document, we also are issuing an interim final rule with comment period to establish the Medicare Physician Fee Schedule payment rates for the nonexcepted items and services billed by a nonexcepted off-campus provider-based department of a hospital in accordance with the provisions of section 603.

DATES: *Effective date:* This final rule with comment period and the interim final rule with comment period are effective on January 1, 2017.

Comment period: To be assured consideration, comments on: (1) The payment classifications assigned to new Level II HCPCS codes and recognition of new and revised Category I and III CPT codes in this final rule with comment period; (2) the 20-hour a week minimum requirement for partial hospitalization services in this final rule with comment period; (3) the potential limitation on clinical service line expansion or volume of services by nonexcepted off-campus PBDs in this final rule with comment period; and (4) 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 in the interim final rule with comment period must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on December 31, 2016.

ADDRESSES: In commenting, please refer to file code CMS–1656–FC when commenting on the issues in the final rule with comment period and CMS–1656–IFC when commenting on issues in the interim final rule with comment period. 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–

1656–FC or CMS–1656–IFC (as appropriate), 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–1656–FC or CMS–1656–IFC (as appropriate), 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: Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact Katherine Eastridge at (410) 786–4474.

Ambulatory Surgical Center (ASC) Payment System, contact Elisabeth Daniel at (410) 786–0237.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia at (410) 786-7236.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Measures, contact Vinitha Meyyur at (410) 786-8819.

Blood and Blood Products, contact Lela Strong at (410) 786-3213.

Cancer Hospital Payments, contact David Rice at (410) 786-6004.

Chronic Care Management (CCM) Hospital Services, contact Twi Jackson at (410) 786-1159.

CPT and Level II Alphanumeric HCPCS Codes—Process for Requesting Comments, contact Marjorie Baldo at (410) 786-4617.

CMS Web Posting of the OPSS and ASC Payment Files, contact Chuck Braver at (410) 786-9379.

Composite APCs (Low Dose Brachytherapy and Multiple Imaging), contact Twi Jackson at (410) 786-1159.

Comprehensive APCs, contact Lela Strong at (410) 786-3213.

Hospital Observation Services, contact Twi Jackson at (410) 786-1159.

Hospital Outpatient Quality Reporting (OQR) Program Administration, Validation, and Reconsideration Issues, contact Elizabeth Bainger at (410) 786-0529.

Hospital Outpatient Quality Reporting (OQR) Program Measures, contact Vinitha Meyyur at (410) 786-8819.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Twi Jackson at (410) 786-1159.

Hospital Value-Based Purchasing (VBP) Program, contact Grace Im at (410) 786-0700.

Inpatient Only Procedures List, contact Lela Strong at (410) 786-3213.

Medicare Electronic Health Record (EHR) Incentive Program, contact Kathleen Johnson at (410) 786-3295 or Steven Johnson at (410) 786-3332.

New Technology Intraocular Lenses (NTIOLs), contact Elisabeth Daniel at (410) 786-0237.

No Cost/Full Credit and Partial Credit Devices, contact Twi Jackson at (410) 786-1159.

OPSS Brachytherapy, contact Elisabeth Daniel at (410) 786-0237.

OPSS Data (APC Weights, Conversion Factor, Copayments, Cost-to-Charge Ratios (CCRs), Data Claims, Geometric Mean Calculation, Outlier Payments, and Wage Index), contact David Rice at (410) 786-6004.

OPSS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Twi Jackson at (410) 786-1159.

OPSS Exceptions to the 2 Times Rule, contact Marjorie Baldo at (410) 786-4617.

OPSS Packaged Items/Services, contact Lela Strong at (410) 786-3213.

OPSS Pass-Through Devices and New Technology Procedures/Services, contact Lela Strong at (410) 786-3213.

OPSS Status Indicators (SI) and Comment Indicators (CI), contact Marina Kushnirova at (410) 786-2682.

Organ Procurement Organization (OPO) Reporting and Communication, contact Peggye Wilkerson at (410) 786-4857 or Melissa Rice at (410) 786-3270.

Partial Hospitalization Program (PHP) and Community Mental Health Center (CMHC) Issues, contact Marissa Kellam at (410) 786-3012 or Katherine Lucas at (410) 786-7723.

Rural Hospital Payments, contact David Rice at (410) 786-6004.

Section 603 of the Bipartisan Budget Act of 2015—Items and Services Furnished by Off-Campus Departments of a Provider, contact David Rice at (410) 786-6004 or Elisabeth Daniel at (410) 786-0237.

Section 603 of the Bipartisan Budget Act of 2015—MPFS Payment Rates for Nonexcepted Off-Campus Provider-Based Departments of Hospitals, contact Geri Mondowney at (410) 786-1172, Patrick Sartini at (410) 786-9252, or Isadora Gil at (410) 786-4532.

Transplant Enforcement, contact Paula DiStabile at (410) 786-3039 or Caecilia Blondiaux at (410) 786-2190.

All Other Issues Related to Hospital Outpatient and Ambulatory Surgical Center Payments Not Previously Identified, contact Lela Strong at (410) 786-3213.

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 OPSS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with the CY 2012 OPSS/ASC proposed rule, all of the Addenda no longer appear in the **Federal Register** as part of the annual OPSS/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 OPSS 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

ACOT Advisory Committee on Organ Transplantation
 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	HCUP Healthcare Cost and Utilization Project	MR Medical review
CAUTI Catheter-associated urinary tract infection	HEU Highly enriched uranium	MRA Magnetic resonance angiography
CBSA Core-Based Statistical Area	HH QRP Home Health Quality Reporting Program	MRGFUS Magnetic Resonance Image Guided Focused Ultrasound
CCM Chronic care management	HHS Department of Health and Human Services	MRI Magnetic resonance imaging
CCN CMS Certification Number	HIE Health information exchange	MRSA Methicillin-Resistant Staphylococcus Aureus
CCR Cost-to-charge ratio	HIPAA Health Insurance Portability and Accountability Act of 1996, Public Law 104-191	MS-DRG Medicare severity diagnosis-related group
CDC Centers for Disease Control and Prevention	HOP Hospital Outpatient Payment [Panel]	MSIS Medicaid Statistical Information System
CED Coverage with Evidence Development	HOPD Hospital outpatient department	MUC Measure under consideration
CERT Comprehensive Error Rate Testing	HOP QDRP Hospital Outpatient Quality Data Reporting Program	NCCI National Correct Coding Initiative
CfC Conditions of coverage	HPMS Health Plan Management System	NEMA National Electrical Manufacturers Association
CFR Code of Federal Regulations	IBD Inflammatory bowel disease	NHSN National Healthcare Safety Network
CI Comment indicator	ICC Interclass correlation coefficient	NOTA National Organ and Transplantation Act
CLABSI Central Line [Catheter] Associated Blood Stream Infection	ICD Implantable cardioverter defibrillator	NOS Not otherwise specified
CLFS Clinical Laboratory Fee Schedule	ICD-9-CM International Classification of Diseases, Ninth Revision, Clinical Modification	NPI National Provider Identifier
CMHC Community mental health center	ICD-10 International Classification of Diseases, Tenth Revision	NPWT Negative Pressure Wound Therapy
CMS Centers for Medicare & Medicaid Services	ICH In-center hemodialysis	NQF National Quality Forum
CoP Condition of participation	ICR Information collection requirement	NQS National Quality Strategy
CPI-U Consumer Price Index for All Urban Consumers	IME Indirect medical education	NTIOL New technology intraocular lens
CPT Current Procedural Terminology (copyrighted by the American Medical Association)	IDTF Independent diagnostic testing facility	NUBC National Uniform Billing Committee
CR Change request	IGI IHS Global Insight, Inc.	OACT [CMS] Office of the Actuary
CRC Colorectal cancer	IHS Indian Health Service	OBRA Omnibus Budget Reconciliation Act of 1996, Public Law 99-509
CSAC Consensus Standards Approval Committee	I/OCE Integrated Outpatient Code Editor	O/E Observed to expected event
CT Computed tomography	IOL Intraocular lens	OIG [HHS] Office of the Inspector General
CV Coefficient of variation	IORT Intraoperative radiation treatment	OMB Office of Management and Budget
CY Calendar year	IPFQR Inpatient Psychiatric Facility Quality Reporting	ONC Office of the National Coordinator for Health Information Technology
DFO Designated Federal Official	IPPS [Hospital] Inpatient Prospective Payment System	OPD [Hospital] Outpatient Department
DIR Direct or indirect remuneration	IQR [Hospital] Inpatient Quality Reporting	OPO Organ Procurement Organization
DME Durable medical equipment	IRF Inpatient rehabilitation facility	OPPS [Hospital] Outpatient Prospective Payment System
DMEPOS Durable Medical Equipment, Prosthetic, Orthotics, and Supplies	IRF QRP Inpatient Rehabilitation Facility Quality Reporting Program	OPSF Outpatient Provider-Specific File
DRA Deficit Reduction Act of 2005, Public Law 109-171	IT Information technology	OPTN Organ Procurement and Transplantation Network
DSH Disproportionate share hospital	LCD Local coverage determination	OQR [Hospital] Outpatient Quality Reporting
EACH Essential access community hospital	LDR Low dose rate	OT Occupational therapy
EAM Extended assessment and management	LTCH Long-term care hospital	PAMA Protecting Access to Medicare Act of 2014, Public Law 113-93
ECD Expanded criteria donor	LTCHQR Long-Term Care Hospital Quality Reporting	PBD Provider-based department
EBRT External beam radiotherapy	MAC Medicare Administrative Contractor	PCHQR PPS-Exempt Cancer Hospital Quality Reporting
ECG Electrocardiogram	MACRA Medicare Access and CHIP Reauthorization Act of 2015, Public Law 114-10	PCR Payment-to-cost ratio
ED Emergency department	MAP Measure Application Partnership	PDC Per day cost
EDTC Emergency department transfer communication	MDH Medicare-dependent, small rural hospital	PDE Prescription Drug Event
EHR Electronic health record	MedPAC Medicare Payment Advisory Commission	PE Practice expense
E/M Evaluation and management	MEG Magnetoencephalography	PEPPER Program Evaluation Payment Patterns Electronic Report
ESRD End-stage renal disease	MFP Multifactor productivity	PHP Partial hospitalization program
ESRD QIP End-Stage Renal Disease Quality Improvement Program	MGCRB Medicare Geographic Classification Review Board	PHSA Public Health Service Act, Public Law 96-88
FACA Federal Advisory Committee Act, Public Law 92-463	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	PN Pneumonia
FDA Food and Drug Administration	MIPPA Medicare Improvements for Patients and Providers Act of 2008, Public Law 110-275	POS Place of service
FFS [Medicare] Fee-for-service	MLR Medical loss ratio	PPI Producer Price Index
FTE Full-time equivalent	MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173	PPS Prospective payment system
FY Fiscal year	MMEA Medicare and Medicaid Extenders Act of 2010, Public Law 111-309	PQRI Physician Quality Reporting Initiative
GAO Government Accountability Office	MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Public Law 110-173	PQRS Physician Quality Reporting System
GI Gastrointestinal	MPFS Medicare Physician Fee Schedule	QDC Quality data code
GME Graduate medical education		QIO Quality Improvement Organization
HAI Healthcare-associated infection		RFA Regulatory Flexibility Act
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems		RHQDAPU Reporting Hospital Quality Data for Annual Payment Update
HCERA Health Care and Education Reconciliation Act of 2010, Public Law 111-152		RTI Research Triangle Institute, International
HCP Health care personnel		RVU Relative value unit
HCPCS Healthcare Common Procedure Coding System		SAD Self-administered drug
HCRIS Healthcare Cost Report Information System		SAMS Secure Access Management Services
		SCH Sole community hospital
		SCOD Specified covered outpatient drugs
		SES Socioeconomic status

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I. Summary and Background

A. Executive Summary of This Document

1. Purpose

In this document, we are updating the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs) beginning January 1, 2017. 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 final rule with comment period. In addition, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

In addition, we are making changes to the conditions for coverage (CfCs) for

organ procurement organizations (OPOs); revisions to the outcome requirements for solid organ transplant programs, transplant enforcement, and for transplant documentation requirements; a technical correction to enforcement provisions for organ transplant centers; modifications to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs to reduce hospital administrative burden and to allow hospitals to focus more on patient care; and the removal of the HCAHPS Pain Management dimension from the Hospital Value-Based Purchasing (VBP) Program.

Further, we are implementing section 603 of the Bipartisan Budget Act of 2015 relating to payment for nonexcepted items and services furnished by nonexcepted off-campus provider-based departments (PBDs) of a hospital. In conjunction with implementation of section 603 in this final rule with comment period, we are issuing in this **Federal Register** document an interim final rule with comment period that establishes payment rates under the MPFS for nonexcepted items and services furnished by nonexcepted off-campus PBDs of hospitals.

2. Summary of the Major Provisions

- *OPPS Update*: For CY 2017, we are increasing the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 1.65 percent. This increase factor is based on the hospital inpatient market basket percentage increase of 2.7 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the multifactor productivity (MFP) adjustment of 0.3 percentage point, and minus a 0.75 percentage point adjustment required by the Affordable Care Act. Based on this update, we estimate that total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix), for CY 2017 will be approximately \$773 million, an increase of approximately \$5.0 billion compared to estimated CY 2016 OPPS payments.

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

- *Rural Adjustment*: We are continuing the adjustment of 7.1 percent to the OPPS payments to certain rural sole community hospitals (SCHs), including essential access community

hospitals (EACHs). This adjustment applies 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 2017, we are continuing 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. Based on those data, a target PCR of 0.91 will be used to determine the CY 2017 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments will be the additional payments needed to result in a PCR equal to 0.91 for each cancer hospital.

- *Comprehensive APCs*: For CY 2017, we are not making extensive changes to the already established methodology used for C-APCs. However, we are creating 25 new C-APCs that meet the previously established criteria, which, when combined with the existing 37 C-APCs, will bring the total number to 62 C-APCs as of January 1, 2017.

- *Chronic Care Management (CCM)*: For CY 2017, we are making some minor changes to certain CCM scope-of-service elements. We refer readers to the CY 2017 MPFS final rule with comment period for a detailed discussion of these changes to the scope of service elements for CCM. We are applying these changes to CCM furnished to hospital outpatients.

- *Device-Intensive Procedures*: For CY 2017, we are finalizing our policy of determining the payment rate for any device-intensive procedure that is assigned to an APC with fewer than 100 total claims for all procedures in the APC to be based on the median cost instead of the geometric mean cost. We believe that this approach will mitigate significant year-to-year payment rate fluctuations while preserving accurate claims-data-based payment rates for low volume device-intensive procedures. In addition, we are revising the device intensive calculation methodology and calculating the device offset amount at the HCPCS code level rather than at the APC level to ensure that device intensive status is properly assigned to all device-intensive procedures.

- *Outpatient Laboratory Tests*: For CY 2017, we are discontinuing the use of the "L1" modifier to identify unrelated laboratory tests on claims. In addition, we are expanding the laboratory packaging exclusion that currently

applies to Molecular Pathology tests to all laboratory tests designated as advanced diagnostic laboratory tests (ADLTs) that meet the criteria of section 1834A(d)(5)(A) of the Act.

- **Packaging Policies:** The OPPS currently packages many categories of items and services that are typically provided as part of the outpatient hospital service (for example, operating and recovery room, anesthesia, among others). Packaging encourages hospital efficiency, flexibility, and long-term cost containment, and it also promotes the stability of payment for services over time. In CY 2014 and 2015, we added several new categories of packaged items and services. Among these were laboratory tests, ancillary services, services described by add-on codes, and drugs used in a diagnostic test or surgical procedure. For CY 2017, we are aligning the packaging logic for all of the conditional packaging status indicators so that packaging would occur at the claim level (instead of based on the date of service) to promote consistency and ensure that items and services that are provided during a hospital stay that may span more than one day are appropriately packaged according to OPPS packaging policies.

- **Payment Modifier for X-Ray Films:** 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)(i) of the Act provides that, effective for services furnished during 2017 or any subsequent year, the payment under the OPPS 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 OPPS (without application of this paragraph and before application of any other adjustment) shall be reduced by 20 percent. We are requiring that, effective for services furnished on or after January 1, 2017, hospitals are required to use a modifier on claims for X-rays that are taken using film. The use of this modifier will result in a 20-percent payment reduction for the X-ray service, as specified under section 1833(t)(16)(F)(i) of the Act, of the determined OPPS payment amount (without application of paragraph (F) and before any other adjustments under section 1833(t)).

- **Payment for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Departments of a Provider:** We are implementing section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74). This provision requires that certain items and services furnished in certain off-campus PBDs shall not be

considered covered OPD services for purposes of OPPS payment and those nonexcepted items and services will instead be paid “under the applicable payment system” beginning January 1, 2017. We are finalizing, with modification, the policies we proposed relating to which off-campus PBDs and which items and services furnished by such off-campus PBDs may be excepted from application of payment changes under this provision.

In addition, we are establishing that the Medicare Physician Fee Schedule (MPFS) will be the “applicable payment system” for the majority of the nonexcepted items and services furnished by nonexcepted off-campus PBDs. We are establishing new site-of-service payment rates under the MPFS to pay nonexcepted off-campus PBDs for the furnishing of nonexcepted items and services. These nonexcepted items and services must be reported on the institutional claim form and identified with a newly established claims processing modifier.

- **Ambulatory Surgical Center Payment Update:** For CY 2017, we are increasing payment rates under the ASC payment system by 1.9 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This increase is based on a projected CPI-U update of 2.2 percent minus a multifactor productivity adjustment required by the Affordable Care Act of 0.3 percentage point. Based on this update, we estimate that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix), for CY 2017 will be approximately \$4,478 million, an increase of approximately \$177 million compared to estimated CY 2016 Medicare payments.

- **Hospital Outpatient Quality Reporting (OQR) Program:** For the Hospital OQR Program, we are establishing measures and policies for the CY 2018 payment determination, the CY 2019 payment determination and the CY 2020 payment determination and subsequent years. For the CY 2018 payment determination and subsequent years, we are finalizing, as proposed, that we will publicly display data on the *Hospital Compare* Web site, or other CMS Web site, as soon as possible after measure data have been submitted to CMS. In addition, we are finalizing, as proposed, that hospitals will generally have approximately 30 days to preview their data. Lastly, we are finalizing, as proposed, that we also will announce the timeframes for the preview period on a CMS Web site and/or on our applicable listservs. For the CY 2019

payment determination and subsequent years, we are finalizing, as proposed, an extension of the time for filing extraordinary circumstances extensions or exemptions (ECE) requests from 45 days to 90 days from the date that the extraordinary circumstance occurred. For the CY 2020 payment determination and subsequent years, we are finalizing, as proposed, a total of seven measures: Two claims-based measures and five Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures. The two claims-based measures are: (1) OP–35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy and (2) OP–36: Hospital Visits after Hospital Outpatient Surgery (NQF #2687). The five survey-based measures are: (1) OP–37a: OAS CAHPS—About Facilities and Staff; (2) OP–37b: OAS CAHPS—Communication About Procedure; (3) OP–37c: OAS CAHPS—Preparation for Discharge and Recovery; (4) OP–37d: OAS CAHPS—Overall Rating of Facility; and (5) OP–37e: OAS CAHPS—Recommendation of Facility.

- **Ambulatory Surgical Center Quality Reporting (ASCQR) Program:** For the ASCQR Program, we are finalizing our proposals for the CY 2018 payment determination, the CY 2019 payment determination, and the CY 2020 payment determination and subsequent years. For the CY 2018 payment determination and subsequent years, we are finalizing, as proposed, that we will publicly display data on the *Hospital Compare* Web site, or other CMS Web site, as soon as possible after measure data have been submitted to CMS. In addition, we are finalizing, as proposed, that ASCs will generally have approximately 30 days to preview their data. Lastly, we are finalizing, as proposed, that we will announce the timeframes for the preview period on a CMS Web site and/or on our applicable listservs. For the CY 2019 payment determination and subsequent years, we are finalizing our proposal to change the submission deadline to May 15 for all data submitted via a CMS Web-based tool. We also are finalizing, as proposed, the extension of the submission deadline for filing extraordinary circumstances extensions or exemptions (ECE) requests from 45 days to 90 days. For the CY 2020 payment determination and subsequent years, we are finalizing, as proposed, a total of seven measures: Two measures collected via a CMS Web-based tool and five Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and

Systems (OAS CAHPS) Survey-based measures. The two measures that require data to be submitted directly to CMS via a CMS Web-based tool are: (1) ASC-13: Normothermia Outcome and (2) ASC-14: Unplanned Anterior Vitrectomy. The five survey-based measures are: (1) ASC-15a: OAS CAHPS—About Facilities and Staff; (2) ASC-15b: OAS CAHPS—Communication About Procedure; (3) ASC-15c: OAS CAHPS—Preparation for Discharge and Recovery; (4) ASC-15d: OAS CAHPS—Overall Rating of Facility; and (5) ASC-15e: OAS CAHPS—Recommendation of Facility.

- *Hospital Value-Based Purchasing (VBP) Program Update:* Section 1886(o) of the Act requires the Secretary to establish a Hospital VBP Program under which value-based incentive payments are made in a fiscal year to hospitals based on their performance on measures established for a performance period for such fiscal year. In this final rule with comment period, we are removing the HCAHPS Pain Management dimension from the Hospital VBP Program, beginning with the FY 2018 program year.

- *Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs:* In this final rule, we are making changes to the objectives and measures of meaningful use for Modified Stage 2 and Stage 3 starting with the EHR reporting periods in CY 2017. Under both Modified Stage 2 in 2017 and Stage 3 in 2017 and 2018, for eligible hospitals and CAHs attesting to CMS, we are eliminating the Clinical Decision Support (CDS) and Computerized Provider Order Entry (CPOE) objectives and measures, and lowering the reporting thresholds for a subset of the remaining objectives and measures, generally to the Modified Stage 2 thresholds. The reduction of measure thresholds is intended to respond to input we have received from hospitals, hospital associations, health systems, and vendors expressing concerns about the established measures. The revised requirements focus on reducing hospital administrative burden, allowing eligible hospitals and CAHs attesting to CMS to focus more on providing quality patient care, as well as focus on updating and optimizing CEHRT functionalities to sufficiently meet the requirements of the EHR Incentive Program and prepare for Stage 3 of meaningful use. Based on the public comments we received, we are finalizing a policy that these changes to the objectives and measures apply for all eligible hospitals and CAHs that attest to CMS, including eligible hospitals and CAHs that are eligible to

participate in both the Medicare and Medicaid EHR Incentive Programs.

In addition, we are changing the EHR reporting period in CY 2016 and 2017 for eligible professionals, eligible hospitals, and CAHs; reporting requirements for eligible professionals, eligible hospitals, and CAHs that are new participants in 2017; and the policy on measure calculations for actions outside the EHR reporting period. Finally, we are making a one-time significant hardship exception from the 2018 payment adjustment for certain eligible professionals who are new participants in the EHR Incentive Program in 2017 and are transitioning to the Merit-Based Incentive Payment System in 2017. We believe these changes are responsive to additional stakeholder feedback received through both correspondence and in-person meetings and will result in continued advancement of certified EHR technology utilization, particularly among those eligible professionals, eligible hospitals and CAHs that have not previously achieved meaningful use, and result in a program more focused on supporting interoperability and data sharing for all participants under the Medicare and Medicaid EHR Incentive Programs.

- *Transplant Performance Thresholds:* With respect to solid organ transplant programs, we are restoring the effective tolerance range for clinical outcomes that was allowed in our original 2007 rule. These outcome requirements in the Medicare Conditions of Participation (CoPs) have been affected by the nationwide improvement in transplant outcomes, making it now more difficult for transplant programs to maintain compliance with, in effect, increasingly stringent Medicare standards for patient and graft survival. We expect that our policies will increase access to organ transplants while continuing to protect Medicare beneficiaries.

- *Organ Procurement Organizations (OPOs) Changes:* In this final rule with comment period, we are: Changing the current “eligible death” definition to be consistent with the OPTN definition; modifying CMS current outcome measures to be consistent with yield calculations currently utilized by the SRTR; and modifying current requirements for documentation of donor information which is sent to the transplant center along with the organ.

3. Summary of Costs and Benefits

In sections XXIII. and XXIV. of this final rule with comment period, we set forth a detailed analysis of the regulatory and Federalism impacts that

these changes will have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of the OPSS Update

(1) Impacts of All OPSS Changes

Table 52 in section XXIII. of this final rule with comment period displays the distributional impact of all the OPSS changes on various groups of hospitals and CMHCs for CY 2017 compared to all estimated OPSS payments in CY 2016. We estimate that the policies in this final rule with comment period will result in a 1.7 percent overall increase in OPSS payments to providers. We estimate that total OPSS payments for CY 2017, including beneficiary cost-sharing, to the approximate 3,906 facilities paid under the OPSS (including general acute care hospitals, children’s hospitals, cancer hospitals, and CMHCs) will increase by approximately \$773 million compared to CY 2016 payments, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our 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 15.0 percent decrease in CY 2017 payments to CMHCs relative to their CY 2016 payments.

(2) Impacts of the Updated Wage Indexes

We estimate that our update of the wage indexes based on the FY 2017 IPPS final rule wage indexes results in no change for urban hospitals and a 0.3 percent increase for 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 Rural Adjustment and the Cancer Hospital Payment Adjustment

There are no significant impacts of our CY 2017 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not making any change in policies for determining the rural and cancer hospital payment adjustments, and 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 OPD fee schedule increase factor of 1.65 percent to the conversion factor for CY 2017 will 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 will experience increases of approximately 1.7 percent for urban hospitals and 2.2 percent for rural hospitals. Classifying hospitals by teaching status or type of ownership suggests that these hospitals will receive similar increases.

b. Impacts of the ASC Payment Update

For impact purposes, the surgical procedures on the ASC list of covered procedures are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The percentage change in estimated total payments by specialty groups under the CY 2017 payment rates compared to estimated CY 2016 payment rates ranges between 12 percent for cardiovascular system procedures and -15 percent for hemic and lymphatic system procedures.

c. Impacts of the Hospital OQR Program

We do not expect our CY 2017 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 CY 2017 policies to significantly affect the number of ASCs that do not receive a full annual payment update.

e. Impacts for Implementation of Section 603 of the Bipartisan Budget Act of 2015

We estimate that implementation of section 603 of Public Law 114-74 in this interim final rule with comment period will reduce Medicare Part B expenditures by approximately \$50 million in CY 2017, relative to a baseline where section 603 was not implemented in CY 2017. This estimate is a significantly lower impact than the \$330 million reduction estimated for the CY 2017 OPSS proposed rule. This lower impact estimate is primarily a result of changes in technical assumptions regarding the impact of this provision, not a result of the change in payment policy.

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 (MCTRJCA, Pub. L. 112-96), enacted on February 22, 2012; the American Taxpayer Relief Act of 2012 (Pub. L. 112-240), enacted January 2, 2013; the Pathway for SGR Reform Act of 2013 (Pub. L. 113-67) enacted on December 26, 2013; the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113-93), enacted on March 27, 2014; the Medicare Access and CHIP

Reauthorization Act (MACRA) of 2015 (Pub. L. 114-10), enacted April 16, 2015; the Bipartisan Budget Act of 2015 (Pub. L. 114-74), enacted November 2, 2015; and the Consolidated Appropriations Act, 2016 (Pub. L. 114-113), enacted on December 18, 2015.

Under the OPSS, 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 OPSS includes payment for most hospital outpatient services, except those identified in section I.C. of this final rule with comment period. Section 1833(t)(1)(B) of the Act provides for payment under the OPSS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by CMHCs), and certain inpatient hospital services that are paid under Medicare Part B.

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

All services and items within an APC group are comparable clinically and with respect to resource use (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 OPSS may be made in one of two ways. Section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as "transitional pass-through payments," for at least 2 but not more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not

eligible for transitional pass-through payments, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

C. Excluded OPPS Services and Hospitals

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

services furnished by nonexcepted off-campus provider-based departments from the definition of covered outpatient department services.

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/index.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 continues to be technical in nature; is governed by the provisions of the FACA; may convene up to three meetings per year; 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 current charter was renewed 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 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 will transition to one meeting per year, which will be scheduled in the summer (81 FR 31941).

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.

Each of these subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended at the August 22, 2016 meeting that the subcommittees continue. We accepted this recommendation.

Discussions of the other recommendations made by the Panel at the March 14, 2016 and August 22, 2016 Panel meetings are included in the sections of this final rule with comment period that are specific to each recommendation. For discussions of earlier Panel meetings and recommendations, we refer readers to previously published OPSS/ASC proposed and final rules, the CMS Web site mentioned earlier in this section, and the FACA database at: <http://facadatabase.gov/>.

F. Public Comments Received on the CY 2016 OPSS/ASC Final Rule With Comment Period

We received 25 timely pieces of correspondence on the CY 2016 OPSS/

ASC final rule with comment period that appeared in the **Federal Register** on November 13, 2015 (80 FR 70298), 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). Summaries of the public comments on new or replacement Level II HCPCS codes are set forth in this CY 2017 final rule with comment period under the appropriate subject matter headings.

II. Updates Affecting OPSS Payments

A. Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review not less often than annually and revise the relative payment weights for APCs. In the April 7, 2000 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 the CY 2017 OPSS/ASC proposed rule (81 FR 45615), for CY 2017, we proposed to recalibrate the APC relative payment weights for services furnished on or after January 1, 2017, and before January 1, 2018 (CY 2017), using the same basic methodology that we described in the CY 2016 OPSS/ASC final rule with comment period (80 FR 70309 through 70321). That is, we proposed 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 2017, we used 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, 2015, and before January 1, 2016.

Addendum N to the proposed rule included the proposed list of bypass codes for CY 2017. The proposed list of bypass codes contains codes that were reported on claims for services in CY 2015 and, therefore, includes codes that were in effect in CY 2015 and used for billing, but were deleted for CY 2016. We retained these deleted bypass codes on the proposed CY 2017 bypass list

because these codes existed in CY 2015 and were covered OPD services in that period, and CY 2015 claims data are used to calculate CY 2017 payment rates. Keeping these deleted bypass codes on the bypass list potentially allows us to create more “pseudo” single procedure claims for ratesetting purposes. “Overlap bypass codes” that are members of the proposed multiple imaging composite APCs were identified by asterisks (*) in the third column of Addendum N to the proposed rule. HCPCS codes that we proposed to add for CY 2017 were identified by asterisks (*) in the fourth column of Addendum N.

We did not receive any public comments on our general proposal to recalibrate the relative payment weights for each APC based on claims and cost report data for HOPD services or on our proposed bypass code process. Therefore, we are adopting as final the proposed “pseudo” single claims process and the final CY 2017 bypass list of 194 HCPCS codes, as displayed in Addendum N to this final rule with comment period (which is available via the Internet on the CMS Web site). For this final rule with comment period, for the purpose of recalibrating the final APC relative payment weights for CY 2017, we used approximately 86 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, 2015, and before January 1, 2016. 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 2017 OPSS/ASC final rule with comment period on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

Table 1 below contains the list of codes that we are removing from the CY 2017 bypass list.

TABLE 1—HCPCS CODES REMOVED FROM THE CY 2017 BYPASS LIST

HCPCS code	HCPCS short descriptor
95925	Somatosensory testing.
95808	Polysom any age 1–3> param.
90845	Psychoanalysis.
96151	Assess hlth/behave subseq.
31505	Diagnostic laryngoscopy.
95872	Muscle test one fiber.

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

For CY 2017, in the CY 2017 OPSS/ASC proposed rule (81 FR 45616), we

proposed to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. To calculate the APC costs on which the CY 2017 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 2015 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most cases, are from CY 2014. For the proposed CY 2017 OPPS payment rates, we used the set of claims processed during CY 2015. 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>.

To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2015 (the year of claims data we used to calculate the proposed CY 2017 OPPS payment rates) and found that the National Uniform Billing Committee (NUBC) did not add any new revenue codes to the NUBC 2015 Data Specifications Manual.

In accordance with our longstanding policy, we calculated CCRs for the standard and nonstandard cost centers accepted by the electronic cost report database. In general, the most detailed level at which we calculated CCRs was the hospital-specific departmental level. For a discussion of the hospital-specific overall ancillary CCR calculation, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 67983 through 67985). The calculation of blood costs is a longstanding exception (since the CY 2005 OPPS) to this general methodology for calculation of CCRs used for converting charges to costs on each claim. This exception is discussed in detail in the CY 2007 OPPS/ASC final rule with comment period and discussed further in section II.A.2.b.(1) of the proposed rule (81 FR 45617) and of this final rule with comment period.

Comment: One commenter supported the CY 2014 final rule transitional policy of excluding providers that use a "square foot" methodology to calculate CCRs used to estimate costs associated with the CT and MRI APCs for CYs

2014–2017, as discussed in the CY 2017 OPPS proposed rule claims accounting narrative on pages 33 through 37, that was made available under supporting documentation for the CY 2017 OPPS/ASC proposed rule on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>. However, the commenter opposed the provision of the CY 2014 final rule policy that was discussed in the CY 2017 OPPS proposed rule claims accounting narrative that sunsets this transitional policy after CY 2017.

Response: We thank the commenter for its support of our proposed CY 2017 policy. In response to the commenter's concern about the sunset of the transitional policy after CY 2017, while CY 2018 payment policies will be addressed in the CY 2018 OPPS/ASC proposed rule, we note that the sunset of this transitional policy for CY 2018 was discussed in the CY 2014 OPPS/ASC final rule with comment period. We believe that 4 years is sufficient time for hospitals that have not done so to transition to a more accurate cost allocation method and for the related data to be available for ratesetting purposes. After consideration of the public comment we received on the general CCR process, we are finalizing using the hospital-specific overall ancillary and departmental CCRs to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk and the established methodology for CY 2017.

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

In this section of this final rule with comment period, we discuss the use of claims to calculate the OPPS payment rates for CY 2017. The Hospital OPPS page on the CMS Web site on which this final rule with comment period is posted (<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>) provides an accounting of claims used in the development of the final payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, below in this section we discuss the file of claims that comprises the data set that is available for purchase 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 purchasing the "OPPS Limited Data Set," which now includes the additional variables previously available only in the OPPS Identifiable Data Set,

including ICD–9–CM diagnosis codes and revenue code payment amounts. This file is derived from the CY 2015 claims that were used to calculate the payment rates for the CY 2017 OPPS.

In the history of the OPPS, we have traditionally established the scaled relative weights on which payments are based using APC median costs, which is a process described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188). However, as discussed in more detail in section II.A.2.f. of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271), we finalized the use of geometric mean costs to calculate the relative weights on which the CY 2013 OPPS payment rates were based. While this policy changed the cost metric on which the relative payments are based, the data process in general remained the same, under the methodologies that we used to obtain appropriate claims data and accurate cost information in determining estimated service cost. For CY 2017, in the CY 2017 OPPS/ASC proposed rule (81 FR 45616), we proposed to continue to use geometric mean costs to calculate the relative weights on which the CY 2017 OPPS payment rates are based.

We did not receive any public comments on this proposed process and are finalizing our proposed methodology for calculating geometric mean costs for purposes of creating relative payment weights and subsequent APC payment rates for the CY 2017 OPPS. We used the methodology described in sections II.A.2.a. through II.A.2.d. of this final rule with comment period to calculate the costs we used to establish the relative payment weights used in calculating the final OPPS payment rates for CY 2017 shown in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site). We refer readers to section II.A.4. of this final rule with comment period for a discussion of the conversion of APC costs to scaled payment weights.

For details of the claims process used in this final rule with comment period, we refer readers to the claims accounting narrative under supporting documentation for this CY 2017 OPPS/ASC final rule with comment period on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

a. Recommendations of the Advisory Panel on Hospital Outpatient Payment (the Panel) Regarding Data Development

As we discussed in the CY 2017 OPPTS/ASC proposed rule (81 FR 45616 through 45617), at the March 14, 2016 meeting of the Panel, we presented our standard analysis of APCs, specifically those APCs for which geometric mean costs in the CY 2015 claims data through September 2015 varied significantly from the CY 2014 claims data used for the CY 2016 OPPTS/ASC final rule with comment period. At the March 14, 2016 Panel meeting, the Panel made three recommendations related to the data process. The Panel's data-related recommendations and our responses follow.

Recommendation: The Panel recommends that CMS provide the Data Subcommittee a list of APCs fluctuating significantly in costs prior to each Panel meeting.

CMS Response: We accepted this recommendation.

Recommendation: The Panel recommends that the work of the Data Subcommittee continue.

CMS Response: We accepted this recommendation.

Recommendation: The Panel recommends that Michael Schroyer continue serving as subcommittee Chair for the August 2016 HOP Panel.

CMS Response: We accepted this recommendation.

At the August 22, 2016 meeting of the Panel, we provided the Data Committee a list of APCs for CY 2017 for which geometric mean costs in the CY 2015 claims data varied significantly from the CY 2014 claims data used for the CY 2016 OPPTS/ASC final rule with comment period. At the August 22, 2016 Panel meeting, the Panel made four recommendations related to the data process. The Panel's data-related recommendations and our responses follow.

Recommendation: The Panel recommends that CMS provide the Data Subcommittee a list of APCs fluctuating significantly in costs prior to each Panel meeting.

CMS Response: We are accepting this recommendation.

Recommendation: The Panel recommends that CMS provide the Data Subcommittee a presentation on the claims accounting process prior to each HOP Panel meeting.

CMS Response: We are accepting this recommendation.

Recommendation: The Panel recommends that the work of the data subcommittee continue.

CMS Response: We are accepting this recommendation.

Recommendation: The Panel recommends that Michael Schroyer continue serving as Chair of the Data Subcommittee.

CMS Response: We are accepting this recommendation.

b. Calculation of Single Procedure APC Criteria-Based Costs

(1) Blood and Blood Products

(a) Methodology

Since the implementation of the OPPTS 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 OPPTS payments for specific blood product APCs.

For CY 2017, in the CY 2017 OPPTS/ASC proposed rule (81 FR 45617), we proposed to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers, and past public comments indicating that the former OPPTS 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 proposed to continue to simulate blood CCRs for each hospital that does not report a blood cost center by calculating the ratio of the blood-specific CCRs to hospitals' overall CCRs for those hospitals that do report costs and charges for blood cost centers. We also proposed to apply this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports in order to simulate blood-specific CCRs for those hospitals. We proposed to calculate the costs upon which the CY 2017 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 2017 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 CY 2014 OPPTS/ASC final rule with comment period (78 FR 74861 through 74910), the CY 2015 OPPTS/ASC final rule with comment period (79 FR 66798 through 66810), and the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70325 through 70339), we defined a comprehensive APC (C-APC) as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Under this policy, we include the costs of blood and blood products when calculating the overall costs of these C-APCs. We proposed to continue to apply the blood-specific CCR methodology described in this section when calculating the costs of the blood and blood products that appear on claims with services assigned to the C-APCs. Because the costs of blood and blood products will be reflected in the overall costs of the C-APCs (and, as a result, in the payment rates of the C-APCs), we proposed 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 OPPTS/ASC final rule with comment period (79 FR 66796)).

We invited public comments on these proposals. We also referred readers to Addendum B to the proposed rule (which was available via the Internet on the CMS Web site) for the proposed CY 2017 payment rates for blood and blood products (which were identified with status indicator "R"). For a more detailed discussion of the blood-specific CCR methodology, we refer readers to the CY 2005 OPPTS 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).

Comment: Commenters supported the proposal to continue to separately pay for blood and blood products using a blood-specific CCR methodology.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our CY 2017 proposal to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology. The final CY 2017 payment rates for blood and blood products (which are identified with status indicator "R") are reflective of the use of the hospital-specific simulated blood-specific CCR methodology and can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

(b) Solicitation of Public Comments

As discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70323), we are in the process of examining the current set of HCPCS P-codes for blood products, which became effective many years ago. Because these HCPCS P-codes were created many years ago, we are considering whether this code set could benefit from some code descriptor revisions, updating, and/or consolidation to make these codes properly reflect current product descriptions and utilization while minimizing redundancy and potentially outdated descriptors. In the CY 2017 OPPS/ASC proposed rule (81 FR 45617 through 45618), we requested public comments regarding the adequacy and necessity (in terms of the existing granularity) of the current descriptors for the HCPCS P-codes describing blood products. Specifically, there are three main categories of blood products: Red blood cells; platelets; and plasma. In each of these categories, there are terms that describe various treatments or preparations of the blood products, with each, in several cases, represented individually and in combination. For example, for pheresis platelets, there are codes for "leukocyte reduced," "irradiated," "leukocyte reduced + irradiated," and "leukocyte reduced + irradiated + CMV-negative," among others. We asked the blood product stakeholder community whether the current blood product HCPCS P-code descriptors with the associated granularity best describe the state of the current technology for blood products

that hospitals currently provide to hospital outpatients. In several cases, the hospital costs as calculated from the CMS claims data are similar for blood products of the same type (for example, pheresis platelets) that have different code descriptors, which indicates to us that there is not a significant difference in the resources needed to produce the similar products. Again, we invited public comments on the current set of active HCPCS P-codes that describe blood products regarding how the code descriptors could be revised and updated (if necessary) to reflect the current blood products provided to hospital outpatients. The current set of active HCPCS P-codes that describe blood products can be found in Addendum B to the proposed rule and this final rule with comment period (which is available via the Internet on the CMS Web site).

Comment: Several commenters responded to the solicitation for public comments and supported a thorough examination of the current set of HCPCS P-codes for blood products as a necessary undertaking because the HCPCS P-codes were created several years ago. Several commenters recommended that CMS convene a stakeholder group that includes representatives of hospitals, blood banks, the American Red Cross, and others to discuss a framework to systematically review and revise the HCPCS P-codes for blood products. Commenters also encouraged CMS to retain individual HCPCS P-codes for unique blood products with significant therapeutic distinctions, as opposed to creating modifiers to be applied to the existing HCPCS P-codes. Commenters also suggested that CMS establish a "not otherwise classified (NOC)" code for blood products, which would allow hospitals to begin immediately billing for a new blood product that is not described by a specific HCPCS P-code. One commenter supported the use of broader descriptions for HCPCS P-codes when more granular language is no longer meaningful for differentiating between different types of blood and blood products, and where the costs and volume of the HCPCS P-codes are similar. Other commenters suggested specific modifications to the order, classification, and code descriptors of the blood and blood product HCPCS P-codes.

Response: We appreciate the commenters' detailed responses. These comments will be taken into consideration in the development of proposals to update the HCPCS P-codes that describe blood products.

(c) 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: <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>). This guidance encourages the use of rapid bacterial testing devices 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), CMS established three HCPCS P-codes for pathogen-reduced blood products, which became effective January 1, 2016. These codes included: HCPCS code P9070 (Plasma, pooled multiple donor, pathogen reduced, frozen, each unit); HCPCS code P9071 (Plasma (single donor), pathogen reduced, frozen, each unit); and HCPCS code P9072 (Platelets, pheresis, pathogen reduced, each unit).

The HCPCS Workgroup has decided to revise the HCPCS code established in CY 2016 for pathogen-reduced platelets (HCPCS code P9072) to include the use of pathogen-reduction technology or rapid bacterial testing. Specifically, the descriptor for this code will be 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). When claims data become available for HCPCS code P9072, we will establish a payment rate for this code using that data and our blood-specific CCR methodology. The revised HCPCS code descriptor and final payment rate for this service can be found in Addendum B of this final rule with comment period (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 OPSS payment for brachytherapy sources, we refer readers to prior OPSS final rules, such as the CY 2012 OPSS/ASC final rule with comment period (77 FR 68240 through 68241). As we have stated in prior OPSS updates, we believe that adopting the general OPSS prospective payment methodology for brachytherapy sources is appropriate for a number of reasons (77 FR 68240). The general OPSS 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 OPSS 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 the CY 2017 OPSS/ASC proposed rule (81 FR 45618), for CY 2017, we proposed to use the costs derived from CY 2015 claims data to set the CY 2017 payment rates for brachytherapy sources because CY 2015 is the same year of data we proposed to use to set the proposed payment rates for most other items and services that would be paid under the CY 2017 OPSS. We proposed to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we proposed for other items and services paid under the OPSS, as discussed in section II.A.2. of the proposed rule. We also proposed 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 proposed 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 2017 and subsequent years, we also proposed 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 2017 payment rates for brachytherapy sources were included in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site) and were identified with status indicator “U”. We note that, for CY 2017, we proposed to assign new proposed status indicator “E2” (Items and Services for Which Pricing Information and Claims Data Are Not Available) to HCPCS code C2644 (Brachytherapy cesium-131 chloride) because this code was not reported on CY 2015 claims. Therefore, we are unable to calculate a payment rate based on the general OPSS ratesetting methodology described earlier. Although HCPCS code C2644 became effective July 1, 2014, and although we would expect that if a hospital furnished a brachytherapy source described by this code in CY 2015, HCPCS code C2644 should appear on the CY 2015 claims, there are no CY 2015 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 C2644 for CY 2017.

Therefore, we proposed to assign new proposed status indicator “E2” to HCPCS code C2644.

We invited public comments on this proposed policy. We also requested recommendations for new HCPCS codes to describe new brachytherapy sources consisting of a radioactive isotope, including a detailed rationale to support recommended new sources.

Comment: One commenter requested that CMS establish a new HCPCS code to specifically describe the use of CivaString®, a linear, low dose rate polymer encapsulated palladium-103

brachytherapy source. The commenter stated that CivaString® became commercially available in CY 2013, and providers began reporting charges for the brachytherapy source using HCPCS code C2636 (Brachytherapy linear, non-stranded, palladium-103). However, the commenter believed that providers experienced confusion regarding the appropriate reporting of HCPCS code C2636. The commenter stated that six hospitals reported charges using HCPCS code C2636 over the past 6 years, without purchasing a linear, non-stranded palladium-103 brachytherapy source. Moreover, the commenter believed that providers may have inappropriately reported charges using HCPCS code C2636, including instances where providers reported charges for the use of HCPCS code 2636 although acquisition of CivaString® had not been obtained when it became commercially available in CY 2013. In addition, the commenter stated that the National Correct Coding Initiative (NCCI) established a medically unlikely edit (MUE) for HCPCS code C2636 in the outpatient hospital setting for 150 mm, effective April 1, 2010. Subsequently, in November 2015, the manufacturer of CivaString® requested that the MUE be increased to 900 mm based on the recommended clinical usage of CivaString®. In response to that request, the NCCI increased the MUE to 600 mm, effective April 1, 2016. However, the commenter further stated that claims for the use of CivaString® with the appropriate number of units continued to be denied based on the MUE. Because of these concerns, the commenter requested that CMS establish a new HCPCS code to specifically describe the use of CivaString®, as well as an increase in the payment rate proposed to adequately pay for the costs of this brachytherapy source.

Response: Section 1833(t)(2)(h) of the Act requires that the Secretary create additional groups of covered outpatient department services that classify brachytherapy sources separately from other services in a manner reflecting the number, isotope, and radioactive intensity of such sources. As such, we believe that HCPCS code C2636 adequately describes the clinical properties of CivaString®. Therefore, it is not necessary and would be duplicative to create a separate group for another linear, non-stranded palladium-103 source.

HCPCS code C2636 has been active since January 1, 2005. In response to the commenter's concerns regarding hospitals that may have inappropriately reported charges using HCPCS code C2636 although acquisition of

CivaString® had not been obtained, as a matter of general policy, we rely on hospitals to report all HCPCS codes on claims accurately in accordance with their code descriptors and CPT and CMS instructions, as applicable, and to report charges on claims and charges and costs on their Medicare hospital cost reports appropriately. We stated in the CY 2011 OPPTS/ASC final rule with comment period (75 FR 71838) that the quality and accuracy of reported units and charges significantly influence the geometric mean costs that are the basis for our payment rates, especially for low-volume items and services. Beyond our standard OPPTS trimming methodology that we apply to those claims that have passed various types of claims processing edits, it is not our general policy to judge the accuracy of hospital coding and charging for purposes of ratesetting.

With regard to the MUE value, we note that the MUE for HCPCS code C2636 is a date-of-service edit. This means if billed units of service (UOS) for HCPCS code C2636 are denied based on the MUE value, the provider may appeal the denial. Medicare Administrative Contractors (MACs) may pay UOS in excess of the MUE value if medical record documentation supports medically reasonable and necessary UOS in excess of the MUE value. Therefore, we are not establishing a new HCPCS code for the use of CivaString® because we believe that HCPCS code C2636 adequately describes the clinical properties of CivaString®. We refer readers to the facility outpatient services MUE table, which is available on the CMS Web site at: <https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/MUE.html>.

Comment: One commenter acknowledged the proposed increased CY 2017 payment rate for brachytherapy sources described by HCPCS code C2616 (Brachytx, non-str, yttrium-90) in comparison to the CY 2016 payment rate, but continued to believe that the proposed CY 2017 payment rate would not adequately pay a hospital's true cost for purchasing the device. The commenter supported the proposed CY 2017 increase in the payment rate for HCPCS code C2616, but remained concerned that the limited increase in payment would not adequately pay for all costs incurred by the hospital such as storage, handling, and disposal costs. In addition, based on the commenter's analysis of Medicare Provider Analysis and Review (MedPAR) data, which contain data from claims for services provided to beneficiaries admitted to Medicare certified inpatient hospitals and skilled nursing facilities, the

commenter noted that a few hospitals inconsistently or incorrectly reported revenue code assignments with incorrect facility charge data. As a result of the erroneous and/or inaccurate coding, the commenter believed that the claims data used for CY 2017 ratesetting are adversely affected, which resulted in the inadequate proposed payment rate for HCPCS code C2616. Based on these concerns, the commenter requested that CMS eliminate outlier data that is out of range of other accurately reporting facilities. Specifically, the commenter requested that CMS eliminate claims from facilities that report a purchase price of \$1.00 or other costs dramatically less than the \$16,000 selling price.

Response: As previously discussed, under the OPPTS, we use cost-based weights to determine relative costliness for outpatient items and services. The relativity of weights is used to set APC payment rates for brachytherapy sources, not the invoice cost or list price. Therefore, under a prospective payment system based on relative weights, items and services may not be paid at 100 percent of the reported costs.

With regard to the commenter's analysis of MedPAR data on claims that reported HCPCS code C2616, we note that MedPAR data consolidate inpatient hospital or skilled nursing facility (SNF) claims data from the National Claims History (NCH) files into stay level records. Because MedPAR data do not include OPPTS claims, it is incorrect for the commenter to conclude that the CY 2017 OPPTS proposed payment rate is inadequate as a result of erroneous and/or inaccurate coding on inpatient hospital or SNF claims. We have no reason to believe that prospective payment rates based on outpatient claims data from those providers furnishing a brachytherapy source described by HCPCS code C2616 do not appropriately reflect the cost of that source to hospitals. Therefore, we are not excluding or eliminating any claims with paid lines for HCPCS code C2616 in ratesetting for CY 2017.

Comment: A few commenters expressed concern regarding the outpatient hospital claims data that CMS used to set the prospective payment rates for brachytherapy sources. The commenters stated that high dose rate (HDR) brachytherapy devices are renewable because the devices have a 90-day use span and are used in the treatment of multiple patients during this 90-day span. According to the commenters, the true cost of treatment involving brachytherapy sources depends on the

number of patients treated by a hospital within a 90-day period, as well as the number of treatments required and the intensity of the treatments. For this reason, the commenters believed that it is difficult to establish fair and adequate prospective payment rates for brachytherapy sources. The commenters also noted that the brachytherapy source payment data continue to show huge variation in per unit cost across hospitals.

In addition, the commenters believed that CMS' claims data contain rank order anomalies, causing the usual cost relationship between the high activity palladium-103 source (HCPCS code C2635, Brachytherapy source, non-stranded, high activity, palladium-103, greater than 2.2 mci (NIST) per source) and the low activity palladium-103 sources (HCPCS code C2640, Brachytherapy source, stranded, palladium-103, per source and HCPCS code C2641, Brachytherapy source, non-stranded, palladium-103, per source) to be reversed. The commenters noted that the proposed geometric mean costs of the brachytherapy source HCPCS codes are approximately \$26, \$77, and \$70, respectively. The commenters stated that, based on their experience, stranded palladium-103 sources (HCPCS code C2640) always cost more than non-stranded palladium-103 sources (HCPCS code C2641), which was not reflected in the proposed rule claims data that CMS used.

In addition, the commenters expressed concern that payment for several brachytherapy sources are unstable and fluctuate significantly since CMS implemented the prospective payment methodology based on source-specific median cost in CY 2010 and geometric mean unit cost in CY 2013.

As a result of these concerns, the commenters requested that CMS adopt policies that more accurately account for the costs associated with HDR brachytherapy treatment delivery and to limit the overall fluctuation in payment for brachytherapy devices.

Response: We have received similar public comments regarding payment rates for HDR brachytherapy sources, payment rates for low and high activity palladium sources, and the year-to-year variation in payment rates for most brachytherapy sources in response to prior proposed rules and have addressed these public comments in prior final rules with comment period. We refer readers to 72 FR 66782; 74 FR 60534; 75 FR 71979; 76 FR 74161; 77 FR 68241; 78 FR 74861; 79 FR 66796; and 80 FR 70324 for our past responses to these similar comments. In these rules, we explain the characteristics of a

prospective payment system and how low-volume services are more susceptible to payment volatility compared to high-volume services. We also describe our expectation for how hospitals should treat HDR brachytherapy sources that can be used on multiple patients during its use span. In addition, we address concerns on varied cost distributions and their impact on the observed relationship in geometric mean cost between the different types of sources.

After consideration of the public comments we received, we are finalizing our proposal to continue to set the payment rates for brachytherapy sources using our established prospective payment methodology, which is based on geometric mean costs. In addition, we are finalizing our proposal to assign new status indicator "E2" to HCPCS code C2644 because there are no CY 2015 claims reporting use of this code and, therefore, we are unable to determine a payment rate for CY 2017.

The final CY 2017 payment rates for brachytherapy sources are included in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site) and are identified with status indicator "U".

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.

c. Comprehensive APCs (C-APCs) for CY 2017

(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.

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 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 final rule with comment period (which is available via the Internet on the CMS Web site).

The C-APC policy payment methodology set forth in the CY 2014 OPSS/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 OPSS/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 OPSS. 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 OPSS/ASC final rule with comment period, we expanded the C-APC payment methodology with the establishment of status indicator "J2". The assignment of status indicator "J2" to a specific combination of services performed in combination with each other, as opposed to a single, primary service, allows for all other OPSS 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 OPSS) 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 outpatient department services that are similar to therapy services and delivered either by therapists or non-therapists 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 outpatient department services. Payment for these non-therapy 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 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, excluding 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 "J1" service code combinations or 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 implement this type of complexity adjustment when the 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).
- 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 they meet the complexity adjustment criteria. For new HCPCS codes, we determine initial C-APC assignments and complexity adjustments using the best available information, crosswalking the new HCPCS codes to predecessor codes 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 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 code combination for services assigned to a C-APC would be the highest paying C-APC in the clinical family (79 FR 66802).

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

To determine which combinations of primary service codes reported in conjunction with an add-on code may

qualify for a complexity adjustment for CY 2017, in the CY 2017 OPPI/ASC proposed rule (81 FR 45620), we proposed to apply the frequency and cost criteria thresholds discussed above, testing claims reporting one unit of a single primary service assigned to status indicator “J1” and any number of units of a single add-on code. 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, 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 combination to a higher cost C-APC within the same clinical family of C-APCs. If any add-on code combination reported in conjunction with the primary service code does not qualify for a complexity adjustment, payment for these services is packaged within the payment for the complete comprehensive service. We listed the complexity adjustments proposed for add-on code combinations for CY 2017, along with all of the other proposed complexity adjustments, in Addendum J to the proposed rule (which is available via the Internet on the CMS Web site). For CY 2017, we proposed to discontinue the requirement that a code combination (that qualifies for a complexity adjustment by satisfying the frequency and cost criteria thresholds described earlier) also not create a 2 times rule violation in the higher level or receiving APC (80 FR 70328). We believe that this requirement is not useful because most code combinations fall below our established frequency threshold for considering 2 times rule violations, which is described in section III.B. of this final rule with comment period. Therefore, because the 2 times rule would not typically apply to complexity-adjusted code combinations, we proposed to discontinue this requirement.

We provided in Addendum J to the proposed rule a breakdown of cost statistics for each code combination that would qualify for a complexity adjustment (including primary code and add-on code combinations). Addendum J to the proposed rule also contained summary cost statistics for each of the 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 code combinations that are proposed to be reassigned to C-APC 5224 when CPT code 33208 is the primary code. Providing the information contained in Addendum J to the proposed rule allowed stakeholders the opportunity to better assess the impact associated with the proposed reassignment of each of the code combinations eligible for a complexity adjustment.

Comment: Commenters generally supported the proposal to no longer require that a code combination (that qualifies for a complexity adjustment by satisfying the frequency and cost criteria thresholds) be evaluated for a 2 times rule violation in the higher level or receiving APC. One commenter requested that CMS allow the complexity-adjusted pair to move up an additional level in the clinical family if the code combination creates a 2 times rule violation in the receiving APC. Several other commenters requested that CMS review and modify the established C-APC complexity adjustment criteria to allow for complexity adjustments for specific “J1” service code combinations or code combinations of “J1” services and certain add-on codes that do not qualify under the current criteria.

Response: We appreciate the commenters’ support. We continue to believe that the complexity adjustment criteria, which require a frequency of 25 or more claims reporting a code combination and a violation of the 2 times rule in the originating C-APC in order to receive payment in the next higher cost C-APC within the clinical family, is adequate to determine if a combination of procedures represents a complex, costly subset of the primary service. If a code combination meets these criteria, the combination receives payment at the next higher cost C-APC. Code combinations that do not meet these criteria receive the C-APC payment rate associated with the primary “J1” service. A minimum of 25 claims is already very low for a national payment system. Lowering the minimum of 25 claims further could lead to unnecessary complexity adjustments for service combinations that are rarely performed. The complexity adjustment cost threshold compares the code combinations to the lowest cost significant procedure assigned to the APC. If the cost of the

code combination does not exceed twice the cost of the lowest cost significant procedure within the APC, no complexity adjustment is made. Lowering this threshold also could remove too many claims from the accounting for the primary J1 service, which would undermine the C-APC policy. We are finalizing the policy proposal to discontinue the requirement that a code combination (that qualifies for a complexity adjustment by satisfying the frequency and cost criteria thresholds) also not create a 2 times rule violation in the higher level or receiving APC as proposed. We are not otherwise changing the complexity adjustment criteria.

Comment: Other commenters requested that CMS ensure that claims for bilateral C-APC procedures that are correctly reported with modifier “50” (a modifier used to report bilateral procedures that are performed at the same operative session as a single line item) are accounted for in the evaluation of complexity adjustments, as well as the C-APC claims accounting. The commenters believed that these claims should be recognized as reporting two units of the service in the evaluation of the frequency of the code combination and the payment of the complexity-adjusted C-APC rate.

Response: The issue of complexity adjustments for bilateral, status indicator “J1” procedures reported with modifier “50” was addressed in the April 2016 Integrated OCE Specifications Quarterly Release Files (Attachment A—Integrated OCE Specs, Appendix L: Comprehensive APC Assignment Logic). In that document, the C-APC assignment logic was updated to specify the following: Once the highest ranked comprehensive procedure is determined, if there are multiple comprehensive procedures present with status indicator “J1” or there are qualifying add-on procedure codes present (status indicator “N”), determine if there are any pairings that may qualify for a complexity adjustment. Multiple occurrences or service units of the same comprehensive procedure, or the reporting of modifier “50,” may qualify for a complexity adjustment. If there is a qualifying pair present associated with the highest ranked comprehensive procedure, assign the complexity-adjusted comprehensive APC. This change was made retroactive to January 2015. As of January 1, 2015, status indicator “J1” procedure claims with modifier “50” also will be included in the C-APC claims accounting and the complexity adjustment evaluations.

Comment: One commenter requested that CMS eliminate one of the criterion for assignment to status indicator “J2” and C-APC 8011 (Comprehensive Observation Services). Specifically, the commenter stated that claims that otherwise would qualify for payment through C-APC 8011, but contain a procedure described by a HCPCS code assigned to 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, should not be excluded from receiving payment through C-APC 8011.

Response: Services that would otherwise qualify for the observation C-APC (C-APC 8011) are not considered to be observation services when they are associated with a surgical procedure (assigned to status indicator “T”). Instead, they are considered to be perioperative recovery, which is always packaged in with the surgical procedure.

Comment: Some commenters submitted comments regarding C-APC 5627 (Level 7 Radiation Therapy) and the treatment planning and preparation services involved with stereotactic radiosurgery (SRS) treatment. Commenters urged CMS to continue the policy finalized in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70337) that pays separately for certain SRS planning and preparation services (a policy that is a temporary special exception for APC 5627 to the C-APC packaging policy that packages all adjunctive services (with a few exceptions listed in Addendum J)). Commenters believed that CMS should not package treatment planning and preparation into the C-APC payment rate for Level 7 Radiation Therapy in the future as discussed in the CY 2016 OPPS/ASC final rule with comment period because SRS claims may include other unrelated radiation therapy services.

Response: For CY 2017, we will continue the policy for the payment of SRS treatment as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70337). This policy removes claims reporting certain planning and preparation services for SRS treatment from our geometric mean cost calculation for the CY 2017 payment rate for C-APC 5627 and pays separately for these planning and preparation services. For 2018, we will again examine the claims for cranial single session SRS patients and evaluate the services reported with modifier “CT” (Adjunctive service related to a procedure assigned to a comprehensive ambulatory payment classification [C-

APC] procedure). 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 in order to preserve the integrity of the C-APC policy and the OPSS as a prospective payment system.

Comment: Commenters noted that claims that included several insertion codes for brachytherapy devices (namely CPT codes 57155, 20555, 31643, 41019, 43241, 55920, and 58346) often did not also contain a brachytherapy treatment delivery code. The commenters concluded that brachytherapy delivery charges are being underrepresented in ratesetting under the C-APC methodology because a correctly coded claim should always include an insertion and treatment delivery code combination. One commenter suggested that CMS adopt a composite APC methodology for CPT code 57155 similar to the composite methodology for LDR prostate brachytherapy services.

Response: The calculation of OPSS relative payment weights that reflect the relative resources required for HOPD services is the foundation of the OPSS. We rely on hospitals to bill all HCPCS codes accurately in accordance with their code descriptors and CPT and CMS instructions, as applicable, and to report charges on claims and charges and costs on their Medicare hospital cost reports appropriately (77 FR 68324). Moreover, we generally do not remove claims from the claims accounting when stakeholders believe that hospitals included incorrect information on some claims. Therefore, we are not excluding claims from the ratesetting calculation that include procedures described by CPT codes 57155, 20555, 31643, 41019, 43241, 55920, and 58346. In the future, we will examine the claims for these brachytherapy insertion codes and determine if any future adjustment to the methodology (or possibly code edits) would be appropriate.

(2) C-APCs for CY 2017

(a) Additional C-APCs for CY 2017

For CY 2017 and subsequent years, in the CY 2017 OPPS/ASC proposed rule (81 FR 45620), we proposed to continue to apply the C-APC payment policy methodology made effective in CY 2015, as described in detail below. We proposed to continue to define the services assigned to C-APCs as primary services or a specific combination of services performed in combination with each other. We also proposed to define a C-APC as a classification for the

provision of a primary service or specific combination of services and all adjunctive services and supplies provided to support the delivery of the primary or specific combination of services. We also proposed to continue to follow the C-APC payment policy methodology of packaging all covered OPD services on a hospital outpatient claim reporting a primary service that is assigned to status indicator “J1” or reporting the specific combination of services assigned to status indicator “J2,” excluding services that are not covered OPD services or that cannot by statute be paid under the OPSS.

As a result of our annual review of the services and APC assignments under the OPSS, we proposed 25 additional C-APCs to be paid under the existing C-APC payment policy beginning in CY 2017. The proposed additional CY 2017 C-APCs were listed in Table 2 of the proposed rule. All C-APCs, including those effective in CY 2016 and those being proposed for CY 2017, also were 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 contained all of the data related to the C-APC payment policy methodology, including the list of proposed complexity adjustments and other information.

Comment: Many commenters supported the proposal to expand the C-APC policy to include new C-APCs. However, several commenters requested that CMS delay the expansion of the C-APC policy and expressed concerns that the costs of procedures and services paid through a C-APC are not being accurately captured and C-APC payment rates do not adequately cover the costs associated with the primary and adjunctive services. Commenters also requested more information regarding the rationale for the assignment of services to a C-APC and stated that more time is needed to analyze and assess the financial impact of the proposed C-APC policy changes. One commenter expressed concerns that CMS may not be fully considering the impact of adding relatively low cost (below \$2,227) procedures to C-APCs and suggested the establishment of a minimum cost threshold for a procedure to be assigned to a C-APC. Other commenters requested a delay in the assignment of new codes, including add-on codes, to C-APCs unless a crosswalk exists from the old code to the new code.

Response: We appreciate the commenters’ support. With regard to the comments relating to delaying the expansion of the C-APC policy, we do

not believe that we should delay implementation of the proposed CY 2017 C-APCs. C-APCs were introduced in 2015, and, like all of the payment policies contained in the OPSS, are reviewed annually, as provided at section 1833(t)(9)(A) of the Act. We communicate with various stakeholders on an ongoing basis as a part of our mutual efforts to further improve the OPSS. We believe that sufficient information is available for stakeholders to evaluate how C-APCs affect payment for services, and that there is sufficient time for the public to review and analyze our proposed payment policies. This is evidenced by the many stakeholders that submit public comments, including, for example, analyses of the C-APC payment policy. Regarding the comment about creating a cost threshold for assignment of a procedure to a C-APC, we do not believe that this is necessary. Procedures assigned to C-APCs are primary services (mostly major surgical procedures) that are typically the focus of the hospital outpatient stay. We do not believe that a cost threshold would help to differentiate primary from secondary or adjunctive services. Lastly, we assign new codes to APCs (including C-APCs) based on predecessor code APC assignments, comparisons to similar codes, clinical comparability, and estimates of the resource intensity, as well as other relevant information. If we failed to assign new codes to C-APCs, this could result in significant underpayment for some new codes if a C-APC is the most appropriate APC for the new procedure.

Comment: A few commenters requested that CMS not convert APCs 5153 through 5155 (Levels 3 through 5 Airway Endoscopy) into C-APCs. The commenters expressed concerns regarding reduced payments for sinus surgeries when a patient has multiple surgeries during a single operative session. The major concern focused on the loss of additional payments for multiple procedures under the C-APC

methodology. Commenters stated that multiple procedures (coded either as a bilateral case or with multiple different CPT codes) are common for the treatment of sinus diseases. One commenter noted that the AMA CPT Editorial Panel is in the process of revising some of the sinus surgery codes and bundling some of these codes. Another commenter believed that payment reductions for sinus surgery could negatively affect opportunities for resident training on these procedures.

Response: The commenters concerns are not unique to sinus surgery. The C-APC methodology relies on the average cost of the range of cases included in the claims accounting for the primary service code. We believe that this approach is better suited to a prospective payment system like the OPSS that relies on average cost payments that sometimes exceed the cost of a given case and other times are less than the cost of a given case. If, as the commenters suggest, bilateral surgery and/or multiple procedures are common in sinus surgery, the costs of this approach would be reflected in the geometric mean cost of the primary procedure under the C-APC methodology. It also seems that, according to one commenter, the AMA is preparing to address what might be fragmented codes in this clinical area. We are finalizing as proposed the conversion of the three highest level airway endoscopy APCs to C-APCs as a part of our continuing effort to direct the OPSS more towards a prospective payment system and away from a per service or per code fee schedule in which every coded item or service results in additional payment. We also do not agree that this payment policy raises concerns regarding the training of otolaryngology residents in sinus surgery, but we will monitor these APCs as we do with all others as a part of our annual OPSS/ASC rulemaking.

Comment: One commenter stated that while APC 5153 (Level 3 Airway Endoscopy Procedures) is a proposed C-

APC for CY 2017, one of the codes assigned to APC 5153, namely CPT code 31649 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), each additional lobe (List separately in addition to code for primary procedure)), is assigned a status indicator of "Q2" and not "J1." The commenter requested that this procedure be assigned to status indicator "J1."

Response: This procedure is assigned status indicator "Q2" because it describes the removal of a device, specifically a bronchial valve. In the CY 2014 OPSS/ASC final rule with comment period (78 FR 74926), we finalized a proposal to conditionally package device removal procedures. This procedure is separately paid unless it is billed on the same date of service as a surgical procedure assigned to status indicator "J1" or "T" that involves repair or replacement of the device. The procedure was placed in a C-APC on the basis of resource and clinical homogeneity. For these reasons, we do not agree with the commenters, and are not assigning CPT code 31649 to status indicator "J1."

After consideration of the public comments we received, we are finalizing the proposal for 25 additional C-APCs to be paid under the existing C-APC payment policy beginning in CY 2017.

Table 2 below lists the final additional C-APCs for CY 2017, including the C-APCs currently effective for CY 2016. All C-APCs, including those effective in CY 2016 and those finalized for CY 2017, also are displayed in Addendum J to this final rule with comment period. Addendum J to this final rule with comment period (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 complexity adjustments and other information.

TABLE 1—CY 2017 C-APCs

C-APC	CY 2017 APC title	Clinical family	New C-APC
5072	Level 2 Excision/Biopsy/Incision and Drainage	EBIDX	*
5073	Level 3 Excision/Biopsy/Incision and Drainage	EBIDX	*
5091	Level 1 Breast/Lymphatic Surgery and Related Procedures	BREAS	*
5092	Level 2 Breast/Lymphatic Surgery and Related Procedures	BREAS	*
5093	Level 3 Breast/Lymphatic Surgery & 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	

TABLE 1—CY 2017 C-APCs—Continued

C-APC	CY 2017 APC title	Clinical family	New C-APC
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	*
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	

* New C-APC for CY 2017.

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.

(b) New Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) C-APC

Allogeneic hematopoietic stem cell transplantation (HSCT) involves the intravenous infusion of hematopoietic stem cells derived from the bone marrow, umbilical cord blood, or peripheral blood of a donor to a recipient. Allogeneic hematopoietic

stem cell collection procedures, which are performed not on the beneficiary but on a donor, cannot be paid separately under the OPSS because hospitals may bill and receive payment only for services provided to a Medicare beneficiary who is the recipient of the HSCT and whose illness is being treated with the transplant. Currently, under

the OPSS, payment for these acquisition services is packaged into the APC payment for the allogeneic HSCT when the transplant occurs in the hospital outpatient setting (74 FR 60575). In the CY 2016 OPSS/ASC final rule with comment period, we assigned allogeneic HSCT to APC 5281 (Apheresis and Stem

Cell Procedures), which has a CY 2016 OPPS payment rate of \$3,015.

As provided in the Medicare Claims Processing Manual, Pub. 100-04, Chapter 4, section 231.11, donor acquisition charges for allogeneic HSCT may include, but are not limited to, charges for the costs of several services. These services include, but are not necessarily limited to, National Marrow Donor Program fees, if applicable, tissue typing of donor and recipient, donor evaluation, physician pre-procedure donor evaluation services, costs associated with the collection procedure (for example, general routine and special care services, procedure/operating room and other ancillary services, apheresis services, among others), post-operative/post-procedure evaluation of donor, and the preparation and processing of stem cells.

When the allogeneic stem cell transplant occurs in the hospital outpatient setting, providers are instructed to report stem cell donor acquisition charges for allogeneic HSCT separately in Field 42 on Form CMS-1450 (or UB-04) by using revenue code 0819 (Organ Acquisition: Other Donor). Revenue code 0819 charges should include all services required to acquire hematopoietic stem cells from a donor, as defined earlier, and should be reported on the same date of service as the transplant procedure in order to be appropriately packaged for payment purposes. Revenue code 0819 maps to cost center code 086XX (Other organ acquisition where XX is "00" through "19") and is reported on line 112 (or applicable subscripts of line 112) of the Medicare cost report.

In recent years, we have received comments from stakeholders detailing concerns about the accuracy of ratesetting for allogeneic HSCT (79 FR 40950 through 40951; 79 FR 66809; and 80 FR 70414 through 70415). Stakeholders have presented several issues that could result in an inappropriate estimation of provider costs for these procedures, including outpatient allogeneic HCST reported on claims being identified as multiple procedure claims that are unusable under the standard OPPS ratesetting methodology. Stakeholders also have indicated that the requirement for the reporting of revenue code 0819 on claims reporting allogeneic HSCTs and the lack of a dedicated cost center for stem cell transplantation donor acquisition costs have led to an overly broad CCR being applied to these procedures, which comprise a very low volume of the services reported within the currently assigned cost center. In addition, commenters noted that it is

likely that there are services being reported with the same revenue code (0819) and mapped to the same cost center code (086XX) as allogeneic HSCT donor acquisition charges that are unrelated to these services. Lastly, providers have commented that the donor acquisition costs of allogeneic HSCT are much higher relative to their charges when compared to the other items and services that are reported in the current cost center. Providers also have stated that hospitals have difficulty applying an appropriate markup to donor acquisition charges that will sufficiently generate a cost that approximates the total cost of donor acquisition. Through our examination of the CY 2016 claims data, we believe that the issues presented above provide a persuasive rationale for payment adjustment for donor acquisition costs for allogeneic HCST.

Stakeholders suggested that the establishment of a C-APC for stem cell transplant services would improve payment adequacy by allowing the use of multiple procedure claims, provided CMS also create a separate and distinct CCR for donor search and acquisition charges so that they are not diluted by lower cost services. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70414 through 70415), we stated that we would not create a new C-APC for stem cell transplant procedures at that time and that we would instead continue to pay for the services through the assigned APCs while continuing to monitor the issue.

Based on our current analysis of this longstanding issue and stakeholder input, in the CY 2017 OPPS/ASC proposed rule (81 FR 45623), for CY 2017, we proposed to create a new C-APC 5244 (Level 4 Blood Product Exchange and Related Services) and to assign procedures described by CPT code 38240 (Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor) to this C-APC and to assign status indicator "J1" to the code. The creation of a new C-APC for allogeneic HSCT and the assignment of status indicator "J1" to CPT code 38240 would allow for the costs for all covered OPD services, including donor acquisition services, included on the claim to be packaged into the C-APC payment rate. These costs also will be analyzed using our comprehensive cost accounting methodology to establish future C-APC payment rates. We proposed to establish a payment rate for proposed new C-APC 5244 of \$15,267 for CY 2017.

In order to develop an accurate estimate of allogeneic HSCT donor acquisition costs for future ratesetting, for CY 2017 and subsequent years, we

proposed to update the Medicare hospital cost report (Form CMS-2552-10) by adding a new standard cost center 112.50, "Allogeneic Stem Cell Acquisition," to Worksheet A (and applicable worksheets) with the standard cost center code of "11250." The proposed new cost center, line 112.50, would be used for the recording of any acquisition costs related to allogeneic stem cell transplants as defined in Section 231.11, Chapter 4, of the Medicare Claims Processing Manual (Pub. 100-04). Acquisition charges for allogeneic stem cell transplants apply only to allogeneic transplants for which stem cells are obtained from a donor (rather than from the recipient). Acquisition charges do not apply to autologous transplants (transplanted stem cells are obtained from the recipient) because autologous transplants involve services provided to a beneficiary only (and not to a donor), for which the hospital may bill and receive payment. Acquisition costs for allogeneic stem cells are included in the prospective payment. This cost center flows through cost finding and accumulates any appropriate overhead costs.

In conjunction with our proposed addition of the new "Allogeneic Stem Cell Acquisition" standard cost center, we proposed to use the newly created revenue code 0815 (Allogeneic Stem Cell Acquisition Services) to identify hospital charges for stem cell acquisition for allogeneic bone marrow/stem cell transplants. Specifically, for CY 2017 and subsequent years, we proposed to require hospitals to identify stem cell acquisition charges for allogeneic bone marrow/stem cell transplants separately in Field 42 on Form CMS-1450 (or UB-04), when an allogeneic stem cell transplant occurs. Revenue code 0815 charges should include all services required to acquire stem cells from a donor, as defined above, and should be reported on the same date of service as the transplant procedure in order to be appropriately packaged for payment purposes. The proposed new revenue code 0815 would map to the proposed new line 112.50 (with the cost center code of "11250") on the Form CMS-2552-10 cost report. In addition, for CY 2017 and subsequent years, we proposed to no longer use revenue code 0819 for the identification of stem cell acquisition charges for allogeneic bone marrow/stem cell transplants. We invited public comments on these proposals.

Comment: Several commenters supported the proposal to create a new C-APC for allogeneic HSCT (C-APC 5244) and the assignment of status

indicator “J1” to CPT code 38240. However, many commenters believed that the proposed payment for C-APC 5244 continued to be significantly less than the overall cost of the service. Some commenters stated that CMS used claims to calculate the proposed payment rate for this service that were incomplete and did not adhere to CMS billing instructions for providers for allogeneic bone marrow/stem cell transplants. Specifically, the commenters stated that there were claims included in the geometric mean cost calculation for allogeneic HSCT (CPT code 38240) that did not include donor acquisition costs reported with revenue code 0819 on the same date of service as the transplant. According to the commenters, this resulted in an inaccurate and low estimation of the total cost of this service. The commenters requested that CMS exclude these claims from ratesetting for allogeneic HSCT. Commenters also suggested that CMS institute an edit beginning in CY 2017 that requires both the donor acquisition revenue code and the stem cell transplant CPT code on the claim to ensure that Medicare receives correctly coded claims for this relatively costly service.

Lastly, commenters stated that the new cost center and revenue code should be utilized for both inpatient and outpatient donor acquisition cost reporting, requested instructions from CMS on how to reclassify expenses into the new cost center from ancillary departments, and also suggested that CMS reconsider the use of cost center line 112.50 because this line is designated for solid organ acquisition costs, which are paid at cost. According to these commenters, these costs do not carry to Worksheet C and, for calculation of CCR, are dropped from cost report after accumulation of overhead. The commenter suggested the use of a cost center in the range of lines 50 through 76.99.

Response: We are persuaded by the commenters and note that at the summer 2016 meeting of the Advisory Panel on Hospital Outpatient Payment (HOP Panel), the panel also recommended that CMS use only the claims that include both CPT code 38240 and revenue code 0819 in calculating the CY 2017 payment rates for allogeneic HSCT. Therefore, we believe it is preferable to use only the claims with both the CPT code for the transplant (CPT code 38240) and the revenue code for the donor acquisition costs (revenue code 0819) to calculate the payment rate for this service under the new C-APC. We agree, in this case, to use only the subset of claims that

include both codes because hospitals were specifically instructed in the CMS Internet Only Manual and in prior final rule preamble language to use revenue code 0819 to report donor acquisition costs. This instruction is different from our general instructions regarding correct coding in that this instruction is very specific and was issued to address problems associated with the reporting of donor acquisition costs. We also agree with the commenters’ that implementing a code edit beginning in CY 2017 that will require revenue code 0815 to be on a claim with CPT code 38240 is appropriate because this practice will help to ensure that donor acquisition costs for allogeneic HSCT are reported with the appropriate revenue code and that these costs are accurately recorded in the Medicare hospital cost report. This edit will become effective January 1, 2017, and will return claims to the provider if CPT code 38240 is present for the transplant procedure without a separate line on the claim reporting revenue code 0815 for donor acquisition services. Again, we emphasize that this is an exceptional circumstance. We do not anticipate taking any similar actions for any other existing or future APCs or C-APCs. The combination of forming a new C-APC, providing unusually specific instructions in the CMS Internet Only Manual, needing to create a new cost center on the hospital cost report, and the clear recommendation from the HOP Panel—following both its and our thorough analysis of the issue—make this case particularly unique.

Regarding the comment related to the use of cost center line 112.50 to report allogeneic HSCT donor acquisition costs, we agree with the commenter that cost report lines 105 through 117 are designated for solid organ acquisition costs and other data for informational purposes. The commenter also indicated that the proposed line 112.50 does not carry over to Worksheet C for the calculation of a CCR and drops off after accumulation of overhead. The commenter makes a valid point regarding the proposed line 112.50, and we agree that the proposed new revenue code 0815 should be mapped to a different cost center. The commenters recommended the use of a cost center in the range of lines 50 through 76.99. However these cost centers have standard cost center descriptions that do not have a logical subscript for the proposed new line “Allogeneic Stem Cell Acquisition”. Also, line 76 is used for too many variables and would not provide the needed isolation of costs or charges. However, the Medicare hospital

cost report contains an available expansion in the range of lines 77 through 87. We are revising our proposal to update the Medicare hospital cost report (Form CMS-2552-10) by adding proposed new line 112.50 (with the cost center code of “11250”) and are instead adding a new standard cost center 77, “Allogeneic Stem Cell Acquisition,” to Worksheet A (and applicable worksheets) with the standard cost center code of “07700.” The new cost center, line 77, will be used for the recording of any acquisition costs related to allogeneic stem cell transplants as defined in Section 231.11, Chapter 4, of the Medicare Claims Processing Manual (Pub. 100-04).

After consideration of the public comments we received, we are finalizing the proposal for C-APC 5244 (Level 4 Blood Product Exchange and Related Services), with the modification to exclude claims that do not include donor acquisition costs reported with revenue code 0819 from ratesetting. In addition, for CY 2017 and subsequent years, we are finalizing the proposal to no longer use revenue code 0819 for the identification of stem cell acquisition charges for allogeneic bone marrow/stem cell transplants. We are establishing a final payment rate for new C-APC 5244 of \$27,752 for CY 2017.

d. 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 OPPTS/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 OPPTS/ASC final rule with comment period (76 FR 74163) for more recent background. In the CY 2017 OPPTS/ASC proposed rule (81 FR 45623), for CY 2017 and subsequent years, we proposed to continue our composite APC payment policies for LDR prostate brachytherapy services, mental health services, and multiple imaging services, as discussed below.

At its August 22, 2016 meeting the HOP Panel recommended that CMS develop a composite APC for pathology services when multiple pathology services are reported on a claim with no other payable services.

Comment: Several commenters supported the HOP Panel's recommendation to develop a composite APC for pathology services when multiple pathology services are reported on a claim with no other payable services and urged CMS to propose and finalize a policy to create such a composite APC. Some commenters also requested that CMS create additional composite APCs for X-ray services, respiratory services, cardiology services, and allergy testing services.

Response: We appreciate the HOP Panel's recommendation, as well as the commenters' request to create new composite APCs for additional services. However, we did not propose to create any new composite APCs for CY 2017. Therefore, we are not accepting the HOP Panel's recommendation at this time. We may consider this HOP Panel recommendation in conjunction with the commenters' request for the creation of new additional composite APCs for future rulemaking.

(1) Low Dose Rate (LDR) Prostate Brachytherapy Composite APC

LDR prostate brachytherapy is a treatment for prostate cancer in which hollow needles or catheters are inserted into the prostate, followed by permanent implantation of radioactive sources into the prostate through the needles/catheters. At least two CPT codes are used to report the composite treatment service because there are separate codes that describe placement of the needles/catheters and the application of the brachytherapy sources: CPT code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) and CPT code 77778 (Interstitial radiation source application; complex),

which are generally present together on claims for the same date of service in the same operative session. In order to base payment on claims for the most common clinical scenario, and to further our goal of providing payment under the OPPTS for a larger bundle of component services provided in a single hospital encounter, beginning in CY 2008, we began providing a single payment for LDR prostate brachytherapy when the composite service, reported as CPT codes 55875 and 77778, is furnished in a single hospital encounter. We base the payment for composite APC 8001 (LDR Prostate Brachytherapy Composite) on the geometric mean cost derived from claims for the same date of service that contain both CPT codes 55875 and 77778 and that do not contain other separately paid codes that are not on the bypass list. We refer readers to the CY 2008 OPPTS/ASC final rule with comment period (72 FR 66652 through 66655) for a full history of OPPTS payment for LDR prostate brachytherapy services and a detailed description of how we developed the LDR prostate brachytherapy composite APC.

In the CY 2017 OPPTS/ASC proposed rule (81 FR 45623 through 45624), we proposed to continue to pay for LDR prostate brachytherapy services using the composite APC payment methodology proposed and implemented for CY 2008 through CY 2016. That is, we proposed to use CY 2015 claims reporting charges for both CPT codes 55875 and 77778 on the same date of service with no other separately paid procedure codes (other than those on the bypass list) to calculate the proposed payment rate for composite APC 8001. Consistent with our CY 2008 through CY 2016 practice, in the CY 2017 OPPTS/ASC proposed rule, we proposed not to use the claims that meet these criteria in the calculation of the geometric mean costs of procedures or services assigned to APC 5375 (Level IV Cystourethroscopy and Other Genitourinary Procedures) and APC 5641 (Complex Interstitial Radiation Source Application), the APCs to which CPT codes 55875 and 77778 are assigned, respectively. We proposed to continue to calculate the proposed geometric mean costs of procedures or services assigned to APCs 5375 and 5641 using single and "pseudo" single procedure claims. We continue to believe that composite APC 8001 contributes to our goal of creating hospital incentives for efficiency and cost containment, while providing hospitals with the most flexibility to manage their resources. We also

continue to believe that data from claims reporting both services required for LDR prostate brachytherapy provide the most accurate geometric mean cost upon which to base the proposed composite APC payment rate.

Using a partial year of CY 2015 claims data available for the CY 2017 OPPTS/ASC proposed rule, we were able to use 202 claims that contained both CPT codes 55875 and 77778 to calculate the proposed geometric mean cost of approximately \$3,581 for these procedures upon which the proposed CY 2017 payment rate for composite APC 8001 was based.

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal, without modification, to continue to use the payment rate for composite APC 8001 to pay for LDR prostate brachytherapy services for CY 2017 and to set the payment rate for this APC using our established methodology. Using the CY 2015 claims data available for this CY 2017 final rule with comment period, we were able to use 224 claims that contained both CPT codes 55875 and 77778 to calculate the geometric mean cost of approximately \$3,598 for these procedures upon which the final CY 2017 payment rate for composite APC 8001 is based.

(2) Mental Health Services Composite APC

In the CY 2017 OPPTS/ASC proposed rule (81 FR 45624), we proposed to continue our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the payment for a day of partial hospitalization services provided by a hospital, which we consider to be the most resource-intensive of all outpatient mental health services. We refer readers to the April 7, 2000 OPPTS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy and the CY 2012 OPPTS/ASC final rule with comment period (76 FR 74168) for more recent background.

Specifically, we proposed that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on one 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 assigned to composite APC 8010 (Mental Health Services Composite). We also proposed to continue to set the payment rate for

composite APC 8010 at the same payment rate that we proposed to establish for APC 5862 (Level 2 Partial Hospitalization (4 or more services) for hospital-based PHPs), 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 5862 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 OPSS than the highest partial hospitalization per diem payment rate for hospitals.

In the CY 2017 OPSS/ASC proposed rule (81 FR 45667 through 45678), we proposed 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 proposed new APC 5863 (Partial Hospitalization (3 or more services per day)). This proposal is being finalized in section VIII. of this final rule with comment period. In light of this policy, we are modifying our final policy for CY 2017, as fully discussed below.

We did not receive any public comments on this proposal. Therefore, we are finalizing our CY 2017 proposal, without modification, that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services will be paid through composite APC 8010 (Mental Health Services Composite) for CY 2017. In addition, we are finalizing our CY 2017 proposal, with modification, to set the payment rate for composite APC 8010 for CY 2017 at the same payment rate that we established for new 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.

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

In the CY 2017 OPSS/ASC proposed rule (81 FR 45624 through 45625), we proposed to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. We continue to believe that this policy will reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session.

The proposed CY 2017 payment rates for the five multiple imaging composite APCs (APCs 8004, 8005, 8006, 8007, and 8008) were based on proposed geometric mean costs calculated from a partial year of CY 2015 claims available for the CY 2017 OPSS/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 OPSS/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 OPSS/ASC final rule with comment period (78 FR 74918), were identified by asterisks in Addendum N to the CY 2017 OPSS/ASC proposed rule (which is available via the Internet on the CMS Web site) and were discussed in more detail in section II.A.1.b. of the CY 2017 OPSS/ASC proposed rule. For the CY 2017 OPSS/ASC proposed rule, we were able to identify approximately 599,294 “single session” claims out of an estimated 1.6 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately 38 percent of all eligible claims, to calculate the proposed CY 2017 geometric mean costs for the multiple imaging composite APCs. Table 7 of the CY 2017 OPSS/

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 2017.

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal to continue the use of multiple imaging

composite APCs to pay for services providing more than one imaging procedure from the same family on the same date, without modification. For this CY 2017 final rule with comment period, we were able to identify approximately 635,363 “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 37 percent of all eligible claims, to calculate the final CY 2017 geometric mean costs for the multiple imaging composite APCs. Table 3 below lists the HCPCS codes that are subject to the multiple imaging composite APC policy and their respective families and approximate composite APC geometric mean costs for CY 2017.

TABLE 3—FINAL OPPTS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1—Ultrasound	
CY 2017 APC 8004 (ultrasound composite)	CY 2017 Approximate APC geometric mean cost = \$296
76604	Us exam, chest.
76700	Us exam, abdom, complete.
76705	Echo exam of abdomen.
76770	Us exam abdo back wall, comp.
76775	Us exam abdo back wall, lim.
76776	Us exam k transpl w/Doppler.
76831	Echo exam, uterus.
76856	Us exam, pelvic, complete.
76870	Us exam, scrotum.
76857	Us exam, pelvic, limited.
Family 2—CT and CTA with and without contrast	
CY 2017 APC 8005 (CT and CTA without contrast composite) *	CY 2017 Approximate APC geometric mean cost = \$325
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.
CY 2017 APC 8006 (CT and CTA with contrast composite)	CY 2017 Approximate APC geometric mean cost = \$548
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.

CY 2017 APC 8006 (CT and CTA with contrast composite)	CY 2017 Approximate APC geometric mean cost = \$548
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.

Family 3—MRI and MRA with and without Contrast

CY 2017 APC 8007 (MRI and MRA without contrast composite) *	CY 2017 Approximate APC geometric mean cost = \$631
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.

CY 2017 APC 8008 (MRI and MRA with contrast composite)	CY 2017 Approximate APC geometric mean cost = \$945
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.

CY 2017 APC 8008 (MRI and MRA with contrast composite)	CY 2017 Approximate APC geometric mean cost = \$945
73720	Mri lwr extremity w/o & w/dye.
73722	Mri joint of lwr extr w/dye.
73723	Mri joint lwr extr w/o & w/dye.
74182	Mri abdomen w/dye.
74183	Mri abdomen w/o & w/dye.
75561	Cardiac mri for morph w/dye.
75563	Card mri w/stress img & dye.
C8900	MRA w/cont, abd.
C8902	MRA w/o fol w/cont, abd.
C8903	MRI w/cont, breast, uni.
C8905	MRI w/o fol w/cont, brst, un.
C8906	MRI w/cont, breast, bi.
C8908	MRI w/o fol w/cont, breast,.
C8909	MRA w/cont, chest.
C8911	MRA w/o fol w/cont, chest.
C8912	MRA w/cont, lwr ext.
C8914	MRA w/o fol w/cont, lwr ext.
C8918	MRA w/cont, pelvis.
C8920	MRA w/o fol w/cont, pelvis.
C8931	MRA, w/dye, spinal canal.
C8933	MRA, w/o&w/dye, spinal canal.
C8934	MRA, w/dye, upper extremity.
C8936	MRA, w/o&w/dye, upper extr.

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

3. Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPS

Like other prospective payment systems, the OPPS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular patient. The OPPS packages 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 OPPS to maximize hospitals' incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more costly than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than to routinely use a more expensive item, which often results 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 OPPS since its implementation in August 2000. For an extensive discussion of the history and background of the OPPS packaging policy, we refer readers to the CY 2000 OPPS final rule (65 FR 18434), the CY 2008 OPPS/ASC final rule with comment period (72 FR 66580), the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66817), and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70343). As we continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of

care, we have expanded the OPPS packaging policies. Most, but not necessarily all, items and services currently packaged in the OPPS are listed in 42 CFR 419.2(b). Our overarching goal is to make OPPS payments for all services paid under the OPPS more consistent with those of a prospective payment system and less like those of a per service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided under the OPPS to determine which OPPS services can be packaged to further achieve the objective of advancing the OPPS toward a more prospective payment system.

For CY 2017, we have examined our OPPS packaging policies, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services that are packaged into payment for the primary service that they support. In the CY 2017 OPPS/ASC proposed rule (81 FR 45628), we proposed some modifications to our packaging policies. The specific proposals and any applicable summations of and responses to any public comments received in response to these proposals are discussed under the sections below.

b. Clinical Diagnostic Laboratory Test Packaging Policy

(1) Background

In CY 2014, we finalized a policy to package payment for most clinical

diagnostic laboratory tests in the OPSS (78 FR 74939 through 74942, and 42 CFR 419.2(b)(17)). In CY 2016, we made some minor modifications to this policy (80 FR 70348 through 70350). Under current policy, certain clinical diagnostic laboratory tests that are listed on the Clinical Laboratory Fee Schedule (CLFS) are packaged in the OPSS as integral, ancillary, supportive, dependent, or adjunctive to the primary service or services provided in the hospital outpatient setting. Specifically, we conditionally package laboratory tests and only pay separately for laboratory tests when (1) they are the only services provided to a beneficiary on a claim; (2) they are “unrelated” laboratory tests, meaning they are on the same claim as other hospital outpatient services, but are ordered for a different diagnosis than the other hospital outpatient services and are ordered by a different practitioner than the practitioner who ordered the other hospital outpatient services; (3) they are molecular pathology tests; or (4) the laboratory tests are considered preventive services.

(2) “Unrelated” Laboratory Test Exception

Laboratory tests are separately paid in the HOPD when they are considered “unrelated” laboratory tests. Unrelated laboratory tests are tests on the same claim as other hospital outpatient services, but are ordered for a different diagnosis than the other hospital outpatient services and are ordered by a different practitioner than the practitioner who ordered the other hospital outpatient services. Unrelated laboratory tests are designated for separate payment by hospitals with the “L1” modifier. This is the only use of the “L1” modifier.

For CY 2017, in the CY 2017 OPSS/ASC proposed rule (81 FR 45628), we proposed to discontinue the unrelated laboratory test exception (and the “L1” modifier) for the following reasons: We believe that, in most cases, “unrelated” laboratory tests are not significantly different than most other packaged laboratory tests provided in the HOPD. Multiple hospitals have informed us that the “unrelated” laboratory test exception is not useful to them because they cannot determine when a laboratory test has been ordered by a different physician and for a different diagnosis than the other services reported on the same claim. We agree with these hospitals, and we also believe that the requirements for “unrelated” laboratory tests (different diagnosis and different ordering physician) do not necessarily correlate

with the relatedness of a laboratory test to the other HOPD services that a patient receives during the same hospital stay. In the context of most hospital outpatient encounters, most laboratory tests are related in some way to other services being provided because most common laboratory tests evaluate the functioning of the human body as a physiologic system and, therefore, relate to other tests and interventions that a patient receives. Also, it is not uncommon for beneficiaries to have multiple diagnoses, and often times the various diagnoses are related in some way. Therefore, the associated diagnosis is not necessarily indicative of how related a laboratory test is to other hospital outpatient services performed during a hospital stay, especially given the granularity of ICD-10 diagnosis coding. Packaging of other ancillary services in the OPSS is not dependent upon a common diagnosis with the primary service into which an ancillary service is packaged. Therefore, we do not believe that this should be a requirement for laboratory test packaging. Furthermore, we believe that just because a laboratory test is ordered by a different physician than the physician who ordered the other hospital outpatient services furnished during a hospital outpatient stay does not necessarily mean that the laboratory test is not related to other services being provided to a beneficiary.

Therefore, because the “different physician, different diagnosis” criteria for “unrelated” laboratory tests do not clearly identify or distinguish laboratory tests that are not integral, ancillary, supportive, dependent, or adjunctive to other hospital outpatient services provided to the beneficiary during the hospital stay, we proposed to no longer permit the use of the “L1” modifier to self-designate an exception to the laboratory test packaging under these circumstances, and seek separate payment for such laboratory tests at the CLFS payment rates. Instead, we proposed to package any and all laboratory tests (except molecular pathology tests, certain ADLTs, and preventive tests) if they appear on a claim with other hospital outpatient services.

We invited public comments on this proposal.

Comment: The majority of commenters supported the proposal. Some of the commenters believed that the proposal would reduce administrative burden. Other commenters opposed the proposal and stated that, despite the burden, they would rather have the opportunity for separate payment for “unrelated”

laboratory tests. Some commenters believed that the proposal would result in no separate payment for laboratory tests when laboratory tests are the only services provided.

Response: We appreciate the commenters’ support. The proposal was made in response to concerns raised by hospitals about when to use modifier “L1,” and because we agreed with the commenters’ concerns as noted above. We also do not believe that the discontinuation of the modifier “L1” policy is inconsistent with our policy to package items and services that are integral, ancillary, supportive, dependent, or adjunctive to other hospital outpatient services. Also, we stated in the CY 2017 OPSS/ASC proposed rule (81 FR 45628) that “[i]n the context of most hospital outpatient encounters, most laboratory tests are related in some way to other services being provided because most common laboratory tests evaluate the functioning of the human body as a physiologic system and therefore relate to other tests and interventions that a patient receives.” Therefore, we do not believe that it is necessary to attempt to identify certain laboratory tests as unrelated to other services furnished to a patient. Finally, the discontinuation of the “L1” modifier and the associated policy does not affect the separate payment for laboratory tests when these procedures are the only services that are provided to the beneficiary.

After consideration of the public comments we received, we are finalizing, as proposed, the discontinuation of the “unrelated” laboratory test exception and consequently the “L1” modifier.

(3) Molecular Pathology Test Exception

In 2014, we excluded from the laboratory packaging policy molecular pathology tests described by CPT codes in the ranges of 81200 through 81383, 81400 through 81408, and 81479 (78 FR 74939 through 74942). In 2016, we expanded this policy to include not only the original code range but also all new molecular pathology test codes. Molecular pathology laboratory tests were excluded from packaging because we believed that these relatively new tests 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 the more common and routine laboratory tests that are packaged (80 FR 70348 through 70350).

In response to the CY 2016 OPSS/ASC proposed rule, commenters argued that CMS’ rationale for excluding molecular

pathology tests from the laboratory test packaging policy also applies to certain CPT codes that describe some new multianalyte assays with algorithmic analyses (MAAAs).

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70349 through 70350), we stated that “we may consider whether additional exceptions to the OPPS laboratory test packaging policy should apply to tests other than molecular pathology tests in the future.” After further consideration, we agree with these commenters that the exception that currently applies to molecular pathology tests may be appropriately applied to other laboratory tests that, like molecular pathology 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 the more common and routine laboratory tests that are packaged. Therefore, for CY 2017, in the CY 2017 OPPS/ASC proposed rule (81 FR 45628), we proposed an expansion of the laboratory packaging exception that currently applies to molecular pathology tests to also apply to all advanced diagnostic laboratory tests (ADLTs) that meet the criteria of section 1834A(d)(5)(A) of the Act. We believe that some of these diagnostic tests that meet these criteria will not be molecular pathology tests but will also 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 the more common and routine laboratory tests that are packaged. We proposed to assign status indicator “A” (Separate payment under the CLFS) to ADLTs once a laboratory test is designated an ADLT under the CLFS.

We invited public comments on this proposal.

Comment: Many commenters supported the proposal. A few commenters suggested that CMS apply the exception not just to ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act, but to all MAAAs.

Response: We appreciate the commenters’ support. Regarding the suggestion that we exempt all MAAAs from OPPS packaging, we do not believe that this would be prudent, as MAAAs are a broad category of tests. We are limiting the expansion of this exception to only those ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act, which are defined as tests that provide an analysis of multiple biomarkers of DNA, RNA, or proteins

combined with a unique algorithm to yield a single patient-specific result.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to assign status indicator “A” (Separate payment under the CLFS) to ADLTs once a laboratory test is designated an ADLT under the CLFS.

c. Conditional Packaging Status Indicators “Q1” and “Q2”

(1) Background

Packaged payment versus separate payment of items and services in the OPPS is designated at the code level through the assignment of a status indicator to all CPT and HCPCS codes. One type of packaging in the OPPS is conditional packaging, which means that, under certain circumstances, items and services are packaged, and under other circumstances, they are paid separately. There are several different conditional packaging status indicators. Two of these status indicators indicate packaging of the services with other services furnished on the same date of service: Status indicator “Q1,” which packages items or services on the same date of service with services assigned status indicator “S” (Procedure or Service, Not Discounted When Multiple), “T” (Procedure or Service, Multiple Procedure Reduction Applies), or “V” (Clinic or Emergency Department Visit); and status indicator “Q2,” which packages items or services on the same date of service with services assigned status indicator “T.” Other conditional packaging status indicators, “Q4” (Conditionally packaged laboratory tests) and “J1”/“J2” (Hospital Part B services paid through a comprehensive APC), package services on the same claim, regardless of the date of service.

(2) Change in Conditional Packaging Status Indicators Logic

We do not believe that some conditional packaging status indicators should package based on date of service, while other conditional packaging status indicators package based on services reported on the same claim. For CY 2017, we proposed to align the packaging logic for all of the conditional packaging status indicators and change the logic for status indicators “Q1” and “Q2” so that packaging would occur at the claim level (instead of based on the date of service) to promote consistency and ensure that items and services that are provided during a hospital stay that may span more than one day are appropriately packaged according to OPPS packaging policies (81 FR 45629). We pointed out that this would increase

the conditional packaging of conditionally packaged items and services because conditional packaging would occur whenever a conditionally packaged item or service is reported on the same claim as a primary service without regard to the date of service.

We invited public comments on this proposal.

Comment: The majority of commenters opposed the proposal. These commenters opposed the proposal primarily because of a general opposition to packaging in the OPPS. Other commenters supported the proposal and acknowledged CMS’ efforts to promote consistency in the OPPS. Some commenters requested further information on the impacts of the proposed change.

Response: We thank the commenters who support this proposal. The commenters who opposed the proposal did not provide specifics as to why the proposed change would be inconsistent with OPPS packaging policies. We believe that conditional packaging should operate at the claim level for an entire hospital stay and not be limited to a single date of service. We refer the commenters interested in the impacts of this and other policies to section XXIII. of this final rule with comment period.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to align the packaging logic for all of the conditional packaging status indicators and change the logic for status indicators “Q1” and “Q2” so that packaging occurs at the claim level (instead of based on the date of service).

4. Calculation of OPPS Scaled Payment Weights

We established a policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68283) of using geometric mean-based APC costs to calculate relative payment weights under the OPPS. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70350 through 70351), we applied this policy and calculated the relative payment weights for each APC for CY 2016 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 2017, we proposed to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2017 using geometric mean-based APC costs (81 FR 45629).

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 2017, we proposed to continue to standardize all of the relative payment weights to APC 5012 (81 FR 45629). 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 2017, in the CY 2017 OPSS/ASC proposed rule (81 FR 45629), we proposed to assign APC 5012 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the geometric mean cost for APC 5012 to derive the unscaled relative payment weight for each APC. The choice of the APC on which to standardize the relative payment weights does not affect payments made under the 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 2017 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 proposed to compare the estimated aggregate weight using the CY 2016 scaled relative payment weights to the estimated aggregate weight using the

proposed CY 2017 unscaled relative payment weights.

We did not receive any public comments on our proposal to use the geometric mean cost of renumbered APC 5012 to standardize relative payment weights. Therefore, we are finalizing our proposal and assigning APC 5012 the relative payment weight of 1.00, and using the relative payment weight for APC 5012 to derive the unscaled relative payment weight for each APC for CY 2017.

For CY 2016, we multiplied the CY 2016 scaled APC relative payment weight applicable to a service paid under the OPSS by the volume of that service from CY 2015 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 2017, in the CY 2017 OPSS/ASC proposed rule (81 FR 45629), we proposed to apply the same process using the estimated CY 2017 unscaled relative payment weights rather than scaled relative payment weights. We proposed to calculate the weight scalar by dividing the CY 2016 estimated aggregate weight by the unscaled CY 2017 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 2017 OPSS final rule link and open the claims accounting document link at the bottom of the page.

In the CY 2017 OPSS/ASC proposed rule (81 FR 45630), we proposed to compare the estimated unscaled relative payment weights in CY 2017 to the estimated total relative payment weights in CY 2016 using CY 2015 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we proposed to adjust the calculated CY 2017 unscaled relative payment weights for purposes of budget neutrality. We proposed to adjust the estimated CY 2017 unscaled relative payment weights by multiplying them by a weight scalar of 1.4059 to ensure that the proposed CY 2017 relative payment weights are scaled to be budget neutral. The proposed CY 2017 relative payment weights listed in Addenda A and B to the proposed rule (which are available via the Internet on the CMS Web site) were scaled and incorporated the recalibration adjustments discussed

in sections II.A.1. and II.A.2. of the 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 final rule with comment period) is included in the budget neutrality calculations for the CY 2017 OPSS.

We did not receive any public comments on the proposed weight scalar calculation.

Therefore, we are finalizing our proposal to use the calculation process described in the proposed rule, without modification. Using updating final rule claims data, we are updating the estimated CY 2017 unscaled relative payment weights by multiplying them by a weight scalar of 1.4208 to ensure that the final CY 2017 relative payment weights are scaled to be budget neutral.

B. Conversion Factor Update

Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor used to determine the payment rates under the OPSS 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 2017 IPPS/LTCH PPS final rule (81 FR 56938 through 81 FR 56939), consistent with current law, based on IHS Global Insight, Inc.'s second quarter 2016 forecast of the FY 2017 market basket increase, the FY 2017 IPPS market basket update is 2.7 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 2017.

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 2017 IPPS/LTCH PPS final rule (81 FR 56938 through 81 FR 56939), we discussed the calculation of the final MFP adjustment for FY 2017, which is 0.3 percentage point.

In the CY 2017 OPPS/ASC proposed rule, we proposed that if more recent data became subsequently available after the publication of the 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 2017 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 this CY 2017 OPPS/ASC final rule with comment period. Consistent with that proposal, and the FY 2017 IPPS/LTCH PPS final rule, we applied the updated final FY 2017 market basket percentage increase (2.7 percent) and the MFP adjustment (0.3 percent) to the OPD fee schedule increase factor for the CY 2017 OPPS.

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 2017, 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, in the CY 2017 OPPS/ASC proposed rule, we proposed to apply a 0.75 percentage point reduction to the OPD fee schedule increase factor for CY 2017.

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 applying an OPD fee schedule increase factor of 1.65 percent for the CY 2017 OPPS (which is 2.7 percent, the final estimate of the hospital inpatient market basket percentage increase, less the final 0.3 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 final rule with comment period.

In the CY 2017 OPPS/ASC proposed rule, we proposed to amend 42 CFR 419.32(b)(1)(iv)(B) by adding a new paragraph (8) to reflect the requirement in section 1833(t)(3)(F)(i) of the Act that, for CY 2017, 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 2017.

We did not receive any public comments on the proposed adjustments to the OPD fee schedule increase factor or on the proposed changes to the regulations at 42 CFR 419.32(b)(1)(iv)(B). For the reasons discussed above, we are adjusting the OPD fee schedule increase factor and finalizing the changes to the regulations as proposed. To set the OPPS conversion factor for the CY 2017 proposed rule, we proposed to increase the CY 2016 conversion factor of \$73.725 by 1.55 percent. In accordance with section 1833(t)(9)(B) of the Act, we proposed further to adjust the conversion factor for CY 2017 to ensure that any revisions made to the wage index and rural adjustment were made on a budget neutral basis. We proposed to calculate an overall budget neutrality factor of 1.0000 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2017 IPPS wage indexes to those payments using the FY

2016 IPPS wage indexes, as adopted on a calendar year basis for the OPPS.

For the CY 2017 proposed rule, we proposed to maintain the current rural adjustment policy, as discussed in section II.E. of this final rule with comment period. Therefore, the proposed budget neutrality factor for the rural adjustment was 1.0000.

For the CY 2017 proposed rule, we proposed to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act, as discussed in section II.F. of this final rule with comment period. We proposed to calculate a CY 2017 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing estimated total CY 2017 payments under section 1833(t) of the Act, including the proposed CY 2017 cancer hospital payment adjustment, to estimated CY 2017 total payments using the CY 2016 final cancer hospital payment adjustment as required under section 1833(t)(18)(B) of the Act.

The CY 2017 proposed estimated payments applying the proposed CY 2017 cancer hospital payment adjustment were identical to estimated payments applying the CY 2016 final cancer hospital payment adjustment. Therefore, we proposed to apply a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment.

For CY 2017, we proposed to apply a budget neutrality adjustment factor of 1.0003 to increase the conversion factor to account for our proposal to package unrelated laboratory tests into OPPS payment.

For the proposed rule, we estimated that proposed pass-through spending for drugs, biologicals, and devices for CY 2017 would equal approximately \$148.3 million, which represented 0.24 percent of total projected CY 2017 OPPS spending. Therefore, the proposed conversion factor would be adjusted by the difference between the 0.26 percent estimate of pass-through spending for CY 2016 and the 0.24 percent estimate of proposed pass-through spending for CY 2017, resulting in a proposed adjustment for CY 2017 of 0.02 percent. Proposed estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2017. We estimated for the proposed rule that outlier payments would be 0.96 percent of total OPPS payments in CY 2016; the 1.0 percent for proposed outlier payments in CY 2017 would constitute a 0.04 percent increase in payment in CY 2017 relative to CY 2016.

Comment: One commenter requested that CMS verify the amount of dollars

used to calculate the adjustment of the conversion factor from the policy change to include payments for unrelated laboratory services with modifier “L1” that will be packaged into OPSS services starting in CY 2017. The commenter believed that the cost of packaging those services would be approximately \$40 million rather than the approximately \$22 million that CMS identified using the methodology and claims data from the CY 2017 OPSS/ASC proposed rule (81 FR 45631).

Response: We appreciate the commenter’s review of our analysis. We note that, while estimated cost is generally used for ratesetting purposes to establish the relative payment weights, our proposed policy of including those payments for unrelated laboratory services with the “L1” modifier that would be newly packaged would be in the context of budget neutralizing those payments into the OPSS. While the costs used from these services in establishing the relative weights would be approximately \$45 million, the payments that would be used for budget neutralization would be approximately \$25 million, using the same source claims dataset as in the CY 2017 OPSS/ASC final rule with comment period. We then determine how to adjust the OPSS conversion factor by comparing the CY 2015 aggregate payment of approximately \$25 million to the total estimated payment for the CY 2015 OPSS, which results in a final conversion factor adjustment for this final laboratory services policy change of 1.0004.

For the proposed rule, we also proposed that hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor. For hospitals that fail to meet the requirements of the Hospital OQR Program, we proposed to make all other adjustments discussed above, but use a reduced OPD fee schedule update factor of -0.45 percent (that is, the proposed OPD fee schedule increase factor of 1.55 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2017 of 73.411 for hospitals that fail to meet the Hospital OQR requirements (a difference of -1.498 in the conversion factor relative to hospitals that met the requirements).

In summary, for CY 2017, we proposed to amend § 419.32(b)(1)(iv)(B) by adding a new paragraph (8) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2017 to satisfy the statutory

requirements of sections 1833(t)(3)(F) and (t)(3)(G)(v) of the Act. We proposed to use a reduced conversion factor of 73.411 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of -1.498 in the conversion factor relative to hospitals that met the requirements).

We invited public comments on these proposals. However, we did not receive any public comments. Therefore, we are finalizing these proposals without modification. For CY 2017, we proposed to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act, as discussed in section II.F. of this final rule with comment period. Based on the final rule updated data used in calculating the cancer hospital payment adjustment in section II.F. of this final rule with comment period, the target payment-to-cost ratio for the cancer hospital payment adjustment, which was 0.92 for CY 2016, is 0.91 for CY 2017. As a result, we are applying a budget neutrality adjustment factor of 1.0003 to the conversion factor for the cancer hospital payment adjustment.

As a result of these finalized policies, the OPD fee schedule increase factor for the CY 2017 OPSS is 1.65 percent (which is 2.7 percent, the estimate of the hospital inpatient market basket percentage increase, less the 0.3 percentage point MFP adjustment, and less the 0.75 percentage point additional adjustment). For CY 2017, we are using a conversion factor of \$75.001 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the OPD fee schedule increase factor of 1.65 percent for CY 2017, the required wage index budget neutrality adjustment of approximately 0.9999, the cancer hospital payment adjustment of 1.0003, the packaging of unrelated laboratory tests adjustment factor of 1.0004, and the adjustment of 0.02 percentage point of projected OPSS spending for the difference in the pass-through spending and outlier payments that result in a conversion factor for CY 2017 of \$75.001.

C. Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner (codified at 42 CFR 419.43(a)). This portion of the

OPSS payment rate is called the OPSS labor-related share. Budget neutrality is discussed in section II.B. of this final rule with comment period.

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). In the CY 2017 OPSS/ASC proposed rule (81 FR 45631), we proposed to continue this policy for the CY 2017 OPSS. We refer readers to section II.H. of this final rule with comment period 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 section II.A.2.c. of this final rule with comment period, for estimating APC costs, we standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2017 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 new 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 2017 OPPS, we proposed 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, rural and imputed floors, and rural floor budget neutrality) is less than 1.00. Because the HOPD receives a wage index based on the geographic location of the specific inpatient hospital with which it is associated, the frontier State wage index adjustment applicable for the inpatient hospital also would apply for any associated HOPD. We refer readers to the 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.

In addition to the changes required by the Affordable Care Act, we note that the FY 2017 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 and imputed floor provisions, an adjustment for occupational mix, and an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment). We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56912 through 56937) for a detailed discussion of all changes to the FY 2017 IPPS wage indexes. 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: <http://www.whitehouse.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 that were based on the 2010 Decennial Census data, effective October 1, 2014.

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/omb/bulletins/default>.

OMB Bulletin No. 15–01 made the following changes that are relevant to the IPPS and OPPS wage index:

- Garfield County, OK, with principal city Enid, OK, which was a Micropolitan (geographically rural) area, now qualifies as an urban new CBSA 21420 called Enid, OK.
- The county of Bedford City, VA, a component of the Lynchburg, VA CBSA 31340, changed to town status and is added to Bedford County. Therefore, the

county of Bedford City (SSA State county code 49088, FIPS State County Code 51515) is now part of the county of Bedford, VA (SSA State county code 49090, FIPS State County Code 51019). However, the CBSA remains Lynchburg, VA 31340.

- The name of Macon, GA, CBSA 31420, as well as a principal city of the Macon-Warner Robins, GA combined statistical area, is now Macon-Bibb County, GA. The CBSA code remains as 31420.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25062), we proposed to implement these revisions, effective October 1, 2016, beginning with the FY 2017 wage indexes. In the FY 2017 IPPS/LTCH PPS proposed rule, we proposed to use these new definitions to calculate area IPPS wage indexes in a manner that is generally consistent with the CBSA-based methodologies finalized in the FY 2005 and the FY 2015 IPPS final rules. Implementation of these revisions for the IPPS/LTCH PPS was finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913). 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 proposed rule (81 FR 45632), we proposed to implement these revisions to the OMB statistical area delineations, effective January 1, 2017, beginning with the CY 2017 OPPS wage indexes. We invited public comments on these proposals for the CY 2017 OPPS wage indexes. We note that Tables 2 and 3 for the FY 2017 IPPS/LTCH PPS final 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 the CBSA changes. These two tables are available via the Internet on the CMS Web site.

In the CY 2017 OPPS/ASC proposed rule, we proposed to use the FY 2017 hospital IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment standardized amount for CY 2017. Therefore, we stated that any adjustments that were proposed for the FY 2017 IPPS post-reclassified wage index would be reflected in the proposed CY 2017 OPPS wage index, including the revisions to the OMB labor market delineations discussed above, as set forth in OMB Bulletin No.

15–01. (We refer readers to the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25062 through 25076) and final rule (81 FR 56912 through 56937), and the proposed and final FY 2017 hospital wage index files posted on the CMS Web site.)

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 proposed to continue this policy for CY 2017. The following is a brief summary of the major FY 2017 IPPS wage index policies and adjustments that we proposed to apply to these hospitals under the OPSS for CY 2017. We further refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56912 through 56937) for a detailed discussion of the final changes to the FY 2017 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 2017, we proposed 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). Therefore, for the CY 2017 OPSS, consistent with the FY 2017 IPPS/LTCH PPS final rule (81 FR 56912 through 56937), this 3-year transition will continue for the third year in CY 2017.

In addition, for the FY 2017 IPPS, we extended the imputed floor policy (both the original methodology and alternative methodology) for another year, through September 30, 2017 (81 FR 56919 through 56922). For purposes of the CY 2017 OPSS, we proposed to apply the imputed floor policy to hospitals paid under the OPSS but not under the IPPS so long as the IPPS continues an imputed floor policy.

For CMHCs, for CY 2017, we proposed to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. 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). Consistent with our current policy, the wage index that applies to CMHCs includes both the imputed floor adjustment and the rural floor adjustment, but does not include the out-migration adjustment because that adjustment only applies to hospitals.

We did not receive any public comments on our proposals as discussed above.

Therefore, for the reasons discussed above and in the CY 2017 OPSS/ASC proposed rule, we are finalizing our proposals, without modification, to:

- Continue to use an OPSS labor-related share of 60 percent of the national OPSS payment for the CY 2017 OPSS;

- Use the final FY 2017 IPPS post-reclassified wage index for urban and rural areas in its entirety, including the frontier State wage index floor, the rural floor, geographic reclassifications, and all other applicable wage index adjustments, as the final CY 2017 wage index for OPSS hospitals and CMHCs based on where the facility is located for both the OPSS payment rate and the

copayment standardized amount, as discussed above and as set forth in the CY 2017 OPSS/ASC proposed rule (81 FR 45631 through 45633). (We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56912 through 56937) and the final FY 2017 hospital wage index files posted on the CMS Web site.);

- Implement the revisions to the OMB statistical area delineations set forth in OMB Bulletin No. 15–01 effective January 1, 2017, beginning with the CY 2017 OPSS wage indexes;
- Implement the frontier State floor provisions in the same manner as we have since CY 2011 as discussed above;
- For non-IPPS hospitals paid under the OPSS, continue 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;
- Apply the imputed floor policy to hospitals paid under the OPSS but not under the IPPS so long as the IPPS continues an imputed floor policy, which CMS has extended for an additional year under the IPPS in the FY 2017 IPPS/LTCH PPS final rule; and
- 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).

Table 2 associated with the FY 2017 IPPS/LTCH PPS final 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 will receive the adjustment for FY 2017. We are including the out-migration adjustment information from Table 2 associated with the FY 2017 IPPS/LTCH PPS final rule as Addendum L to this final rule with comment period with the addition of non-IPPS hospitals that will receive the section 505 out-migration adjustment under the CY 2017 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 final FY 2017 IPPS wage index tables and Addendum L.

D. 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 OPSS 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 above 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 the CY 2017 OPSS/ASC proposed rule (81 FR 45633), we proposed to update the default ratios for CY 2017 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 OPSS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009. For detail on our process for calculating the statewide average CCRs, we referred readers to the CY 2017

OPSS proposed rule Claims Accounting Narrative that was posted on the CMS Web site. Table 4 published in the proposed rule (81 FR 45634 through 45635) listed the proposed statewide average default CCRs for OPSS services furnished on or after January 1, 2017.

We did not receive any public comments on the proposed statewide average default CCR policy. Therefore, we are finalizing our proposal, without modification, to apply our standard methodology of calculating the statewide average default CCRs using the same hospital overall CCRs that we used to adjust charges to costs on claims data for setting the final CY 2017 OPSS relative payment weights. Table 4 below lists the statewide average default CCRs for OPSS services furnished on or after January 1, 2017 based on final rule data.

TABLE 4—CY 2017 STATEWIDE AVERAGE CCRS

State	Urban/rural	CY 2017 default CCR	Previous default CCR (CY 2016 OPSS final rule)
ALASKA	RURAL	0.449	0.588
ALASKA	URBAN	0.237	0.269
ALABAMA	RURAL	0.196	0.224
ALABAMA	URBAN	0.158	0.168
ARKANSAS	RURAL	0.196	0.223
ARKANSAS	URBAN	0.205	0.218
ARIZONA	RURAL	0.238	0.246
ARIZONA	URBAN	0.176	0.170
CALIFORNIA	RURAL	0.179	0.179
CALIFORNIA	URBAN	0.188	0.190
COLORADO	RURAL	0.354	0.366
COLORADO	URBAN	0.208	0.208
CONNECTICUT	RURAL	0.402	0.366
CONNECTICUT	URBAN	0.253	0.257
DISTRICT OF COLUMBIA	URBAN	0.286	0.298
DELAWARE	URBAN	0.288	0.308
FLORIDA	RURAL	0.169	0.170
FLORIDA	URBAN	0.143	0.150
GEORGIA	RURAL	0.230	0.251
GEORGIA	URBAN	0.196	0.199
HAWAII	RURAL	0.338	0.339
HAWAII	URBAN	0.319	0.313
IOWA	RURAL	0.291	0.305
IOWA	URBAN	0.252	0.256
IDAHO	RURAL	0.341	0.337
IDAHO	URBAN	0.401	0.459
ILLINOIS	RURAL	0.241	0.234
ILLINOIS	URBAN	0.209	0.208
INDIANA	RURAL	0.272	0.314
INDIANA	URBAN	0.218	0.237
KANSAS	RURAL	0.269	0.287
KANSAS	URBAN	0.194	0.209
KENTUCKY	RURAL	0.194	0.202
KENTUCKY	URBAN	0.189	0.203
LOUISIANA	RURAL	0.217	0.256
LOUISIANA	URBAN	0.201	0.202
MASSACHUSETTS	RURAL	0.316	0.324
MASSACHUSETTS	URBAN	0.345	0.330
MAINE	RURAL	0.425	0.470
MAINE	URBAN	0.413	0.395
MARYLAND	RURAL	0.264	0.277
MARYLAND	URBAN	0.229	0.234
MICHIGAN	RURAL	0.295	0.317
MICHIGAN	URBAN	0.324	0.319

TABLE 4—CY 2017 STATEWIDE AVERAGE CCRs—Continued

State	Urban/rural	CY 2017 default CCR	Previous default CCR (CY 2016 OPPS final rule)
MINNESOTA	RURAL	0.398	0.449
MINNESOTA	URBAN	0.319	0.377
MISSOURI	RURAL	0.222	0.238
MISSOURI	URBAN	0.261	0.253
MISSISSIPPI	RURAL	0.224	0.235
MISSISSIPPI	URBAN	0.167	0.169
MONTANA	RURAL	0.450	0.480
MONTANA	URBAN	0.368	0.403
NORTH CAROLINA	RURAL	0.216	0.229
NORTH CAROLINA	URBAN	0.223	0.235
NORTH DAKOTA	RURAL	0.411	0.443
NORTH DAKOTA	URBAN	0.334	0.355
NEBRASKA	RURAL	0.294	0.283
NEBRASKA	URBAN	0.238	0.238
NEW HAMPSHIRE	RURAL	0.320	0.306
NEW HAMPSHIRE	URBAN	0.279	0.306
NEW JERSEY	URBAN	0.195	0.194
NEW MEXICO	RURAL	0.225	0.280
NEW MEXICO	URBAN	0.280	0.290
NEVADA	RURAL	0.196	0.219
NEVADA	URBAN	0.123	0.146
NEW YORK	RURAL	0.309	0.311
NEW YORK	URBAN	0.292	0.298
OHIO	RURAL	0.292	0.295
OHIO	URBAN	0.207	0.212
OKLAHOMA	RURAL	0.231	0.255
OKLAHOMA	URBAN	0.180	0.192
OREGON	RURAL	0.280	0.265
OREGON	URBAN	0.344	0.341
PENNSYLVANIA	RURAL	0.274	0.277
PENNSYLVANIA	URBAN	0.179	0.195
PUERTO RICO	URBAN	0.527	0.590
RHODE ISLAND	URBAN	0.291	0.290
SOUTH CAROLINA	RURAL	0.185	0.188
SOUTH CAROLINA	URBAN	0.190	0.197
SOUTH DAKOTA	RURAL	0.383	0.367
SOUTH DAKOTA	URBAN	0.229	0.224
TENNESSEE	RURAL	0.181	0.198
TENNESSEE	URBAN	0.180	0.177
TEXAS	RURAL	0.214	0.238
TEXAS	URBAN	0.177	0.179
UTAH	RURAL	0.349	0.493
UTAH	URBAN	0.315	0.325
VIRGINIA	RURAL	0.191	0.195
VIRGINIA	URBAN	0.226	0.233
VERMONT	RURAL	0.426	0.434
VERMONT	URBAN	0.340	0.336
WASHINGTON	RURAL	0.271	0.349
WASHINGTON	URBAN	0.294	0.308
WISCONSIN	RURAL	0.354	0.317
WISCONSIN	URBAN	0.290	0.296
WEST VIRGINIA	RURAL	0.266	0.276
WEST VIRGINIA	URBAN	0.285	0.294
WYOMING	RURAL	0.429	0.433
WYOMING	URBAN	0.311	0.311

E. Adjustment for Rural SCHs and EACHs Under Section 1833(t)(13)(B) of the Act

In the CY 2006 OPSS final rule with comment period (70 FR 68556), we finalized a payment increase for rural SCHs of 7.1 percent for all services and procedures paid under the OPSS, excluding drugs, biologicals,

brachytherapy sources, and devices paid under the pass-through payment policy in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPSS payments for rural

hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPSS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPSS, excluding separately

payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In the CY 2007 OPPI/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 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 OPPI 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 2016. Further, in the CY 2009 OPPI/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 the CY 2017 OPPI/ASC proposed rule (81 FR 45635), for the CY 2017 OPPI, we proposed 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 OPPI, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs (80 FR 39244).

Comment: Commenters supported the proposed payment adjustment for rural SCHs and EACHs, and stated that this adjustment would support access to care in rural areas.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing the proposal for CY 2017 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 OPPI, excluding separately payable drugs and

biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs.

F. Payment Adjustment for Certain Cancer Hospitals for CY 2017

1. Background

Since the inception of the OPPI, 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 OPPI for covered outpatient hospital services. These cancer hospitals are exempted from payment under the IPPI. 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 OPPI 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 OPPI 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 OPPI than the payment amount they would have received before implementation of the OPPI, 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 OPPI, 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, 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 OPPI hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPI/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 OPPI/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 OPPI. 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 OPPI/ASC final rule with comment period (80 FR 70362 through 70363).

b. Proposed and Finalized Policy for CY 2017

In the CY 2017 OPPTS/ASC proposed rule (81 FR 45636), for CY 2017, we proposed to continue our policy 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 OPPTS hospitals using the most recent submitted or settled cost report data that are available at the time of the development of the proposed rule. To calculate the proposed CY 2017 target PCR, we used the same extract of cost report data from HCRIS, as discussed in section II.A. of the proposed rule, used to estimate costs for the CY 2017 OPPTS. 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 2015 claims data that we used to model the impact of the proposed CY 2017 APC relative payment weights (3,716 hospitals) because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled CY 2017 OPPTS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2012 to 2015. We then removed the cost report data of the 50 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 OPPTS and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed the cost report data of 14 hospitals because these hospitals had cost report data that were not complete (missing aggregate OPPTS 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 3,652 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated that, on average, the OPPTS payments to other hospitals furnishing services under the OPPTS were approximately 92 percent of reasonable cost (weighted average PCR of 0.92). Therefore, we proposed that the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement would be the additional payment needed to result in a proposed target PCR equal to 0.92 for each cancer hospital. Table 5 of the proposed rule indicated the proposed estimated percentage increase in OPPTS payments to each cancer hospital for CY 2017 due to the cancer hospital payment adjustment policy.

Comment: Several commenters supported the proposed cancer hospital payment adjustment for CY 2017.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our cancer hospital payment adjustment methodology as proposed. For this final rule with comment period, we are using the most recent cost report data through June 30, 2016 to update the adjustment. This update yields a target PCR of 0.91. We limited the dataset to the hospitals with CY 2015 claims data that we used to model the impact of the CY 2017 APC relative payment weights (3,744 hospitals) because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled CY 2017 OPPTS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2012 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 OPPTS and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed the cost report data of 13 hospitals because these hospitals had cost report data that were not complete (missing aggregate OPPTS 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 3,682 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated that, on average, the OPPTS payments to other hospitals furnishing services under the OPPTS are approximately 91 percent of reasonable cost (weighted average PCR of 0.91). Therefore, we are finalizing that the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement will be the additional payment needed to result in a PCR equal to 0.91 for each cancer hospital.

Table 5 below indicates the final estimated percentage increase in OPPTS payments to each cancer hospital for CY 2017 due to the finalized cancer hospital payment adjustment policy. The actual amount of the CY 2017 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2017 payments and costs. We note that the requirements contained in section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs will be assessed as usual after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

TABLE 5—ESTIMATED CY 2017 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider No.	Hospital name	Estimated percentage increase in OPPTS payments for CY 2017 due to payment adjustment (%)
050146	City of Hope Comprehensive Cancer Center	25.8
050660	USC Norris Cancer Hospital	14.0
100079	Sylvester Comprehensive Cancer Center	32.4
100271	H. Lee Moffitt Cancer Center & Research Institute	27.3
220162	Dana-Farber Cancer Institute	49.8
330154	Memorial Sloan-Kettering Cancer Center	50.4
330354	Roswell Park Cancer Institute	30.0
360242	James Cancer Hospital & Solove Research Institute	37.9
390196	Fox Chase Cancer Center	16.6
450076	M.D. Anderson Cancer Center	52.3

TABLE 5—ESTIMATED CY 2017 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT—Continued

Provider No.	Hospital name	Estimated percentage increase in OPPS payments for CY 2017 due to payment adjustment (%)
500138	Seattle Cancer Care Alliance	58.7

G. Hospital Outpatient Outlier Payments

1. Background

The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. As explained in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66832 through 66834), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for the prospective year. Outlier payments are provided on a service-by-service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by a certain amount) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain amount of dollars). In CY 2016, 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 \$3,250 (the fixed-dollar amount threshold) (80 FR 70365). If the cost of a service exceeds both the multiplier threshold and the fixed-dollar threshold, the outlier payment is calculated as 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount. Beginning with CY 2009 payments, outlier payments are subject to a reconciliation process similar to the IPPS outlier reconciliation process for cost reports, as discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the OPPS. In the CY 2017 OPPS/ASC proposed rule (81 FR 45637), we indicated that our estimate of total outlier payments as a percent of total CY 2015 OPPS payment, using CY 2015 claims available for the proposed rule and the revised OPPS

expenditure estimate for the FY 2016 President's Budget, was approximately 1.0 percent of the total aggregated OPPS payments. For CY 2015, we continue to estimate that we paid the outlier target of 1.0 percent of total aggregated OPPS payments.

As stated in the proposed rule, using CY 2015 claims data and CY 2016 payment rates, we estimated that the aggregate outlier payments for CY 2016 would be approximately 1.0 percent of the total CY 2016 OPPS payments. Using an updated claims dataset and OPPS ancillary CCRs, we estimate that we paid approximately 0.96 percent of the total CY 2016 OPPS payments, in OPPS outliers. We provided estimated CY 2017 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.gov web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

2. Outlier Calculation for CY 2017

In the CY 2017 OPPS/ASC proposed rule (81 FR 45637), for CY 2017, we proposed to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We proposed that a portion of that 1.0 percent, an amount equal to less than 0.01 percent of outlier payments (or 0.0001 percent of total OPPS payments) would be allocated to CMHCs for PHP outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated OPPS outlier payments. As discussed in section VIII.C. of the proposed rule and this final rule with comment period, we proposed to continue our longstanding policy that if a CMHC's cost for partial hospitalization services, paid under proposed APC 5853 (Partial Hospitalization for CMHCs), exceeds 3.40 times the payment rate for proposed APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the proposed APC

5853 payment rate. For further discussion of CMHC outlier payments, we refer readers to section VIII.D. of the proposed rule and this final rule with comment period.

To ensure that the estimated CY 2017 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we proposed that the hospital outlier threshold be set so that outlier payments would be triggered when a hospital's cost of furnishing a service exceeds 1.75 times the APC payment amount and exceeds the APC payment amount plus \$3,825.

We calculated the proposed fixed-dollar threshold of \$3,825 using the standard methodology most recently used for CY 2016 (80 FR 70364 through 70365). For purposes of estimating outlier payments for the proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2016 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCRs, which are maintained by the MACs and used by the OPPS Pricer to pay claims. The claims that we use to model each OPPS update lag by 2 years.

In order to estimate the CY 2017 hospital outlier payments for the proposed rule, we inflated the charges on the CY 2015 claims using the same inflation factor of 1.0898 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25270 through 25273). We used an inflation factor of 1.0440 to estimate CY 2016 charges from the CY 2015 charges reported on CY 2015 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 OPPS final rule with comment period (69 FR 65845), we believe that the use of these charge inflation factors are appropriate for the OPPS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and outpatient cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPTS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPTS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we proposed to apply the same CCR inflation adjustment factor that we proposed to apply for the FY 2017 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2017 OPPTS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2017, we proposed to apply an adjustment factor of 0.9696 to the CCRs that were in the April 2016 OPSF to trend them forward from CY 2016 to CY 2017. The methodology for calculating this proposed adjustment was discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25272).

To model hospital outlier payments for the proposed rule, we applied the overall CCRs from the April 2016 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.9696 to approximate CY 2017 CCRs) to charges on CY 2015 claims that were adjusted (using the proposed charge inflation factor of 1.0898 to approximate CY 2017 charges). We simulated aggregated CY 2017 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 2017 OPPTS payments. We estimated that a proposed fixed-dollar threshold of \$3,825, combined with the proposed multiplier threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPTS 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 proposed 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 final rule with comment period.

Comment: One commenter suggested that the OPPTS outlier fixed-dollar threshold of \$3,825 was too high for CMS to pay the target aggregate outlier payment amount of 1.0 percent of the estimated aggregate total payments under the OPPTS for the prospective year. The commenter suggested that CMS reduce the OPPTS outlier threshold to compensate for the difference between the proposed and final fixed-dollar thresholds for outlier payments under the IPPS.

Response: As indicated earlier, we introduced a fixed-dollar threshold in order to better target outlier payments to those high-cost and complex procedures where a very costly service could present a hospital with significant financial loss. We maintain the target outlier percentage of 1.0 percent of estimated aggregate total payment under the OPPTS and have a fixed-dollar threshold so that OPPTS outlier payments are made only when the hospital would experience a significant loss for furnishing a particular service. The methodology we use to calculate the fixed-dollar threshold for the prospective payment year factors is based on several data inputs that may change from prior payment years. For instance, updated hospital CCR data and changes to the OPPTS payment methodology influence projected outlier payments in the prospective year. For this final rule with comment period, we used the same methodology for calculating the outlier fixed-dollar threshold that we used for the proposed rule but used updated data. We do not believe that incorporating the percentage difference between the proposed and final fixed-dollar thresholds under the IPPS would improve our methodology to meet our target outlier payment percentage of 1.0 percent.

After consideration of the public comments we received, we are finalizing our proposal to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPTS and to use our established methodology to set the OPPTS outlier fixed-dollar loss threshold for CY 2017.

3. Final Outlier Calculation

Consistent with historical practice, we used updated data for this final rule with comment period for outlier calculations. For CY 2017, we are applying the overall CCRs from the July 2016 OPSF file after adjustment (using the CCR inflation adjustment factor of 0.9688 to approximate CY 2017 CCRs) to charges on CY 2015 claims that were adjusted (using the charge inflation factor of 1.0984 to approximate CY 2017 charges). These are the same CCR adjustment and charge inflation factors that were used to set the IPPS fixed-dollar thresholds for the FY 2017 IPPS/LTCH PPS final rule (81 FR 57286). We simulated aggregated CY 2017 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiple threshold constant and assuming that outlier payments will continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2017 OPPTS payments. We estimated that a fixed-dollar threshold of \$3,825, combined with the multiple threshold of 1.75 times the APC payment rate, will allocate 1.0 percent of aggregated total OPPTS payments to outlier payments. For CMHCs, if a CMHC's cost for partial hospitalization services, paid under APC 5853 exceeds 3.40 times the payment rate, the outlier payment will be calculated as 50 percent of the amount by which the cost exceeds 3.40 times APC 5853.

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

The basic methodology for determining prospective payment rates for HOPD services under the OPPTS is set forth in existing regulations at 42 CFR part 419, subparts C and D. For this CY 2017 OPPTS/ASC final rule with comment period, the payment rate for most services and procedures for which payment is made under the OPPTS is the product of the conversion factor calculated in accordance with section II.B. of this final rule with comment period and the relative payment weight determined under section II.A. of this

final rule with comment period. Therefore, the national unadjusted payment rate for most APCs contained in Addendum A to this final rule with comment period (which is available via the Internet on the CMS Web site) and for most HCPCS codes to which separate payment under the OPSS has been assigned in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site) was calculated by multiplying the CY 2017 scaled weight for the APC by the CY 2017 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 final rule with comment period.

In the CY 2017 OPSS/ASC proposed rule (81 FR 45638), we demonstrated 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 the 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 noted that, although blood and blood products with status indicator "R" and brachytherapy sources with status indicator "U" are not subject to wage adjustment, they are subject to reduced payments when a

hospital fails to meet the Hospital OQR Program requirements.

We did not receive any public comments on these steps under the methodology that we included in the proposed rule to determine the APC payments for CY 2017. Therefore, we are using the steps in the methodology specified below, as we proposed, to demonstrate the calculation of the final CY 2017 OPSS payments using the same parameters.

Individual providers interested in calculating the payment amount that they will receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the "full" national unadjusted payment rate. We refer to the national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the "reduced" national unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.980 times the "full" national unadjusted payment rate. The national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements in order to receive the full CY 2017 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 CY 2017 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 I.C. of this final rule with comment period. The wage index values assigned to each area reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2017 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 changes to the FY 2017 IPPS wage indexes, as applied to the CY 2017 OPSS, we refer readers to section I.C. of this final rule with comment period. As we proposed, we are continuing 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 final rule with comment period (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 2017 IPPS, which are listed in Table 2 in the FY 2017 IPPS/LTCH PPS final rule and correction notice tables and 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 CY 2017 full national unadjusted payment rate for APC 5071 is approximately \$538.88. The reduced national unadjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is approximately \$528.10. This reduced rate is calculated by multiplying the reporting ratio of 0.980 by the full unadjusted payment rate for APC 5071.

The FY 2017 wage index for a provider located in CBSA 35614 in New York is 1.2936. The labor-related portion of the full national unadjusted

payment is approximately \$418.26 ($.60 * \$538.88 * 1.2936$). The labor-related portion of the reduced national unadjusted payment is approximately \$409.89 ($.60 * \$528.10 * 1.2936$). The nonlabor-related portion of the full national unadjusted payment is approximately \$215.55 ($.40 * \538.88). The nonlabor-related portion of the reduced national unadjusted payment is approximately \$211.24 ($.40 * \528.10). The sum of the labor-related and nonlabor-related portions of the full national adjusted payment is approximately \$633.81 ($\$418.26 + \215.55). The sum of the portions of the reduced national adjusted payment is approximately \$621.13 ($\$409.89 + \211.24).

I. Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services. Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the Act, the effective copayment rate for a covered OPD service paid under the 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. OPSS Copayment Policy

In the CY 2017 OPSS/ASC proposed rule (81 FR 45640), for CY 2017, we proposed to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. (We refer readers to the November 7, 2003 OPSS final rule with comment period (68 FR 63458).) In addition, we proposed to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. (We refer readers to the CY 2008 OPSS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles.) We included the proposed national unadjusted copayment amounts for services payable under the OPSS that would be effective January 1, 2017, in Addenda A and B to the proposed rule (which are available via the Internet on the CMS Web site).

As discussed in section XIII.E. of the proposed and this final rule with comment period, for CY 2017, the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We note that 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 is consistent with the

Congressional goal of achieving 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).

We did not receive any public comments on the copayment policy proposal. For the reasons set forth in this final rule with comment period, we are finalizing our proposed CY 2017 copayment policy without modification.

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

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

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its payment rate. For example, using APC 5071, \$107.78 is approximately 20 percent of the full national unadjusted payment rate of \$538.88. For APCs with only a minimum unadjusted copayment in Addenda A and B to this final rule with comment period (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 final rule with comment period. Calculate the rural adjustment for eligible providers as indicated in Step 6 under section II.H. of this final rule with comment period.

Step 3. Multiply the percentage calculated in Step 1 by the payment rate calculated in Step 2. The result is the wage-adjusted copayment amount for the APC. The formula below is a mathematical representation of Step 3 and applies the beneficiary payment

percentage to the adjusted payment rate for a service calculated under section II.H. of this final rule with comment period, with and without the rural adjustment, to calculate the adjusted beneficiary copayment for a given service.

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

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

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

The unadjusted copayments for services payable under the OPSS that will be effective January 1, 2017, are shown in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site). We note that the national unadjusted payment rates and copayment rates shown in Addenda A and B to this final rule with comment period reflect the CY 2017 OPD fee schedule increase factor discussed in section II.B. of this final rule with comment period.

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. OPSS Ambulatory Payment Classification (APC) Group Policies

A. 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 OPSS are published both through the annual rulemaking cycle and through

the OPSS 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 OPSS quarterly update CRs. Based on our review, we assign the new CPT and Level II HCPCS codes to interim status indicator (SI) and APC assignments. These interim assignments are finalized in the OPSS/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 OPSS, the APC assignment determines the payment rate for an item, procedure, or service. For those items, procedures, or services not paid separately under the

hospital OPSS, they are assigned to appropriate status indicators. Section XI. of this final rule with comment period provides a discussion of the various status indicators used under the OPSS. Certain payment status indicators provide separate payment while other payment status indicators do not.

In Table 6 below, we summarize our current process for updating codes through our OPSS quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the OPSS.

TABLE 6—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPSS quarterly update CR	Type of code	Effective date	Comments sought	When finalized
April 1, 2016	Level II HCPCS Codes	April 1, 2016	CY 2017 OPSS/ASC proposed rule.	CY 2017 OPSS/ASC final rule with comment period.
July 1, 2016	Level II HCPCS Codes	July 1, 2016	CY 2017 OPSS/ASC proposed rule.	CY 2017 OPSS/ASC final rule with comment period.
October 1, 2016	Category I (certain vaccine codes) and III CPT codes. Level II HCPCS Codes	July 1, 2016	CY 2017 OPSS/ASC proposed rule.	CY 2017 OPSS/ASC final rule with comment period.
January 1, 2017	Level II HCPCS Codes	October 1, 2016	CY 2017 OPSS/ASC final rule with comment period.	CY 2018 OPSS/ASC final rule with comment period.
	Category I and III CPT Codes	January 1, 2017	CY 2017 OPSS/ASC final rule with comment period.	CY 2018 OPSS/ASC final rule with comment period.
		January 1, 2017	CY 2017 OPSS/ASC proposed rule.	CY 2017 OPSS/ASC final rule with comment period.

1. Treatment of New Level II HCPCS Codes Effective April 1, 2016 for Which We Solicited Public Comments in the CY 2017 OPSS/ASC Proposed Rule

Through the April 2016 OPSS quarterly update CR (Transmittal 3471, Change Request 9549, dated February 26, 2016) we recognized several new Level II HCPCS codes for separate payment under the OPSS. Effective April 1, 2016, we implemented 10 new HCPCS codes and also assigned them to appropriate interim OPSS status indicators and APCs. Specifically, as displayed in Table 7 of the CY 2017 OPSS/ASC proposed rule (81 FR 45642), we provided separate payment for HCPCS codes C9137, C9138, C9461, C9470, C9471, C9472, C9473, C9474, C9475, and J7503. We note that HCPCS code J7503 was initially assigned to OPSS status indicator “E” (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type) when the code was established on January 1,

2016. However, we revised its OPSS status indicator from “E” to “G” (Pass-Through Drugs and Biologicals. Paid under OPSS; separate APC payment) effective April 1, 2016, when the drug associated with HCPCS code J7503 was approved for pass-through payment status under the hospital OPSS.

In the CY 2017 OPSS/ASC proposed rule, we solicited public comments on the proposed APC and status indicator assignments for the 10 HCPCS codes implemented on April 1, 2016. We indicated that the proposed payment rates for these codes, where applicable, could be found in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site).

We did not receive any public comments on the proposed APC and status indicator assignments for the HCPCS codes implemented in April 2016. Therefore, we are finalizing the proposed APC assignments and status indicators for the new HCPCS codes that

were implemented on April 1, 2016. The final APC and status indicator assignments are listed in Table 7 below.

We note that, for the CY 2017 update, the HCPCS Workgroup replaced the temporary drug HCPCS C-codes that were listed in Table 7 of the proposed rule with permanent HCPCS J-codes effective January 1, 2017. Because the replacement HCPCS J-codes describe the same drugs with the same dosage descriptors as their predecessor HCPCS C-codes, they will continue to receive pass-through payment status in CY 2017. Therefore, we are assigning the replacement HCPCS J-codes to the same APCs and status indicators as their predecessor HCPCS C-codes, as shown in Table 7 below. The final payment rates for these codes, where applicable, can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

TABLE 7—FINAL CY 2017 STATUS INDICATOR (SI) AND APC ASSIGNMENTS FOR THE NEW LEVEL II HCPCS CODES THAT WERE IMPLEMENTED ON APRIL 1, 2016

CY 2016 HCPCS code	CY 2017 HCPCS code	CY 2017 long descriptor	Final CY 2017 SI	Final CY 2017 APC
C9137	J7207	Injection, factor viii, (antihemophilic factor, recombinant), PEGylated, 1 i.u.	G	1844
C9138	J7209	Injection, factor viii, (antihemophilic factor, recombinant), (Nuwiq), 1 i.u.	G	1846
C9461	A9515	Choline c-11, diagnostic, per study dose up to 20 millicuries	G	9461

TABLE 7—FINAL CY 2017 STATUS INDICATOR (SI) AND APC ASSIGNMENTS FOR THE NEW LEVEL II HCPCS CODES THAT WERE IMPLEMENTED ON APRIL 1, 2016—Continued

CY 2016 HCPCS code	CY 2017 HCPCS code	CY 2017 long descriptor	Final CY 2017 SI	Final CY 2017 APC
C9470	J1942	Injection, aripiprazole lauroxil, 1 mg	G	9470
C9471	J7322	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg	G	9471
C9472	J9325	Injection, talimogene laherparepvec, per 1 million plaque forming units	G	9472
C9473	J2182	Injection, mepolizumab, 1 mg	G	9473
C9474	J9205	Injection, irinotecan liposome, 1 mg	G	9474
C9475	J9295	Injection, necitumumab, 1 mg	G	9475
J7503	J7503	Tacrolimus, extended release, (Envarsus XR), oral, 0.25 mg	G	1845

2. Treatment of New CPT and Level II HCPCS Codes Effective July 1, 2016 for Which We Solicited Public Comments in the CY 2017 OPPS/ASC Proposed Rule

Effective July 1, 2016, we implemented several new CPT and Level II HCPCS codes under the hospital OPPS. Through the July 2016 OPPS quarterly update CR (Transmittal 3523, Change Request 9658, dated May 13, 2016), we assigned nine new Category III CPT codes and nine Level II HCPCS codes that were made effective July 1, 2016, to interim OPPS status indicators and APCs. Specifically, as displayed in Table 8 of the CY 2017 OPPS/ASC proposed rule (81 FR 45643), we established interim OPPS status indicator and APC assignments for Category III CPT codes 0438T, 0440T, 0441T, 0442T, and 0443T, and Level II HCPCS codes C9476, C9477, C9478, C9479, C9480, Q5102, Q9981, Q9982, and Q9983. We noted that Category III CPT codes 0437T, 0439T, 0444T, and 0445T are assigned to OPPS status indicator “N” to indicate that the services described by the codes are packaged and their payment is included

in the primary procedure codes reported with these codes.

Table 8 of the CY 2017 OPPS/ASC proposed rule listed the CPT and Level II HCPCS codes that were implemented on July 1, 2016, along with the proposed status indicators and proposed APC assignments, where applicable, for CY 2017. We solicited public comments on the proposed APC and status indicator assignments.

We received one comment related to the proposed APC assignment for Category III CPT codes 0440T, 0441T, and 0442T, which we address in section III.D.10. of this final rule with comment period. We did not receive any public comments on the proposed APC and status indicator assignments for the other 15 codes that were listed in Table 8 of the CY 2017 OPPS/ASC proposed rule. Therefore, in this final rule with comment period, we are adopting as final, without modification, the proposed APC and/or status indicator assignments for Category III CPT codes 0437T, 0438T, 0439T, 0444T, and 0445T and Level II HCPCS codes C9476, C9477, C9478, C9479, C9480, Q5102, Q9981, Q9982, and Q9983. However, we are modifying the OPPS status indicator

for CPT code 0443T from “T” to “N” because this is an add-on code. Since January 1, 2014, payment for procedures described by add-on codes have been packaged under the hospital OPPS.

In addition, for the CY 2017 update, the HCPCS Workgroup replaced temporary HCPCS codes C9476, C9477, C9478, C9480, and Q9981 with permanent HCPCS J-codes effective January 1, 2017. Because the replacement HCPCS J-codes describe the same drugs with the same dosage descriptors as their predecessor HCPCS C-codes and Q-codes, they will continue to receive pass-through payment status in CY 2017. Consequently, we are assigning the replacement HCPCS J-codes to the same APCs and status indicators as their predecessor HCPCS C-codes and Q-codes, as shown in Table 8 below. Table 8 lists the CPT and Level II HCPCS codes that were implemented on July 1, 2016, along with the final status indicators and APC assignments for CY 2017. The final payment rates for these codes, where applicable, can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

TABLE 8—FINAL CY 2017 STATUS INDICATORS (SI) AND APC ASSIGNMENTS FOR THE NEW CATEGORY III CPT AND LEVEL II HCPCS CODES IMPLEMENTED ON JULY 1, 2016

CY 2016 CPT/HCPCS code	CY 2017 CPT/HCPCS code	CY 2017 long descriptor	Final CY 2017 SI	Final CY 2017 APC
C9476	J9145	Injection, daratumumab, 10 mg	G	9476
C9477	J9176	Injection, elotuzumab, 1 mg	G	9477
C9478	J2840	Injection, sebelipase alfa, 1 mg	G	9478
C9479	J7342	Instillation, ciprofloxacin otic suspension, 6 mg	G	9479
C9480	J9352	Injection, trabectedin, 0.1 mg	G	9480
Q5102	Q5102	Injection, Infliximab, Biosimilar, 10 mg	E2	N/A
Q9981	J8670	Rolapitant, oral, 1 mg	K	1761
Q9982 *	Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	G	9459
Q9983 **	Q9983	Florbetaben f18, diagnostic, per study dose, up to 8.1 millicuries	G	9458
0437T	0437T	Implantation of non-biologic or synthetic implant (e.g., polypropylene) for fascial reinforcement of the abdominal wall (List separately in addition to primary procedure).	N	N/A
0438T	0438T ***	Transperineal placement of biodegradable material, peri-prostatic (via needle), single or multiple, includes image guidance.	T	5374
0439T	0439T	Myocardial contrast perfusion echocardiography; at rest or with stress, for assessment of myocardial ischemia or viability (List separately in addition to primary procedure).	N	N/A

TABLE 8—FINAL CY 2017 STATUS INDICATORS (SI) AND APC ASSIGNMENTS FOR THE NEW CATEGORY III CPT AND LEVEL II HCPCS CODES IMPLEMENTED ON JULY 1, 2016—Continued

CY 2016 CPT/HCPCS code	CY 2017 CPT/HCPCS code	CY 2017 long descriptor	Final CY 2017 SI	Final CY 2017 APC
0440T	0440T	Ablation, percutaneous, cryoablation, includes imaging guidance; upper extremity distal/peripheral nerve.	J1	5432
0441T	0441T	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve.	J1	5432
0442T	0442T	Ablation, percutaneous, cryoablation, includes imaging guidance; nerve plexus or other truncal nerve (e.g., brachial plexus, pudendal nerve).	J1	5432
0443T	0443T	Real time spectral analysis of prostate tissue by fluorescence spectroscopy ...	N	N/A
0444T	0444T	Initial placement of a drug-eluting ocular insert under one or more eyelids, including fitting, training, and insertion, unilateral or bilateral.	N	N/A
0445T	0445T	Subsequent placement of a drug-eluting ocular insert under one or more eyelids, including re-training, and removal of existing insert, unilateral or bilateral.	N	N/A

* HCPCS code C9459 (Flutemetamol f18, diagnostic, per study dose, up to 5 millicuries) was deleted June 30, 2016, and replaced with HCPCS code Q9982 effective July 1, 2016.
 ** HCPCS code C9458 (Florbetaben f18, diagnostic, per study dose, up to 8.1 millicuries) was deleted June 30, 2016, and replaced with HCPCS code Q9983 effective July 1, 2016.
 *** HCPCS code C9743 (Injection/implantation of bulking or spacer material (any type) with or without image guidance (not to be used if a more specific code applies) was deleted June 30, 2016 and replaced with CPT code 0438T effective July 1, 2016.

3. Process for New Level II HCPCS Codes That Became Effective October 1, 2016 and New Level II HCPCS Codes That Will Be Effective January 1, 2017 for Which We Are Soliciting Public Comments in This CY 2017 OPPTS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new Level II HCPCS codes that are effective October 1 and January 1 in the final rule with comment period thereby updating the OPPTS for the following calendar year. These codes are released to the public through the October and January OPPTS quarterly update CRs and via the CMS HCPCS Web site (for Level II HCPCS codes). For CY 2017, we proposed to continue our established policy of assigning comment indicator “NI” to these codes to indicate that we are assigning them an interim payment status which is subject to public comment (81 FR 45643). Specifically, the status indicators and the APC assignments for codes flagged with comment indicator “NI” are open to public comment in this final rule with comment period, and we will respond to these public comments in the OPPTS/ASC final rule with comment period for the next year’s OPPTS/ASC update. For CY 2017, we proposed to include in Addendum B to the CY 2017 OPPTS/ASC final rule with comment period the following new HCPCS codes:

- New Level II HCPCS codes effective October 1, 2016, that would be incorporated in the October 2016 OPPTS quarterly update CR;
- New Level II HCPCS codes effective January 1, 2017, that would be

incorporated in the January 2017 OPPTS quarterly update CR.

As stated above, the October 1, 2016 and January 1, 2017 codes are flagged with comment indicator “NI” in Addendum B to this CY 2017 OPPTS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPPTS payment status for CY 2017. We are inviting public comments on the interim status indicator and APC assignments and payment rates for these codes, if applicable, that will be finalized in the CY 2018 OPPTS/ASC final rule with comment period.

4. Treatment of New and Revised CY 2017 Category I and III CPT Codes That Will Be Effective January 1, 2017, for Which We Solicited Public Comments in the CY 2017 OPPTS/ASC Proposed Rule

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. 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 OPPTS/ASC proposed rules, along with proposed APC and status indicator assignments for them, and to finalize the APC and status indicator assignments in the OPPTS/ASC final rules beginning with the CY 2016 OPPTS update. For those new/revised CPT codes that were received too late for inclusion in the OPPTS/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 noted 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 OPPTS 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 establishing HCPCS G codes and the resulting delay in utilization of the most current CPT codes. In addition, 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 2017 OPPTS update, we received the CY 2017 CPT codes that will be effective January 1, 2017, from the AMA in time for inclusion in the CY 2017 OPPTS/ASC proposed rule. In the proposed rule (81 FR 45643 through 45644), we indicated that the new and revised CY 2017 Category I and III CPT codes could be found in OPPTS Addendum B to the proposed rule and were 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. We further stated that comments would be accepted on the proposed APC assignment and status indicator.

In addition, we reminded readers that the CPT code descriptors that appeared in OPSS Addendum B are short descriptors and do not accurately describe the complete procedure, service, or item described of the CPT code. Therefore, we included the 5-digit placeholder codes and their long descriptors in Addendum O to the proposed rule (which is available via the Internet on the CMS Web site) so that the public could adequately comment on our proposed APCs and status indicator assignments. The 5-digit placeholder codes were listed in Addendum O of the proposed rule, specifically under the column labeled “CY 2017 OPSS/ASC Proposed Rule 5-Digit Placeholder Code.” We also indicated that the final CPT code numbers would be included in this CY 2017 OPSS/ASC final rule with comment period. The final CPT code numbers, along with their corresponding 5-digit placeholder codes, can be found in Addendum O of this final rule with comment period.

We note that not every code listed in Addendum O of the proposed rule was subject to comment. For the new/revised Category I and III CPT codes, we requested public comments on only those codes that were assigned to comment indicator “NP.” We indicated that public comments would not be accepted for new Category I CPT laboratory codes that were not assigned to “NP” comment indicator in Addendum O to the proposed rule. We stated that comments to these codes must be submitted at the Clinical Laboratory Fee Schedule (CLFS) Public Meeting, which was scheduled for July 18, 2016.

We received public comments on several of the new CPT codes that were assigned to comment indicator “NP” in Addendum B of the CY 2017 OPSS/ASC proposed rule. We respond to these comments in section III.D. of this CY 2017 OPSS/ASC final rule with comment period.

The final status indicators, APC assignments, and payment rates for the new CPT codes that will be effective January 1, 2017, can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

B. OPSS 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 § 419.31 of the regulations. 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 final rule with comment period.

Under the OPSS, we generally pay for covered hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. In the CY 2017 OPSS/ASC proposed rule (81 FR 45644), for CY 2017, we proposed that each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in APC 5012 (Clinic Visits and Related Services). The APC relative payment weights are scaled to APC 5012 because it is the

hospital clinic visit APC and clinic visits are among the most frequently furnished services in the hospital outpatient setting.

2. Application of the 2 Times Rule

Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and revise the APC groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Section 1833(t)(9)(A) of the Act also requires the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the APC groups and the relative payment weights. We note that the Panel recommendations for specific services for the CY 2017 OPSS and our responses to them are discussed in the relevant specific sections throughout this final rule with comment period.

In addition, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or service within the same group (referred to as the “2 times rule”). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act).

Therefore, 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 if there are any APC violations of the 2 times rule and whether there are any appropriate revisions to APC assignments that may be necessary or exceptions to be made. 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 have both greater 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 claims (or less than 1,000 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 which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost. In the CY 2017 OPPS/ASC proposed rule (81 FR 45644 through 45645), we proposed to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as low-volume items and services.

For the CY 2017 OPPS update, we identified the APCs with violations of the 2 times rule, and we proposed changes to the procedure codes assigned to these APCs in Addendum B to the CY 2017 OPPS/ASC proposed rule. We noted that Addendum B did not appear in the printed version of the **Federal Register** as part of the CY 2017 OPPS/ASC proposed rule. Rather, it was published and made available via the Internet on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>. In these cases, to eliminate a violation of the 2 times rule or to improve clinical and resource homogeneity, in the CY 2017 OPPS/ASC proposed rule (81 FR 45645), we proposed to reassign these procedure codes to new APCs that contain services that are similar with regard to both their clinical and resource characteristics. In many cases, the proposed procedure code reassignments and associated APC reconfigurations for CY 2017 included in the proposed rule are related to changes in costs of services that were observed in the CY 2015 claims data newly available for CY 2017 ratesetting. We also proposed changes to the status indicators for some procedure codes that were not specifically and separately discussed in the proposed rule. In these cases, we proposed to change the status indicators for these procedure codes because we believe that another status indicator would more accurately describe their payment status from an OPPS perspective based on the policies that we proposed for CY 2017. Addendum B to the CY 2017 OPPS/ASC proposed rule identified with a comment indicator “CH” those procedure codes for which we proposed

a change to the APC assignment or status indicator, or both, that were initially assigned in the April 1, 2016 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>). In contrast, Addendum B to this final rule with comment period (available via the Internet on the CMS Web site) identifies with the “CH” comment indicator the final CY 2017 changes compared to the HCPCS codes’ status as reflected in the October 2016 Addendum B update.

3. APC Exceptions to the 2 Times Rule

Taking into account the APC changes that we proposed for CY 2017, we reviewed all of the APCs to determine which APCs would not meet the requirements of the 2 times rule. We used the following criteria to evaluate whether to propose exceptions to the 2 times rule for affected APCs:

- Resource homogeneity;
- Clinical homogeneity;
- Hospital outpatient setting utilization;
- Frequency of service (volume); and
- Opportunity for upcoding and code fragments.

Based on the CY 2015 claims data available for the CY 2017 proposed rule, we found 4 APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs that we proposed to make exceptions for under the 2 times rule for CY 2017, and identified 4 APCs that met the criteria for an exception to the 2 times rule based on the CY 2015 claims data available for the proposed rule. 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).

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

Table 9 of the proposed rule listed the 4 APCs that we proposed to make exceptions for under the 2 times rule for CY 2017 based on the criteria cited above and claims data submitted between January 1, 2015, and December 31, 2015, and processed on or before December 31, 2015. We indicated that,

for the final rule with comment period, we intend to use claims data for dates of service between January 1, 2015, and December 31, 2015, that were processed on or before June 30, 2016, and updated CCRs, if available.

Based on the updated final rule CY 2015 claims data, we found 7 APCs with violations of the 2 times rule for this final rule with comment period. We applied the criteria as described earlier to identify the APCs that are exceptions to the 2 times rule for CY 2015, and identified 4 additional APCs that meet the criteria for exception to the 2 times rule for this final rule with comment period, but that did not meet the criteria using proposed rule claims data. Specifically, we found that the following 4 additional APCs violated the 2 times rule using the final rule with comment period claims data:

- APC 5181 (Level 1 Vascular Procedures)
- APC 5732 (Level 2 Minor Procedures)
- APC 5821 (Level 1 Health and Behavior Services)
- APC 5823 (Level 3 Health and Behavior Services)

After considering the public comments we received on APC assignments and our analysis of the CY 2015 costs from hospital claims and cost report data available for this final rule with comment period, we are finalizing our proposals with some modifications. Specifically, we are finalizing our proposal to except 3 of the 4 proposed APCs from the 2 times rule for CY 2017 (APCs 5521, 5735, and 5771), and also excepting 4 additional APCs (APCs 5181, 5732, 5821, and 5823). APC 5841 (Psychotherapy), which appeared as one of the 4 APCs in Table 9 of the CY 2017 OPPS/ASC proposed rule, no longer met the criteria for exception to the 2 times rule in this final rule with comment period. Table 9 below lists the 7 APCs that we are excepting from the 2 times rule for CY 2017 based on the criteria described earlier and a review of updated claims data. We note that, for cases in which a recommendation by the HOP Panel appears to result in or allow a violation of the 2 times rule, we generally accept the Panel’s recommendation because those recommendations are based on explicit consideration of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates. The geometric mean costs for hospital outpatient services for these and all other APCs that were used in the development of this final rule with comment period can be found on the CMS Web site at: <http://www.cms.gov/>

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

TABLE 9—FINAL CY 2017 APC EXCEPTIONS TO THE 2 TIMES RULE

CY 2017 APC	CY 2017 APC title
5181	Level 1 Vascular Procedures.
5521	Level 1 Imaging without Contrast.
5732	Level 2 Minor Procedures.
5735	Level 5 Minor Procedures.
5771	Cardiac Rehabilitation.
5821	Level 1 Health and Behavior Services.
5823	Level 3 Health and Behavior Services.

C. New Technology APCs

1. Background

In the November 30, 2001 final rule (66 FR 59903), we finalized changes to the time period a service was 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 2016, there are 48 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 1599 (New Technology—Level 48 (\$90,001–\$100,000)). In the CY 2004 OPSS final rule with comment period (68 FR 63416), we restructured the New Technology APCs to make the cost intervals more consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of New Technology APCs, one set with a status indicator of “S” (Significant Procedures, Not Discounted when Multiple. Paid under OPSS; separate APC payment) and the other set with a status indicator of “T” (Significant Procedure, Multiple Reduction Applies. Paid under OPSS; separate APC payment). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently.

We note that the cost bands for the New Technology APCs, specifically,

APCs 1491 through 1599, vary with increments ranging from \$10 to \$9,999. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPSS. Payment for each APC is made at the mid-point of the APC’s assigned cost band. For example, payment for New Technology APC 1507 (New Technology—Level 7 (\$501–\$600)) is made at \$550.50.

Every year we receive several requests for higher payment amounts under the New Technology APCs for specific procedures paid under the OPSS 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 OPSS and Medicare, as specified in the CY 2016 OPSS/ASC final rule with comment period (80 FR 70374).

Under the OPSS, one of our goals is to make payments that are appropriate for the services that are necessary for the treatment of Medicare beneficiaries. The OPSS, like other Medicare payment systems, is budget neutral and increases are limited to the annual hospital 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. Additional New Technology APC Groups

As stated above, for the CY 2017 update, there are 48 levels of New Technology APC groups with two parallel status indicators; one set with a status indicator of “S” and the other set with a status indicator of “T.” To improve our ability to pay appropriately for new technology services and procedures, in the CY 2017 OPSS/ASC proposed rule (81 FR 45646), we proposed to expand the New Technology APC groups by adding 3 more levels, specifically, adding New Technology Levels 49 through 51. We proposed this expansion to accommodate the assignment of retinal prosthesis implantation procedures to a New Technology APC, which is discussed in section III.C.3. of this final rule with comment period. Therefore, for the CY 2017 OPSS update, we proposed to establish 6 new groups of New Technology APCs, APCs 1901 through 1906 (for New Technology APC Levels 49 through 51), with procedures assigned to both OPSS status indicators “S” and “T.” These new groups of APCs have the same payment levels with one set subject to the multiple procedure payment reduction (procedures assigned to status indicator “T”) and the other set not subject to the multiple procedure

payment reduction (procedures assigned to status indicator “S”). Each proposed set of New Technology APC groups has identical group titles, payment rates, and minimum unadjusted copayments, but a different status indicator assignment. Table 10 of the CY 2017 OPPTS/ASC proposed rule included the complete list of the proposed additional

6 New Technology APC groups for CY 2017 (81 FR 45646). We did not receive any public comments on the proposed expansion of the New Technology APC groups, specifically, adding New Technology Levels 49 through 51 for New Technology APCs 1901 through 1906. Therefore, we are finalizing our proposal, without modification. Table

10 lists the final CY 2017 New Technology APCs and the group titles for New Technology Levels 49 through 51. The payment rates for New Technology APCs 1901 through 1906 can be found in Addendum A to this final rule with comment period (which is available via the Internet on the CMS Web site).

TABLE 10—FINAL CY 2017 ADDITIONAL NEW TECHNOLOGY APC GROUPS

New CY 2017 APC	CY 2017 APC title	Final CY 2017 SI
1901	New Technology—Level 49 (\$100,001–\$120,000)	S
1902	New Technology—Level 49 (\$100,001–\$120,000)	T
1903	New Technology—Level 50 (\$120,001–\$140,000)	S
1904	New Technology—Level 50 (\$120,001–\$140,000)	T
1905	New Technology—Level 51 (\$140,001–\$160,000)	S
1906	New Technology—Level 51 (\$140,001–\$160,000)	T

3. Procedures Assigned to New Technology APC Groups for CY 2017

a. Overall Proposal

As we explained in the CY 2002 OPPTS 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. However, 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), or 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 2017, in the CY 2017 OPPTS/ASC proposed rule (81 FR 45646), we proposed to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to a clinically appropriate APC. The flexibility associated with this policy allows us to reassign a service from a New Technology APC in less than 2 years if sufficient claims data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient claims data upon which to base a decision for

reassignment have not been obtained (66 FR 59902).

For CY 2016, only two procedure codes, specifically, HCPCS codes C9740 (Cystourethroscopy, with insertion of transprosthetic implant; 4 or more implants) and 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy) received payment through a New Technology APC. In the CY 2017 OPPTS/ASC proposed rule (81 FR 45646 through 45648), we proposed to reassign HCPCS code C9740 from APC 1565 (New Technology—Level 28 (\$5000–\$5500)) to APC 5376 (Level 6 Urology and Related Services), and to reassign CPT code 0100T from APC 1599 (New Technology—Level 48 (\$90,000–\$100,000)) to APC 1906 (New Technology—Level 51 (\$140,001–\$160,000)). We received public comments on the proposed APC assignment revisions for both procedure codes. Below in section III.C.3.b. of this final rule with comment period, we discuss the public comments we received, our responses, and our final policy for CY 2017 for CPT code 0100T on the retinal prosthesis implant procedure. In section III.D.4.a. of this final rule with comment period, we discuss the public comments we received, our responses, and our final policy for CY 2017 for HCPCS code C9740 on cystourethroscopy.

b. Retinal Prosthesis Implant Procedure

As stated above, in the CY 2017 OPPTS/ASC proposed rule, we proposed to revise the APC assignment for CPT code 0100T from New Technology APC 1599 to New Technology APC 1906.

CPT code 0100T describes the implantation of a retinal prosthesis, specifically, a procedure involving 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 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 OPPTS 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 is assigned to APC 1599 with a payment rate of \$95,000. 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) believe that the CY 2016 payment rate for the procedure involving the Argus® II System is 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 the CY 2017 update, analysis of the CY 2015 OPPTS claims data used for the CY 2017 proposed rule showed 5 single claims (out of 7 total claims) for CPT code 0100T, with a geometric mean

cost of approximately \$141,900 based on claims submitted between January 1, 2015, through December 31, 2015, and processed through December 31, 2015. In the proposed rule, we noted that the final payment rate in the CY 2017 OPPS/ASC final rule with comment period would be based on claims submitted between January 1, 2015, and December 31, 2015, and processed through June 30, 2016.

Based on the CY 2015 OPPS claims data available for the proposed rule and our understanding of the Argus® II procedure, we proposed to reassign CPT code 0100T from APC 1599 to APC 1906 with a proposed payment rate of approximately \$150,000 for CY 2017. We stated that we believe that APC 1906 is the most appropriate APC assignment for the Argus® II procedure. 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).

Comment: Several commenters supported CMS' proposal to reassign CPT code 0100T from APC 1599 to APC 1906, which had a proposed CY 2017 payment rate of \$150,000, and stated that the proposed payment better aligns with the cost of providing the service. However, one commenter stated that, while this change may benefit some hospitals, it does not help hospitals with a low wage-index value because the cost of the technology itself is not affected by the hospital's wages relative to other hospitals. The commenter further stated that the use of such new technologies as the Argus® II procedure underpays hospitals in less costly wage areas and, therefore, limit its use. Consequently, the commenter suggested that CMS consider the effect of setting new technology payments for hospitals assigned to less costly wage areas.

Response: We appreciate the commenters' support. Based on the updated CY 2015 hospital outpatient claims data used for this final rule with comment period, which is based on claims submitted between January 1, 2015, and December 31, 2015, and processed through June 30, 2016, we believe that APC 1906 remains the most appropriate APC assignment for CPT code 0100T. The latest claims data showed 9 single claims (out of 13 total claims) for CPT code 0100T, with a geometric mean cost of approximately \$142,003. We believe that the payment for APC 1906 appropriately captures the cost of providing the service associated with the Argus® II procedure.

With respect to the issue of hospitals with a low wage index, we appreciate the commenter's interest in refining the methodology for new technology APCs

under the OPPS. Because we did not propose a change to hospitals with a low wage index values, we will take this comment into consideration in future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to reassign CPT code 0100T from APC 1599 (New Technology—Level 48 (\$90,001–\$100,000)) to APC 1906 (New Technology—Level 51 (\$140,001–\$160,000)), which has a final payment rate of \$150,000.50 for CY 2017. We note this payment includes both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841).

D. OPPS APC-Specific Policies

1. Cardiovascular Procedures/Services a. Cardiac Event Recorder (APC 5071)

We proposed to assign procedures described by CPT code 33284 (Removal of an implantable, patient-activated cardiac event recorder) to APC 5071 (Level 1 Excision/Biopsy/Incision and Drainage) for CY 2017. Based on the CY 2015 claims data used for the proposed rule, the geometric mean cost of procedures described by CPT code 33284 was approximately \$733 (2,650 single claims), and the geometric mean cost of APC 5071 was approximately \$555. In addition, CPT code 33284 is assigned to status indicator "Q2," which indicates that the service is conditionally packaged under the OPPS. Therefore, when this procedure is performed in conjunction with a revision or replacement procedure, the payment for the procedure described by CPT code 33284 is packaged under the OPPS.

Comment: One commenter requested that CMS assign procedures described by CPT code 33284 to a higher paying APC. In particular, the commenter requested that procedures described by CPT code 33284 be assigned to APC 5211 (Level 1 Electrophysiologic Procedures) instead of APC 5071. The commenter believed that the procedure described by CPT code 33284 is more similar clinically and in terms of resource use to the services assigned to APC 5211 than to those assigned to APC 5071.

Response: We disagree with the commenter. We believe that the procedures described by CPT code 33284 are appropriately assigned to APC 5071. Based on updated claims data used for the final rule, the geometric mean cost of CPT code 33284 (approximately \$715) is more comparable to the geometric mean cost

of APC 5071 (approximately \$554) than to the geometric mean cost of APC 5072 (approximately \$1,271). Therefore, we do not believe that it would be appropriate to assign procedures described by CPT code 33284 to a higher level within the Excision/Biopsy/Incision and Drainage APC series. In addition, the procedures described by CPT code 33284 are not electrophysiology services and, therefore, do not appropriately correlate with the services assigned to APC 5211. Therefore, we are finalizing our CY 2017 proposal to assign the procedures described by CPT code 33284 to APC 5071.

b. Cardiac Telemetry (APC 5733)

As listed in Addendum B of the CY 2017 OPPS/ASC proposed rule, we proposed to reassign CPT code 93229 (External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ecg data storage (retrievable with query) with ecg triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional) from APC 5722 (Level 2 Diagnostic Tests and Related Services) to APC 5734 (Level 4 Minor Procedures), with a proposed payment rate of \$95.66.

Comment: One commenter disagreed with the proposed reassignment of CPT code 93229 to APC 5734, and stated that the proposed payment rate represents a 60-percent decrease from the CY 2016 payment rate of \$220.35. The commenter indicated that the proposed underpayment of \$95.66 does not reflect the significant costs involved in providing the service. The commenter added that the wearable device used by the beneficiary costs over \$21,000. The commenter explained that because of the significant resource costs associated with performing the service described by CPT code 93229, most hospital outpatient facilities that provide this service contract the work to a remote cardiac monitoring service company because HOPDs do not have the devices, technology, or infrastructure in place to provide the service in-house. In addition, the commenter believed that hospitals are still confused about how to code for remote cardiac diagnostic tests, and indicated that the proposed payment rate of \$95.66 for CPT code 93229 is the result of hospitals

miscoding the service on claims. The commenter believed that the coding education provided in the April 2015 edition of the Coding Clinic for HCPCS will assist hospitals in coding appropriately for the service. However, until the coding education effort effectuates changes in coding practices, the commenter believed that the true cost of furnishing the service described by CPT code 93229 is more comparable to the OPFS payment rate of approximately \$795 made in CY 2012, and recommended that CMS reassign this service to APC 5724 (Level 4 Diagnostic Tests and Related Services), with a proposed payment rate of \$870.62. Alternatively, if CMS is unable to reassign the service to APC 5724, the commenter suggested that CMS continue the CY 2016 APC assignment for CPT code 93229 to APC 5722, with a payment rate of \$220.35. The commenter further stated that when the service described by CPT code 93229 is provided under the MPFS, the payment rate for performing this service is \$732.68. The commenter believed that continuing to assign CPT code 93229 to APC 5722 for CY 2017 will provide payment stability for this service while coding education efforts continue.

Response: Based on our analysis of the CY 2015 claims data used for the proposed rule, we proposed to reassign CPT code 93229 to APC 5734. Specifically, our analysis showed a geometric mean cost of approximately \$77 based on 1,847 single claims (out of 3,747 total claims). Based on its clinical and resource homogeneity to the other services, we proposed to reassign the service described by CPT code 93229 to APC 5734, whose geometric mean cost was approximately \$100. We did not propose to continue to assign CPT code 93229 to APC 5722 because the geometric mean cost for this APC was approximately \$242, which would result in a significant overpayment for the service. However, based on our review of the updated CY 2015 claims data used for this final rule with comment period, we found the geometric mean cost for CPT code 93229 to be lower than the proposed rule geometric mean cost. We note that the proposed rule claims data were based on claims submitted from January 1, 2015, through December 31, 2015, and processed through December 31, 2015, while the final rule with comment period claims data are based on claims submitted from January 1, 2015, through December 31, 2015, and processed through June 30, 2016. Based on our analysis of the final rule with comment period claims data, we found a

geometric mean cost of approximately \$71 for the service described by CPT code 93229 based on 2,323 single claims (out of 4,495 total claims). The geometric mean cost for the service described by CPT code 93229 is more similar to that of APC 5733 (Level 3 Minor Procedures), which has a geometric mean cost of approximately \$56, than to the geometric mean cost of approximately \$103 for APC 5734. Consequently, we believe that CPT code 93229 should be reassigned to APC 5733, rather than APC 5734.

Also, as we have stated repeatedly, beyond our standard OPFS trimming methodology that we apply to those claims that have passed various types of claims processing edits, it is not our general policy to judge the accuracy of hospital coding and charging for purposes of ratesetting. (We refer readers to the CY 2011 OPFS/ASC final rule with comment period (75 FR 71838) for further discussion.) Hospitals are responsible for accurately coding the performance of procedures and services and the items furnished to beneficiaries.

In summary, after evaluating the public comment we received and our subsequent analysis of the updated claims data for this final rule with comment period, we are modifying our proposal and reassigning the service described by CPT code 93229 to APC 5733 for CY 2017. The final payment rate for this code can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

2. Eye-Related Services

Comment: A few commenters requested that CMS assign new CPT code 0465T (Suprachoroidal injection of a pharmacologic agent (does not include supply of medication)) to APC 5694 (Level 4 Drug Administration) instead of APC 5693 (Level 3 Drug Administration) because the commenters believed that the service is clinically similar and similar from a resource-use perspective to CPT code 67028 (Intravitreal injection of a pharmacologic agent (separate procedure), which is assigned to APC 5694).

Response: We agree with the commenters. We are modifying our proposal and assigning CPT code 0465T to APC 5694 for CY 2017. Because CPT code 0465T is new, we do not have claims data upon which to base an initial APC assignment. However, we believe that the clinical and resource similarities of the procedure described by CPT code 0465T, when compared to the procedure described by CPT code 67028, support assigning CPT code 0465T to APC 5694 at this time. When

cost and claims data become available for CPT code 0465T, we will reevaluate the APC assignment.

Comment: One commenter requested that CMS pay separately for the new CPT codes 0444T (Initial placement of a drug-eluting ocular insert under one or more eyelids, including fitting, training, and insertion, unilateral or bilateral) and 0445T (Subsequent placement of a drug-eluting ocular insert under one or more eyelids, including re-training, and removal of existing insert, unilateral or bilateral) instead of unconditionally packaging the payment for these services, as proposed.

Response: We disagree with the commenters. The procedure to place one of these inserts under an eyelid (as described by these procedure codes) is a very minor service (not unlike delivering eye drops) that requires little time or effort from a nurse or technician. Any associated additional cost associated with performing these procedures are appropriately packaged with another service.

3. Gastrointestinal Procedures and Services

a. Esophageal Sphincter Augmentation (APC 5362)

For CY 2017, we proposed to assign the procedures described by new CPT code 43284 (Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device, including cruroplasty when performed) to APC 5362 (Level 2 Laparoscopy and Related Services), with a geometric mean cost of approximately \$7,183. CPT code 43284 replaces CPT code 0392T, which replaced HCPCS code C9737. HCPCS code C9737 was in effect for the first half of CY 2015, and CPT code 0392T became effective beginning in the second half of CY 2015 and will be deleted at the end of CY 2016. Based on the claims data used for the proposed rule, the geometric mean cost for the procedure described by HCPCS code C9737 was approximately \$10,260 (45 single claims) and the geometric mean cost for the procedure described by CPT code 0392T was approximately \$8,453 (19 single claims).

Comment: One commenter disagreed with the proposed APC assignment for procedures described by CPT code 43284 to APC 5362. The commenter stated that the proposed payment rate for APC 5362 does not accurately reflect the anticipated cost of providing the services described by CPT code 43284. The commenter suggested that CMS create a new Level 3 APC within the laparoscopy and related services APC

series that would contain the 20 most costly procedures that are currently assigned to APC 5362. According to the commenter, the creation of this new Level 3 Laparoscopy APC would be more representative of the resource costs for services described by CPT code 43284.

Response: Based on updated claims data for the final rule, we compared the geometric mean cost for procedures described by CPT code 0392T (the predecessor code for CPT code 43284) to the geometric mean cost of APC 5362. The geometric mean cost for procedures described by CPT code 0392T is \$8,715 based on 24 single claims, which is \$1,551 greater than the geometric mean cost for APC 5362 of \$7,164. Furthermore, since CPT code 0392T replaced HCPCS code C9737, the cost of this service has decreased from \$10,388 for HCPCS code C9737 to \$8,715 for CPT code 0392T. The commenter identified 9,276 single claims using data published with the proposed rule that could be used to create a new Level 3 Laparoscopy and Related Services APC. However, this subgroup of procedures from APC 5362 only contains two significant procedures, and 23 percent of the 40,035 single claims from APC 5362. The services for the suggested Level 3 Laparoscopy and Related Services APC have both sufficient clinical and resource homogeneity to the other procedures assigned to APC 5362. Therefore, we do not believe that there is a need to create another APC for these services.

After consideration of the public comment we received, we are finalizing our proposal, without modification, to assign procedures described by CPT code 43284 to APC 5362, effective January 1, 2017. The final payment rate for CPT code 43284 can be found in Addendum B to this final rule with comment period, which is available via the Internet on the CMS Web site.

b. Esophagogastroduodenoscopy: Transmural Drainage of Pseudocyst (APC 5303)

For CY 2017, we proposed to assign CPT code 43240 (Esophagogastroduodenoscopy, flexible, transoral; with transmural drainage of pseudocyst (includes placement of transmural drainage catheter(s)/stent(s), when performed, and endoscopic ultrasound, when performed)) to APC 5303 (Level 3 Upper GI Procedures), for

which we proposed a CY 2017 geometric mean cost of approximately \$2,598.

Comment: Commenters disagreed with CMS' proposal to assign CPT code 43240 to APC 5303. The commenters believed that CPT code 43240 would be more appropriately assigned to APC 5331 (Complex GI Procedures), for which we proposed a CY 2017 geometric mean cost of approximately, based upon the procedure's clinical similarity to other endoscopy procedures involving stent placement currently assigned to APC 5331. Additionally, commenters stated that the proposed CY 2017 geometric mean cost of \$2,578 may underrepresent the true costs of the procedure because of underreporting of the C-code for stents.

Response: We disagree with the commenters' assertion that CPT code 43240 would be more appropriately assigned to APC 5331. While we acknowledge that a number of endoscopy procedures involving stent placement are currently assigned to APC 5331, we continue to believe that based on our claims data available for CY 2017 ratesetting, the proposed assignment of CPT code 43240 to APC 5303 is appropriate.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to assign CPT code 43240 to APC 5303, which has a final CY 2017 APC geometric mean cost of approximately \$2,581. The final payment rate for this code can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

Comment: One commenter requested that we create a new APC and assign the following four codes to this new APC: (1) HCPCS code G0105 (Colorectal cancer screening; colonoscopy on individual at high risk); (2) HCPCS code G0121 (Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk); (3) CPT code 44388 (Colonoscopy through stoma; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)); and (4) CPT code 45378 (Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)). The commenters emphasized the clinical importance of colonoscopy in the detection and treatment of colon

cancer as a motivation for the creation of this new APC.

Response: We recognize the importance of colonoscopies to Medicare beneficiaries and believe that the OPPS and ASC payment policies for colonoscopies allow full access to these services. As a part of our multi-year review, which includes restructuring and reorganization and consolidation of the OPPS APCs, we have been creating larger APCs based on simpler and more intuitive clinical groupings. We believe that APC 5311 (Level 1 Lower GI Procedures) is an appropriate APC assignment for these four codes from a clinical and resource perspective. We also fail to recognize any particular advantage of creating the suggested new APC that would contain only four codes. The geometric mean cost of CPT code 45378 drives the payment rate for APC 5311 because it represents 81 percent of the single claims in this APC. As we discuss later in the section on the imaging APCs, we are reassigning HCPCS codes G0105 and G0121 to APC 5311. We believe that all four of these codes are clinically similar (all are similar colonoscopy services) and are similar in terms of resource costs based on their geometric mean costs. We are finalizing the proposal to assign HCPCS codes G0105 and G0121, and CPT codes 44388 and 45378 to APC 5311 for CY 2017.

Comment: One commenter believed that some of the tube and catheter placement procedure codes (for example, CPT code 32561 (Installation(s), via chest tube/catheter agent for fibrinolysis (e.g., fibrinolytic agent for break up of multiloculated effusion); initial day) that were assigned to APC 5301 (Level 1 Upper GI Procedures) in the proposed rule are not clinically similar to the endoscopy procedures that have traditionally been grouped together in APC 5301 (or its predecessor APC). The commenter requested that CMS reassign the catheter and tube placement procedure codes to other APCs that would be more clinically suitable.

Response: Upon further review of the procedure codes assigned to APC 5301, we agree with the commenter. Table 11 below shows the final APC reassignments for the tube and catheter placement and removal procedure codes that were assigned to APC 5301 in the proposed rule.

TABLE 11—TUBE AND CATHETER CODES REASSIGNED FROM APC 5301

CPT code	Descriptor	Final CY 2017 APC	Final CY 2017 SI
32552	Removal of indwelling tunneled pleural catheter with cuff	5181	Q2
32554	Thoracentesis, needle or catheter, aspiration of the pleural space; without imaging guidance	5181	T
32555	Thoracentesis, needle or catheter, aspiration of the pleural space; with imaging guidance	5181	T
32560	Instillation, via chest tube/catheter, agent for pleurodesis (e.g., talc for recurrent or persistent pneumothorax).	5181	T
32561	Installation(s), via chest tube/catheter agent for fibrinolysis (e.g., fibrinolytic agent for break up of multiloculated effusion); initial day.	5181	T
32562	(Installation(s), via chest tube/catheter agent for fibrinolysis (e.g., fibrinolytic agent for break up of multiloculated effusion); subsequent day.	5181	T
32960	Pneumothorax, therapeutic, intrapleural injection of air	5181	T
36575	Repair of tunneled or non-tunneled central venous access catheter, without subcutaneous port or pump, central or peripheral insertion site.	5181	T
36589	Removal of tunneled central venous catheter, without subcutaneous port or pump	5181	Q2
61070	Puncture of shunt tubing or reservoir for aspiration or injection procedure	5442	T

We are reassigning all of the procedure codes listed in the above table to APC 5181 (Level 1 Vascular Procedures), except for CPT code 61070 which we are reassigning to APC 5442. We believe that APC 5181 is the most appropriate APC assignment because it currently contains various catheter insertion and removal codes and similar procedures that use catheters. We do not believe that the nine procedures codes that we are reassigning to APC 5181 are sufficiently unique that a new APC specifically for assignment of these nine codes is warranted. We also understand that these codes are at the low end of the cost range for the procedures assigned to APC 5181, but APC 5181 is the lowest cost APC in this series. We also understand that the lung procedures that we are proposing to reassign to APC 5181 are not vascular procedures, but we believe that they are generally sufficiently similar to vascular catheter insertion procedures such that assignment to APC 5181 is clinically appropriate, and that a dedicated lung procedures APC is not necessary. However, to acknowledge that these APCs includes services that are not strictly “vascular,” we are renaming the Vascular Procedures APCs (5181 through 5183) Levels 1 through 3 to “Vascular Procedures & Related Services.”

4. Musculoskeletal Procedures/Services

Consistent with CMS’ statutory requirement under section 1833(t)(9)(A) of the Act to review and revise APC assignments annually and to construct the most appropriate APC groupings, as well as, to the extent desirable, correct any 2 times rule violations, we evaluated the resource costs and clinical coherence of the procedures associated with the Closed Treatment Fracture and Related Services (APCs 5111, 5112, and

5113) and Musculoskeletal Procedures APCs (APCs 5121, 5122, 5123, 5124, and 5125). For the CY 2017 OPSS update, we reviewed the procedures assigned to the Closed Treatment Fracture and Musculoskeletal Procedures APCs, and consolidated the two APC groups into the Musculoskeletal APC group, with six Levels, to improve the homogeneity of the procedures within these two APC groups. Based on our analysis of the CY 2015 hospital outpatient claims data used for the proposed rule, we proposed some modifications to these groups as reflected in Addendum B to the CY 2017 OPSS/ASC proposed rule. Specifically, we proposed to reassign certain procedures from one level within an APC to another; either from a lower-level paying APC to a higher-level paying APC, or from a higher-level paying APC to a lower-level paying APC, depending on the geometric mean cost for each procedure code. In addition, we proposed to revise the APC group title from “Closed Treatment Fracture and Related Services” to “Musculoskeletal Procedures,” and also proposed to establish a new level within the APC, specifically, Level 6, for the assignment of musculoskeletal procedures. We believe that the proposed restructuring and consolidation of the musculoskeletal APCs more appropriately group the musculoskeletal services according to their current resource costs, as well as their clinical characteristics.

Comment: Some commenters supported the reorganization and the increase in the number of musculoskeletal APC levels from five to six. One commenter expressed approval for the number of procedures assigned to Level 6 within the APC and stated that the methodology for assigning procedures to this level is logical,

consistent with other APCs, and leads to more appropriate hospital payments. One commenter also stated that the change will help correct the problem associated with those musculoskeletal procedures that had previously shifted to the more costly inpatient setting because of inadequate payments under the hospital OPSS. Consequently, these commenters requested that CMS finalize the proposal.

Response: We appreciate the commenters’ support.

Comment: One commenter requested that CMS reevaluate the procedure codes assigned to Level 4 within the Musculoskeletal Procedures APC to ensure that these services are paid appropriately. The commenter expressed concern with the range of costs for the procedures assigned to Level 4 and 5, and stated that the current proposal underpays for some of the procedures assigned to Level 4. To correct the variation of costs between Level 4 and 5, the commenter suggested reassigning some of the procedures from Level 4 to Level 5, or alternatively, establishing a new, intermediate level APC whose geometric mean cost is between Level 4 and 5.

Response: We appreciate the commenter’s suggestion. However, we believe that the proposed structure of the musculoskeletal APCs with six levels, compared to last year’s five levels, improves the homogeneity of the procedures within the musculoskeletal APC group. As we do annually, we will again review and evaluate the APC assignments for all items, procedures, and services paid under the hospital OPSS for the CY 2018 rulemaking.

We also received several public comments concerning the proposed reassignment of certain procedures assigned to the Musculoskeletal Procedures APCs. A summary of the

public comments and our responses follow.

a. Auditory Osseointegrated Implants/ Bone-Anchored Hearing Systems (APCs 5114, 5115, and 5116)

In Addendum B of the CY 2017 OPPS/ASC proposed rule, we proposed to reassign four auditory osseointegrated implant procedures. Specifically, as listed in Table 12 below, we proposed to reassign CPT code 69714 from APC 5125 (Level 5—Musculoskeletal Procedures) to APC 5115 (Level 5—Musculoskeletal Procedures), CPT code 69715 from APC 5125 to APC 5116 (Level 6—Musculoskeletal Procedures), CPT code 69717 from APC 5123 (Level 3—Musculoskeletal Procedures) to APC 5114 (Level 4—Musculoskeletal Procedures), and CPT code 69718 from APC 5124 (Level 4—Musculoskeletal Procedures) to APC 5115.

TABLE 12—PROPOSED CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR THE AUDITORY OSSEOINTEGRATED PROCEDURES

CPT code	Long descriptors	CY 2016 OPPS SI	CY 2016 OPPS APC	CY 2016 OPPS payment rate	Proposed CY 2017 OPPS SI	Proposed CY 2017 OPPS APC	Proposed CY 2017 OPPS payment rate
69714	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy.	J1	5125	\$10,537.90	J1	5115	\$9,491.00
69715	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy.	J1	5125	10,537.90	J1	5116	14,444.00
69717	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy.	J1	5123	4,969.26	J1	5114	5,199.03
69718	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy.	J1	5124	7,064.07	J1	5115	9,491.00

Comment: One commenter expressed appreciation for the proposed payment increase for CPT codes 69715, 69717, and 69718. However, several commenters opposed the proposed payment decrease for CPT code 69714. The commenters who disagreed with the APC reassignment indicated that the data used by CMS are flawed and do not accurately capture the cost of performing an osseointegrated implant surgery. Some commenters stated that the proposed payment rate for CPT code 69714 would be inadequate to cover the cost of the procedure. These commenters noted that the list price for a Cochlear™ Baha® Implant System ranges from \$6,887 to \$8,435. Consequently, several commenters requested that CMS not finalize the proposed payment reduction for CPT code 69714 pending the collection of accurate claims data.

Response: As stated above, 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. As such, we review on an annual basis all APC assignments for both general appropriateness and for violations of the 2 times rule, and when necessary, reassign CPT codes to more appropriate APCs. Although there was no violation of the 2 times rule within the Closed Treatment Fracture and Related Services and Musculoskeletal Procedures APCs, based on our review of the updated CY 2015 claims data used for this CY 2017 OPPS/ASC final rule with comment period, we believe that revising the Musculoskeletal Procedure APC structure is necessary to maintain the clinical homogeneity and resource characteristics of the procedures within this APC group.

In addition, review of the latest hospital outpatient claims data used for this final rule with comment period shows the geometric mean cost for CPT code 69714 is approximately \$9,407 based on 703 single claims (out of 713

total claims), which is relatively similar to and slightly less than the final rule geometric mean cost of \$9,828 for APC 5115. Therefore, we continue to believe that the procedure described by CPT code 69714 is appropriately placed in APC 5115 based on resource and clinical homogeneity to other procedures currently assigned to APC 5115.

Further, as we do every year, we evaluate our claims data to determine the appropriateness of the APC assignments for all payable services and items under the hospital OPPS. For the CY 2017 OPPS update, based on our review, we proposed to revise the APC assignments for four auditory osseointegrated implant procedures, specifically, CPT codes 69714, 69715, 69717, and 69718. As a result of our APC review for the CY 2017 OPPS update, we note that, based on our review of the final rule with comment period claims data, three of the four procedures, specifically, CPT codes 69715, 69717, and 69718, will receive an increase in payment for CY 2017 under the hospital OPPS.

Comment: Some commenters believed that the proposed payment reduction for CPT code 69714 would restrict Medicare beneficiary access to the procedure.

Response: We disagree with the commenters. We do not believe that the revised payment for CPT code 69714

will affect beneficiaries' access to reasonable and appropriate care. Moreover, we believe that providers will continue to perform this procedure when medically necessary.

After consideration of the public comments we received, we are finalizing our CY 2017 proposal,

without modification, to reassign CPT codes 69714, 69715, 69717 and 69718 to APCs 5115, 5116, 5114, and 5115, respectively. Table 13 below lists the final status indicator and APC assignments, and payment rates for the four auditory osseointegrated procedures.

TABLE 13—FINAL CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR THE AUDITORY OSSEOINTEGRATED PROCEDURES

CPT code	Long descriptors	CY 2016 OPPS SI	CY 2016 OPPS APC	CY 2016 OPPS payment rate	Final CY 2017 OPPS SI	Final CY 2017 OPPS APC	Final CY 2017 OPPS payment rate
69714	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy.	J1	5125	\$10,537.90	J1	5115	\$9,557.20
69715	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy.	J1	5125	10,537.90	J1	5116	14,697.92
69717	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy.	J1	5123	4,969.26	J1	5114	5,219.36
69718	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy.	J1	5124	7,064.07	J1	5115	9,557.20

b. Bunion Correction/Foot Fusion (APC 5114)

In Addendum B of the CY 2017 OPPS/ASC proposed rule, we proposed to reassign CPT codes 28297 (Correction, hallux valgus (bunion), with or without sesamoidectomy; lapidus-type) and 28740 (Arthrodesis, midtarsal or tarsometatarsal, single joint) to APC 5114 (Level 4—Musculoskeletal Procedures) with status indicator “J1.” Both CPT codes 28297 and 28740 have a CY 2016 payment rate of approximately \$7,064 and a proposed CY 2017 payment rate of approximately \$5,199.

Comment: One commenter expressed concern with the reassignment of CPT codes 28297 and 28740 to C-APC 5114, and stated that the proposed payment would result in a significantly lower payment rate for these services. The commenter indicated that its invoices document the total equipment cost at approximately \$7,490, which is more than the proposed payment rate for C-APC 5114. The commenter also believed that CPT codes 28297 and 28740 are inappropriately assigned to C-APC 5114

because this APC does not reflect the resource or clinical complexity of these procedures. In addition, the commenter stated that the Musculoskeletal APCs are not granular enough to account for the costs associated with the broad range of orthopedic procedures performed in the hospital outpatient setting. Finally, this same commenter recommended that CMS establish an additional APC level that is not designated as a comprehensive APC for musculoskeletal procedures whose costs are in the range of \$7,000 to \$7,999. The commenter requested that CMS reassign CPT codes 28297 and 28740 to this new APC level, with a payment rate of approximately \$7,500. If CMS is unable to establish an additional APC, the commenter recommended that CMS retain the CY 2016 Musculoskeletal APC structure and payment levels. However, if CMS finalizes the proposal, the commenter requested that CMS ensure that all hospital costs for CPT codes 28297 and 28740 are captured appropriately and that the payment rate for C-APC 5114 is adjusted to reflect the cost of providing these services.

Response: We do not believe that it is necessary to create an additional APC level for these musculoskeletal procedures. We believe that CPT codes 28297 and 28740 are clinically similar to the other procedures assigned to C-APC 5114 with similar resource costs. As the commenter observed, the musculoskeletal APCs include various orthopedic procedures representing a range of costs from \$3,774 (CPT code 27385) to \$7,283 (CPT code 28740). The payment for procedures assigned to C-APC 5114 is based on the weighted average geometric mean cost for all of the procedures assigned to C-APC 5114. As with most other APCs, because the payment is based on an average of the costs of all of the procedures assigned to the APC, the payment rate can be either above or below the cost of a specific procedure. We believe that the assignment of CPT codes 28297 and 28740 to C-APC 5114 satisfies both the requirement for clinical similarity and resource similarity. There are several other similar foot surgical procedures assigned to C-APC 5114. Further, our claims data do not reveal any 2 times

rule violations in C-APC 5114. We also note that certain complex multi-procedure cases, including cases involving the procedures described by both CPT code 28297 and 28740, receive a complexity adjustment and reassignment to C-APC 5115, which results in a significantly higher payment for these more costly cases. For CY 2017, the payment rate for C-APC 5115 is approximately \$9,557. We remind hospitals that, as we do every year, we will again review the APC assignments for all services under the hospital OPSS for the CY 2018 rulemaking.

After consideration of the public comments received, we are finalizing our CY 2017 proposal, without modification, to reassign CPT codes 28297 and 28740 to C-APC 5114. Table 14 below lists the final CY 2017 OPSS status indicator and APC assignments, and payment rates for CPT codes 28297 and 28740. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPSS. Addendum B is available via the Internet on the CMS Web site. In addition, the list of codes that qualify

for complexity adjustments can be found in Addendum J to this final rule with comment period (which is available via the Internet on the CMS Web site). Addendum J to this final rule with comment period also contains the summary cost statistics for each of the code combinations that describe a complex code combination that qualify for a complexity adjustment and are reassigned to the next higher cost C-APC within the clinical family.

TABLE 14—FINAL CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR CPT CODES 28297 AND 28740

CPT code	Long descriptors	CY 2016 OPSS SI	CY 2016 OPSS APC	CY 2016 OPSS payment rate	Final CY 2017 OPSS SI	Final CY 2017 OPSS APC	Final CY 2017 OPSS payment rate
28297	Correction, hallux valgus (bunion), with or without sesamoidectomy; lapidus-type procedure.	J1	5124	\$7,064.07	J1	5114	\$5,219.36
28740	Arthrodesis, midtarsal or tarsometatarsal, single joint.	J1	5124	7,064.07	J1	5114	5,219.36

c. Intervertebral Biomechanical Devices

For CY 2017, the AMA CPT Editorial Panel deleted CPT code 22851 and replaced it with three new codes, effective January 1, 2017. Table 15 below lists the long descriptor for the procedure described by CPT code 22851, as well as the replacement codes, specifically, CPT codes 22853, 22854,

and 22859. We note that the deleted and replacement codes were listed in Addendum B and Addendum O to the CY 2017 OPSS/ASC proposed rule. Addendum B listed the proposed status indicator assignments for the replacement codes, which are assigned to comment indicator “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.), while Addendum O listed the placeholder/proposed CY 2017 CPT codes and their long descriptors.

TABLE 15—CY 2017 STATUS INDICATOR (SI) ASSIGNMENTS FOR THE APPLICATION/INSERTION OF THE INTERVERTEBRAL BIOMECHANICAL DEVICES

Proposed CY 2017 CPT code	Final CY 2017 CPT code	Long descriptors	Proposed CY 2017 OPSS SI	Final CY 2017 OPSS SI
22851	22851	Application of intervertebral biomechanical device(s) (e.g., synthetic cage(s), methylmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure).	D	D
22X81	22853	Insertion of interbody biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure).	N	N
22X82	22854	Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure).	N	N
22X83	22859	Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure).	N	N

Comment: One commenter suggested that CMS pay separately for the

replacement CPT codes 22X81, 22X82, and 22X83 and assign the new codes to

New Technology APCs to enable CMS to collect cost information and determine

whether to pay separately or package the procedures in the future. The commenter explained that the cost of providing the procedures associated with these new spine instrumentation codes are costly and include high-cost implants. The commenter also believed that, while CMS has a policy for packaging payment for procedures described by add-on codes under the hospital OPPS, it is not required to do so because its regulation refers only to packaging of certain services described by add-on codes.

Response: We do not agree with the commenter that the spine instrumentation procedures described by proposed CPT codes 22X81, 22X82, and 22X83 (replacement CPT codes 22853, 22854, and 22859) are new technology procedures that warrant an assignment to a new technology APC. These procedures have been performed for some time now in the hospital outpatient setting, and as evidenced by the predecessor code, CPT code 22851 which was established in 1996, these procedures are not new. In addition, we do not agree with the commenter that we should pay separately for replacement CPT codes 22853, 22854, and 22859 because these codes describe add-on services. Since January 1, 2014, payment for procedures described by add-on codes have been packaged under the hospital OPPS. Because the predecessor CPT code 22851 was assigned to a packaged status indicator under the hospital OPPS, we are assigning CPT codes 22853, 22854, and 22859 to status indicator "N" to indicate that payment for these services are packaged under the hospital OPPS for CY 2017.

After consideration of the public comment we received, we are finalizing our proposal, without modification, to assign CPT codes 22853, 22854, and 22859 to status indicator "N" for CY 2017.

d. Percutaneous Vertebral Augmentation/Kyphoplasty (APC 5114)

In Addendum B of the CY 2017 OPPS/ASC proposed rule, we proposed to reassign CPT codes 22513 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (e.g., kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic) and 22514 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (e.g., kyphoplasty), 1 vertebral body, unilateral or bilateral

cannulation, inclusive of all imaging guidance; lumbar) from APC 5124 (Level 4 Musculoskeletal Procedures) to APC 5114 (Level 4 Musculoskeletal Procedures). Both CPT codes have a CY 2016 payment rate of approximately \$7,064 and a proposed CY 2017 payment rate of approximately \$5,199. Because CPT code 22515 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (e.g., kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; each additional thoracic or lumbar vertebral body (list separately in addition to code for primary procedure) is an add-on code, we proposed to continue its packaged status.

Based on the CY 2015 hospital outpatient claims data available for the proposed rule, our analysis revealed a geometric mean cost of approximately \$5,434 for APC 5114, while the geometric mean cost for CPT codes 22513 and 22514 is approximately \$6,664 and \$6,672, respectively. Because the proposed geometric mean cost for APC 5115, which is the Level 5 Musculoskeletal Procedures APC, is significantly higher at \$9,920 compared to the geometric mean cost for CPT codes 22513 and 22514, we proposed to assign CPT codes 22513 and 22514 to APC 5114 for CY 2017.

At the August 22, 2016 HOP Panel meeting, a presenter requested the reassessment of the proposed revised Musculoskeletal APC groupings that result in payment reductions for CPT codes 22513 and 22514. Specifically, the commenter observed that the proposed modification to the musculoskeletal APCs reduces the payment for these procedures by 26 percent for CY 2017. During the Panel discussion, CMS indicated that, in the CY 2016 OPPS/ASC proposed rule, the Agency initially proposed to establish four levels of the musculoskeletal APCs. However, based on the comments received on the CY 2016 proposal, CMS agreed with the request to establish a new level, specifically, Level 5 Musculoskeletal Procedures APC, for the CY 2016 update. In addition, during the discussion at the August 2016 Panel meeting, CMS informed the Panel that, for the CY 2017 update, CMS proposed to establish an additional level, specifically, Level 6 Musculoskeletal Procedures APC, for the musculoskeletal procedures. At the August 2016 HOP meeting, despite the request from the presenter, the Panel made no recommendation related to this issue.

Comment: Several commenters disagreed with the proposal and stated that the proposed reassignment of these procedures to APC 5114 would result in significant underpayment for these services. Some commenters noted that the proposed CY 2017 payment rate of \$5,199.03 for CPT codes 22513 and 22514 is lower than the geometric mean costs of \$6,664 for CPT code 22513 and \$6,672 for CPT code 22514. These commenters requested that CMS reassign CPT codes 22513 and 22514 to APC 5115 (Level 5 Musculoskeletal Procedures APC), whose proposed CY 2017 payment rate is \$9,491.

Response: We do not agree with the commenters that we should reassign these procedures to APC 5115. Based on the updated CY 2015 hospital outpatient claims data used for this final rule with comment period, our analysis reveals a geometric mean cost of approximately \$5,367 for APC 5114, which is lower than the geometric mean cost of approximately \$6,674 for CPT code 22513 based on 8,553 single (out of 8,665 total claims), or the geometric mean cost of approximately \$6,643 for CPT code 22514 based on 10,451 single claims (out of 10,609 total claims). Because the difference between the geometric mean cost for APC 5115 (\$9,828) and the geometric mean costs of CPT code 22513 (\$6,674) and CPT code 22514 (\$6,643) is significantly greater than the difference between the geometric mean cost of CPT codes 22513 and 22514 and the geometric mean cost of APC 5114 (\$5,367), we believe these procedures should be assigned to APC 5114.

In addition, we do not agree with the commenters' assertion that the current assignment of CPT codes 22513 and 22514 in APC 5114 would result in significant underpayment for these services. OPPS payments are based on the geometric mean costs of all of the services assigned to the APC. By definition the costs of some services must be below the geometric mean and others must be above the geometric mean. As we have stated in the past (72 FR 66639), in some cases, payment exceeds the average cost of the CPT code, and in other cases, payment is less than the average cost of the CPT code.

Comment: One commenter stated that procedures described by add-on codes are paid separately in physician offices. However, payment for these services are packaged under the hospital OPPS. This difference results in higher payments for percutaneous vertebral augment/kyphoplasty procedures performed in the office setting compared to the HOPD setting. The commenter further noted that this discrepancy indicates that CMS

may be using a flawed methodology, similar to the CPT Committee and RUC, in determining payment rates for services under the hospital OPSS. Finally, the commenter requested that CMS increase the payment rate for CPT codes 22513 and 22514 to equalize payment for these procedures across all settings.

Response: The hospital OPSS and the MPFS that applies to physician’s office services are fundamentally different payment systems with essential differences in their payment policies and structures. Specifically, the hospital OPSS is a prospective payment system, based on the concept of payment for groups of services that share clinical and resource characteristics. Payment is made under the hospital OPSS according to prospectively established payment rates that are related to the relative costs of hospital resources for services. The MPFS is a fee schedule based on the relative value of each

individual component of services. Furthermore, physician fee schedule payments include payment for physician professional work, which is not a part of the OPSS payment to hospitals.

In addition, consistent with our general add-on code packaging policy, we package payment for certain procedures described by add-on codes under the hospital OPSS. Because CPT code 22515 is an add-on code, we have assigned this code to a packaged payment status. We believe that the procedure is a service that is always furnished in addition to another procedure (in this case, either CPT code 22513 or 22514) and cannot be performed independently. Under the MPFS approach, separate payment is made for add-on procedures provided in the physician’s office, but the OPSS packages payment for add-on codes into the associated procedure code payment for the APC group. We recognize that

the MPFS pays separately for CPT code 22515, as it does for other add-on codes. However, the MPFS and the OPSS are very different payment systems. Each is established under a different set of statutory and regulatory principles and the policies established under the MPFS do not have bearing on the payment policies under the OPSS. Given the fundamental difference between the MPFS payment mechanism and the OPSS payment mechanism, differences in the degrees of packaged payment and separate payment between these two systems are to be expected.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to reassign CPT codes 22513 and 22514 to APC 5114. Table 16 below lists the final OPSS status indicator and APC assignments and payment rates for CPT codes 22513 and 22514 for CY 2017.

TABLE 16—FINAL CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR THE PERCUTANEOUS VERTEBRAL AUGMENTATION/KYPHOPLASTY PROCEDURES

CPT code	Long descriptors	CY 2016 OPSS SI	CY 2016 OPSS APC	CY 2016 OPSS payment rate	Final CY 2017 OPSS SI	Final CY 2017 OPSS APC	Final CY 2017 OPSS payment rate
22513	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (e.g., kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic.	J1	5124	\$7,064.07	J1	5114	\$5,219.36.
22514	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (e.g., kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar.	J1	5124	7,064.07	J1	5114	5,219.36.
22515	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (e.g., kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; each additional thoracic or lumbar vertebral body (list separately in addition to code for primary procedure).	N	N/A	Packaged	N	N/A	Packaged.

e. Strapping and Casting Applications (APCs 5101 and 5102)

For the CY 2016 update, APCs 5101 (Level 1 Strapping and Cast Application) and 5102 (Level 2 Strapping and Cast Application) are assigned to OPSS status indicator “S”

(Procedure or Service, Not Discounted When Multiple; Paid under OPSS; separate APC payment) to indicate that the procedures and/or services assigned to these APCs are not discounted when two or more services are billed on the same date of service.

For the CY 2017 update, based on our analysis of the procedures assigned to APCs 5101 and 5102, in the CY 2017 OPSS/ASC proposed rule (81 FR 45648), we proposed to revise the status indicator assignment for these procedures from “S” to “T” (Procedure or Service, Multiple Procedure

Reduction Applies; Paid under OPPS; separate APC payment) to indicate that the services are paid separately under the OPPS, but a multiple procedure payment reduction applies when two or more services assigned to status indicator “T” are billed on the same date of service. Because the procedures assigned to APCs 5101 and 5102 are often associated with surgical treatments, we stated that we believe that the proposed reassignment of these procedures to status indicator “T” is appropriate and ensures adequate payment for the procedures, even when the multiple procedure discounting policy applies. Also, there is no payment reduction unless there is another status indicator “T” procedure reported on the claim describing cast/splint/strap services. Consequently, we also proposed to revise the status indicator assignment for APCs 5101 and 5102 from “S” to “T” for the CY 2017 OPPS update to appropriately categorize the procedures assigned to these two APCs.

Comment: Several commenters opposed the status indicator reassignment from “S” to “T” for APCs 5101 and 5102, and stated that CMS did not provide substantive information for the proposed change, making it difficult for stakeholders to properly analyze the effects of the proposed change. Other commenters indicated that such a change contradicts current coding guidelines.

Response: As stated above, as part of our annual review, we examine the APC assignments for all items and services under the OPPS, which include review of status indicators, for appropriate placements in the context of our proposed policies for the update year. Although not every code, status indicator, or APC revision is discussed in the preamble of the proposed rule, they are nonetheless listed in Addendum B of the proposed rule. We note that Addendum B of the proposed rule is an Excel file that is arranged in CPT/HCPCS code order and shows the proposed OPPS status indicator and

APC assignments, relative payment weights, and payment rates for every procedure code reported under the hospital OPPS.

Comment: Some commenters indicated that the National Correct Coding Initiative (NCCI) guidelines prevent the reporting of casting/strapping services when performed as part of a surgical procedure. Other commenters stated that the AMA CPT code instructions indicate that CPT codes 29700 through 29799 are only reported when the service is for a replacement procedure following a period of follow-up, or when the service is performed as the primary treatment without an associated restorative treatment or procedure(s). The commenters urged CMS not to finalize the proposal.

Response: We do not believe that the commenters completely understand the NCCI or CPT coding guidelines associated with the strapping and casting services. While it is true that strapping and casting services cannot be reported separately when performed as part of a surgical procedure, there are certain circumstances when strapping and casting services can be performed separate from a surgical procedure. It should be noted that Chapter IV (Surgery: Musculoskeletal System) of the 2016 NCCI Policy Manual for Medicare Services states that hospitals paid under the OPPS should report the appropriate casting, splinting, or strapping code in certain instances. Specifically, the NCCI Policy Manual specifies that for payment under the OPPS, if a hospital treats a fracture, dislocation, or injury with a cast, splint, or strap as an initial service without any other definitive procedure or treatment, the hospital should report the appropriate casting/splinting/strapping CPT code. In addition, while it is true that the procedures described by CPT codes 29700 through 29799 are only reported when the service is for a replacement procedure following a period of follow-up, or when the service is performed as the primary treatment

without an associated restorative treatment or procedure(s), the CPT guidelines also elaborate that these removal/repair codes can be reported separately if the initial application of the cast, splint, or strapping was performed by a different entity.

Comment: Some commenters stated that casting and strapping services are performed in the emergency department for Medicare patients following a fall or injury, and these patients often require an extended period of observation before they are discharged. These commenters stated that revising the status indicator assignment for APCs 5101 and 5102 from “S” to “T” would no longer qualify hospitals for comprehensive observation service APC payments.

Response: We do not anticipate that this will be a significant issue because all observation services that are less than 8 hours are packaged into the payment for the emergency department visit. We do not believe that most Medicare beneficiaries would require long periods of observation after receiving cast/splint/strap services in the emergency room. Instead, we believe that physicians would appropriately assess the patient and determine whether the patient should be discharged to home or admitted as an inpatient.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to revise the status indicator assignment for APCs 5101 and 5102 from “S” to “T” for CY 2017.

5. Nervous System Procedures/Services
a. Transcranial Magnetic Stimulation Therapy (TMS) (APCs 5721 and 5722)

Currently, three CPT codes exist to describe TMS therapy, specifically, CPT codes 90867, 90868, and 90869. As shown on Table 17 below, for CY 2016, we proposed to assign these codes to APC 5722 (Level 2 Diagnostic Tests and Related Services).

TABLE 17—PROPOSED CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR THE TRANSCRANIAL MAGNETIC STIMULATION THERAPY (TMS) CODES

CPT code	Long descriptors	CY 2016 OPPS SI	CY 2016 OPPS APC	CY 2016 OPPS payment rate	Proposed CY 2017 OPPS SI	Proposed CY 2017 OPPS APC	Proposed CY 2017 OPPS payment rate
90867	Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; initial, including cortical mapping, motor threshold determination, delivery and management.	S	5722	\$220.35	S	5722	\$231.67

TABLE 17—PROPOSED CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR THE TRANSCRANIAL MAGNETIC STIMULATION THERAPY (TMS) CODES—Continued

CPT code	Long descriptors	CY 2016 OPPS SI	CY 2016 OPPS APC	CY 2016 OPPS payment rate	Proposed CY 2017 OPPS SI	Proposed CY 2017 OPPS APC	Proposed CY 2017 OPPS payment rate
90868	Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; subsequent delivery and management, per session.	S	5722	220.35	S	5722	231.67
90869	Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; subsequent motor threshold re-determination with delivery and management.	S	5722	220.35	S	5721	127.42

As we do every year, we review the APC assignments for all services under the hospital OPSS based on the latest claims data. For CY 2017, we did not propose to make any changes to the APC assignment for CPT codes 90867 and 90868, and proposed to continue to assign the procedures described by these procedure codes to APC 5722 because the geometric mean cost for these procedures were within the range of the geometric mean costs for procedures assigned to APC 5722. Specifically, our proposed rule claims data showed a geometric mean cost of approximately \$196 based on 136 single claims (out of 136 total claims) for CPT code 90867, and approximately \$187 for CPT code 90868 based on 5,239 single claims (out of 5,287 total claims). Because the geometric mean cost of \$196 and \$187 are relatively similar to the geometric mean cost of \$242 for APC 5722, we proposed to continue to assign CPT codes 90867 and 90868 to APC 5722. However, for CPT code 90869, we proposed to reassign CPT code 90869 to APC 5721 (Level 1 Diagnostic Tests and Related Services) based on the latest claims data used for the proposed rule. Specifically, our claims data showed a geometric mean cost of approximately \$119 based on 47 single claims (out of 47 total claims). Because the geometric mean cost of \$133 for APC 5721 is relatively similar to the geometric mean cost of \$119 for CPT code 90869, we proposed to reassign the procedure code to APC 5721.

Comment: One commenter disagreed with the proposal to reassign CPT code 90869 to APC 5721, and requested that CMS continue to assign the procedure to APC 5722. The commenter believed that the proposed CY 2017 payment rate of \$127.42 is the result of low-volume and incorrect revenue code reporting. The commenter noted that, based on its analysis of the claims data, one

hospital's inappropriate revenue code assignment resulted in a low cost-to-charge ratio, thereby decreasing the proposed payment rate. In addition, the commenter believed that the proposed payment rate for CPT code 90869, which involves a redetermination and TMS delivery and management services, should be higher than the proposed payment rate for CPT code 90868, which involves only TMS delivery and management services.

Response: As we have stated in section 20.5 (Clarification of HCPCS Code to Revenue Code Reporting) of Chapter 4 of the Medicare Claims Processing Manual, hospitals are responsible for reporting the correct revenue code on the claim form. Specifically, we state that we do not instruct hospitals on how to report the assignment of HCPCS codes to revenue codes for services provided under OPSS because hospitals' costs vary. Where explicit instructions are not provided, providers should report their charges under the revenue code that will result in the charges being assigned to the same cost center to which the cost of those services are assigned in the cost report. We note that the Medicare cost report form allows hospitals to report in a manner that is consistent with their own financial accounting systems and, therefore, should be accurate for each individual hospital. Moreover, we believe that the cost report data and their use in the OPSS cost estimation and payment rate development process, combined with potential penalties for inaccurate reporting, provide financial incentive for hospitals to report costs accurately. Furthermore, as we have stated repeatedly, beyond our standard OPSS trimming methodology that we apply to those claims that have passed various types of claims processing edits, it is not our general policy to judge the accuracy of hospital coding and

charging for purposes of ratesetting. (We refer readers to the CY 2011 OPSS/ASC final rule with comment period (75 FR 71838) for further discussion.) Therefore, we will not question the accuracy of the coding and charging practices in this case.

In addition, based on the latest hospital outpatient claims data used for the final rule with comment period, we believe that APC 5721 is the most appropriate APC assignment for CPT code 90869. Specifically, our claims data show a geometric mean cost of approximately \$107 for CPT code 90869 based on 54 single claims (out of 54 total claims), which is similar to the geometric mean cost of approximately \$131 for APC 5721. We do not agree with the commenter that maintaining the assignment for CPT code 90869 to APC 5722 is appropriate because its geometric mean cost of approximately \$239 is significantly higher than the geometric mean cost of \$107 for CPT code 90869. Compared to the geometric mean cost of approximately \$239 for APC 5722, we believe that APC 5721 is the most appropriate assignment for CPT code 90869 based on clinical and resource homogeneity with other procedures and services in the APC.

After consideration of the public comment we received, we are finalizing our proposal, without modification, to assign CPT code 90869 to APC 5721 for CY 2017. In addition, we are adopting as final, without modification, the proposed APC assignments for CPT codes 90867 and 90868 for CY 2017. Table 18 below lists the final status indicator and APC assignments and payment rates for the three TMS CPT codes for CY 2017. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPSS. Addendum B is available via the Internet on the CMS Web site.

TABLE 18—FINAL CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR THE TRANSCRANIAL MAGNETIC STIMULATION THERAPY (TMS) CODES

CPT code	Long descriptors	CY 2016 OPPS SI	CY 2016 OPPS APC	CY 2016 OPPS payment rate	Final CY 2017 OPPS SI	Final CY 2017 OPPS APC	Final CY 2017 OPPS payment rate
90867	Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; initial, including cortical mapping, motor threshold determination, delivery and management.	S	5722	\$220.35	S	5722	\$232.21
90868	Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; subsequent delivery and management, per session.	S	5722	220.35	S	5722	232.21
90869	Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; subsequent motor threshold re-determination with delivery and management.	S	5722	220.35	S	5721	127.05

b. Percutaneous Epidural Adhesiolysis (APC 5443)

As listed in Addendum B of the CY 2017 OPPS/ASC proposed rule, we proposed to continue to assign CPT codes 62263 (Percutaneous lysis of epidural adhesions using solution injection (*e.g.*, hypertonic saline, enzyme) or mechanical means (*e.g.*, catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 2 or more days) and 62264 (Percutaneous lysis of epidural adhesions using solution injection (*e.g.*, hypertonic saline, enzyme) or mechanical means (*e.g.*, catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 1 day) to APC 5443 (Level 3 Nerve Injections), with a proposed CY 2017 payment rate of approximately \$711.

Comment: One commenter expressed concern with the proposed payment rate for CPT codes 62263 and 62264. The commenter stated that these codes were paid for appropriately in CY 2014 and CY 2015. However, the commenter believed that the payment for these procedures has declined beginning in CY 2016. The commenter also suggested that CMS reevaluate the APC structure and consider reinstating the APC classification that was in place during CY 2014 and CY 2015 in which the percutaneous adhesiolysis and radiofrequency neurotomy procedures were combined in the same APC. The commenter stated that the payment rate for the percutaneous adhesiolysis procedures should be the same as the radiofrequency neurotomy procedures, which are assigned to APC 5431 (Level

1 Nerve Procedures), with a proposed payment rate of approximately \$1,557.

Response: Based on our analysis of the claims data used for the proposed rule, APC 5443 is the most appropriate APC assignment for CPT codes 62263 and 62264 based on its clinical and resource similarity to the procedures within this APC. Specifically, our analysis revealed a geometric mean cost of approximately \$1,149 for CPT code 62263 based on 97 single claims (out of 107 total claims), and a geometric mean cost of approximately \$839 for CPT code 62264 based on 2,188 single claims (out of 3,726 total claims). We believe that the geometric mean costs of CPT codes 62263 and 62264 are more similar to the geometric mean cost of approximately \$743 for APC 5443. We believe that APC 5431 is not a more appropriate APC for CPT codes 62263 and 62264 because the geometric mean cost for this APC is approximately \$1,627.

We also note that we reviewed the updated CY 2015 claims data used for this final rule with comment period. The proposed rule claims data were based on claims submitted from January 1, 2015 through December 31, 2015 and processed through December 31, 2015, while the final rule with comment period claims data are based on claims submitted from January 1, 2015 through December 31, 2015 and processed through June 30, 2016. Based on our analysis of the final rule with comment period claims data, we found a similar pattern for CPT codes 62263 and 62264. Specifically, we found a geometric mean cost of approximately \$1,138 for CPT code 62263 based on 109 single claims (out of 121 total claims), and a geometric mean cost of approximately \$842 for CPT code 62264 based on 2,243

single claims (out of 3,972 total claims). We note that the geometric mean costs for the significant procedures within APC 5443 range between \$603 (CPT code 62310) and \$1,083 (CPT code 64640). Because the geometric mean cost for APC 5431 is approximately \$1,607, which is greater than the geometric mean cost for either CPT code 62263 or 62264, we believe that APC 5443 is the more appropriate APC assignment for these procedures.

After consideration of the public comment we received, we are adopting as final, without modification, the APC assignment to APC 5443 for CPT codes 62263 and 62264 for CY 2017. The final payment rates for these codes can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

c. Neurostimulator (APC 5463)

For CY 2017, we proposed to assign CPT code 0268T (Implantation or replacement of a carotid sinus baroreflex activation device; pulse generator only (includes intraoperative interrogation, programming, and repositioning when performed)) to APC 5463 (Level 3 Neurostimulator and Related Procedures), for which we proposed a CY 2017 geometric mean cost of approximately \$18,325.

Comment: Commenters disagreed with CMS' proposal to assign CPT code 0268T to APC 5463. The commenters believed that CPT code 0268T would be more appropriately assigned to APC 5464 (Level 4 Neurostimulator and Related Procedures), for which we proposed a CY 2017 geometric mean cost of approximately \$27,907. The commenters stated that the relatively

few claims submitted to CMS that are eligible for CY 2017 ratesetting do not accurately reflect the cost of performing this procedure.

Response: We disagree with commenters' assertion that CPT code 0268T would be more appropriately assigned to APC 5464, which has a final CY 2017 APC geometric mean cost of approximately \$27,802. Based on available claims data used for CY 2017 ratesetting, the proposed assignment of CPT code 0268T, which has a final CY 2017 geometric mean cost of approximately \$21,794, to APC 5463 is appropriate. After consideration of the public comments we received, we are finalizing our proposal, without modification, to assign CPT code 0268T to APC 5463, which has a final CY 2017 APC geometric mean cost of approximately \$18,300. The final payment rate for CPT code 0268T can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

6. Radiologic Procedures and Services

a. Imaging APCs

As a part of our CY 2016 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 of the OPSS APC groupings for imaging services was to improve the clinical and resource homogeneity of the services classified within the imaging APCs. Recently some stakeholders that provide imaging services in hospitals recommended some further restructuring of the OPSS imaging APCs, again for the purpose of improving the clinical and resource homogeneity of the services classified within these APCs. After reviewing the stakeholder recommendations, we agreed that further improvements can be achieved by making further changes to the structure of the APC groupings of the imaging services classified within the imaging APCs. Therefore, in the CY 2017 OPSS/ASC proposed rule (81 FR 45647), for CY 2017, we proposed to make further changes to the structure of the imaging APCs. In Table 11 of the proposed rule, we listed the CY 2016 imaging APCs, and in Table 12 of the proposed rule we listed our proposed CY 2017 changes to the imaging APCs. This proposal would consolidate the imaging APCs from 17 APCs in CY 2016 to 8 in CY 2017. The specific APC assignments for each service grouping were listed in Addendum B to the proposed rule, which is available via the

Internet on the CMS Web site. We noted in the proposed rule that some of the imaging procedures are assigned to APCs that are not listed in the tables of the proposed rule (for example, the vascular procedure APCs). Also, the nuclear medicine services APCs were not included in this proposed APC restructuring. We invited public comments on our proposal to consolidate the imaging APCs from 17 APCs in CY 2016 to 8 in CY 2017.

Comment: One of the stakeholders mentioned above who suggested further restructuring of the OPSS imaging services earlier this year expressed concern with CMS' proposed restructured imaging APCs. In particular, the stakeholder was disappointed that the proposed restructured imaging APCs differed from its specific recommendations. The stakeholder supported, in part, CMS' proposal; in particular, the reassignment of the interventional radiology procedures from imaging APCs to vascular procedure APCs and the maintenance of separate APCs for nuclear medicine procedures. In addition, several other commenters also agreed with CMS' proposal to not change the nuclear medicine APCs. Further, the stakeholder and other commenters requested that CMS provide additional explanation regarding the clinical similarity of the services assigned to the proposed restructured APCs. These commenters also were displeased that CMS assigned procedures that are primarily performed by cardiologists (for example, echocardiography) to APCs that also include imaging tests that are primarily interpreted by radiologists. They requested that CMS separate echocardiography services from other imaging tests. They also pointed out that the proposed groupings are broader than the APC title (that use the term "Diagnostic Radiology") descriptions because the proposed APC groupings include imaging tests that are interpreted by physicians other than radiologists. They also suggested additional APC and HCPCS code-specific assignments that are addressed below. The stakeholder and other commenters asked that CMS not adopt the proposed restructuring, and instead adopt their suggested APC structure, which would consolidate the imaging APCs, but would maintain separate APCs for echocardiography services that do not include x-ray, CT, and MRI services. Other commenters also requested that CMS not adopt the restructured imaging APCs. Some of these commenters suggested

alternatives, such as maintaining separate APCs for ultrasound tests, but the commenters' primary focus was the payment rates and APC assignments of specific codes, which we discuss in detail below.

Response: We appreciate the stakeholder's and the commenters' support. We agree with the stakeholder that the term "Imaging" is more accurate for the titles for this series of APCs instead of the term "Diagnostic Radiology." Therefore, we are modifying our proposal and changing the titles of this diagnostic radiology series of APCs to "Level X Imaging" (either without contrast or with contrast). Regarding the commenters' request for further explanation on the clinical similarity of the services assigned to the imaging APCs, we remind commenters that we proposed to reassign the interventional radiology procedures to vascular procedure APCs (APCs 5181, 5182, 5183), recognizing the greater clinical similarity of the reassigned interventional services to the vascular/catheterization procedures that are currently assigned to the vascular procedure APCs. The remaining services that are assigned to the restructured imaging APCs are all diagnostic imaging services that almost all belong to one of the following four primary, well-established imaging modalities: x-ray, ultrasound, computed tomography (CT), or magnetic resonance (MR). When these services are performed in the hospital outpatient department, a technician (sometimes aided by a physician) captures the images by operating one of the types of equipment used for x-ray, ultrasound, CT, or MR. These imaging services are assigned to an APC in either the "without contrast" imaging series or the "with contrast" imaging series, as required by section 1833(t)(2)(G) of the Act. Assignment of an imaging service to a specific APC within each of these two imaging series (with or without contrast) depends upon the use (or non-use) of a contrast agent and the geometric mean cost of the service, with the range of geometric mean costs within an APC governed by the 2 times rule. It is not relevant to the structure of the APC groupings that physicians of different specialties interpret certain tests (for example, cardiologists generally interpret imaging of the heart, radiologists interpret most other imaging tests, orthopedic surgeons interpret extremity images, and neurologists interpret brain images, among others). Furthermore, APC groupings in general do not necessarily correspond to groupings of procedures that are performed by a given physician

specialty. Some of the APC groupings resemble to some extent traditional physician specialty classifications (for example, the urology series of APCs), but many others do not. We believe that imaging services, which are diagnostic tests including x-rays, ultrasounds (including echocardiography), CT scans, and MRIs are sufficiently clinically similar for APC grouping purposes. We also believe that there is no special advantage to the current CY 2016 scheme that subdivides imaging services into subclasses for x-rays, ultrasounds, etc. The commenters believed that their suggested restructured APCs that were presented to CMS included APCs that grouped these four modalities together (except echocardiography). We believe that the proposed structure of the imaging services APCs satisfies the requirements of section 1833(t)(2)(B) of the Act with greater flexibility (versus the current structure) and without unnecessarily restrictive groupings limited to clinically insignificant traditional modality classifications (for example, CT and x-ray, among others). We see no compelling reason to separate echocardiography procedures, an imaging test of the heart, from other imaging tests in the APC groupings. Furthermore, all other nonimaging diagnostic tests are grouped in APCs (APCs 5721 through 5724) that are separate and distinct from the imaging services APCs because we believe that these nonimaging diagnostic tests are sufficiently clinically dissimilar to imaging tests to warrant separate APCs.

Comment: One commenter objected to the proposed exception to the 2 times rule for APC 5521 (Level 1 Diagnostic Radiology without Contrast), and requested that we explain the basis for the exception further. The commenter also requested that CMS reassign CPT code 75571 from APC 5521 to a higher paying APC for CY 2017.

Response: We explain the basis for the 2 times rule and the proposed exceptions in the CY 2017 OPPS/ASC of the proposed rule (81 FR 45644 through 45645). Table 9 of the CY 2017 OPPS/ASC of the proposed rule listed the proposed APC exceptions to the 2 times rule for CY 2017 (81 FR 45645). The proposal to grant an exception to the 2 times rule for APC 5521 followed from a request made prior to the proposed rule. At that time, the request was that CMS reassign CPT code 75571 from APC 5731 (Level 1 Minor Procedures) to an imaging APC based on greater clinical similarity to other CT services assigned to the imaging APCs. We agreed with the request and proposed to reassign CPT code 75571 to APC 5521, which is the lowest cost imaging APC in

the series. Because CPT code 75571 has such a low geometric mean cost (\$22.87), its assignment to any imaging APC, even the lowest cost imaging APC 5521 (with a geometric mean cost of \$61.53), results in a 2 times rule violation. We proposed to make an exception to the 2 times rule for APC 5521 for CY 2017 because we believed that, for clinical reasons, CPT code 75571 should be assigned to an imaging APC with the other CT services. Therefore, we are finalizing our proposal, without modification, to reassign CPT code 75571 to APC 5521 as a result of the low geometric mean cost of the procedure. The payment rate for CPT code 75571 increases from \$12.70 in CY 2016 to \$59.84 in CY 2017.

Comment: Several commenters objected to the proposed assignment of CPT code 77080 (Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (e.g., hips, pelvis, spine)) to APC 5521. The proposed assignment would reduce the payment rate for this procedure from its current CY 2016 payment rate of \$100.69 to \$63.33 in CY 2017. The commenters believed that the payment reduction could impair access to this valuable preventive service. The commenters requested that CMS assign CPT code 77080 to a higher paying imaging APC, along with other services that have greater resource similarity to the procedure described by CPT code 77080.

Response: We agree with the commenters. Therefore, we are modifying our proposal, and assigning CPT code 77080 to APC 5522 (Level 2 Diagnostic Radiology without Contrast) for CY 2017. CPT code 77080 has a geometric mean cost of \$91.08, which increases the probability of a 2 times rule violation when compared to the second lowest-cost significant procedure assigned to APC 5521, the procedure described by CPT code 71010, which has a geometric mean cost of \$46.11. We note that we are not comparing the geometric mean cost of CPT code 77080 to that of CPT code 75571, which is a significant procedure assigned to APC 5521 and that has a geometric mean cost of \$22.87, for a 2 times rule violation because as described above, this procedure code assignment was the basis for the exception from the 2 times rule for APC 5521 in the proposed rule. In summary, we are assigning CPT code 77080 to APC 5522, with a final payment rate of \$112.69 for CY 2017.

Comment: Several commenters objected to the proposed assignment of HCPCS code G0297 (Low dose CT scan (LDCT) for lung cancer screening) to

APC 5521 because it would reduce the payment rate for this procedure from \$112.49 in CY 2016 to \$63.33 in CY 2017. The commenters expressed concern that such a payment reduction could result in fewer Medicare beneficiaries receiving this service. The commenters also expressed concern about the APC assignment of HCPCS code G0296 (Counseling visit to discuss need for lung cancer screening (LDCT) using low dose CT scan (service is for eligibility determination and shared decision making)) to APC 5821 (Level 1 Health and Behavior Services). The commenters believed that the proposed assignment also would result in a payment reduction from \$69.65 in CY 2016 to \$25.09 in CY 2017, and could impair access to this cancer screening service. The commenters requested that CMS assign these services to higher paying APCs in the CY 2017 final rule with comment period.

Response: We agree, in part, with the commenters. There were no claims data for these services in CY 2016. Therefore, the CY 2016 APC assignments reflected our best estimate at an appropriate APC assignment in the absence of cost information. For CY 2017, we have cost information for each of these services from the CY 2015 claims data. For HCPCS code G0296, the final rule geometric mean cost is \$130.44, but with only 21 single claims. Therefore, we believe that this service should be assigned to APC 5822 (Level 2 Health and Behavior Services), with a payment rate of \$70.23. We believe that the services in APC 5822 have greater resource similarity to the procedure described by HCPCS code G0296 than the services assigned to APC 5821. We will reevaluate the APC assignment of this procedure for the CY 2018 rulemaking. For HCPCS code G0297, the CY 2017 final rule geometric mean cost is \$49.38. APC 5521, to which we proposed to assign HCPCS code G0297, has a geometric mean cost of \$65.16. The next higher level APC in the imaging without contrast APC series, APC 5522, has a geometric mean cost of \$119.56. Because the geometric mean cost of HCPCS code G0297 is more comparable to the geometric mean cost of APC 5521 than APC 5522, we believe that resource homogeneity is better supported by the assignment of HCPCS code G0297 to APC 5521. Therefore, in summary, we are modifying our proposal and assigning HCPCS code G0296 to APC 5822. However, we are finalizing our proposal, without modification, to assign HCPCS code G0297 to APC 5521 for CY 2017.

Comment: One commenter requested that CMS not reassign CPT code 78811

(Positron emission tomography (PET) imaging; limited area (e.g., chest, head/neck) from APC 5594 (Level 4 Nuclear Medicine and Related Services) to APC 5593 (Level 3 Nuclear Medicine and Related Services) for CY 2017. The commenter believed that the reassignment is premature because of the lack of sufficient claims data to support the reassignment from the CY 2016 assignment to APC 5594.

Response: We disagree with the commenter. Although there are only 117 single claims for this service in the final rule data, we believe that this is a sufficient number upon which to base an APC assignment. The geometric mean cost of CPT code 78811 has been consistent for the past 2 years. In CY 2016 the geometric mean cost was \$912.62 (based on 112 single claims), and the geometric mean cost for CY 2017 is \$918.39 (based on 117 single claims). Furthermore, the geometric mean cost of CPT code 78811 is significantly lower than the geometric mean cost of APC 5593 (\$1,170.73). Therefore, we believe that APC 5593 is the most appropriate APC assignment for CPT code 78811.

Comment: A few commenters requested that CMS maintain the CY 2016 APC assignment for CPT code 75563 (Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences; with stress imaging) to APC 5593 (Level 3 Nuclear Medicine and Related Services), instead of its proposed assignment to APC 5573 (Level 3 Diagnostic Radiology with Contrast). The commenters expressed concern that the proposed payment reduction from \$1,108 to \$777 could reduce access to this imaging test. The commenters believed that CPT code 75563 has greater clinical and resource similarity to the services in APC 5593 than the services in APC 5573. In particular, the commenters asserted that CPT code 75563 is similar to CPT code 78452 (Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection) because both tests are performed under a stress protocol. The commenter also requested that CMS reassign CPT code 75557 (Cardiac magnetic resonance imaging for morphology and function without contrast material) from APC 5523 (Level 3 Imaging without Contrast) to APC

5591 (Level 1 Nuclear Medicine and Related Services). The commenter believed that such a reassignment would improve clinical and resource similarity with regard to CPT code 75557. Another commenter requested that CMS not assign any non-nuclear medicine services to the nuclear medicine APC series.

Response: We agree with the commenter that requested that we not assign any of these magnetic resonance procedure codes to nuclear medicine APCs. For instance, APC 5593 contains procedures that describe nuclear medicine tests, and CPT code 75563 is a specific type of MRI and not a nuclear medicine test. Also, the geometric mean cost of CPT code 75563 is \$745 and the geometric mean cost of the APC to which it is assigned, APC 5573, is \$781. These geometric mean costs are very similar. However, the geometric mean cost of APC 5593 is \$1,171, which is significantly higher than the geometric mean cost of CPT code 75563. Therefore, assigning CPT code 75563 to APC 5593 would assign the procedure to an APC with clinically dissimilar nuclear medicine tests and resource dissimilar tests that have a geometric mean cost of \$1,171 (as compared to the \$745 geometric mean cost of CPT code 75563). Therefore, we are finalizing our proposal, without modification, to assign CPT code 75563 to APC 5573. Similarly, the procedure described by CPT code 75557 is not a nuclear medicine test and, therefore, should not be assigned to a nuclear medicine APC such as APC 5591. The geometric mean cost of CPT code 75557 is \$266, and the geometric mean cost of the APC to which it is assigned (APC 5523) is \$223. Therefore, we believe that APC 5523 is an appropriate APC assignment for CPT code 75557 from a resource perspective. Also, there are many other MRI procedure codes, like CPT code 75557, assigned to APC 5523. In addition, we are reassigning a related code, CPT code 75559 (Cardiac magnetic resonance imaging for morphology and function without contrast material; with stress imaging), from APC 5592 (Level 2 Nuclear Medicine and Related Services) to APC 5523 (Level 3 Imaging without Contrast). The geometric mean costs of these two APCs are comparable, but because the procedure described by CPT code 75559 is not a nuclear medicine test, we believe that APC 5523 is a more appropriate APC assignment than APC 5592 for reasons of clinical similarity.

Comment: One commenter requested that CMS reassign CPT code 70559 (Magnetic resonance (e.g., proton) imaging, brain (including brain stem and skull base), during open intracranial

procedure (e.g., to assess for residual tumor or residual vascular malformation); without contrast material(s), followed by contrast material(s) and further sequences) from APC 5181 (Level 1 Vascular Procedures) to an imaging APC because the commenter believed that an imaging APC would be more clinically appropriate than a vascular procedures APC.

Response: We agree with the commenter that CPT code 70559 should be assigned to an imaging APC because this service is more similar to other imaging services than to the procedures assigned to APC 5181. Therefore, we are modifying our proposal, and reassigning CPT code 70559 to APC 5571 (Level 1 Imaging with Contrast).

Comment: A few commenters requested that CMS reassign four HCPCS/CPT codes from APC 5572 (Level 2 Diagnostic Radiology with Contrast) to APC 5573 (Level 3 Diagnostic Radiology with Contrast):

- HCPCS code C8929 (Transthoracic echocardiography, with contrast, or without contrast followed by with contrast, real-time with image documentation (2D), includes M-mode recording, when performed, complete, with spectral Doppler echocardiography, and with color flow Doppler echocardiography);
- CPT code 73722 (Magnetic resonance (e.g., proton) imaging, any joint of lower extremity; with contrast material(s));
- CPT code 73222 (Magnetic resonance (e.g., proton) imaging, any joint of upper extremity; with contrast material(s)); and
- CPT code 72126 (Computed tomography, cervical spine; with contrast material).

These commenters believed that the procedures described by these four codes have greater clinical and resource similarity to the procedures assigned to APC 5573.

Response: We agree, in part, with the commenters. In particular, we believe that HCPCS code C8929 belongs in the same APC with the other echocardiography with contrast services, which is APC 5573, based on clinical and resource similarity resulting from the use of contrast. We also believe that the geometric mean costs of CPT code 73722 (\$559.13) and CPT code 73222 (\$606.13) support the assignment of these procedures to APC 5573, which has a geometric mean cost of \$675.23. However, the final rule geometric mean cost for CPT code 72126 is \$363.15. Therefore, we believe that APC 5572 is the more appropriate APC assignment for this procedure.

Comment: A few commenters requested that CMS reassign HCPCS codes G0105 (Colorectal cancer screening; colonoscopy on individual at high risk) and G0121 (Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk) from APC 5525 (Level 5 Diagnostic Radiology without Contrast) to a more clinically appropriate gastroenterology APC.

Response: We agree with the commenters that a gastroenterology APC would be more clinically appropriate for these colonoscopy services. Therefore, we are modifying our proposal, and reassigning HCPCS codes G0105 and

G0121 to APC 5311 (Level 1 Lower GI Procedures). With the reassignment of HCPCS codes G0105 and G0121 from APC 5525 to APC 5311, only five procedures remain in APC 5525. We believe that these remaining five procedures (four of which are non-contrast echocardiography services) can be grouped into APC 5524 (Level 4 Diagnostic Radiology without Contrast), which will be renamed Level 4 Imaging without Contrast. APC 5524 contains other clinically similar non-contrast echocardiography services and the reassignment of these five procedures comports with the provision of the 2

times rule. Therefore, we also are reassigning CPT codes 75984, 93312, 93313, 93315, and 93318 from APC 5525 to APC 5524, and deleting APC 5525.

Comment: Some commenters requested that several procedures be reassigned to the next higher level imaging APC within the APC series. The commenters believed that reassignment of these procedures would improve resource homogeneity within these APCs. These procedures and our responses to this request are listed in Table 19 below.

TABLE 19—SERVICES REQUESTED TO BE REASSIGNED TO THE NEXT HIGHER LEVEL IMAGING APC

CPT code	Long descriptor	Proposed CY 2017 SI	Proposed CY 2017 APC	CMS response (agree or disagree with commenter)	Final CY 2017 SI	Final CY 2017 APC
70545	Magnetic resonance angiography, head; with contrast material(s).	S	5571	Disagree	S	5571
70548	Magnetic resonance angiography, head; with contrast material(s).	S	5571	Disagree	S	5571
70557	Magnetic resonance (e.g., proton) imaging, brain (including brain stem and skull base), during open intracranial procedure (e.g., to assess for residual tumor or residual vascular malformation); without contrast material.	S	5523	Disagree	S	5523
71270	Computed tomography, thorax; without contrast material, followed by contrast material(s) and further sections.	Q3	5571	Disagree	Q3	5571
76010	Radiologic examination from nose to rectum for foreign body, single view, child.	Q1	5521	Disagree	Q1	5521
76498	Unlisted magnetic resonance procedure (e.g., diagnostic, interventional).	S	5521	Disagree	S	5521
76641	Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete.	Q1	5521	Agree	Q1	5522
76642	Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; limited.	Q1	5521	Disagree	Q1	5521
76816	Ultrasound, pregnant uterus, real time with image documentation, follow-up (e.g., re-evaluation of fetal size by measuring standard growth parameters and amniotic fluid volume, re-evaluation of organ system(s) suspected or confirmed to be abnormal on a previous scan), transabdominal approach, per fetus.	Q1	5521	Agree	Q1	5522
76821	Doppler velocimetry, fetal; middle cerebral artery.	Q1	5521	Agree	Q1	5522
76857	Ultrasound, pelvic (nonobstetric), real time with image documentation; limited or follow-up (e.g., for follicles).	Q3	5521	Agree	Q3	5522
C8903	Magnetic resonance imaging with contrast, breast; unilateral.	Q3	5571	Disagree	Q3	5571
C8918	Magnetic resonance angiography with contrast, pelvis.	Q3	5571	Disagree	Q3	5571

Response: For the procedures in the above table that we disagreed with the commenter regarding the most appropriate APC assignment, the geometric mean cost of each of these procedure codes is very similar to the geometric mean cost of the APC to

which we proposed to reassign the procedure in the proposed rule. Therefore, we are finalizing our proposal, without modification, to reassign these proposed procedures to the proposed APCs indicated. For the procedure codes in the table above that

we are modifying our proposal to reassign to a different APC than that which was proposed, the geometric mean cost of the procedure is more consistent with the next higher level APC to which we agree supports a more appropriate APC assignment.

Comment: One commenter requested that CMS reassign several procedures to APCs other than any of the imaging APCs. The commenter believed that these procedures are not clinically similar to the other imaging services assigned to the imaging APCs. These

procedure codes and our responses are listed in Table 20 below.

Response: We refer readers to the table below for the final CY 2017 APC assignments for the suggested procedure codes. We agree with the commenter that all of the suggested procedures

should be reassigned to a different APC, except for the procedures described by CPT code 62303 and HCPCS code C9733. We believe that these two procedure codes describe imaging tests and, therefore, are properly assigned to an APC in the imaging APC series.

TABLE 20—ADDITIONAL SERVICES REQUESTED TO BE REASSIGNED TO NON-IMAGING APCS

CPT/ HCPCS code	Long descriptor	Proposed CY 2017 SI	Proposed CY 2017 APC	CMS response (agree or disagree with commenter)	Final CY 2017 SI	Final CY 2017 APC
36002	Injection procedures (e.g., thrombin) for percutaneous treatment of extremity pseudoaneurysm.	S	5524	Agree	T	5181
43752	Naso- or oro-gastric tube placement, requiring physician's skill and fluoroscopic guidance (includes fluoroscopy, image documentation and report).	Q3	5523	Agree	Q1	5735
43756	Duodenal intubation and aspiration, diagnostic, includes image guidance; single specimen (e.g., bile study for crystals or afferent loop culture).	Q1	5524	Agree	Q1	5301
47531	Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (e.g., ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; existing access.	Q2	5524	Agree	Q2	5341
62303	Myelography via lumbar injection, including radiological supervision and interpretation; thoracic.	Q2	5524	Disagree	Q2	5524
75801	Lymphangiography, extremity only, unilateral, radiological supervision and interpretation.	Q2	5524	Agree	Q2	5181
91200	Liver elastography, mechanically induced shear wave (e.g., vibration), without imaging, with interpretation and report.	Q1	5521	Agree	Q1	5721
93982	Noninvasive physiologic study of implanted wireless pressure sensor in aneurysmal sac following endovascular repair, complete study including recording, analysis of pressure and waveform tracings, interpretation and report.	Q1	5521	Agree	Q1	5721
C9733	Non-ophthalmic fluorescent vascular angiography.	Q2	5523	Disagree	Q2	5523

Comment: One commenter requested that CMS reassign CPT code 91200 from APC 5521 to APC 5721, and modify the proposed status indicator assignment from “Q1” (conditionally packaged) to “S” (Paid under OPPTS; separate APC payment.) in order to separately pay for the test under all circumstances.

Response: Although we agree with the commenter regarding the APC assignment for clinical similarity purposes, we disagree with the commenter regarding the status indicator assignment. The procedure described by CPT code 91200 is an ancillary ultrasound diagnostic test, not unlike the ultrasound tests that were packaged as a part of our ancillary services packaging policy in CY 2015. (We refer readers to the CY 2015 OPPTS/ASC final rule with comment period (79 FR 66819) for a further discussion of the ancillary services packaging policy.)

Therefore, we are finalizing our proposal, without modification, to assign CPT code 91200 to APC 5721, with a status indicator of assignment of “Q1” for CY 2017.

Comment: A few commenters requested that CMS modify the status indicator assignment for HCPCS code C9733 from “Q2” to a separately payable status indicator (for example, status indicator “S”). The commenters noted that status indicator “Q2” indicates that payment for the procedure described by HCPCS code C9733 is conditionally packaged when provided in conjunction with other procedures assigned to status indicator “T,” which are primarily surgical procedures.

Response: We have responded to this comment in past rules. The service described by HCPCS code C9733 is primarily an intraoperative imaging

service. Therefore, it is conditionally packaged under § 419.2(b)(14), which packages intraoperative items and services. When the procedure described by HCPCS code C9733 is not furnished in conjunction with a surgical procedure, then the service is paid separately. We believe that the OPPTS payments, separate or packaged, for surgical procedures in which this test is performed in conjunction with (for example, breast reconstruction) are more than adequate to cover the cost of the service described by HCPCS code C9733 for Medicare beneficiaries in need of this service.

Comment: One commenter requested that CMS assign three procedures from APC 5181 (Level 1 Vascular Procedures) to APC 5182 (Level 2 Vascular Procedures) because the geometric mean costs of these procedures are more

comparable to the geometric mean cost of APC 5182 than that of APC 5181:

- CPT code 75731 (Angiography, adrenal, unilateral, selective, radiological supervision and interpretation);
- CPT code 75746 (Angiography, pulmonary, by nonselective catheter or venous injection, radiological supervision and interpretation); and
- CPT code 75810 (Splenoportography, radiological supervision and interpretation).

Response: We disagree with the commenter. Based on the CY 2017 final rule updated claims data, CPT code 75731 only has one single claim, CPT code 75746 only has 5 single claims, and CPT code 75810 only has 2 single claims. The number of claims for these services is too low upon which to base an APC reassignment for better resource homogeneity. Therefore, we are finalizing our proposal, without modification, to assign these three procedures to APC 5181.

After consideration of the public comments we received, we are finalizing the proposals, with the modifications as described above in the responses to the comments on the restructuring and reorganization of the imaging APCs. Table 21 below lists the final seven CY 2017 imaging APCs (not including the four nuclear medicine APCs). All of these APCs are assigned to status indicator “S,” although payment for some of the procedures assigned to these APCs are conditionally packaged and are instead assigned to status indicator “Q1” or “Q2.”

TABLE 21—FINAL CY 2017 IMAGING APCs

CY 2017 APC	CY 2017 APC 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.

b. Radiation Oncology (APCs 5092, 5611, and 5627)

Comment: A few commenters disagreed with CMS’ proposed reassignment of CPT code 19298 (Placement of radiotherapy afterloading 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) to APC 5092 (Level 2 Breast/Lymphatic Surgery and Related Procedures), with a payment rate of approximately \$4,395 for CY 2017. In CY 2016, this code is assigned to APC 5093 (Level 3 Breast/Lymphatic Surgery and Related Procedures), with a payment rate of approximately \$7,558. The commenters believed that the previous APC assignment to APC 5093 is appropriate and requested that CMS continue to assign CPT code 19298 to APC 5093 for CY 2017.

Response: The geometric mean cost for CPT code 19298 decreased from approximately \$6,269 in CY 2016 to approximately \$5,128 for CY 2017. This change prompted the proposed reassignment of this code from the Level 3 APC to Level 2. We do not believe that the CY 2017 geometric mean cost supports continued assignment to APC 5093. After consideration of the public comment we received, we are finalizing our proposal, without modification, and reassigning CPT code 19298 to APC 5092 for CY 2017.

Comment: A few commenters suggested that CMS reassign CPT codes 77424 (Intraoperative radiation treatment delivery, x-ray, single treatment session) and 77425 (Intraoperative radiation treatment delivery, electrons, single treatment session) to an APC in the radiation therapy series other than APC 5093 (Level 3 Breast/Lymphatic Surgery and Related Procedures) because these radiation treatment services are not clinically similar to the breast procedures that are assigned to APC 5093.

Response: We agree with the commenters. The assignment of these codes to APC 5093 was intended to be temporary until more claims data for these codes was available. Based on these codes being radiation treatment delivery codes and their geometric mean costs for CPT codes 77424 (approximately \$8,701) and 77425 (approximately \$7,172), we are reassigning these services to APC 5627 (Level 7 Radiation Therapy), with a geometric mean cost of approximately \$7,664. We note that if planning and preparation and imaging services are repackaged into the single session cranial SRS codes (that are assigned to APC 5627) in the future, this could cause the geometric mean cost for the single session cranial SRS codes to increase such that it may no longer be appropriate to group CPT codes 77424 and 77425 with the single session SRS codes in the same APC. However, for CY 2017, APC 5627 is the most appropriate APC for CPT codes 77424 and 77425,

both clinically and from a resource-cost perspective. The final payment rate for these codes can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

Comment: A few commenters requested that CMS create a fourth level in the Therapeutic Radiation Treatment Preparation APC series and assign CPT code 77301 (Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications) to this new APC. The commenters believed that the costs from the claims data for CPT code 77301 are lower than the actual current costs because the AMA CPT Editorial Panel bundled simulation services (that used to be separately coded) into the payment for CPT code 77301.

Response: We prefer to wait for the actual claims data before reassigning a code because the cost of a new bundled code is often difficult to predict and often the cost of the new bundled code is significantly less than the sum of the costs of the individual codes that contribute to the bundle. For CY 2017, we are finalizing our proposal to reassign CPT code 77301 to APC 5613.

Comment: A few commenters requested that CMS not reassign CPT codes 77370, 77280, and 77333 to APC 5611 (Level 1 Therapeutic Radiation Treatment Preparation) for CY 2017. These codes are currently assigned to the Level 2 Therapeutic Radiation Treatment Preparation APC (APC 5612) in CY 2016. The payment would decrease from \$167 in CY 2016 to \$117 in CY 2017.

Response: As we do annually, we examined the APCs in this series. We noticed that the difference in the geometric mean costs between Level 1 and 2 was not significant. Therefore, we proposed to consolidate these two APCs into a single APC and reduce the number of levels in the Therapeutic Radiation Treatment Preparation APC series from four to three. We believe that this change promotes resource homogeneity without excessive granularity with consecutive levels having almost the same mean cost. The range of geometric mean costs for significant services in the proposed CY 2017 APC 5611 (Level 1 Therapeutic Radiation Treatment Preparation) is \$101 to \$197, which comports with the 2 times rule. Therefore, we are finalizing this proposed APC structure and CPT codes 77370, 77280, and 77333 are assigned to APC 5611 for CY 2017.

7. Skin Substitutes (APCs 5053 through 5055)

For CY 2017, we proposed to assign skin substitute procedures to APCs 5053 through 5055 (Level 3 through 5 Skin Procedures). The cost of the procedures is affected by whether the skin substitute product is low cost or high cost, the surface area of the wound, and the location of the wound.

Comment: Commenters disagreed with the proposed APC assignments for procedures described by HCPCS code C5277 (Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 cm²; First 100 cm² wound surface area, or 1% of body area of infants and children) to APC 5053 (Level 3 Skin Procedures) and procedures described by CPT code 15277 (Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 cm²; First 100 cm² wound surface area, or 1% of body area of infants and children) to APC 5054 (Level 4 Skin Procedures). The commenters stated that the proposed payment rates for APC 5053 and APC 5054 do not accurately reflect the cost of providing the services described by HCPCS code C5277 and CPT code 15277. The commenters further stated that the cost of applying a skin substitute product to a larger wound (surface area greater than or equal to 100 cm²) should be similar, irrespective of whether the product is applied to the head, genitalia, hands, or feet as compared to the trunk, legs, or arms. The commenters compared the differences between procedures described by HCPCS code C5277 and procedures described by HCPCS code C5273 (Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 cm²; First 100 cm² wound surface area, or 1% of body area of infants and children). Procedures described by HCPCS code C5273 are assigned to APC 5054, which has a higher geometric mean cost than APC 5053. The commenters did a similar comparison between procedures described by CPT code 15277 and procedures described by CPT code 15273 (Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 cm²; First 100 cm² wound surface area, or 1% of body area of infants and children). Procedures described by CPT code 15273 are assigned to APC 5055 (Level 5 Skin Procedures), which has a higher geometric mean cost than APC

5054. One commenter believed that the low volume of single claims for procedures described by HCPCS code C5277 and CPT code 15277 may have resulted in inaccurately low geometric mean costs.

Response: We disagree with the commenters. We reviewed the services in both APC 5053 and APC 5054 and found that procedures described by HCPCS code C5277 and CPT code 15277 have both clinical and resource homogeneity to the other 11 procedures assigned to these two APCs. Therefore, there is no justification to assign these procedures to APCs with higher geometric mean costs. The final geometric mean cost of procedures described by HCPCS code C5277 is approximately \$810 (based on 26 single claims), which is more comparable to the final geometric mean cost of APC 5053 (\$466) than the geometric mean cost of APC 5054 (\$1,468). Also, regarding the accuracy of the cost data for these codes, we again note our longstanding policy provides that, beyond our standard OPSS trimming methodology that we apply to those claims that have passed various types of claims processing edits, it is not our general policy to judge the accuracy of hospital coding and charging for purposes of ratesetting. (We refer readers to 75 FR 71838 for a detailed discussion.) Therefore, after consideration of the public comments we received, we are finalizing our proposal, without modification, to assign HCPCS code C5277 to APC 5053 and CPT code 15277 to APC 5054.

Comment: Commenters requested that APC 5053 (Level 3 Skin Procedures) be divided into two APCs in order to separate more resource intensive services using skin substitute products (procedures described by HCPCS codes C5271, C5275, and C5277) from other, less resource intensive skin procedures. The commenters believed an additional APC level within the skin procedures APC series between the current level 3 and level 4 would more closely reflect the cost of the low cost skin substitute application procedures. The commenters also believed that the current APC structure incentivizes hospitals to prefer high cost skin substitutes over low cost skin substitutes.

Response: We disagree with the commenters. We do not believe that it is necessary to expand the skin procedures APC series to six levels. We reviewed the services assigned to APC 5053 and found that all of the procedures assigned to the APC have both sufficient clinical and resource homogeneity. The highest volume low

cost skin substitute application procedure, described by HCPCS code C5271 (Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area), had a final geometric mean cost of \$596 (11,256 single claims), and the final geometric mean cost of APC 5053 was \$466. While the geometric mean cost of procedures described by HCPCS code C5271 is higher than the geometric mean cost of APC 5053, the difference is well within the span of the two times rule.

In conclusion, we do not believe that there is justification to create another level within the skin procedures APC series by dividing APC 5053 into two APCs. Therefore, after consideration of the public comments we received, we are finalizing our proposal, without modification, to maintain the current five levels of skin procedures APCs.

8. Urology System Procedures and Services

a. Chemodenervation of the Bladder (APC 5373)

As listed in Addendum B of the CY 2017 OPSS/ASC proposed rule, we proposed to continue to assign CPT code 52287 (Cystourethroscopy, with injection(s) for chemodenervation of the bladder) to APC 5373 (Level 3 Urology and Related Services), with a payment rate of approximately \$1,642. In addition, we proposed to reassign its status indicator from "T" (Procedure or Service, Multiple Procedure Reduction Applies. Paid under OPSS; separate APC payment.) to "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 primary "J1" service for the claim, except for services with OPSS status indicators "F," "G," "H," "L," and "U"; ambulance services; diagnostic and screening mammography; all preventive services; and certain Part B inpatient services.

We proposed to continue to assign CPT code 52287 to APC 5373 based on the claims data used for the proposed rule. Specifically, our analysis of the claims data showed a geometric mean cost of approximately \$2,219 for CPT code 52287 based on 7,464 single claims (out of 7,609 total claims), which fits more appropriately in APC 5373, whose geometric mean cost is approximately \$1,716. We did not propose to assign CPT code 52287 to APC 5374 (Level 4 Urology and Related Services) because we would have overpaid for the procedure because the geometric mean

cost for this APC is approximately \$2,642.

Comment: One commenter disagreed with the proposed APC assignment for CPT code 52287, and requested that CMS reassign the procedure to APC 5374. The commenter explained that CPT code 52287 describes a procedure that involves the use of the BOTOX® drug for the treatment of overactive bladder (OAB) and detrusor overactivity associated with a neurologic condition (NDO). The commenter also stated that because of the proposed revision to the code's status indicator from "T" to "J1," the BOTOX® used in the procedure would no longer be paid separately, whereas in CY 2016 the drug is paid separately under HCPCS code J0585 (Injection, onabotulinumtoxin a, 1 unit). According to the commenter, the resource cost of performing the procedure with 200 units of the drug is significantly greater than that of furnishing 100 units. Consequently, the commenter stated that the payment rate for APC 5373 is inadequate to cover the resource costs associated with performing the procedure and furnishing the drug. The commenter recommended that CMS reconfigure APCs 5373 and 5374 so that all procedures with a geometric mean cost greater than \$2,150 are assigned to APC 5374, and to reassign CPT code 52287 to APC 5374. Alternatively, if CMS does not reassign CPT code 52287 to APC 5374, the commenter suggested that CMS establish a complexity adjustment for those procedures that involve a dose of 200 units of BOTOX®.

Response: We believe that APC 5373 is the most appropriate APC assignment for CPT code 52287 based on its resource and clinical homogeneity to the other procedures within the APC. Based on updated CY 2015 claims data for this final rule with comment period, the range of geometric mean costs for significant procedures assigned to APC 5373 is between \$1,175 and \$2,275. The geometric mean cost of \$2,196 for CPT code 52287 is within this range. We do not believe that it would be appropriate to assign CPT code 52287 to APC 5374, whose geometric mean cost is approximately \$2,613.

With respect to the issue of the drug cost, the payment for the BOTOX® drug is included in the payment for the procedure described by CPT code 52287. As stated in section II.A.2.c. of this final rule with comment period, the payment for procedures assigned to a "J1" status indicator include all drugs,

biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and those drugs that are usually self-administered (SADs), unless they function as packaged supplies (78 FR 74868 through 74869, 74909, and 79 FR 66800).

On the issue of a complexity adjustment, as listed in Addendum J of the CY 2017 OPPS/ASC proposed rule, specifically, in the "Complexity Adjustments" tab of the Excel file, we proposed to reassign CPT code 52287 to a complexity adjustment APC. In particular, we proposed to assign CPT code 52287 to APC 5374 when the procedure is performed in conjunction with other procedures during the same hospital stay that meet the complexity adjustment criteria discussed in section II.A.2.c. of this final rule with comment period.

After consideration of the public comment we received, we are finalizing our proposal, without modification, to assign CPT code 52287 to APC 5373 for CY 2017. The final status indicator and APC assignments and payment rate for this code, where applicable, can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site). The list of the complexity adjustments for add-on code combinations for CY 2017, along with all of the other complexity adjustments, can be found in Addendum J to this final rule with comment period (which is available via the Internet on the CMS Web site). Addendum J to this final rule with comment period also contains the summary cost statistics for each of the code combinations that describe a complex code combination that will qualify for a complexity adjustment and will be reassigned to the next higher cost C-APC within the clinical family.

b. Temporary Prostatic Urethral Stent (APC 5373)

As listed in Addendum B of the CY 2017 OPPS/ASC proposed rule, we proposed to continue to assign CPT code 53855 (Insertion of a temporary prostatic urethral stent, including urethral measurement) to APC 5372 (Level 2 Urology and Related Services), with a payment rate of approximately \$561.

Comment: One commenter disagreed with the proposed assignment of CPT code 53855 to APC 5372. The commenter believed that the proposed payment rate of approximately \$561 for

APC 5372 is inadequate to cover the cost of providing the service. The commenter stated that the payment rate of approximately \$1,642 for APC 5373 better supports the resource costs and clinical characteristics associated with the procedure described by CPT code 53855 and recommended that CMS reassign the CPT code to this APC for CY 2017.

Response: Based on our analysis of the updated CY 2015 hospital outpatient claims used for this final rule with comment period, we agree with the commenter. Our claims data showed a geometric mean cost of approximately \$1,860 for CPT code 53855 based on 31 single claims (out of 31 total claims), which is similar to the geometric mean cost of approximately \$1,691 for APC 5373.

After consideration of the public comment we received, we are modifying our proposal and assigning CPT code 53855 to APC 5373 for CY 2017. The final CY 2017 payment rate for this procedure can be found in Addendum B to this CY 2017 OPPS/ASC final rule with comment period (which is available via the Internet on the CMS Web site).

c. Transprostatic Urethral Implant Procedure (TUIP) (APCs 5375 and 5376)

Currently, there are four procedure codes that describe transprostatic urethral implant procedures, specifically, HCPCS codes C9739 and C9740, and CPT codes 52441 and 52442. As shown in Table 22 below, and as listed in Addendum B of the CY 2017 OPPS/ASC proposed rule, we proposed to continue to assign HCPCS code C9739 to APC 5375 (Level 5 Urology and Related Services). We also proposed to reassign HCPCS code C9740 from New Technology APC 1565 (New Technology—Level 28 (\$5001-\$5500)) to APC 5376 (Level 6 Urology and Related Services), and to reassign the status indicator for HCPCS code C9740 from "T" to "J1." In addition, we proposed to continue to assign CPT codes 52441 and 52442 to status indicator "B" to indicate that these codes are not recognized by OPPS when submitted on a hospital outpatient Part B bill type (12x and 13x). As we discussed in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66853 through 66854), we do not recognize CPT codes 52441 and 52442 because the code descriptors do not accurately capture the number of implants typically provided in a hospital outpatient or ASC setting.

TABLE 22—PROPOSED CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR THE TRANSPROSTATIC URETHRAL IMPLANT PROCEDURES

CPT/HCPCS code	Long descriptors	CY 2016 OPSS SI	CY 2016 OPSS APC	CY 2016 OPSS payment rate	Proposed CY 2017 OPSS SI	Proposed CY 2017 OPSS APC	Proposed CY 2017 OPSS payment rate
C9739	Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants.	J1	5375	\$3,393.73	J1	5375	\$3,460.41
C9740	Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants.	T	1565	5,250.00	J1	5376	7,389.67
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant.	B	N/A	N/A	B	N/A	N/A
52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (list separately in addition to code for primary procedure).	B	N/A	N/A	B	N/A	N/A

Comment: One commenter expressed concern with the proposed reassignment of HCPCS code C9740 to APC 5376. The commenter stated that the reassignment may not be aligned with the current clinical homogeneity of other procedures assigned to APC 5376 because the procedure described by HCPCS code C9740 is performed through a natural orifice (urethra) and can be performed with local anesthesia. To ensure clinical homogeneity within APC 5376, the commenter requested that CMS reevaluate the appropriate APC assignment for HCPCS code C9740.

Response: As we do every year, we review the APC assignments for all services and items paid under the OPSS. Based on resource and clinical homogeneity, we believe that HCPCS code C9740 is more appropriately assigned to the Urology and Related Services APC series. We reviewed the procedures assigned to the Urology and Related Services APCs and, based on its resource cost and clinical homogeneity, we determined that HCPCS code C9740 most appropriately aligns with the other procedures in the Level 6 APC within the Urology and Related Services APC grouping.

For the proposed rule, our claims data showed a geometric mean cost of

approximately \$6,312 for HCPCS code C9740 based on 585 single claims (out of 606 total claims), which is relatively similar to the geometric mean cost of approximately \$7,723 for APC 5376. We believe that neither APC 5375 (Level 5 Urology and Related Services), whose geometric mean cost is approximately \$3,617 or APC 5377 (Level 7 Urology and Related Services), whose geometric mean cost is approximately \$15,377, would have been appropriate APC assignments. When compared to the geometric mean cost of \$6,312 for HCPCS code C9740, an APC assignment to APC 5375 would underpay for the procedure, while an APC assignment to APC 5377 would overpay for the service. For the final rule with comment period, our updated claims data showed a similar pattern. Specifically, our analysis showed a geometric mean cost of approximately \$6,167 for HCPCS code C9740 based on 691 single claims (out of 701 total claims), which is comparable to the geometric mean cost of approximately \$7,661 for APC 5376. We believe that an APC assignment to either APC 5375, whose geometric mean cost is approximately \$3,581 or APC 5377, whose geometric mean cost is approximately \$14,764, would be inappropriate. Based on the updated

claims data for the final rule with comment period, we believe that APC 5376 is the most appropriate APC assignment for HCPCS code C9740 based on its clinical homogeneity and resource cost compared to the other procedures within this APC.

Comment: Several commenters agreed with CMS' proposal to continue to assign HCPCS code C9739 to APC 5375 and to reassign HCPCS code C9740 to APC 5376 for CY 2017. The commenters requested that CMS finalize the proposal.

Response: We appreciate the commenters' support. After consideration of the public comments we received, we are adopting as final, without modification, the proposed APC and status indicator assignments for HCPCS codes C9739 and C9740, and CPT codes 52441 and 52442 for CY 2017. Table 23 below lists the final status indicator and APC assignments and payment rates for the transprostatic urethral implant procedures for CY 2017. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPSS. Addendum B is available via the Internet on the CMS Web site.

TABLE 23—FINAL CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS AND PAYMENT RATES FOR THE TRANSPROSTATIC URETHRAL IMPLANT PROCEDURES

CPT/HCPCS code	Long descriptors	CY 2016 OPSS SI	CY 2016 OPSS APC	CY 2016 OPSS payment rate	Final CY 2017 OPSS SI	Final CY 2017 OPSS APC	Final CY 2017 OPSS payment rate
C9739	Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants.	J1	5375	\$3,393.73	J1	5375	\$3,482.54

TABLE 23—FINAL CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS AND PAYMENT RATES FOR THE TRANSPROSTATIC URETHRAL IMPLANT PROCEDURES—Continued

CPT/HCPCS code	Long descriptors	CY 2016 OPSS SI	CY 2016 OPSS APC	CY 2016 OPSS payment rate	Final CY 2017 OPSS SI	Final CY 2017 OPSS APC	Final CY 2017 OPSS payment rate
C9740	Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants.	T	1565	5,250.00	J1	5376	7,449.52
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant.	B	N/A	N/A	B	N/A	N/A
52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (list separately in addition to code for primary procedure).	B	N/A	N/A	B	N/A	N/A

9. Other Procedures and Services

a. Cryoablation Procedures (APCs 5114, 5361, 5362, and 5432)

As part of our standard annual OPSS update process, we review each APC assignment for the clinical similarity and resource homogeneity of the procedures assigned to each APC. Based on our analysis of the hospital outpatient claims data used for the proposed rule, we made some modifications to the APC assignments of certain cryoablation procedures. Specifically, for the CY 2017 OPSS

update, we proposed to delete APC 5352 (Level 2 Percutaneous Abdominal/Biliary Procedures and Related Procedures), and reassign the cryoablation procedures that were previously assigned to this APC to APC 5361 (Level 1 Laparoscopy and Related Services). As shown in Table 24 below, and as listed in Addendum B of the CY 2017 OPSS/ASC proposed rule, we proposed to reassign CPT codes 20983, 47383, 50593, and 0340T from APC 5352 to APC 5361. Through our continuing efforts to simplify the APCs

through consolidation and to improve clinical and resource homogeneity for the APCs, we believe that these cryoablation procedures that were previously assigned to APC 5352 would be more appropriately assigned to APC 5361 based on their geometric mean costs for the CY 2017 OPSS update. Further, we believe that the proposed revision appropriately categorized these cryoablation procedures in APC 5361 based on clinical coherence and resource costs compared to the other procedures in the same APC.

TABLE 24—PROPOSED CY 2017 STATUS INDICATORS (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR CERTAIN CRYOABLATION PROCEDURES

CPT/HCPCS code	Long descriptors	CY 2016 OPSS SI	CY 2016 OPSS APC	CY 2016 OPSS payment rate	Proposed CY 2017 OPSS SI	Proposed CY 2017 OPSS APC	Proposed CY 2017 OPSS payment rate
20983	Ablation therapy for reduction or eradication of 1 or more bone tumors (e.g., metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; cryoablation.	T	5352	\$4,118.23	J1	5361	\$4,178.33
47383	Ablation, 1 or more liver tumor(s), percutaneous, cryoablation.	T	5352	4,118.23	J1	5361	4,178.33
50593	Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy.	T	5352	4,118.23	J1	5361	4,178.33
0340T	Ablation, pulmonary tumor(s), including pleura or chest wall when involved by tumor extension, percutaneous, cryoablation, unilateral, includes imaging guidance.	T	5352	4,118.23	J1	5361	4,178.33
0440T	Ablation, percutaneous, cryoablation, includes imaging guidance; upper extremity distal/peripheral nerve.	J1	5361	4,001.15	J1	5361	4,178.33
0441T	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve.	J1	5361	4,001.15	J1	5361	4,178.33

TABLE 24—PROPOSED CY 2017 STATUS INDICATORS (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR CERTAIN CRYOABLATION PROCEDURES—Continued

CPT/HCPCS code	Long descriptors	CY 2016 OPSS SI	CY 2016 OPSS APC	CY 2016 OPSS payment rate	Proposed CY 2017 OPSS SI	Proposed CY 2017 OPSS APC	Proposed CY 2017 OPSS payment rate
0442T	Ablation, percutaneous, cryoablation, includes imaging guidance; nerve plexus or other truncal nerve (e.g., brachial plexus, pudendal nerve).	T	5352	4,118.23	J1	5361	4,178.33

Comment: One commenter expressed concern with the proposed assignment of the kidney, lung, liver, bone and nerve cryoablation procedures, specifically, the procedure codes listed in Table 24, to APC 5361. The commenter stated that APC 5361 does not appropriately reflect the clinical nature of the procedures and inadequately recognizes the resources needed to perform the services. The commenter further stated that reassigning the procedures previously assigned to APC 5361 results in a lack of clinical coherence because the APC would include various diagnostic and therapeutic procedures that consist of a wide range of anatomic systems with disparate costs. Consequently, the commenter urged CMS to reevaluate the APC assignments for the cryoablation procedures listed in Table 24, and suggested that CMS either create a new APC that includes both the cryoablation and radiofrequency ablation procedures, or reassign the procedures to APCs that groups the ablation procedures with other clinically similar procedures.

Response: We reviewed the updated CY 2015 hospital outpatient claims data used for this final rule with comment period. Based on our review, we agree

with the commenter that some of these procedures should be reassigned to more appropriate APCs. First, although we have no claims data for CPT codes 0440T, 0441T, and 0442T because these codes are new for CY 2016, we believe that these procedures more appropriately align, based on clinical characteristics, with the procedures in APC 5432 (Level 2 Nerve Procedures). Therefore, we are reassigning CPT codes 0440T, 0441T, and 0442T to APC 5432 for CY 2017. Secondly, based on our analysis, we found a geometric mean of approximately \$5,416 for CPT code 20983 based on 98 single claims (out of 100 total claims), which is similar to the geometric mean of approximately \$5,367 for APC 5114. Therefore, we are reassigning CPT code 20983 to APC 5114. In addition, we found a geometric mean cost of approximately \$5,944 for CPT code 50593 based on 1,811 single claims (out of 1,823 total claims). Furthermore, a high percentage of CPT code 50593 cases were complexity adjusted to APC 5362 in the proposed rule. Given that the geometric mean cost of CPT code 50593 is at the very top of the geometric mean cost range for APC 5361 and the need for a complexity adjustment for many of the cases into

APC 5362, we are reassigning CPT code 50593 to APC 5362 for CY 2017. In addition, our analysis of the final rule with comment period data showed a geometric mean costs for CPT codes 0340T (approximately \$5,519) and 47383 (approximately \$5,178) indicates that the proposed rule assignment to APC 5361 for these cryoablation procedures is appropriate because their geometric mean costs are closer to the geometric mean cost of APC 5361 (approximately \$4,316) than to the geometric mean cost of APC 5362 (approximately \$7,164).

After consideration of the public comment we received, we are adopting as final, without modification, the proposal to assign CPT codes 0340T and 47383 to APC 5361. However, we are modifying our proposal and reassigning CPT codes 0440T, 0441T, 0442T, 20983, and 50593 to the final APCs listed in Table 25 below. Table 25 shows the final status indicator, APC assignments, and payment rates for the cryoablation procedures for CY 2017. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPSS. Addendum B is available via the Internet on the CMS Web site.

TABLE 25—FINAL CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR CERTAIN CRYOABLATION PROCEDURES

CPT/HCPCS code	Long descriptors	CY 2016 OPSS SI	CY 2016 OPSS APC	CY 2016 OPSS payment rate	Final CY 2017 OPSS SI	Final CY 2017 OPSS APC	Final CY 2017 OPSS payment rate
20983	Ablation therapy for reduction or eradication of 1 or more bone tumors (e.g., metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; cryoablation.	T	5352	\$4,118.23	J1	5114	\$5,219.36
47383	Ablation, 1 or more liver tumor(s), percutaneous, cryoablation.	T	5352	4,118.23	J1	5361	4,197.36
50593	Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy.	T	5352	4,118.23	J1	5362	6,966.89

TABLE 25—FINAL CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR CERTAIN CRYOABLATION PROCEDURES—Continued

CPT/HCPCS code	Long descriptors	CY 2016 OPSS SI	CY 2016 OPSS APC	CY 2016 OPSS payment rate	Final CY 2017 OPSS SI	Final CY 2017 OPSS APC	Final CY 2017 OPSS payment rate
0340T	Ablation, pulmonary tumor(s), including pleura or chest wall when involved by tumor extension, percutaneous, cryoablation, unilateral, includes imaging guidance.	T	5352	4,118.23	J1	5361	4,197.36
0440T	Ablation, percutaneous, cryoablation, includes imaging guidance; upper extremity distal/peripheral nerve.	J1	5361	4,001.15	J1	5432	4,150.11
0441T	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve.	J1	5361	4,001.15	J1	5432	4,150.11
0442T	Ablation, percutaneous, cryoablation, includes imaging guidance; nerve plexus or other truncal nerve (e.g., brachial plexus, pudendal nerve).	T	5352	4,118.23	J1	5432	4,150.11

b. Comprehensive Dialysis Circuit Procedures (APCs 5181, 5192, and 5193)

For CY 2017, the AMA CPT Editorial Panel deleted CPT codes 36147 and 36148 and replaced them with nine new codes, effective January 1, 2017. Table 26 below list the complete descriptors for the deleted and replacement codes.

We note that the deleted and replacement codes were listed in Addendum B and Addendum O to the CY 2017 OPSS/ASC proposed rule. Addendum B listed the proposed status indicator assignments for the replacement codes and assigned them to comment indicator “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.), while Addendum O listed the placeholder/ proposed CY 2017 CPT codes and their long descriptors.

TABLE 26—CODING CHANGES FOR THE DIALYSIS CIRCUIT PROCEDURES EFFECTIVE JANUARY 1, 2017

Placeholder/ proposed CY 2017 CPT code	Final CY 2017 CPT code	Long descriptors
36147	36147	Introduction of needle and/or catheter, arteriovenous shunt created for dialysis (graft/fistula); initial access with complete radiological evaluation of dialysis access, including fluoroscopy, image documentation and report (includes access of shunt, injection[s] of contrast, and all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava.
36148	36148	Introduction of needle and/or catheter, arteriovenous shunt created for dialysis (graft/fistula); additional access for therapeutic intervention (list separately in addition to code for primary procedure).
369X1	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.
369X2	36902	Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report; with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty.
369X3	36903	Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report; with transcatheter placement of intravascular stent(s) peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the stenting, and all angioplasty within the peripheral dialysis segment.
369X4	36904	Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s).

TABLE 26—CODING CHANGES FOR THE DIALYSIS CIRCUIT PROCEDURES EFFECTIVE JANUARY 1, 2017—Continued

Placeholder/ proposed CY 2017 CPT code	Final CY 2017 CPT code	Long descriptors
369X5	36905	Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s); with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty.
369X6	36906	Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s); with transcatheter placement of an intravascular stent(s), peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the stenting, and all angioplasty within the peripheral dialysis circuit.
369X7	36907	Transluminal balloon angioplasty, central dialysis segment, performed through dialysis circuit, including all imaging and radiological supervision and interpretation required to perform the angioplasty (List separately in addition to code for primary procedure).
369X8	36908	Transcatheter placement of an intravascular stent(s), central dialysis segment, performed through dialysis circuit, including all imaging and radiological supervision and interpretation required to perform the stenting, and all angioplasty in the central dialysis segment (List separately in addition to code for primary procedure).
369X9	36909	Dialysis circuit permanent vascular embolization or occlusion (including main circuit or any accessory veins), endovascular, including all imaging and radiological supervision and interpretation necessary to complete the intervention (List separately in addition to code for primary procedure).

As shown in Table 27 below, and as listed in Addendum B of the CY 2017 OPPS/ASC proposed rule, we proposed to package payment for some of these new CY 2017 CPT codes and to also assign the procedures to APC 5181 (Level 1 Vascular Procedures), 5192 (Level 2 Endovascular Procedures), 5193 (Level 3 Endovascular Procedures), or 5194 (Level 2 Endovascular Procedures).

Specifically, we proposed to assign CPT code 369X1 (CY 2017 CPT code 36901) to APC 5181, CPT codes 396X2 (CY 2017 CPT code 36902) and 369X4 (CY 2017 CPT code 36904) to APC 5192, CPT codes 396X3 (CY 2017 CPT code 36903) and 369X5 (CY 2017 CPT code 36905) to APC 5193, and CPT code 369X6 (CY 2017 CPT code 36906) to APC 5194. In addition, we proposed to

assign CPT codes 369X7 (CY 2017 CPT code 36907), 369X8 (CY 2017 CPT code 36908), and 369X9 (CY 2017 CPT code 36909) to status indicator “N” (Items and Services Packaged into APC Rates) to indicate that these service are paid under OPPS. However, their payment is packaged into the payment for other services.

TABLE 27—PROPOSED CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR THE DIALYSIS CIRCUIT PROCEDURES

Proposed CY 2017 CPT code	CY 2017 CPT code	Short descriptors	CY 2016 OPPS SI	CY 2016 OPPS APC	CY 2016 OPPS payment rate	Proposed CY 2017 OPPS SI	Proposed CY 2017 OPPS APC	Proposed CY 2017 OPPS payment rate
36147	36147	Access av dial grft for eval	T	5181	*\$862.51	D	N/A	N/A
36148	36148	Access av dial grft for proc	N	N/A	N/A	D	N/A	N/A
369X1	36901	Intro cath dialysis circuit	N/A	N/A	N/A	T	5181	\$867.68
369X2	36902	Intro cath dialysis circuit	N/A	N/A	N/A	J1	5192	4,800.45
369X3	36903	Intro cath dialysis circuit	N/A	N/A	N/A	J1	5193	9,726.54
369X4	36904	Thrmc/nfs dialysis circuit	N/A	N/A	N/A	J1	5192	4,800.45
369X5	36905	Thrmc/nfs dialysis circuit	N/A	N/A	N/A	J1	5193	9,726.54
369X6	36906	Thrmc/nfs dialysis circuit	N/A	N/A	N/A	J1	5194	14,511.21
369X7	36907	Balo angiop ctr dialysis seg	N/A	N/A	N/A	N	N/A	N/A
369X8	36908	Stent plmt ctr dialysis seg	N/A	N/A	N/A	N	N/A	N/A
369X9	36909	Dialysis circuit embolj	N/A	N/A	N/A	N	N/A	N/A

Comment: One commenter agreed with the proposed APC assignments for CPT codes 36902, 36903, 36905, and 36906, and requested that CMS finalize the proposal. However, this commenter disagreed with the proposed APC assignment for CPT code 36904 and the proposed status indicator assignment for CPT codes 36907, 36908, and 36909. In particular, the commenter believed that the proposed assignment of APC 5192 fails to reflect the clinical complexity

and resource costs associated with performing the procedure described by CPT code 36904. The commenter recommended that CMS assign CPT code 36904 to APC 5193 based on its clinical and resource homogeneity to the other procedures in this APC. In addition, the commenter disagreed with the packaging of payment for services described by CPT codes 36907, 36908, and 36909 because these procedures involve substantial device costs. As an

interim measure, the commenter recommended that the procedure codes be assigned to New Technology APC 1564 (New Technology—Level 27 (\$4501-\$5000), with a status indicator of “S” (Procedure or Service, Not Discounted When Multiple. Paid under OPPS; separate APC payment.), until sufficient claims data is available on which to base assignment of the new codes to a more appropriate clinical APC. If CMS continued to believe that

the New Technology APC assignment is inappropriate, the commenter urged CMS to create a composite APC for the dialysis circuit CPT codes.

Response: We appreciate the commenter's support for the proposed APC assignments for CPT codes 36902, 36903, 36905, and 36906. We are finalizing our proposal for these codes. However, with respect to the proposed assignment of CPT code 36904, we believe that, based on its similarity to the other procedures in APC 5192, and a comparison to other codes in this series we believe that APC 5192 is the most appropriate APC for this

procedure. In addition, because CPT codes 36907, 36908, and 36909 are add-on codes, we assigned these codes to a status indicator that indicates packaged payment status. Because of our packaging policy for add-on codes, we would not consider these codes for a composite APC. We note that since January 1, 2014, payment for services described by add-on codes have been packaged under the hospital OPPS. As we do every year for all items and services under OPPS, we will reevaluate the APC assignments for these services in the CY 2018 OPPS rulemaking.

In summary, after consideration of the public comment received, we are finalizing our proposal, without modification, to assign the dialysis circuit procedures to the APC and status indicators listed in Table 28 below. Table 28 shows the final status indicator, APC assignments, and payment rates for the dialysis circuit services for CY 2017. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the Internet on the CMS Web site.

TABLE 28—FINAL CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR THE DIALYSIS CIRCUIT PROCEDURES

Proposed CY 2017 CPT code	Final CY 2017 CPT code	Short descriptors	CY 2016 OPPS SI	CY 2016 OPPS APC	CY 2016 OPPS payment rate	Final CY 2017 OPPS SI	Final CY 2017 OPPS APC	Final CY 2017 OPPS payment rate
36147	36147	Access av dial grft for eval	T	5181	\$862.51	D		
36148	36148	Access av dial grft for proc	N			D		
369X1	36901	Intro cath dialysis circuit				T	5181	\$683.84
369X2	36902	Intro cath dialysis circuit				J1	5192	4,823.16
369X3	36903	Intro cath dialysis circuit				J1	5193	9,748.31
369X4	36904	Thrmc/nfs dialysis circuit				J1	5192	4,823.16
369X5	36905	Thrmc/nfs dialysis circuit				J1	5193	9,748.31
369X6	36906	Thrmc/nfs dialysis circuit				J1	5194	14,775.90
369X7	36907	Balo angiop ctr dialysis seg				N	N/A	N/A
369X8	36908	Stent plmt ctr dialysis seg				N	N/A	N/A
369X9	36909	Dialysis circuit embolj				N	N/A	N/A

c. Blood Product Exchange and Related Services (APCs 5241 and 5242)

For CY 2017, we proposed to assign CPT code 36456 (Partial exchange transfusion, blood, plasma or crystalloid necessitating the skill of a physician or other qualified health care professional, newborn) (described as code 364X1 in the proposed rule) to APC 5241 (Level 1 Blood Product Exchange and Related Services), with a proposed mean geometric mean cost of approximately \$364.

Comment: One commenter disagreed with the CMS proposal to assign CPT code 36456 to APC 5241. The commenter stated that APC 5182 (Level 2 Vascular Procedures) is a more appropriate APC assignment because of the clinical similarity and similar resource intensity to other services assigned to APC 5182.

Response: We disagree with the commenter's statement. We do not believe that the procedure described by CPT code 36456 is comparable to the services in APC 5182 in terms of resource intensity or clinical similarity. We do believe that CPT code 36456 is similar to the other services assigned to APC 5241, such as CPT code 36450 (Exchange transfusion, blood; newborn). When claims data become available for

this new code, we will consider if assignment to another APC is appropriate. After consideration of the public comment we received, we are finalizing our proposal to assign CPT code 36456 to APC 5241.

Comment: For CY 2017, we proposed to assign CPT codes 38230 (Bone marrow harvesting for transplantation; allogeneic), 38241 (Hematopoietic progenitor cell (HPC); autologous transplantation, 38242 (Allogeneic lymphocyte infusions) and 38243 (HPC Boost) to APC 5242 (Level 2 Blood Product Exchange and Related Services). This APC has a proposed CY 2017 geometric mean cost of approximately \$1,129. One commenter stated that the proposed payment rate of approximately \$1,078 for this APC was a 66 percent decrease in payment from the final CY 2016 payment rate. The commenter also noted that the services in this APC were not likely to be submitted on a single procedure claim and, as a result, the CMS ratesetting methodology may be based on incorrectly coded claims. In addition, the commenter requested that CMS consider the use of C-APCs to provide for payment for low-volume, clinically significant services.

Response: The commenter is correct that each of these services represent a low volume in the OPPS. The geometric mean cost for each of the codes is within the geometric mean cost range (\$1,111 to \$1,518) for significant services assigned to APC 5242. We will monitor these claims and determine if any future adjustment to the methodology (such as the C-APC methodology) would be more appropriate.

d. 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. 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 29 below, and as listed in Addendum B of the CY 2017 OPPS/ASC proposed rule, we proposed to continue to assign CPT codes 0071T and 0072T to APC 5414, with a payment

rate of approximately \$2,074. We also proposed to reassign the APC's status indicator to "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 OPSS 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 proposed to reassign HCPCS code C9734 from APC 5122

(Level 2 Musculoskeletal Procedures) to APC 5114 (Level 4 Musculoskeletal Procedures), with a payment rate of approximately \$5,199. We also proposed to reassign the HCPCS code's status indicator from "T" to "J1."

Further, we proposed to reassign CPT code 0398T from a nonpayable status indicator, specifically, "E" (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) to a separately payable APC, specifically, APC 5462 (Level 2 Neurostimulator and Related Procedures), with a payment rate of approximately \$5,840. We note

that APC 5462 is assigned to status indicator "J1." This APC assignment was based on a comparison to a similar procedure, specifically, HCPCS code C9734, with a geometric mean cost of approximately \$8,565 based on 9 single claims (out of 9 total claims). The MRgFUS equipment used in the performance of the procedure described by CPT code 0398T is very similar to the MRgFUS equipment used in the performance of the procedure described by HCPCS code C9734. Both machines are manufactured by the same manufacturer.

TABLE 29—PROPOSED CY 2017 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 2016 OPSS SI	CY 2016 OPSS APC	CY 2016 OPSS payment rate	Proposed CY 2017 OPSS SI	Proposed CY 2017 OPSS APC	Proposed CY 2017 OPSS payment rate
0071T	Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume less than 200 cc of tissue.	T	5414	\$1,861.18	J1	5414	\$2,074.22
0072T	Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume greater or equal to 200 cc of tissue.	T	5414	1,861.18	J1	5414	2,074.22
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.	E	N/A	N/A	J1	5462	5,839.83
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance.	T	5122	2,395.59	J1	5114	5,199.03

Comment: All of the commenters disagreed with the proposed assignment of CPT code 0398T to APC 5462 for CY 2017. The commenters stated that the proposed payment severely underestimates the resources required to provide the treatment. Some commenters indicated that compared to HCPCS code C9734, which requires only one physician and 3 hours of MRI time, the resources for CPT code 0398T is significantly greater and requires the services of a multidisciplinary staff (including a neurosurgeon and a radiologist), as well as 6 hours of MRI time. Several commenters indicated that MRgFUS for essential tremor is a better alternative to deep brain stimulation (DBS) because there is no risk of infection or implanted hardware, no need for multiple hospital outpatient visits or postoperative programming sessions, and lower cost because there is no battery to surgically remove and replace every few years. Some

commenters pointed out that the cost of providing a DBS procedure is between \$40,000 and \$50,000, while the MRgFUS procedure costs approximately \$20,000. One commenter stated that the capital equipment used in the performance of the procedure described by CPT code 0398T is more costly, at approximately \$2 million, compared to the capital equipment used in the performance of the procedure described by HCPCS C9734, which is approximately \$750,000. The commenter also stated that CPT code 0398T uses additional equipment (for example, stereotactic head frame) and supplies resulting in higher costs for the procedure. Several commenters expressed concern that the proposed payment for CPT code 0398T is inadequate to cover the hospital cost of providing the service and recommended that CMS reassign CPT code 0398T to either a more appropriate APC that reflects the cost of providing the

treatment, or to APC 5463 (Level 3 Neurostimulator and Related Procedures). Some commenters suggested that a low reimbursement rate for the procedure could jeopardize Medicare access to this emerging technology.

Response: CPT code 0398T is a new code for CY 2016. Therefore, we do not have available claims data for the CY 2017 ratesetting. HCPCS code C9734 describes a similar service that uses the same MRgFUS technology, and as noted above, has a geometric mean cost of \$8,565. However, the manufacturer has indicated that the essential tremor MRgFUS service uses a more costly version of the MRgFUS equipment, takes longer, and uses some additional supplies and equipment, which makes the procedure described by CPT code 0398T more costly than the procedure described by HCPCS code C9734. We believe that the procedure described by CPT code 0398T can also be compared

to the procedure described by CPT code 77371 (Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesions(s) consisting of 1 session; multi-source Cobalt-60 based). In particular, both procedures use capital equipment of approximately equal cost, both employ a stereotactic head frame to treat intracranial lesions, and both require similar staffing. CPT code 77371 is assigned to APC 5627 (Level 7 Radiation Therapy), with a final payment rate of approximately \$7,453. The final geometric mean cost of CPT code 77371 is \$10,105. We believe that the geometric mean cost of CPT code 77371 provides an indication of the initial payment rate for CPT code 0398T relative to the related service described by HCPCS code C9734, for which we have some claims data. Consequently, because there is no clinical APC that contains clinically similar and resource-cost similar services, we believe that the

most appropriate initial assignment for CPT code 0398T is APC 1537 (New Technology—Level 37 (\$9501-\$10000)), which has a final payment rate of approximately \$9,751. The assignment to APC 1537 will result in a 67-percent increase in the CY 2017 payment rate compared to the \$5,840 proposed payment rate. It is also significantly above the payment rate of approximately \$5,219 for HCPCS code C9734, to which CPT code 0398T is comparable but according to the commenters is more costly.

Finally, we remind hospitals that, as we do every year, we review the APC assignments for all services and items paid under the OPSS. We will reevaluate the APC assignment for CPT code 0398T once we have claims data for this service.

Comment: One commenter supported CMS' proposal to reassign HCPCS code C9734 to APC 5114, and requested that CMS finalize the proposal.

Response: We appreciate the commenter's support.

After consideration of the public comments we received, we are modifying our proposal and reassigning CPT code 0398T to APC 1537 for CY 2017. In addition, we are finalizing our proposal, without modification, to reassign HCPCS code C9734 to APC 5114. Because we did not receive any public comments related to CPT codes 0071T and 0072T, we are finalizing our proposal, without modification, to continue to assign these codes to APC 5414. Table 30 below shows the final status indicator and APC assignments and payment rates for the MRgFUS procedures for CY 2017. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPSS. Addendum B is available via the Internet on the CMS Web site.

TABLE 30—FINAL CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR THE MAGNETIC RESONANCE IMAGE GUIDED HIGH INTENSITY FOCUSED ULTRASOUND (MRgFUS) PROCEDURES

CPT/HCPCS code	Long descriptors	CY 2016 OPSS SI	CY 2016 OPSS APC	CY 2016 OPSS payment rate	Final CY 2017 OPSS SI	Final CY 2017 OPSS APC	Final CY 2017 OPSS payment rate
0071T	Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume less than 200 cc of tissue.	T	5414	\$1,861.18	J1	5414	\$2,084.59
0072T	Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume greater or equal to 200 cc of tissue.	T	5414	1,861.18	J1	5414	2,084.59
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.	E	N/A	N/A	S	1537	9,750.50
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance.	T	5122	2,395.59	J1	5114	5,219.36

e. Neulasta® On-Body Injector

As listed in Addendum B of the CY 2017 OPSS/ASC proposed rule, we proposed to assign new CY 2017 CPT code 96377 (Application of on-body injector (includes cannula insertion) for timed subcutaneous injection) to status indicator "N" (Items and Services Packaged into APC Rates) to indicate that the service is paid under OPSS; however, its payment is packaged into the payment for other services. We note that CPT code 93677 was listed as placeholder CPT code 963XX in both Addendum B and O of the CY 2017

OPSS/ASC proposed rule. Addendum B listed the short descriptor with the proposed status indicator of "N," while Addendum O listed the complete long descriptor under placeholder CPT code 963XX.

Comment: Some commenters disagreed with the proposed status indicator assignment of "N" for CPT code 963XX (CY 2017 CPT code 96377), and indicated that this is a primary service, not an add-on procedure, that represents a complete and unique drug administration service that a hospital performs for the subcutaneous

administration of Neulasta® with the on-body injector. The commenters stated that the service is similar to the drug administration service described by CPT code 96372 (Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular), which is assigned to APC 5692 (Level 2 Drug Administration) with a proposed payment rate of about \$53. The commenters indicated that the difference between the procedure described by CPT code 96372 and CPT

code 96377 is the use of an on-body injector for CPT code 96377.

Response: We do not believe that the resources necessary to deliver the Neulasta® service warrants separate payment under the OPPS. Because payment for CPT code 96377 will be packaged, the payment for use of the on-body injector will be included in the payment for the primary service (for example, chemotherapy administration, clinic visit, among others) that is reported in conjunction with CPT code 96377. Furthermore, we believe that the packaged payment that includes

payment for the use of the Neulasta® on-body injector adequately covers the costs of the service. After consideration of the public comments we received, we are adopting as final, without modification, the proposal to assign CPT code 96377 to status indicator “N” for CY 2017.

f. Smoking and Tobacco Use Cessation Counseling (APC 5821)

As shown in Table 31 below, and as listed in Addendum B of the CY 2017 OPPS/ASC proposed rule, we proposed to continue to assign CPT codes 99406

and 99407 to APC 5821 (Level 1 Health and Behavior Services), with a proposed payment rate of approximately \$25. In addition, we proposed to delete HCPCS codes G0436 and G0437 because they were replaced with CPT codes 99406 and 99407. Specifically, we stated in the October 2016 Update, Change Request 9768, Transmittal 3602, dated August 26, 2016, that HCPCS codes G0436 and G0437 were deleted on September 30, 2016, because they were replaced with CPT codes 99406 and 99407, effective October 1, 2016.

TABLE 31—PROPOSED CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR THE SMOKING AND TOBACCO USE CESSATION COUNSELING SERVICES

CPT/HCPCS code	Long descriptors	CY 2016 OPPS SI	CY 2016 OPPS APC	CY 2016 OPPS payment rate	Proposed CY 2017 OPPS SI	Proposed CY 2017 OPPS APC	Proposed CY 2017 OPPS payment rate
99406	Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes.	S	5821	\$27.12	S	5821	\$25.09
99407	Smoking and tobacco use cessation counseling visit; intensive, greater than 10 minutes.	S	5821	27.12	S	5821	25.09
G0436	Smoking and tobacco cessation counseling visit for the asymptomatic patient; intermediate, greater than 3 minutes, up to 10 minutes.	S	5821	27.12	D
G0437	Smoking and tobacco cessation counseling visit for the asymptomatic patient; intensive, greater than 10 minutes.	S	5822	69.65	D

Comment: One commenter expressed concern that the proposed payment rate for APC 5821 did not include the costs associated with HCPCS code G0437 because it was previously assigned to APC 5822. The commenter requested that CMS reevaluate the payment rate for APC 5821 and to include the claims data associated with HCPCS code G0437 in the calculation of the geometric mean cost for APC 5821. In addition, because the predecessor HCPCS code G0437 was previously assigned to APC 5822, the commenter believed that CPT code 99407 should also be assigned to the same APC. Moreover, the commenter urged CMS to crosswalk all deleted codes to the same APC assignment as their replacement codes when calculating APC payment rates during the transition.

Response: While we generally crosswalk the APC assignment of deleted codes to the same APC as its replacement code, we acknowledge that our calculation of the geometric mean cost for APC 5821 in the CY 2017 OPPS/ASC proposed rule did not include costs associated with HCPCS code G0437. We appreciate the commenter bringing this

to our attention and have corrected this oversight in this final rule with comment period. In particular, we are assigning CPT codes 99406 and 99407, and HCPCS codes G0436 and G0437 to APC 5821 and are using the geometric mean costs of these procedures in determining the final payment rate for APC 5821. Based on our analysis of the updated claims data for this final rule with comment period, the geometric mean cost of approximately \$32 for CPT code 99407 based on 2,859 single claims (out of 4,148 total claims) is relatively similar to the geometric mean cost of approximately \$26 for APC 5821. We do not agree with the commenter that CPT code 99407 should be assigned to APC 5822 because its geometric mean cost of approximately \$72 is more than twice the geometric mean cost of CPT code 99407. Therefore, based on the resource costs and similar characteristics to the other procedures within APC 5821, we believe that CPT code 99407 is more appropriately assigned to this APC.

Comment: One commenter expressed confusion regarding the reporting of CPT codes 99406 and 99407, and requested that CMS clarify whether

these codes apply to both asymptomatic and symptomatic patients. The commenter noted that the descriptor of HCPCS codes G0436 and G0437 specifically described services for the asymptomatic patient. However, the commenter indicated that this distinction is not included in the code descriptors for CPT codes 99406 and 99407.

Response: While not explicit in their code descriptors, CPT codes 99406 and 99407 apply to both asymptomatic and symptomatic patients. We note that the more recent preventive service policy related to these codes can be found in section 210.4.1 (Counseling to Prevent Tobacco Use (Effective August 25, 2010)) of the Medicare National Coverage Determination Manual, which is can be viewed on the CMS Web site at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ncd103c1_part4.pdf, as well as on the Medicare Coverage Database Web site at: <https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=32>. After consideration of the public comments we received, we

are finalizing our proposal, without modification, to continue to assign CPT codes 99406 and 99407 to APC 5821 for CY 2017. Table 32 below shows the

final status indicator, APC assignment, and payment rate for CPT codes 99406 and 99407 for CY 2017. We refer readers to Addendum B of this final rule with

comment period for the payment rates for all codes reportable under the OPSS. Addendum B is available via the Internet on the CMS Web site.

TABLE 32—FINAL CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR THE SMOKING AND TOBACCO USE CESSATION COUNSELING SERVICES

CPT/HCPCS code	Long descriptors	CY 2016 OPSS SI	CY 2016 OPSS APC	CY 2016 OPSS payment rate	Final CY 2017 OPSS SI	Final CY 2017 OPSS APC	Final CY 2017 OPSS payment rate
99406	Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes.	S	5821	\$27.12	S	5821	\$25.22
99407	Smoking and tobacco use cessation counseling visit; intensive, greater than 10 minutes.	S	5821	27.12	S	5821	25.22
G0436	Smoking and tobacco cessation counseling visit for the asymptomatic patient; intermediate, greater than 3 minutes, up to 10 minutes.	S	5821	27.12	D
G0437	Smoking and tobacco cessation counseling visit for the asymptomatic patient; intensive, greater than 10 minutes.	S	5822	69.65	D

g. Radiofrequency Ablation of Uterine Fibroids (APC 5362)

For CY 2017, the AMA CPT Editorial Panel deleted CPT code 0336T (Laparoscopy, surgical, ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency) and replacing it with CPT code 58674 (Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency), effective January 1, 2017. We proposed to assign CPT code 58674 to APC 5362 (Level 2 Laparoscopy and Related Services), which is the same APC assignment for the predecessor CPT code 0336T. We note that CPT code 58674 was listed as placeholder CPT code 585X1 in both Addendum B and O of the CY 2017 OPSS/ASC proposed rule. Addendum B listed the short descriptor with the proposed APC assignment and payment rate, while Addendum O listed the complete long descriptor under placeholder CPT code 585X1. We note that both Addendum B and O also assigned this code to comment indicator “NP” to indicate that we would be accepting comments on the proposed APC assignment for the new code.

Comment: One commenter agreed with the proposed APC assignment for new CY 2017 CPT code 58674 to APC 5362 and stated that the assignment is consistent with the APC assignment for its predecessor code (CPT code 0336T). The commenter indicated that the resources required to furnish the service

described by CPT code 58674 is similar to the resources of the other procedures assigned to APC 5362. Consequently, the commenter urged CMS to finalize the proposal.

Response: We appreciate the commenter’s support. As noted by the commenter, we assigned new CY 2017 CPT code 58674 to APC 5362 based on its similarity to the other procedures within this APC.

After consideration of the public comment we received, we are finalizing our proposal, without modification, to assign CPT code 58674 to APC 5362. The final status indicator, APC assignment, and payment rate for CPT code 58674 can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

h. Intrapulmonary Surfactant Administration (APC 5791)

As listed in Addendum B of the CY 2017 OPSS/ASC proposed rule, we proposed to continue to assign CPT code 94610 (Intrapulmonary surfactant administration by a physician or other qualified health care professional through endotracheal tube) to APC 5791 (Pulmonary Treatment), with a proposed payment rate of approximately \$161. We also proposed to continue to assign CPT code 94610 to OPSS status indicator “Q1” (STV-Packaged Codes) to indicate that the service is conditionally packaged.

Comment: One commenter disagreed with CMS’ proposal to assign CPT code 94610 to OPSS status indicator “Q1.”

The commenter indicated that this is a primary service, not an ancillary service as designated by the status indicator, and recommended that CMS reassign the CPT code to OPSS status indicator “T” (Procedure or Service, Multiple Procedure Reduction Applies. Paid under OPSS; separate APC payment).

Response: We believe that the commenter may have misunderstood the meaning of OPSS status indicator “Q1.” Assigning a procedure to OPSS status indicator “Q1” indicates that payment for the service is conditionally packaged under the OPSS. A criterion under the conditional packaging policy is that payment for a service is packaged when it is provided in combination with a significant procedure on the same date of service, but the service is separately paid when it is reported on the claim without a significant procedure. Addendum D1 to the CY 2017 OPSS/ASC proposed rule (which is available via the Internet on the CMS Web site) showed the definition of status indicator “Q1.”

In the case of the procedure described by CPT code 94610, payment for this service is included in the payment for the significant procedure when it is reported in combination with HCPCS codes that are assigned to either status indicators “S,” “T,” or “V.” Alternatively, the service is separately paid when performed alone, or when reported in combination with HCPCS codes that described procedures assigned to a status indicator other than “S,” “T,” or “V.” In addition, assignment to OPSS status indicator

“Q1” indicates that the service or procedure is assigned a composite APC payment when billed with specific combinations of services based on OPPS composite-specific payment criteria, and payment is packaged into a single payment for specific combinations of services. We disagree with the commenter that CPT code 94610 should be reassigned to OPPS status indicator “T.” Based on our understanding of the service, we believe that status indicator “Q1” is the most appropriate status indicator assignment for CPT code 94610 because the service is often provided in combination with other services on the same day.

After consideration of the public comment we received, we are finalizing our proposal, without modification, to continue to assign CPT code 94610 to APC 5791, and to assign status indicator “Q1” to the code for CY 2017. The complete list of the OPPS payment status indicators and their definitions for CY 2017 is displayed in Addendum D1 to this final rule with comment period, which is available on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html>. Further, we refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the Internet on the CMS Web site.

i. Non-Contact Low Frequency Ultrasound (NLFU) Therapy (APC 5051)

As listed in Addendum B of the CY 2017 OPPS/ASC proposed rule, we proposed to continue to assign CPT code 97610 (Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day) to APC 5051 (Level 1 Skin Procedures), with a proposed payment rate of approximately \$154. In addition, we proposed to continue to assign CPT

code 97610 to OPPS status indicator “Q1” (STV-Packaged Codes) to indicate that the service is conditionally packaged.

Comment: One commenter disagreed with CMS’ proposal to assign CPT code 97610 to OPPS status indicator “Q1.” The commenter indicated that this is a primary service, not an ancillary service, and providers frequently perform NLFU therapy as a standalone, independent procedure. The commenter further stated that CMS’ proposed OPPS status indicator assignment of “Q1” contradicts AMA’s guidance in the June 2014 CPT Assistant, which clearly describes the service as a standalone procedure. The commenter recommended that CMS reassign CPT code 97610 to OPPS status indicator “T” (Procedure or Service, Multiple Procedure Reduction Applies. Paid under OPPS; separate APC payment.).

Response: Assigning CPT code 97610 to OPPS status indicator “Q1” indicates that payment for the service is conditionally packaged under the OPPS. A criterion under the conditional packaging policy is that payment for a service is packaged when it is provided in combination with a significant procedure on the same date of service, but the service is separately paid when it is reported on the claim without a significant procedure. Addendum D1 to the CY 2017 OPPS/ASC proposed rule (which is available via the Internet on the CMS Web site) showed the definition of status indicator “Q1.”

We note that payment for the procedure described by CPT code 97610 is included in the payment for the significant procedure when it is reported in combination with HCPCS codes that are assigned to any of status indicators “S,” “T,” or “V.”

Alternatively, the service is separately paid when performed alone, or when reported in combination with HCPCS codes that describe procedures assigned to a status indicator other than “S,” “T,” or “V.” In addition, assignment to OPPS status indicator “Q1” indicates that the

service or procedure is assigned a composite APC payment if billed with specific combinations of services based on OPPS composite-specific payment criteria, and payment is packaged into a single payment for specific combinations of services. Based on our understanding of the service, we believe that “Q1” is the most appropriate status indicator assignment for CPT code 97610 because the service is provided in combination with other services on the same day.

After consideration of the public comment we received, we are finalizing our proposal, without modification, to continue to assign CPT code 97610 to APC 5051 and to assign CPT code 97610 to OPPS status indicator “Q1” for CY 2017. The complete list of the OPPS payment status indicators and their definitions for CY 2017 is displayed in Addendum D1 to this final rule with comment period, which is available on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html>. Further, we refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the Internet on the CMS Web site.

j. Pulmonary Rehabilitation Services (APCs 5732 and 5733)

Currently, there are four HCPCS codes that describe pulmonary rehabilitation services, specifically, HCPCS codes G0237, G0238, G0239, and G0424. As shown in Table 33 below and as listed in Addendum B of the CY 2017 OPPS/ASC proposed rule, we proposed to reassign these services to APCs 5734 (Level 4 Minor Procedures), 5735 (Level 5 Minor Procedures), and 5791 (Pulmonary Treatment). In addition, we proposed to continue their status indicator assignment of “Q1” to indicate that these services are conditionally packaged.

TABLE 33—PROPOSED CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR THE PULMONARY REHABILITATION SERVICES

HCPCS code	Long descriptors	CY 2016 OPPS SI	CY 2016 OPPS APC	CY 2016 OPPS payment	Proposed CY 2017 OPPS SI	Proposed CY 2017 OPPS APC	Proposed CY 2017 OPPS payment
G0237	Therapeutic procedures to increase strength or endurance of respiratory muscles, face to face, one on one, each 15 minutes (includes monitoring).	Q1	5734	\$91.18	Q1	5735	\$265.56

TABLE 33—PROPOSED CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR THE PULMONARY REHABILITATION SERVICES—Continued

HCPCS code	Long descriptors	CY 2016 OPPS SI	CY 2016 OPPS APC	CY 2016 OPPS payment	Proposed CY 2017 OPPS SI	Proposed CY 2017 OPPS APC	Proposed CY 2017 OPPS payment
G0238	Therapeutic procedures to improve respiratory function, other than described by G0237, one on one, face to face, per 15 minutes (includes monitoring).	Q1	5733	55.94	Q1	5791	161.29
G0239	Therapeutic procedures to improve respiratory function or increase strength or endurance of respiratory muscles, two or more individuals (includes monitoring).	Q1	5732	30.51	Q1	5734	95.66
G0424	Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per session, up to two sessions per day.	Q1	5733	55.94	Q1	5791	161.29

Comment: Several commenters expressed concern with the proposed status indicator assignment of “Q1” for HCPCS code G0424. The commenters stated that Medicare’s benefit categories for cardiac and pulmonary rehabilitation programs were codified in section 144 of the Medicare Improvements for Patients and Providers Act of 2008, which provides for payment and coverage of pulmonary and cardiac rehabilitation services. Because the payment for this service was established under a statutory provision, the commenters believed that CMS’ proposed status indicator assignment of “Q1” for HCPCS code G0424 is an oversight. The commenters requested that CMS reconsider the issue and revise the status indicator assignment to “S” (Procedure or Service, Not Discounted When Multiple, Paid under OPPS; separate APC payment), similar to the status indicator assignment for the cardiac rehabilitation codes.

Response: We appreciate the commenters’ feedback and agree, in part, with the commenters’ concerns. Consequently, we believe that we should reassign HCPCS code G0424 to status indicator “S.” In addition, we believe that we should reassign HCPCS codes G0237, G0238, and G0239 to status indicator “S” because these codes also describe pulmonary rehabilitation services. However, the rationale for this modification of the proposal for these codes is not related to the statutory provision of section 144 of the Medicare Improvements for Patients and Providers Act of 2008. We believe that pulmonary rehabilitation is not typically ancillary to the other HOPD services that may be furnished to beneficiaries. Pulmonary rehabilitation

is typically a course of treatment that is prescribed after a diagnosis is made and often after other treatments are initiated or completed.

Comment: Several commenters supported the proposed APC reassignments for HCPCS codes G0237, G0238, G0239, and G0424. These commenters indicated that the proposed payment increase for these services appears to be driven by more accurate and complete costs reports submitted by hospitals providing the service, and recommended that CMS finalize the proposed payment rates.

Response: We appreciate the commenters’ support. We note that we proposed to reassign the HCPCS codes for these services based on the claims data used for the proposed rule that reported these codes as being conditionally packaged. Specifically, our analysis revealed a geometric mean cost of approximately \$293 for HCPCS code G0237, which was relatively close to the geometric mean cost of approximately \$278 for APC 5735. We also found that the geometric mean costs of approximately \$165 for HCPCS code G0238 and approximately \$169 for HCPCS code G0424 was relatively similar to APC 5791, which had a geometric mean cost of approximately \$169. In addition, we found that the geometric mean cost of approximately \$121 for HCPCS code G0239 was comparable to the geometric mean cost of approximately \$100 for APC 5374. However, based on our review of the updated CY 2015 claims data used for this final rule with comment period, which included the status indicator revision from “Q1” to “S” for these codes, we found the geometric mean costs for HCPCS codes G0237, G0238, G0239, and G0424 to be significantly

lower than the proposed rule geometric mean costs. This is due to significantly reduced packaged costs from other services after the status indicator was changed from “Q1” to “S.” We also note that the proposed rule claims data were based on claims submitted from January 1, 2015, through December 31, 2015, and processed through December 31, 2015, while the final rule with comment period claims data are based on claims submitted from January 1, 2015, through December 31, 2015, and processed through June 30, 2016. Based on our analysis of the final rule with comment period claims data, we found a geometric mean cost of approximately \$24 for HCPCS code G0237, approximately \$22 for HCPCS code G0238, approximately \$33 for HCPCS code G0239, and approximately \$44 for HCPCS code G0424. As a result of our findings, we are revising the APC assignments for HCPCS codes G0237, G0238, and G0239. Specifically, we found the geometric mean costs for HCPCS code G0237 (\$24), G0238 (\$22), and G0239 (\$33) to be comparable to the geometric mean cost for APC 5732 (\$29), while the geometric cost of HCPCS code G0424 (\$44) was similar to that of APC 5733 (\$56). Based on our analysis of the updated claims data used for the final rule with comment period, we believe that the revised APC assignments for the pulmonary rehabilitation services better reflect their clinical coherence and resource costs.

In summary, after consideration of the public comments we received and our analysis of the updated claims data for this final rule with comment period, we are modifying our proposal and reassigning HCPCS codes G0237, G0238, G0239, and G0424 to status indicator “S.” In addition, we are modifying our

proposal and reassigning HCPCS codes G0237, G0238, and G0239 to the final APCs listed in Table 34 below. Table 34 lists the final status indicator, APC assignments, and payment rates for the pulmonary rehabilitation services for CY 2017. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reported under the OPSS. Addendum B is available via the Internet on the CMS Web site.

TABLE 34—FINAL CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR THE PULMONARY REHABILITATION SERVICES

HCPCS code	Long descriptors	CY 2016 OPSS SI	CY 2016 OPSS APC	CY 2016 OPSS payment	Final CY 2017 OPSS SI	Final CY 2017 OPSS APC	Final CY 2017 OPSS payment
G0237	Therapeutic procedures to increase strength or endurance of respiratory muscles, face to face, one on one, each 15 minutes (includes monitoring).	Q1	5734	\$91.18	S	5732	\$28.37
G0238	Therapeutic procedures to improve respiratory function, other than described by g0237, one on one, face to face, per 15 minutes (includes monitoring).	Q1	5733	55.94	S	5732	28.37
G0239	Therapeutic procedures to improve respiratory function or increase strength or endurance of respiratory muscles, two or more individuals (includes monitoring).	Q1	5732	30.51	S	5732	28.37
G0424	Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per session, up to two sessions per day.	Q1	5733	55.94	S	5733	54.53

IV. OPSS Payment for Devices

A. Pass-Through Payments for Devices

1. Expiration of Transitional Pass-Through Payments for Certain Devices

a. Background

Section 1833(t)(6)(B)(iii) of the Act sets forth the period for which a device category eligible for transitional pass-through payments under the OPSS may be in effect. The implementing regulation at 42 CFR 419.66(g) provides that this pass-through payment eligibility period begins on the date CMS establishes a particular transitional pass-through category of devices. The eligibility period is for at least 2 years but no more than 3 years. We may establish a new device category for pass-through payment in any quarter. Under our current policy, we base the pass-through status expiration date for a device category on the date on which pass-through payment is effective for the category; that is, the date CMS establishes a particular category of devices eligible for transitional pass-through payments. (We note that in this final rule with comment period, in accordance with section 1833(t)(6)(B)(iii)(II) of the Act, we are adopting a policy to base pass-through status expiration for a device category on the first date on which pass-through payment is made under the OPSS.) We propose and finalize the dates for

expiration of pass-through status for device categories as part of the OPSS annual update. 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. CY 2017 Pass-Through Devices

As stated earlier, section 1833(t)(6)(B)(iii) of the Act requires that, under the OPSS, 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 four device categories eligible for pass-through payment: (1) HCPCS code C2624 (Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components), which was established effective January 1, 2015; (2) HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser), which was established effective April 1, 2015; (3) HCPCS code C2613 (Lung biopsy plug with delivery system), which was established effective July 1, 2015; and (4) 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 category for HCPCS code C2624 will end on December 31, 2016. Therefore, in accordance with our current policy, in the CY 2017 OPSS/ASC proposed rule (81 FR 45649), we proposed, beginning in CY 2017, to package the costs of the device described by HCPCS code C2624 into the costs related to the procedure with which the device is reported in the hospital claims data. We stated in the proposed rule that the other three codes listed will continue with pass-through status in CY 2017. We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal to expire device pass-through payments for the device described by HCPCS code C2624, effective January 1, 2017.

2. New Device Pass-Through Applications

a. Background

Section 1833(t)(6) of the Act provides for temporary additional payments, referred to as “transitional 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 transitional pass-through payments. As part of implementing the statute through regulations, we have continued to believe that it is important for hospitals to receive pass-through payments for

devices that offer substantial clinical improvement in the treatment of Medicare beneficiaries to facilitate access by beneficiaries to the advantages of the new technology. Conversely, we have noted that the need for additional payments for devices that offer little or no clinical improvement over previously existing devices is less apparent. In such cases, these devices can still be used by hospitals, and hospitals will be paid for them through appropriate APC payment. Moreover, a goal is to target pass-through payments for those devices where cost considerations might be most likely to interfere with patient access (66 FR 55852; 67 FR 66782; and 70 FR 68629).

As specified in regulations at 42 CFR 419.66(b)(1) through (b)(3), to be eligible for transitional pass-through payment under the OPPS, a device must meet the following criteria: (1) if required by FDA, the device must have received FDA approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA), or another appropriate FDA exemption; and the pass-through payment application must be submitted within 3 years from the date of the initial FDA approval or clearance, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA approval or clearance is granted, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability; (2) the device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as required by section 1862(a)(1)(A) of the Act; and (3) the device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion. In addition, according to 42 CFR 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 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 noted 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 us through the quarterly subregulatory process, but the applications will be subject to notice-and-comment rulemaking in the next applicable OPPS annual rulemaking cycle. Under this process, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle, while submitters of applications that are not approved upon quarterly review will have the option of being included in the next applicable OPPS annual rulemaking cycle or withdrawing their application from consideration. Under this notice-and-comment process, applicants may

submit new evidence, such as clinical trial results published in a peer-reviewed journal, or other materials for consideration during the public comment process for the proposed rule. This process allows those applications that we are able to determine meet all the criteria for device pass-through payment under the quarterly review process to receive timely pass-through payment status, while still allowing for a transparent, public review process for all applications (80 FR 70417 through 70418). More details on the requirements for device pass-through payment applications are included on the CMS 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 2017

We received three applications by the March 1, 2016 quarterly deadline, which was the last quarterly deadline in time to be included for the CY 2017 OPPS/ASC proposed rule. None of these three applications were approved for device pass-through payment during the quarterly review process. Applications received for the later deadlines for the remaining 2016 quarters (June 1, September 1, and December 1), if any, will be presented in the CY 2018 OPPS/ASC proposed rule. We note that the quarterly application process and requirements have not changed in light of the addition of rulemaking review. Detailed instructions on submission of a quarterly device pass-through payment application are included on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf>. A discussion of the three applications received by the March 1, 2016 deadline is presented below, as detailed in the CY 2017 OPPS/ASC proposed rule (81 FR 45650 through 45653).

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

BioMonde US, LLC submitted an application for a new device pass-through category for the BioBag® (larval debridement therapy in a contained dressing) (hereinafter referred to as the

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

With respect to the newness criterion at § 419.66(b)(1), the applicant received FDA clearance for BioBag® through the premarket notification section 510(k) process on August 28, 2013, and its March 1, 2016 application was within 3 years of FDA clearance. The applicant claims that BioBag® is an integral part of the wound debridement, is used for one patient only, comes in contact with human skin, and is applied in or on a wound. In addition, the applicant stated that BioBag® is not an instrument, apparatus, or item for which depreciation and financing expenses are recovered. We believe that BioBag® could be considered to be a surgical supply similar to a surgical dressing that facilitates either mechanical or autolytic debridement (for example, hydrogel dressings), and therefore ineligible for device pass-through payments under the provisions of § 419.66(b)(4)(ii). In the CY 2017 OPPS/ASC proposed rule (81 FR 45650), we invited public comment on whether BioBag® should be eligible under § 419.66(b) to be considered for device pass-through payment.

Comment: One commenter, the manufacturer, submitted comments on whether BioBag® should be considered to be a surgical supply similar to a surgical dressing that facilitates either

mechanical or autolytic debridement. The commenter stated that BioBag® is a “treatment for active and physical wound debridement” that does not function like an autolytic or mechanical debridement, but more like a sharp debridement, surgical debridement or water-jet. The commenter also noted that BioBag® is individualized to the patient and has a limited viability window, and that ordering, manufacturing, storage and handling are different than for a supply.

Response: For purposes of the device pass-through payment process, we are persuaded by this additional information, and we no longer consider the BioBag® product to be an ineligible supply under § 419.66(b)(4)(ii) of the regulations because the BioBag® is not “furnished incident to a service,” as described in § 419.66(b)(4)(ii).

With respect to the existence of a previous pass-through device category that describes the BioBag®, the applicant suggested a category descriptor of “Larval therapy for the debridement of necrotic non-healing skin and soft tissue wounds.” We stated in the proposed rule that we have not identified an existing pass-through payment category that describes the BioBag®, but we welcomed public comments on this issue.

We did not receive any public comments on this issue and have not identified an existing pass-through payment category that describes BioBag®.

With respect to the cost criterion, the applicant stated that BioBag® would be reported with CPT code 97602 (Removal of devitalized tissue from wound(s), non-selective debridement, without anesthesia (e.g., wet-to-moist dressings, enzymatic, abrasion), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session). CPT code 97602 is assigned to APC 5051 (Level 1 Skin Procedures), with a CY 2016 payment rate of \$117.83, and the device offset is \$1.18. The price of BioBag® varies with the size of the bag (\$375 to \$435 per bag), and bag size selection is based on the size of the wound. To meet the cost significance criterion, there are three cost significance subtests that must be met and calculations are noted below. The first cost significance is that the device cost needs to be at least 25 percent of the applicable APC payment rate to reach cost significance, as follows for the highest-priced BioBag®: $\$435 / \$117.83 \times 100 = 369$ percent. Thus, BioBag® meets the first cost significance test. The second cost significance test is 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): $\$435 / \$1.18 \times 100 = 36864$ percent. Thus, BioBag® meets the second cost significance test. The third cost significance test is that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount determined to be associated with the device in the associated APC exceeds 10 percent of the total APC payment: $(\$435 - 1.18) / \$117.83 \times 100 = 368$ percent. Thus, BioBag® meets the third cost significance test and satisfies the cost significance criterion.

With respect to the substantial clinical improvement criterion, the applicant cited a total of 18 articles relating to wound debridement, and most of these articles discussed the use of larval therapy for the treatment of ulcers. One peer-reviewed journal article described a randomized controlled trial with 267 subjects who received loose larvae, bagged larvae, or hydrogel intervention.¹ Results of the study showed that the time to healing was not significantly different between the three groups, but that larval therapy significantly reduced the time to debridement (hazard ratio for the combined larvae group compared with hydrogel was 2.31 (95 percent confidence interval 1.65 to 3.24; $P < 0.001$)); and mean ulcer related pain scores were higher in either larvae group compared with hydrogel (mean difference in pain score: loose larvae versus hydrogel 46.74 (95 percent confidence interval 32.44 to 61.04), $P < 0.001$; bagged larvae versus hydrogel 38.58 (23.46 to 53.70), $P < 0.001$).

Another article described a study of 88 patients (of which 64 patients completed the study) and patients either received a larval therapy dressing (BioFOAM) or hydrogel.² Because the study did not use BioBag® and there was a large drop-out rate that was not fully explained, we did not find this article helpful in determining whether the BioBag® provides a substantial clinical improvement compared to existing wound debridement modalities.

Another article that the applicant submitted was a meta-analysis of maggot debridement therapy compared to standard therapy for diabetic foot

¹ Dumville, et al.: Larval therapy for leg ulcers (VenUS II): randomized controlled trial).

² Mudge, et al.: A randomized controlled trial of larval therapy for the debridement of leg ulcers: Results of a multicenter, randomized, controlled, open, observer blind, parallel group study. *Wound Repair and Regeneration*. 2013, 1–9.

ulcers.³ It compared four studies with a total of 356 participants and the authors concluded that maggot debridement therapy “may be a scientific and effective therapy in treatment of diabetic foot ulcers” but “the evidence is too weak to routinely recommend it for treatment”.

There were some additional articles provided that included a case series of maggot therapy with no control group, a retrospective study with free-range maggot therapy, maggot therapy as treatment of last resort, in vitro studies, economic modeling for wound therapy, an informational review of maggot debridement therapy and other debridement therapies, and research on other wound therapy options. These remaining articles did not assist in assessing substantial clinical improvement of BioBag[®] compared to existing treatments. Based on the evidence submitted with the application, we stated in the proposed rule that we are not yet convinced that the BioBag[®] provides a substantial clinical improvement over other treatments for wound debridement. We invited public comments on whether the BioBag[®] meets the substantial clinical improvement criterion.

Comment: One commenter, the manufacturer, disagreed with CMS’ review of the three cited articles from the initial application (Tian, Dumville, Mudge) and suggested that these articles prove substantial clinical improvement. Specifically, the commenter noted that the meta-analysis by Tian suggests that findings of lower amputation rates, less antibiotic use, increased healing rates and increased healing times for larval therapy over conventional treatments are statistically significant, although the conclusion states that more evidence is needed; and that the randomized controlled trial by Mudge showed that successful wound debridement was 96.9 percent with larvae compared to 34.4 percent with hydrogel. (However, the commenter noted this trial was performed with BioFoam, which is a variation of the current BioBag[®] product, but stated that the two were similar.) In addition, the commenter stated that larval therapy demonstrated healing 9 days faster than hydrogel, although it was not believed to be statistically significant by the authors in the Dumville trial.

Several commenters representing health care professionals who have an interest in wound management supported the BioBag[®] application.

These commenters provided testimonials of their or their patients’ favorable experience with larval therapy. However, these commenters did not provide empirical data pertaining to substantial clinical improvement.

Response: We appreciate the commenters’ responses on the BioBag[®] application. However, none of the commenters provided new empirical evidence that demonstrates clinical superiority of the BioBag[®] over existing treatment options. At this time, we have not been able to determine that the BioBag[®] represents a substantial clinical improvement relative to existing therapies currently available for wound care.

After consideration of the public comments we received, we are not approving device pass-through payment status for the BioBag[®] for CY 2017.

(2) Encore[™] Suspension System

Siesta Medical, Inc. submitted an application for a new device pass-through category for the Encore Suspension System (hereinafter referred to as the Encore[™] System). According to the application, the Encore[™] System is a kit of surgical instruments and implants that are used to perform an adjustable hyoid suspension. In this procedure, the hyoid bone (the U-shaped bone in the neck that supports the tongue) and its muscle attachments to the tongue and airway are pulled forward with the aim of increasing airway size and improving airway stability in the retrolingual and hypopharyngeal airway (airway behind and below the base of tongue). This procedure is indicated for the treatment of mild or moderate obstructive sleep apnea (OSA) and/or snoring, when the patient is unable to tolerate continuous positive airway pressure (CPAP). The current alternative to the hyoid suspension is the hyo-thyroid suspension technique (hyothyroidpexy). The Encore[™] System is designed for hyoid bone suspension to the mandible bone using bone screws and suspension lines. The Encore[™] System kit contains the following items:

- Integrated suture passer pre-loaded with polyester suture;
- Three bone screws and two bone screw inserters;
- Suspension line lock tool;
- Threading tool for suspension lines; and
- Four polyester suspension lines.

With regard to the newness criterion, the Encore[™] System received FDA clearance through the section 510(k) process on March 26, 2014. Accordingly, it appears that the

Encore[™] System is new for purposes of evaluation for device pass-through payments.

Several components of the Encore[™] System appear to be either instruments or supplies, which are not eligible for pass-through according to § 419.66(b)(4)(i) and (ii). For instance, the suture passer is an instrument and the suture is a supply, the bone screw inserters are instruments, the suspension line lock tool is an instrument, the threading tool for suspension lines is an instrument, and the polyester suspension lines are similar to sutures and therefore are supplies. With respect to the presence of a previously established code, the only implantable devices in the kit are the bone screws, and by the applicant’s own admission the bone screws are described by the existing pass-through category HCPCS code C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)). In the CY 2017 OPPI/ASC proposed rule (81 FR 45651), we invited public comments on whether the Encore[™] System bone screws are described by a previously existing category and also whether the remaining kit components are supplies or instruments.

Comment: One commenter, the manufacturer, stated that the Encore[™] bone screws are designed with unique strength, profile and adjustability functions for the Encore[™] System, and therefore the bone screws are not adequately described by HCPCS code C1713. In addition, the commenter stated that the remaining kit components are custom designed for the procedure, would not be available otherwise within the operating room, and, therefore, would not meet the criteria for supplies and instruments, as specified in § 419.66(b)(4)(i)(ii).

Response: We note that manufacturers frequently package a number of individual items used with a device for a particular procedure into a kit. Hospitals may not bill for transitional pass-through payments for supplies that may be contained in kits (Medicare Claims Processing Manual (Pub. 100–04, Chapter 4, Section 60.4)). We continue to believe that the suture passer, the bone screw inserters, the suspension line lock tool, and the threading tool for suspension lines are all instruments and that the sutures and polyester suspension lines are supplies, even though they may have been customized for the procedure. Regarding the bone screws, we continue to believe that the bone screws are described by HCPCS code C1713 because, although customized, the bone screws anchor/

³Tian et al.: Maggot debridement therapy for the treatment of diabetic foot ulcers: a meta-analysis. *Journal of Wound Care*. Vol. 22, No. 9, 2013.

screw for opposing bone-to-bone (hyoid bone to mandible bone).

With regard to the cost criterion, the applicant stated that the Encore™ System would be used in the procedure described by CPT code 21685 (Hyoid myotomy and suspension). CPT code 21685 is assigned to APC 5164 (Level 4 ENT Procedures) with a CY 2016 payment rate of \$1,616.90, and the device offset is \$15.85. The price of the Encore™ System as stated in the application is \$2,200. To meet the cost criterion, there are three cost significance subtests that must be met and the calculations are noted below. The first cost significance is that the device cost needs to be at least 25 percent of the applicable APC payment rate to reach cost significance: $\$2,200 / \$1,616.90 \times 100 \text{ percent} = 136 \text{ percent}$. Thus, the Encore™ System meets the first cost significance test. The second cost significance test is 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): $\$2,200 / \$15.85 \times 100 \text{ percent} = 13880 \text{ percent}$. Thus, the Encore™ System meets the second cost significance test. The third cost significance test is that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount determined to be associated with the device in the associated APC exceeds 10 percent of the total APC payment: $(\$2,200 - \$15.85) / \$1,616.90 \times 100 \text{ percent} = 135 \text{ percent}$. Thus, the Encore™ System meets the third cost significance test. Based on the costs submitted by the applicant and the calculations noted earlier, the Encore™ System meets the cost criterion. However, as stated in the proposed rule, we have concerns about whether the cost criterion would be met if based only on the kit components that are not supplies, not instruments, and not described by an existing category (if any).

We did not receive any public comments related to the cost criterion of the Encore™ System application. As noted earlier in this section, the applicant stated that the Encore™ System would be used in the procedure described by CPT code 21685 (Hyoid myotomy and suspension). CPT code 21685 is assigned to APC 5164 (Level 4 ENT Procedures) with a CY 2016 payment rate of \$1,616.90, and the device offset is \$15.85. The applicant also stated that the price of the Encore™ System is \$2,200. Based on our determination earlier in this section of this final rule with comment period, the device is described by HCPCS code

C1713 and the bone screws and other kit supplies are supplies and instruments. Because of this determination, the cost of the device and the other components in the kit cannot be included in the device costs used to determine whether the device meets the cost criterion. Accordingly, the Encore™ System does not meet the cost threshold.

With regard to the substantial clinical improvement criterion, the applicant provided a thorough review of the hyoid myotomy with suspension and other surgical procedures that treat mild or moderate obstructive sleep apnea. However, specific data addressing substantial clinical improvement with the Encore™ System were lacking. The application included information on a case series of 17 obstructive apnea patients who received an Encore hyomandibular suspension as well as a previous or concurrent uvulopalatopharyngoplasty (UPPP). According to the application, the 17 patients studied demonstrated a 76 percent surgical success, and 73 percent median reduction in the Respiratory Disturbance Index (RDI) at 3 months, significantly reduced surgical time, and 1 infection requiring device removal. This study was a retrospective, single center study with no comparator.

In addition, the American Academy of Otolaryngology Head and Neck Surgery (AAOHNS) "Position Statement: Tongue Based Procedures" (accessed on 3.30.2016 and located at: <http://www.entnet.org/node/215>) considers the Hyoid myotomy and suspension "effective and non-investigational with proven clinical results when considered as part of the comprehensive surgical management of symptomatic adult patients with mild obstructive sleep apnea (OSA) and adult patients with moderate and severe OSA assessed as having tongue base or hypopharyngeal obstruction." The AMA CPT Editorial Panel created CPT code 21685 (Hyoid myotomy and suspension) in 2004. The AAOHNS statement and the age of the CPT code indicate that this is an established surgical procedure. The Encore™ System is a new kit of surgical instruments and implantable materials that are used to perform this procedure. According to the Encore™ System's section 510(k) Summary, "[t]he fundamental scientific technology and technological characteristics of the Encore™ System are the same as the predicate devices," which includes the Medtronic AirVance System (another surgical kit used on CPT code 21685). The applicant claimed several advantages of the Encore™ System over the AirVance System that relate to greater ease of use for the surgeon and

better long-term stability. However, there are no studies comparing the Encore™ System to the AirVance System. There are no clinical data provided by the applicant to suggest that the Encore™ System kit provides a substantial clinical improvement over other instruments/implants that are used to perform Hyoid myotomy and suspension. In the proposed rule, we invited public comments on whether the Encore™ System meets the substantial clinical improvement criterion.

Comment: One commenter stated that the Encore™ System has "provided improved and more consistent results than previous hyoid suspension techniques" and that it is reasonable to assume that a system that provides significantly improved control of the hyoid bone suspension location and greater long-term stability of this surgically modified hyoid bone location will lead to improved and less variable clinical results for the patients treated, including reducing the mortality rate, future hospitalization, and the need for future additional interventions. Numerous commenters who used the Encore™ System supported the application and stated that, in their experience, the system provided a substantial clinical improvement for performing hyomandibular suspension and was superior to the hyo-thyroid technique. These commenters did not provide any new empirical data in support of the application.

Response: As stated in the proposed rule, there were no clinical data provided by the applicant to suggest that the Encore™ System kit provides a substantial clinical improvement over other instruments/implants that are used to perform Hyoid myotomy and suspension. While the commenters provided some suggestions that the Encore™ System kit had clinical merits, these suggestions were anecdotal and largely based on assumptions, not actual empirical clinical evidence. Because no new significant information or data were provided through the public comments, we are not able to determine that the Encore™ System represents a substantial clinical improvement relative to existing medical treatments.

After consideration of the public comments we received, we are not approving device pass-through payment status for the Encore™ System for CY 2017.

(3) Endophys Pressure Sensing System (Endophys PSS) or Endophys Pressure Sensing Kit

Endophys Holdings, LLC. submitted an application for a new device pass-

through category for the Endophys Pressure Sensing System or Endophys Pressure Sensing Kit (hereinafter referred to as the Endophys PSS). The applicant suggested a category descriptor within either the HCPCS code C18XX series or the HCPCS code C26XX series and the device was described by the applicant as a stand-alone catheterization sheath that is inserted percutaneously during intravascular diagnostic or interventional procedures. When applied intravascularly, the two separate functions delivering an improved patient outcome include: (1) Continuous intra-arterial blood pressure monitoring using a high-precision Fabry-Perot pressure sensor located within the device anterior approaching the distal tip of the system; and (2) a conduit that allows the introduction of other devices for cardiovascular or percutaneous interventional procedures.

The Endophys PSS is an introducer sheath (including a dilator and guidewire) with an integrated fiber optic pressure transducer for blood pressure monitoring. The Endophys PSS is used with the Endophys Blood Pressure Monitor to display blood pressure measurements. The sheath is inserted percutaneously during intravascular diagnostic or interventional procedures, typically at the site of the patient's femoral artery. This device facilitates the introduction of diagnostic and interventional devices into the coronary and peripheral vessels while continuously sensing and reporting blood pressure during the interventional procedure. Physicians would use this device to pass guidewires, catheters, stents, and coils, to perform the diagnostic or therapeutic treatment on the coronary or other vasculature. The Endophys PSS provides continuous blood pressure monitor information to the treating physician so that there is no need for an additional arterial access site for blood pressure monitoring.

With respect to the newness criterion, the Endophys PSS received FDA clearance through the section 510(k) process on January 7, 2015, and therefore is new. According to the applicant, the Endophys PSS is an integral part of various endovascular procedures, is used for one patient only, comes in contact with human skin, and is surgically implanted. Endophys PSS is not an instrument, apparatus, implement or item for which depreciation and financing expenses are recovered, and it is not a supply or material.

With respect to the presence of a previously established category, based on our review of the application, we

believe that Endophys PSS may be described by HCPCS code C1894 (Introducer/sheath, other than guiding, other than intracardiac electrophysiological, non-laser). The FDA section 510(k) Summary Product Description Section in the application describes the Endophys PSS as an introducer sheath with an integrated fiber optic pressure transducer. Because the Endophys PSS is an introducer sheath that is not guiding, not intracardiac electrophysiological, and not a laser, we believe that it is described by the previously existing category of HCPCS code C1894 established for transitional pass-through payments. In the CY 2017 OPPS/ASC proposed rule (81 FR 45652), we invited public comment on whether Endophys PSS is described by a previously existing category.

Comment: One commenter, the manufacturer, disagreed with CMS that the Endophys PSS is described by HCPCS code C1894 and states that HCPCS code C1894 “describes a device that does not look like the Endophys PSS, does not provide continuous intraarterial blood pressure readings equivalent to a radial arterial line, is not used or monitored by a physician in a similar manner.” The commenter noted that the design for Endophys PSS is patented. The commenter also noted that FDA has assigned new product codes to the Endophys PSS that are not similar to devices described by HCPCS code C1894.

Response: We continue to believe that HCPCS code C1894 accurately describes the Endophys PSS because it is a type of introducer/sheath (but with a built-in pressure transducer). Also, a new product code from the FDA, which is used by the FDA to classify and track a medical device, is not relevant in CMS' consideration of whether the device is described by an existing HCPCS C-code. The FDA may provide new product codes for items that we consider to be described more broadly and with an existing HCPCS C-code.

With respect to the cost criterion, according to the applicant, the Endophys PSS would be reported with CPT code 36620 (Arterial catheterization or cannulation for sampling, monitoring or transfusion (separate procedure); percutaneous). CPT code 36620 is assigned status indicator “N”, which means its payment is packaged under the OPPS. The applicant stated that its device can be used in many endovascular procedures that are assigned to the APCs listed below:

APC	Description
5188	Diagnostic Cardiac Catheterization.
5191	Level 1 Endovascular Procedures.
5526	Level 6 X-Ray and Related Services.
5183	Level 3 Vascular Procedures.
5181	Level 1 Vascular Procedures.
5182	Level 2 Vascular Procedures.
5291	Thrombolysis and Other Device Revisions.

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. For our calculations, we used APC 5291 (Thrombolysis and Other Device Revisions), which has a CY 2016 payment rate of \$199.80 and the device offset of \$3.38. According to the applicant, the cost of the Endophys PSS is \$2,500. The first cost significance test is that the device cost needs to be at least 25 percent of the applicable APC payment rate to reach cost significance: $\$2,500 / 199.80 \times 100$ percent = 1251 percent. Thus, the Endophys PSS meets the first cost significance test. The second cost significance test is 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): $\$2,500 / 3.38 \times 100$ percent = 73964 percent. Thus, the Endophys PSS meets the second cost significance test. The third cost significance test is that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount determined to be associated with the device in the associated APC exceeds 10 percent of the total APC payment: $(\$2,500 - 3.38) / 199.80 \times 100$ percent = 1250 percent. Thus, the Endophys PSS meets the third cost significance test. Based on the costs submitted by the applicant and the above calculations, the Endophys PSS meets the cost criterion. In the proposed rule, we invited public comments on this issue.

We did not receive any public comments on whether the Endophys PSS meets the cost criterion. We continue to believe that the Endophys PSS meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant stated that the Endophys PSS represents a substantial clinical improvement over existing medical therapies because the Endophys PSS includes a built-in pressure sensor, which eliminates the need for a second arterial line to monitor the blood pressure. The applicant stated that the Endophys PSS reduces the time to treatment for the patient (because there is no time needed to establish the second arterial line) and reduces

potential complications associated with the second arterial line. While several references were provided in support of this application, there were minimal direct clinical data provided on the Endophys PSS to support substantial clinical improvement. The application included slides with statements pertaining to cost savings, reduced morbidity and life saving for a study of 36 patients, but a published study was not submitted and additional information on study design and other details of the study were not provided. Also, the applicant provided six physician testimonials citing support for the Endophys PSS based on between one and six patient experiences with the device.

The published articles provided with the application did not provide any information based on usage of the Endophys PSS. Topics addressed in the references included: Articles on intraarterial treatment for acute ischemic stroke; references providing education on blood pressure measurement and monitoring; articles on complications during percutaneous coronary intervention; and a reference on ultrasound guided placement of arterial cannulas in the critically ill. Given the paucity of studies using the Endophys PSS, we stated in the proposed rule that we have not been persuaded that the threshold for substantial clinical improvement has been met. We invited public comments on whether the Endophys PSS meets the substantial clinical improvement criterion.

Comment: One commenter, the manufacturer, submitted a new publication⁴ that compared a set of patients' radial artery catheterization (RAC) blood pressure measurements, sphygmomanometer readings, and measurements from the Endophys PSS. Study results suggested that the Endophys PSS correlated with the RAC and the blood pressure cuff. The study authors conclude that because the Endophys PSS has "competitive functionality to that seen with a dedicated radial artery catheter for blood pressure monitoring and is available immediately on sheath insertion without the added risk of [RAC] . . . , potential complications from RAC could be avoided." In addition, in its comment, the commenter noted that validation of the patient benefit due to the lack of a second arterial line for blood pressure monitoring in a randomized clinical

trial may not meet the criteria of a well-designed clinical investigation and cited three considerations for why this is the case. The commenter noted that the "clinical evidence is abundant in the published literature reporting the incidence of radial arterial catheterization complications, cost, and patient morbidity. Time saved by eliminating a second RA placement while providing equivalent and continuous arterial pressure readings is obvious, and has cost benefits beyond the purely medical benefits discussed above." The commenter further noted that patients who received Endophys PSS "did not require a RA catheter placement, no serious complications were reported, and that the procedure was completed achieving the therapeutic objective. Reports were received across the centers noting when using accurate continuous arterial pressures the clinician was alerted to serious changes in blood pressure requiring immediate attention. In the absence of the Endophys PSS, the variance would not have been identified causing the patient to suffer complications."

Response: We appreciate the submission of the new study as well as the public comment. We note that the study appears to show correlation on blood pressure readings between the Endophys PSS and RAC, and we believe that a clinical trial of the Endophys PSS versus RAC examining complication rates would be necessary to validate the theory of reduction in complication rates with use of the Endophys PSS. Accordingly, we do not believe the study supports a definitive conclusion that this device provides a substantial clinical improvement over existing modalities.

After consideration of the public comments we received, we are not approving device pass-through payment status for the Endophys PSS for CY 2017.

3. Beginning Eligibility Date for Device Pass-Through Payment Status

The regulation at 42 CFR 419.66(g) currently provides that the pass-through payment eligibility period begins on the date CMS establishes a category of devices. In the CY 2017 OPPS/ASC proposed rule (81 FR 45653), we proposed to amend § 419.66(g) such that it more accurately comports with section 1833(t)(6)(B)(iii)(II) of the Act, which provides that the pass-through eligibility period begins on the first date on which pass-through payment is made. We recognize that there may be a difference between the establishment of a pass-through category and the date

of first pass-through payment for a new pass-through device for various reasons. In most cases, we would not expect this proposed change in the beginning pass-through eligibility date to make any difference in the anticipated pass-through expiration date. However, in cases of significant delay from the date of establishment of a pass-through category to the date of the first pass-through payment, by using the date that the first pass-through payment was made rather than the date on which a device category was established could result in an expiration date of device pass-through eligibility that is later than it otherwise would have been had the clock began on the date the category was first established. We invited public comments on our proposal.

Comment: Many commenters supported the proposal. The commenters' statements of support included that the proposed policy recognizes that the quarterly implementation date may not be aligned with market availability and starting the device pass-through eligibility period on date of first payment would allow for more robust data collection for the purposes of setting future APC rates to accurately include the device costs.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing the proposal to amend § 419.66(g) such that it provides that the pass-through eligibility period begins on the first date on which pass-through payment is made.

4. Policy To Make the Transitional Pass-Through Payment Period 3 Years for All Pass-Through Devices and Expire Pass-Through Status on a Quarterly Rather Than Annual Basis

a. Background

As required by statute, transitional pass-through payments for a device described in section 1833(t)(6)(B)(iii) of the Act can be made for a period of at least 2 years, but not more than 3 years, beginning on the first date on which pass-through payment was made for the product. Our current policy is to accept pass-through applications on a quarterly basis and to begin pass-through payments for new pass-through devices on a quarterly basis through the next available OPPS quarterly update after the approval of a device's pass-through status. However, we expire pass-through status for devices on a calendar-year basis through notice-and-comment rulemaking rather than on a quarterly basis. Device pass-through status currently expires at the end of a

⁴Purdy PD, South C, Klucznik RP et al. *J NeuroIntervent Surg*. Published online first July 16, 2016 doi:10.1136/neurintsurg-2016-012536.

calendar year when at least 2 years of pass-through payments have been made, regardless of the quarter in which it was initially approved. This means that the duration of the pass-through eligibility for a particular device will depend upon when during a year the applicant applies and is approved for pass-through payment. For example, a new pass-through device with pass-through payment status effective on April 1 would receive 2 years and 3 quarters of pass-through payment status, while a pass-through device with pass-through payment status effective on October 1 would receive 2 years and 1 quarter of pass-through payment status.

b. CY 2017 Policy

In the CY 2017 OPPI/ASC proposed rule (81 FR 45653), we proposed, beginning with pass-through devices newly approved in CY 2017 and subsequent calendar years, to allow for a quarterly expiration of pass-through payment status for devices to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through payment devices. This proposed change would eliminate the variability of the pass-through eligibility period, which currently varies based on the timing of the particular application. For example, under this proposal, for a device with pass-through first effective on October 1, 2017, pass-through payment status would expire on September 30, 2020. As stated in the proposed rule, we believe that the payment adjustment for transitional pass-through payments for devices under the OPPI is intended to provide adequate payment for new innovative technology while we collect the necessary data to incorporate the costs for these devices into the calculation of the associated procedure payment rate (66 FR 55861). We believe that the 3-year maximum pass-through payment period for all pass-through devices would better insure robust data collection and more representative procedure payments once the pass-through payment devices are packaged. We invited public comments on this proposal.

Comment: Many commenters, including MedPAC, supported the proposal. Some commenters suggested that, by maximizing the timeframe for receipt of device pass-through payment, there would be more robust cost data that can be utilized for setting future APC rates to accurately include the device costs.

Response: We appreciate the commenters' support.

Comment: One commenter asked whether CMS intends to adjust payment

rates mid-year to include the costs of newly packaged devices upon expiration of device pass-through payments, when a device pass-through payment status expires mid-year. The commenter was concerned that hospitals might not receive adequate payment for the costs of a device, unless the payment was also adjusted, when the device pass-through payment status expired.

Response: We do not generally adjust payment rates mid-year and do not anticipate doing so for this proposal. Under our final policy, we will continue to include all device costs in the associated procedure(s) for ratesetting purposes. The final CY 2017 OPPI policy represents an extension of the timeframe for which device pass-through payment policy applies but does not affect the claims available for ratesetting purposes. We note that our not adjusting rates mid-year will not result in double payment for devices. While the device maintains pass-through payment status, we will reduce APC payment by the device offset and add the device pass-through payment; once the device pass-through payment status expires, hospitals will bill for and receive the full APC payment, which includes packaged device costs.

Comment: Several commenters requested that CMS consider amending the proposal in order to implement the proposed policy retroactively to previously approved devices that were proposed to continue receiving device pass-through payments in CY 2017. The commenters stated that this recommended change would extend the timeframe for receipt of device pass-through payments to current applicants that have already been awarded device pass-through payment status and anticipate receipt of device pass-through payments in CY 2017.

Response: As proposed, the policy begins with pass-through devices newly approved in CY 2017, and we are not going to this policy for devices that received pass-through payment approval prior to CY 2017.

After consideration of the public comments we received, we are finalizing, without modification, our proposal to allow for quarterly expiration of pass-through payment status for devices, beginning with newly approved pass-through payment devices 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.

5. Changes to Cost-to-Charge Ratios (CCRs) That Are Used To Determine Device Pass-Through Payments

a. Background

Section 1833(t)(6)(D)(ii) of the Act and 42 CFR 419.66(h) describe how payment will be determined for pass-through payment devices. Currently, transitional pass-through payments for devices are calculated by taking the hospital charges for each billed device, reducing them to cost by use of the hospital's average CCR across all outpatient departments, and subtracting an amount representing the device cost contained in the APC payments for procedures involving that device (65 FR 18481 and 65 FR 67809). In the original CY 2000 OPPI final rule, we stated that we would examine claims in order to determine if a revenue center-specific set of CCRs should be used instead of the average CCR across all outpatient departments (65 FR 18481).

In the FY 2009 IPPI final rule (73 FR 48458 through 48467), CMS created a cost center for "Medical Supplies Charged to Patients," which are generally low cost supplies, and another cost center for "Implantable Devices Charged to Patients," which are generally high-cost implantable devices. This change was in response to a Research Triangle Institute, International (RTI) study that was discussed in the FY 2009 IPPI final rule and which determined that there was charge compression in both the IPPI and the OPPI cost estimation of expensive and inexpensive medical supplies. Charge compression can result in undervaluing high-cost items and overvaluing low-cost items when an estimate of average markup, embodied in a single CCR (such as the hospital-wide CCR) is applied to items of widely varying costs in the same cost center. By splitting medical supplies and implantable devices into two cost centers, some of the effects of charge compression were mitigated. The cost center for "Implantable Devices Charged to Patients" has been available for use for OPPI cost reporting periods beginning on or after May 1, 2009.

In CY 2013, we began using data from the "Implantable Devices Charged to Patients" cost center to create a distinct CCR for use in calculating the OPPI relative payment weights for CY 2013 (77 FR 68225). Hospitals have adapted their cost reporting and coding practices in order to report usage to the "Implantable Devices Charged to Patients" cost center, resulting in sufficient data to perform a meaningful analysis. However, we have continued to use the hospital-wide CCR in our

calculation of device pass-through payments. We have received a request to consider using the “Implantable Devices Charged to Patients” CCR in the calculation of device pass-through payment and have evaluated this request. An analysis of the CCR data for the CY 2017 OPPI/ASC proposed rule indicated that about two-thirds of providers have an “Implantable Devices Charged to Patients” CCR. At the time of our analysis for the proposed rule, for the hospitals that have an “Implantable Devices Charged to Patients” CCR, the median was 0.3911, compared with a median hospital-wide CCR of 0.2035.

b. CY 2017 Policy

In the CY 2017 OPPI/ASC proposed rule (81 FR 45654), we proposed to use the more specific “Implantable Devices Charged to Patients” CCR instead of the less specific average hospital-wide CCR to calculate transitional pass-through payments for devices, beginning with device pass-through payments in CY 2017. When the CCR for the “Implantable Devices Charged to Patients” CCR is not available for a particular hospital, we would continue to use the average CCR across all outpatient departments to calculate pass-through payments. We believe using the “Implantable Devices Charged to Patients” CCR will provide more accurate pass-through payments for most device pass-through payment recipients and will further mitigate the effects of charge compression. We invited public comments on this proposal.

Comment: Many commenters, including MedPAC, supported the proposal. Commenters generally agreed that use of the “Implantable Devices Charged to Patients” CCR would result in more accurate measurement of costs for pass-through medical devices, by reducing the effects of charge compression when applying the hospital-wide CCR.

Response: We appreciate the commenters’ support.

Comment: One commenter suggested that CMS modify the proposal to allow use of the “Medical Supplies Charged to Patients” CCR, if the hospital does not have an “Implantable Devices Charged to Patients” CCR. The commenter stated that this CCR would be a more accurate cost calculation than the hospital-wide CCR.

Response: In the FY 2009 IPPS final rule (73 FR 48458 through 48467), we created a cost center for “Medical Supplies Charged to Patients,” which generally includes low cost supplies, and another cost center for “Implantable Devices Charged to Patients,” which

generally includes high-cost implantable devices. This change was in response to a Research Triangle Institute, International (RTI) study that was discussed in the FY 2009 IPPS final rule and which determined that there was charge compression in both the IPPS and the OPPI cost estimation of expensive and inexpensive medical supplies. By splitting medical supplies and implantable devices into two cost centers, some of the effects of charge compression were mitigated. We note that the intent of the “Medical Supplies Charged to Patients” CCR is to capture the costs and charges for low cost supplies which would not include implantable devices. Accordingly, in the absence of an “Implantable Devices Charged to Patients” CCR, we believe that the hospital-wide CCR would be an appropriate alternative since the hospital-wide CCR should reflect any implantable device costs that were incurred.

Comment: One commenter stated that providers who have not complied with the requirement to create an “Implantable Devices Charged to Patients” cost center should not receive any indirect payment benefits from their noncompliance.

Response: We note that we provide some flexibility in how hospitals address their cost reporting. As noted in the CY 2010 OPPI/ASC final rule with comment period (74 FR 60344), “We typically do not specify a revenue-code-to-cost center crosswalk that hospitals must adopt to prepare their cost reporting, recognizing hospitals’ need to interpret . . . cost reporting requirements within the context of their own financial systems.”

After consideration of the public comments we received, we are finalizing, without modification, our proposal to use the “Implantable Devices Charged to Patients” CCR instead of the average hospital-wide CCR to calculate transitional pass-through payments for devices, beginning with device pass-through payments in CY 2017. If the CCR for the “Implantable Devices Charged to Patients” CCR is not available for a particular hospital, we will instead use the average hospital-wide CCR to calculate pass-through payments.

6. Provisions for Reducing Transitional Pass-Through Payments To Offset Costs Packaged Into APC Groups

a. Background

Section 1833(t)(6)(D)(ii) of the Act sets the amount of additional pass-through payment for an eligible device as the amount by which the hospital’s charges

for a device, adjusted to cost (the cost of the device), exceeds the portion of the otherwise applicable Medicare outpatient department fee schedule amount (the APC payment amount) associated with the device. We have an established policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of the associated devices that are eligible for pass-through payments (66 FR 59904) for purposes of estimating the portion of the otherwise applicable APC payment amount associated with pass-through devices. For eligible device categories, we deduct an amount that reflects the portion of the APC payment amount that we determine is associated with the cost of the device, defined as the device APC offset amount, from the charges adjusted to cost for the device, as provided by section 1833(t)(6)(D)(ii) of the Act, to determine the pass-through payment amount for the eligible device. We have an established methodology to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of an associated device eligible for pass-through payment, using claims data from the period used for the most recent recalibration of the APC rates (72 FR 66751 through 66752). In the unusual case where the device offset amount exceeds the device pass-through payment amount, the regular APC rate would be paid and the pass-through payment would be \$0.

b. CY 2017 Policy

In the CY 2017 OPPI/ASC proposed rule (81 FR 45654), for CY 2017, we proposed to calculate the portion of the otherwise applicable Medicare OPD fee schedule amount, for each device-intensive procedure payment rate that can reasonably be attributed to (that is, reflect) the cost of an associated device (the device offset amount) at the HCPCS code level rather than at the APC level (which is an average of all codes assigned to an APC). We refer readers to section IV.B. of the proposed rule and of this final rule with comment period for a discussion of this proposal. Otherwise, as stated in the proposed rule, we will continue our established practice of reviewing each new pass-through device category to determine whether device costs associated with the new category replace device costs that are already packaged into the device implantation procedure. If device costs that are packaged into the procedure are related to the new category, then according to our established practice we will deduct the device offset amount from the pass-through payment for the device

category. The list of device offsets for all device procedures is posted on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

We are finalizing, without modification, our proposal to calculate the portion of the otherwise applicable Medicare OPD fee schedule amount for each device-intensive procedure payment rate that can be reasonably attributed to (that is, reflect) the cost of an associated device at the HCPCS code level rather than at the APC level. We refer readers to section IV.B. of this final rule with comment period for a discussion of the proposal to calculate device offsets at the HCPCS level. Otherwise, we will continue our established practice of reviewing each new pass-through device category to determine whether device costs associated with the new category replace device costs that are already packaged into the device implantation procedure. If device costs that are packaged into the procedure are related to the new category, then according to our established practice, we will deduct the device offset amount from the pass-through payment for the device category. The list of device offsets for all device procedures will be posted on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

B. Device-Intensive Procedures

1. Background

Under the OPPI, device-intensive APCs are 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 are calculated and the geometric mean device offset of all of the procedures must 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) applies to device-intensive APCs and is discussed in detail in section IV.B.4. of this final rule with comment period. A related device policy is 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 OPPI/ASC final rule

with comment period (80 FR 70421 through 70426).

2. HCPCS Code-Level Device-Intensive Determination

As stated above, currently the device-intensive methodology assigns device-intensive status to all procedures requiring the implantation of a device, which are assigned to an APC with a device offset greater than 40 percent. Historically, the device-intensive designation has been at the APC level and applied to the applicable procedures within that given APC. In the CY 2017 OPPI/ASC proposed rule (81 FR 45654), for CY 2017, we proposed to modify the methodology for assigning device-intensive status. Specifically, for CY 2017, we proposed 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, as we no longer believe that device-intensive status should be based on APC assignment because APC groupings of clinically similar procedures do not necessarily factor in device cost similarity. In 2016, we restructured many of the APCs, and this resulted in some procedures with significant device costs not being assigned device-intensive status because they were not assigned to a device-intensive APC. Under our proposal, all procedures with significant device costs (defined as a device offset of more than 40 percent) would be assigned device-intensive status, regardless of their APC placement. Also, we believe that a HCPCS code-level device offset would, in most cases, be a better representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all of the procedures assigned to an APC. Unlike a device offset calculated at the APC level, which is a weighted average offset for all devices used in all of the procedures assigned to an APC, a HCPCS code-level device offset is calculated using only claims for a single HCPCS code. We believe that such a methodological change would result in a more accurate representation of the cost attributable to implantation of a high-cost device, which would ensure consistent device-intensive designation of procedures with a significant device cost. Further, we believe a HCPCS code-level device offset would remove inappropriate device-intensive status to procedures without a significant device cost but which are granted such status because of APC assignment.

Under our proposal, procedures that have an individual HCPCS code-level

device offset of greater than 40 percent would be identified as device-intensive procedures and would be subject to all the CY 2017 policies applicable to procedures assigned device-intensive status under our established methodology, including our policies on device edits and device credits. Therefore, under our proposal, all procedures requiring the implantation of a medical device and that have an individual HCPCS code-level device offset of greater than 40 percent would be 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 the proposed rule, respectively. We proposed to amend the regulation at § 419.44(b)(2) to reflect that we would no longer be designating APCs as device-intensive, and instead would be designating procedures as device-intensive.

Comment: The majority of commenters supported the proposal to revise the device-intensive calculation methodology and calculate at the HCPCS code level rather than at the APC level. One commenter believed that device-intensive procedures should not be assigned to an APC that includes procedures that are not device-intensive. A few commenters asked that CMS provide further detail into how device offsets are calculated, and provide examples of how this proposed change might impact existing APCs for both OPPI and ASC payment prior to implementing. One commenter requested that CMS make further refinements to the methodology if needed to ensure the full breadth of implantable device and supply costs are being captured and recommended moving forward that CMS routinely release the device offset calculations with each year's OPPI/ASC proposed rule. Another commenter requested that CMS create two different device offsets based on differing calculations, with the proposed device offset methodology used to calculate a "device offset for device intensive policies" (which would be used to determine if a procedure is device intensive or not) and an alternate methodology used to calculate a "device offset for pass-through payment policy" (which would be used to calculate the portion of the otherwise applicable Medicare OPD fee schedule amount for device pass-through status).

Response: We appreciate the commenters' support. We disagree with the commenter's belief that device-intensive procedures should not be assigned to an APC that includes procedures that are not device-intensive. Under our proposed policy, the APC placement of a device-intensive

procedure will have no bearing on the procedure's device-intensive designation. The device offset is the estimated portion of the payment for a procedure that is attributable to the device. We remind commenters that the list of device offsets for all device procedures is posted on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>. In response to the request to create an additional device offset for pass-through payment policy, in addition to a device offset based on the proposed device offset methodology, we do not see the need for the creation of a second device offset. We believe that a device offset calculated based on the proposed device offset methodology is appropriate and an accurate proxy for a procedure's device costs when calculating the portion of the otherwise applicable Medicare OPD fee schedule amount.

After consideration of the public comments we received, we are finalizing our proposal, without modification, for CY 2017, 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.

In addition, for new HCPCS codes describing procedures requiring the implantation of medical devices that do not yet have associated claims data, we proposed to apply device-intensive status with a default device offset set at 41 percent until claims data are available to establish the HCPCS code-level device offset for the procedures. This default device offset amount of 41 percent 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 implant medical devices would be to ensure ASC access for new procedures until claims data become available. However, as stated in the proposed rule (81 FR 45655), 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 requiring the implantation of a medical device, device-intensive status would be applied to the code if the HCPCS code-level device offset is greater than 40 percent, according to our proposed

policy of determining device-intensive status by calculating the HCPCS code-level device offset. The full listing of proposed device-intensive procedures was included in a new Addendum P to the proposed rule (which is available via the Internet on the CMS Web site).

Comment: A number of commenters supported CMS' proposal to apply a default device offset of at least 41 percent to new implant procedures with the possibility for higher device offset if supported by device costs. Some commenters in support of the proposal asked that CMS specify how additional information can be submitted, including the deadline for submission, the type of information that can be submitted and who it can be submitted by to have CMS consider a higher offset percentage for a new implant procedure. One commenter did not support the proposal under which every new HCPCS code that describes procedures requiring implantation of a device should be assigned a default device offset of 41 percent. This commenter stated that CMS should ensure that all new procedures requiring implantation of a device require use of a device that is described by a device HCPCS code that satisfies the device edit for device intensive procedures, before assigning a default device offset of 41 percent and recognizing the new implantation procedure as a device intensive procedure.

Response: We appreciate the commenters' support. 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 OPPTS/ASC proposed rule or as a public comment in response to an issued OPPTS/ASC proposed rule. Device offset percentages will be set in each year's final rule. In response to the commenter who did not support this proposal, we note that we are creating a new category HCPCS C-code (described in section IV.B.3. of this final rule with comment period) for providers to report when a device implantation or insertion procedure uses a device that is not described by a specific Level II HCPCS C-code so that these device intensive

procedures can satisfy the device edit policy.

After consideration of the public comments we received, we are finalizing our proposal, without modification, 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. For CY 2017, we also are finalizing our proposal, without modification, that in certain rare instances, we may temporarily assign a higher offset percentage if warranted by additional information.

3. Changes to the Device Edit Policy

In the CY 2015 OPPTS/ASC final rule with comment period (79 FR 66795), we finalized a policy and implemented claims processing edits that require any of the device codes used in the previous device-to-procedure edits to be present on the claim whenever a procedure code assigned to any of the APCs listed in Table 5 of the CY 2015 OPPTS/ASC final rule with comment period (the CY 2015 device-dependent APCs) is reported on the claim. In addition, in the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70422), we modified our previously existing policy and applied the device coding requirements exclusively to procedures that require the implantation of a device that are assigned to a device-intensive APC. In the CY 2016 OPPTS/ASC final rule with comment period, we also finalized our policy that the claims processing edits are such that any device code, when reported on a claim with a procedure assigned to a device-intensive APC (listed in Table 42 of the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70422)) will satisfy the edit.

As discussed in the CY 2017 OPPTS/ASC proposed rule (81 FR 45655), as part of our proposal described in section IV.B.2. of the proposed rule to no longer recognize device-intensive APCs and instead recognize device-intensive procedures based on their individual HCPCS code-level device offset being greater than 40 percent, for CY 2017, we proposed to modify our existing device edit policy. Specifically, for CY 2017 and subsequent years, we proposed 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. In addition, we proposed that any device code, when reported on a claim with a device-

intensive procedure, would satisfy the edit.

Comment: A number of commenters urged CMS to restore the specific device-to-procedure and procedure-to-device edits that CMS used to apply and not keep the current “any device” code policy. One commenter asked that CMS require hospitals to report all devices, not just those associated with procedures that CMS has already determined to be device intensive. Another commenter requested that CMS create a miscellaneous C-code for providers to report when a device used does not have a specific Level II HCPCS Category C-code.

Response: As we stated in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66794), we continue to believe that the elimination of device-to-procedure edits and procedure-to-device edits is appropriate due to the experience hospitals now have in coding and reporting these claims fully. More specifically, for the more costly devices, we believe the C-APCs will reliably reflect the cost of the device if charges for the device are included anywhere on the claim. We remind commenters that, under our current policy, hospitals are still expected to adhere to the guidelines of correct coding and append the correct device code to the claim when applicable. We also remind commenters that, as with all other items and services recognized under the OPPS, we expect hospitals to code and report their costs appropriately, regardless of whether there are claims processing edits in place. We agree with the commenter that we should create a miscellaneous HCPCS C-code for providers to report when a device used does not have a specific Level II HCPCS C-code. Therefore, effective January 1, 2017, we are creating HCPCS code C1889 (Implantable/insertable device for device intensive procedure, not otherwise classified) to recognize devices implanted or inserted during a device-intensive procedure that are not described by a specific Level II HCPCS Category C-code.

After consideration of the public comments we received, we are finalizing our proposal 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 are finalizing our proposal that any device code, when reported on a claim with a device-intensive procedure, will satisfy the edit. In addition, we are creating 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.

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

a. Background

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

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), beginning in CY 2014, we modified our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our

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

b. Policy for CY 2017

In the CY 2017 OPPS/ASC proposed rule (81 FR 45656), for CY 2017, we proposed modifications to our current policy for reducing OPPS payment by the full or partial credit a provider receives for a replaced device, in conjunction with our proposal above to recognize the newly defined (individual HCPCS level device offset greater than 40 percent) device-intensive procedures. For CY 2017 and subsequent years, we proposed to reduce OPPS payment for specified procedures when a hospital furnishes a specified device without cost or with a full or partial credit. Specifically, for CY 2017, we proposed to continue to reduce the OPPS

payment, for the device-intensive procedures, by the full or partial credit a provider receives for a replaced device. Under this proposed policy, hospitals would continue to be required to report on the claim the amount of the credit in the amount portion for value code "FD" when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device.

For CY 2017 and subsequent years, we also proposed to determine which procedures our proposed policy would apply to using three criteria analogous to the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which our existing policy applies (71 FR 68072 through 68077).

Specifically, for CY 2017 and subsequent years, we proposed to use the following three criteria for determining the procedures to which our proposed policy would 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 continue to believe these criteria are appropriate because no-cost devices and device credits are likely to be associated with particular cases only when the device must be reported on the claim and is of a type that is implanted and remains in the body when the beneficiary leaves the hospital. We believe that the reduction in payment is appropriate only when the cost of the device is a significant part of the total cost of the procedure into which the device cost is packaged, and that the 40-percent threshold is a reasonable definition of a significant cost. As noted earlier in this section, procedures with a device offset that exceed the 40-percent threshold are called device-intensive procedures.

Comment: One commenter recommended that CMS reinstate the procedure code list that is subject to the no cost/full credit and partial credit devices.

Response: As stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), we no longer believe it is necessary to restrict the application of our policy to reduce the OPPS payment by the full or partial credit a provider receives for a replaced device to a specific list of devices.

Therefore, we no longer believe it is necessary to specify a list of devices to which the OPPS payment adjustment for no cost/full credit and partial credit devices would apply.

After consideration of the public comments we received, for CY 2017, we are finalizing our proposed modifications to our current policy for reducing OPPS payment by the full or partial credit a provider receives for a replaced device, in conjunction with our finalized policy to recognize the newly defined (individual HCPCS level device offset greater than 40 percent) device-intensive procedures. Specifically, for CY 2017, we are finalizing our proposal to continue to reduce the OPPS payment, for the device-intensive procedures, by the full or partial credit a provider receives for a replaced device. In addition, for CY 2017 and subsequent years, we are finalizing our proposal 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.

5. 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 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 particular, we proposed 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. We believe that this approach will help to mitigate to some extent significant year-to-year payment rate fluctuations while preserving accurate claims data-based payment rates for low-volume device-intensive procedures. For CY 2017, this policy would only apply to a procedure described by CPT code 0308T in APC 5495 because this APC is the only APC containing a device-intensive procedure with less than 100 total claims in the APC. The CY 2017 proposed rule median cost for the procedure described by CPT code 0308T was approximately \$17,965 (the median cost was incorrectly stated in the proposed rule as \$15,567). The proposed CY 2017 payment rate (calculated using the median cost and the claims that reported the device consistent with our device edit policy for device intensive procedures) was approximately \$17,189. We invited public comments on this proposal.

Comment: The majority of commenters supported the proposal to base payment on the median cost instead of the geometric mean cost for any device-intensive procedure that is assigned to an APC with fewer than 100 total claims (for all of the services assigned to the APC). One commenter recommended that CMS consider whether refinements to the low-volume, device-intensive procedure policy are

appropriate in future rulemaking, such as using the claims volume at the HCPCS level rather than the APC level.

Response: We appreciate the commenters' support. At this time, we believe it is only appropriate to calculate the payment rate using median cost instead of the geometric mean for a device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC.

After consideration of the public comments we received, we are finalizing our proposal, without modification, 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. 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) is approximately \$21,302, and the median cost is approximately \$19,521. The final CY 2017 payment rate (calculated using the median cost) is approximately \$18,984.

V. OPPTS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

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

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or "transitional pass-through payments" for certain drugs and biologicals. Throughout this final rule with comment period, the term "biological" is used because this is the term that appears in section 1861(t) of the Act. "Biological" as used in this final rule with comment period includes (but is not necessarily limited to) "biological product" or "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 drugs or biologicals that are hospital outpatient services under Medicare Part B for which payment was made on the first

date the hospital OPPTS 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 OPPTS 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. CY 2017 pass-through drugs and biologicals and their designated APCs are assigned status indicator "G" in Addenda A and B to this final rule with comment period (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 OPPTS, 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 final rule with comment period, 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 explained on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html.

2. Policy Change To Make the Transitional Pass-Through Payment Period 3 Years for All Pass-Through Drugs, Biologicals, and Radiopharmaceuticals and Expire Pass-Through Status on a Quarterly Rather Than Annual Basis

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 new pass-through drugs and biologicals on a quarterly basis through the next available OPPTS quarterly update after the approval of a product's pass-through status. However, we expire pass-through status for drugs and biologicals on an annual basis through notice-and-comment rulemaking (74 FR 60480). This means that because the 2-year to 3-year pass-through payment eligibility period starts on the date of first pass-through payment under 42 CFR 419.64(c)(2), the duration of pass-through eligibility for a particular drug or biological will depend upon when during a year the applicant applies for pass-through status. Under the current policy, a new pass-through drug or biological with pass-through status effective on January 1 would receive 3 years of pass-through status; a pass-through drug with pass-through status effective on April 1 would receive 2 years and 3 quarters of pass-through status; a pass-through drug with pass-through status effective on July 1 would receive 2 and ½ years of pass-through status; and a pass-through drug with pass-through status effective on October 1 would receive 2 years and 3 months (a quarter) of pass-through status.

In the CY 2017 OPPTS/ASC proposed rule (81 FR 45657), we proposed, 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 period that is as close to a full 3 years as possible for all pass-through payment drugs, biologicals, and radiopharmaceuticals. This proposed change would eliminate the variability

of the pass-through payment eligibility period, which currently varies based on the timing of the particular application, as we now believe that the timing of a pass-through payment application should not determine the duration of pass-through payment status. For example, for a drug with pass-through status first effective on April 1, 2017, pass-through status would expire on March 31, 2020. This approach would allow for the maximum pass-through period for each pass-through drug without exceeding the statutory limit of 3 years. We invited public comments on this proposal.

Comment: Several commenters supported CMS' proposal to expire pass-through status and payment for pass-through drugs on a quarterly basis rather than an annual basis such that pass-through status would be as close as possible to 3 years for all pass-through drugs and biologicals. Some commenters recommended that CMS apply the proposed policy to all drugs with pass-through payment status in CY 2017 to prevent disparate treatment of such drugs based on their pass-through approval date.

Response: We appreciate commenters' support. In response to commenters' recommendation to expire pass-through status and payment for pass-through drugs on a quarterly basis rather than an annual basis for all drugs with pass-through payment status in CY 2017, we note that the annual expiration of pass-through payment status for all drugs currently assigned pass-through payment status under the OPPTS was

finalized in previous years' OPPTS/ASC rulemaking and was not proposed to be altered in our CY 2017 proposal.

After consideration of the public comments we received, we are finalizing our proposal, without modification, 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 period that is as close to a full 3 years as possible for all pass-through drugs, biologicals, and radiopharmaceuticals.

3. Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2016

In the CY 2017 OPPTS/ASC proposed rule (81 FR 45657), we proposed that the pass-through status of 15 drugs and biologicals would expire on December 31, 2016, as listed in Table 13 of the proposed rule (81 FR 45658). All of these drugs and biologicals will have received OPPTS pass-through payment for at least 2 years and no more than 3 years by December 31, 2016. These drugs and biologicals were approved for pass-through payment status on or before January 1, 2015. 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 OPPTS drug packaging threshold for that calendar year (which is \$110 for CY 2017), as discussed further in section V.B.2. of this final rule with comment period. In the CY 2017 OPPTS/ASC proposed rule (81 FR 45658), we proposed that if the estimated per day cost for the drug or biological is less than or equal to the applicable OPPTS drug packaging threshold, to 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 OPPTS drug packaging threshold, we proposed to provide separate payment at the applicable relative ASP-based payment amount (which was proposed at ASP+6 percent for CY 2017, and is finalized at ASP+6 percent for CY 2017, as discussed further in section V.B.3. of this final rule with comment period).

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal, without modification, to expire the pass-through payment status of the 15 drugs and biologicals listed below in Table 35 on December 31, 2016.

TABLE 35—DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS EXPIRES DECEMBER 31, 2016

CY 2017 HCPCS code	CY 2017 long descriptor	Final CY 2017 status indicator	Final CY 2017 APC
C9497	Loxapine, inhalation powder, 10 mg	K	9497
J1322	Injection, elosulfase alfa, 1 mg	K	1480
J1439	Injection, ferric carboxymaltose, 1 mg	N	N/A
J1447	Injection, TBO-Filgrastim, 1 microgram	N	N/A
J3145	Injection, testosterone undecanoate, 1 mg	N	N/A
J3380	Injection, vedolizumab, 1 mg	K	1489
J7181	Injection, factor xiii a-subunit, (recombinant), per iu	N	N/A
J7200	Factor ix (antihemophilic factor, recombinant), Rixubus, per i.u	N	N/A
J7201	Injection, factor ix, fc fusion protein (recombinant), per iu	N	N/A
J7205	Injection, factor viii fc fusion (recombinant), per iu	K	1656
J7508	Tacrolimus, extended release, (astagraf xl), oral, 0.1 mg	N	N/A
J9301	Injection, obinutuzumab, 10 mg	N	N/A
J9308	Injection, ramucirumab, 5 mg	K	1488
J9371	Injection, Vincristine Sulfate Liposome, 1 mg	K	1466
Q4121	Theraskin, per square centimeter	N	N/A

The final packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

4. Drugs, Biologicals, and Radiopharmaceuticals With New or Continuing Pass-Through Payment Status in CY 2017

In the CY 2017 OPPTS/ASC proposed rule (81 FR 45658), we proposed to continue pass-through payment status in CY 2017 for 38 drugs and biologicals. None of these drugs and biologicals will have received OPPTS pass-through payment for at least 2 years and no more than 3 years by December 31, 2016. These drugs and biologicals, which were approved for pass-through status between January 1, 2015, and July 1, 2016, were listed in Table 14 of the proposed rule (81 FR 45659). The APCs and HCPCS codes for these drugs and biologicals approved for pass-through payment status through July 1, 2016 were assigned status indicator "G" in Addenda A and B to the 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 2017, we proposed to continue to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2017. We proposed that a \$0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2017 OPPTS because the difference between the amount authorized under section 1842(o) of the Act, which was proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which was proposed at ASP+6 percent, is \$0.

In the case of policy-packaged drugs (which include the following: Anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including contrast agents; diagnostic radiopharmaceuticals, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), we proposed that their pass-through

payment amount would be equal to ASP+6 percent for CY 2017 because, if not for their pass-through status, payment for these products would be packaged into the associated procedure.

In addition, we proposed to continue to update pass-through payment rates on a quarterly basis on the CMS Web site during CY 2017 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 OPPTS/ASC final rule with comment period (70 FR 68632 through 68635).

In CY 2017, as is consistent with our CY 2016 policy for diagnostic and therapeutic radiopharmaceuticals, we proposed to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPTS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2017, we proposed to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which was proposed at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we proposed to provide pass-through payment at WAC+6 percent, the equivalent payment provided to pass-through drugs and biologicals without ASP information. If WAC information also is not available, we proposed to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

Comment: Several commenters supported CMS' proposal to continue to provide payment at ASP+6 percent for drugs, biologicals, contrast agents, and radiopharmaceuticals that are granted pass-through payment status. Some commenters requested that CMS provide an additional payment for radiopharmaceuticals that are granted pass-through payment status.

Response: We appreciate the commenters' support. Regarding the commenters' request that CMS provide an additional payment for radiopharmaceuticals that are granted pass-through payment status, we note that, for CY 2017, consistent with our CY 2016 payment policy for diagnostic and therapeutic radiopharmaceuticals, we proposed to provide payment for both diagnostic and therapeutic

radiopharmaceuticals with pass-through payment status based on the ASP methodology. As stated earlier, the ASP methodology, as applied under the OPPTS, uses several sources of data as a basis for payment, including the ASP, the WAC if the ASP is unavailable, and 95 percent of the radiopharmaceutical's most recent AWP if both the ASP and WAC are unavailable. 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 2017, we proposed to follow the standard ASP methodology to determine its pass-through payment rate under the OPPTS to account for the acquisition and pharmacy overhead costs. We continue to believe that a single payment is appropriate for diagnostic radiopharmaceuticals with pass-through payment status in CY 2017, and that the payment rate of ASP+6 percent (or WAC or AWP if ASP is not available) is appropriate to provide payment for both a radiopharmaceutical's acquisition and pharmacy overhead costs. We refer readers to section V.B.3. of this final rule with comment period for further discussion of payment for therapeutic radiopharmaceuticals based on ASP information submitted by manufacturers. We also refer readers to the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1656-FC.html>.

After consideration of the public comments we received, we are finalizing our proposal to provide payment for drugs, biologicals, diagnostic and therapeutic radiopharmaceuticals, and contrast agents that are granted pass-through payment status based on the ASP methodology. If a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2017, we will follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we will 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 will provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP. The 47

drugs and biologicals that continue to have pass-through payment status for CY 2017 or have been granted pass-through payment status as of January 2017 are shown in Table 36 below.

TABLE 36—DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS IN CY 2017

CY 2016 HCPCS code	CY 2017 HCPCS code	CY 2017 long descriptor	CY 2017 status indicator	CY 2017 APC
A9586	A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	1664
N/A	A9588	Fluciclovine f-18, diagnostic, 0.1 mCi	G	9052
N/A	A9587	Gallium Ga-68, dotatate, diagnostic, 1 mCi	G	9056
N/A	C9140	Injection, Factor VIII (antihemophilic factor, recombinant) (Afstyla), 1 I.U.	G	9043
C9137	J7207	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U.	G	1844
C9138	J7209	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), per i.u.	G	1846
C9139	J7202	Injection, Factor IX, albumin fusion protein (recombinant), Idelvion, 1 i.u.	G	9171
C9349	Q4172	PuraPly, and PuraPly Antimicrobial, any type, per square centimeter	G	1657
C9447	C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	1663
C9460	C9460	Injection, cangrelor, 1 mg	G	9460
C9461	A9515	Choline C 11, diagnostic, per study dose	G	9461
C9470	J1942	Injection, aripiprazole lauroxil, 1 mg	G	9470
C9471	J7322	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg	G	9471
C9472	J9325	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)	G	9472
C9473	J2182	Injection, mepolizumab, 1 mg	G	9473
C9474	J9205	Injection, irinotecan liposome, 1 mg	G	9474
C9475	J9295	Injection, necitumumab, 1 mg	G	9475
C9476	J9145	Injection, daratumumab, 10 mg	G	9476
C9477	J9176	Injection, elotuzumab, 1 mg	G	9477
C9478	J2840	Injection, sebelipase alfa, 1 mg	G	9478
C9479	J7342	Instillation, ciprofloxacin otic suspension, 6 mg	G	9479
C9480	J9352	Injection, trabectedin, 0.1 mg	G	9480
C9481	J2786	Injection, reslizumab, 1 mg	G	9481
C9482	C9482	Injection, sotalol hydrochloride, 1 mg	G	9482
C9483	C9483	Injection, atezolizumab, 10 mg	G	9483
N/A	J0570	Buprenorphine implant, 74.2 mg	G	9058
J0596	J0596	Injection, c-1 esterase inhibitor (human), Ruconest, 10 units	G	9445
J0695	J0695	Injection, ceftolozane 50 mg and tazobactam 25 mg	G	9452
J0875	J0875	Injection, dalbavancin, 5 mg	G	1823
J1833	J1833	Injection, isavuconazonium sulfate, 1 mg	G	9456
J2407	J2407	Injection, oritavancin, 10 mg	G	1660
J2502	J2502	Injection, pasireotide long acting, 1 mg	G	9454
J2547	J2547	Injection, peramivir, 1 mg	G	9451
J2860	J2860	Injection, siltuximab, 10 mg	G	9455
J3090	J3090	Injection, tedizolid phosphate, 1 mg	G	1662
N/A	J7179	Injection, von willebrand factor (recombinant), (Vonvendi), 1 i.u. vwf:rc0	G	9059
J7313	J7313	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg	G	9450
J7503	J7503	Tacrolimus, extended release, (envarsus xr), oral, 0.25 mg	G	1845
J8655	J8655	Netupitant (300 mg) and palonosetron (0.5 mg)	G	9448
J9032	J9032	Injection, belinostat, 10 mg	G	1658
J9039	J9039	Injection, blinatumomab, 1 mcg	G	9449
J9271	J9271	Injection, pembrolizumab, 1 mg	G	1490
J9299	J9299	Injection, nivolumab, 1 mg	G	9453
Q5101	Q5101	Injection, Filgrastim (G-CSF), Biosimilar, 1 microgram	G	1822
Q9950	Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9457
C9459	Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	G	9459
C9458	Q9983	Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries	G	9458

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

Under 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 OPPTS/ASC final rule with comment period (80 FR 70430 through 70432). In the CY 2017 OPPTS/ASC proposed rule (81 FR 45660), for CY 2017, as we did in CY 2016, we proposed to continue to apply the same policy packaged offset policy to payment for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes. The proposed APCs to which a diagnostic radiopharmaceutical payment offset may be applicable were the same as for CY 2016 (80 FR 70430). Also, the proposed APCs to which a stress agent payment offset or a skin substitute payment offset were also the same as for CY 2016 (80 FR 70431 through 70432). The proposed APCs to which a contrast agent payment offset may be applicable are APCs 5571 through 5573 (Levels 1–3 Diagnostic Radiology with Contrast), which were listed in Addendum A to the proposed rule (which is available via the Internet on the CMS Web site).

We proposed 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 OPPTS clinical APC.

Comment: One commenter recommended that CMS consider the drug offset amount at the HCPCS level to improve accuracy in isolating potentially duplicative packaged payments.

Response: We thank the commenter for this recommendation. We do not believe that the suggested change is necessary at this time. However, we may consider it in future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal, without modification, for CY 2017 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 as we did in CY 2016. We also are finalizing our proposal 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.

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

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

a. Packaging Threshold

In accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to \$50 per administration during CYs 2005 and 2006. In CY 2007, we used the four quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the \$50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108–173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest \$5 increment in order to determine the CY 2007 threshold amount of \$55. Using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPTS/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 \$100 for CY 2016 (80 FR 70433).

Following the CY 2007 methodology, for the CY 2017 OPPTS/ASC proposed rule (81 FR 45660), 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 2017 and rounded the resulting dollar amount (\$109.03) to the nearest \$5 increment, which yielded a figure of \$110. 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 (OACT). We refer below to this series generally as the PPI for Prescription Drugs. Based on

these calculations, we proposed a packaging threshold for CY 2017 of \$110.

Following the finalized CY 2007 methodology, for this CY 2017 OPPTS/ASC final rule with comment period, 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 2017 and rounded the resulting dollar amount (\$111.65) to the nearest \$5 increment, which yielded a figure of \$110. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from CMS' Office of the Actuary (OACT). Therefore, for this CY 2017 OPPTS/ASC final rule with comment period, using the CY 2007 OPPTS methodology, we are establishing a packaging threshold for CY 2017 of \$110.

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

In the CY 2017 OPPTS/ASC proposed rule (81 FR 45660), to determine the proposed CY 2017 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 2015 and were paid (via packaged or separate payment) under the OPPTS. We used data from CY 2015 claims processed before January 1, 2016 for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages, as described in section V.B.1.d. of the proposed rule, or for the following policy-packaged items that we proposed to continue to package in CY 2017: 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 2017, we used the methodology that was described in detail in the CY 2006 OPPTS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPTS final rule with comment period

(70 FR 68636 through 68638). For each drug and biological HCPCS code, we used an estimated payment rate of ASP+6 percent (which is the payment rate we proposed for separately payable drugs and biologicals for CY 2017, as discussed in more detail in section V.B.2.b. of the proposed rule) to calculate the CY 2017 proposed rule per day costs. We used the manufacturer submitted ASP data from the fourth quarter of CY 2015 (data that were used for payment purposes in the physician's office setting, effective April 1, 2016) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2017, we proposed to use payment rates based on the ASP data from the first quarter of CY 2016 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to the proposed rule (which are available via the Internet on the CMS Web site) because these were the most recent data available for use at the time of development of the proposed rule. These data also were the basis for drug payments in the physician's office setting, effective April 1, 2016. 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 2015 hospital claims data to determine their per day cost.

We proposed to package items with a per day cost less than or equal to \$110, and identify items with a per day cost greater than \$110 as separately payable. Consistent with our past practice, we cross-walked historical OPSS claims data from the CY 2015 HCPCS codes that were reported to the CY 2016 HCPCS codes that we displayed in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site) for proposed payment in CY 2017.

Comment: A few commenters opposed the proposed OPSS packaging threshold of \$110 for CY 2017. These commenters recommended that CMS freeze the packaging threshold at the current level (\$100) or eliminate the packaging threshold and provide separate payment for all drugs with HCPCS codes.

Response: We have received and addressed a similar comment in numerous OPSS/ASC rulemakings in the past. As we stated in the CY 2007 OPSS/ASC final rule with comment period (71 FR 68086), we believe that packaging certain items is a fundamental component of a prospective payment system, that updating the packaging threshold of \$50

for the CY 2005 OPSS is consistent with industry and government practices, and that the PPI for Prescription Drugs is an appropriate mechanism to gauge Part B drug inflation. Therefore, because packaging is a fundamental component of a prospective payment system that continues to provide important flexibility and efficiency in the delivery of high quality hospital outpatient services, we are not adopting the commenters' recommendations to pay separately for all drugs, biologicals, and radiopharmaceuticals for CY 2017, or to eliminate the packaging threshold, or to freeze the packaging threshold at \$100.

After consideration of the public comments we received, and consistent with our methodology for establishing the packaging threshold using the most recent PPI forecast data, we are adopting a CY 2017 packaging threshold of \$110. Our policy during previous cycles of the OPSS 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 OPSS/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 OPSS/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 2017 OPSS/ASC final rule with comment period, we used ASP data from the first 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 July 1, 2016, along with updated hospital claims data from CY 2015. We note that we also used these data for budget neutrality estimates and impact analyses for this CY 2017 OPSS/ASC final rule with comment period.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B for this final rule with comment period are based on ASP data from the third quarter of CY 2016. These data are the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2016. These payment rates will then be updated in the January 2017 OPSS update, based on the most recent ASP data to be used for physician's office and OPSS payment as of January 1, 2017. For items that do not currently

have an ASP-based payment rate, we proposed to recalculate their mean unit cost from all of the CY 2015 claims data and updated cost report information available for this CY 2017 final rule with comment period to determine their final per day cost.

Consequently, as stated in the CY 2017 OPSS/ASC proposed rule (81 FR 45661), the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in the proposed rule may be different from the same drug HCPCS code's packaging status determined based on the data used for the final rule with comment period. Under such circumstances, in the CY 2017 OPSS/ASC proposed rule, we proposed to continue to follow the established policies initially adopted for the CY 2005 OPSS (69 FR 65780) in order to more equitably pay for those drugs whose cost fluctuates relative to the proposed CY 2017 OPSS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2016. These established policies have not changed for many years and are the same as described in the CY 2016 OPSS/ASC final rule with comment period (80 FR 70434).

We did not receive any public comments on our proposal to recalculate the mean unit cost for items that do not currently have an ASP-based payment rate from all of the CY 2015 claims data and updated cost report information available for this CY 2017 final rule with comment period to determine their final per day cost. We also did not receive any public comments on our proposal to continue to follow the established policies initially adopted for the CY 2005 OPSS (69 FR 65780), when the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in the proposed rule may be different from the same drug HCPCS code's packaging status determined based on the data used for the final rule with comment period. Therefore, for CY 2017, we are finalizing these two CY 2017 proposals without modification.

c. Policy Packaged Drugs, Biologicals, and Radiopharmaceuticals

As mentioned briefly earlier, in the OPSS 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. Each of these

policies are either longstanding or based on longstanding principles and inherent to the OPSS and are as follows:

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

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

Comment: A few commenters objected to the packaging of diagnostic radiopharmaceuticals and contrast agents under § 419.2(b)(15). They argued that the service payments that include the payment for the radiopharmaceutical or contrast agent do not cover the cost of expensive diagnostic radiopharmaceuticals or contrast agents. The commenters believed that separate payment should be made for these products.

Response: The packaging policy for these products has been in effect since CY 2008. We refer readers to the CY 2008 OPSS final rule (72 FR 66635 through 66646) for an extensive discussion of the original packaging policy for diagnostic radiopharmaceuticals and contrast agents, and to the CY 2014 OPSS/ASC

final rule with comment period (78 FR 74927 through 74930) for a discussion of the packaging of diagnostic radiopharmaceuticals and contrast agents under § 419.2(b)(15); that is, the broader packaging policy for drugs and biologicals that function as supplies when used in a diagnostic test or procedure. We are not changing this packaging policy for CY 2017.

Comment: One commenter, the manufacturer of the stress agent Lexiscan® (regadenoson), disagreed with CMS’ policy of packaging stress agents under § 419.2(b)(15). The commenter reiterated comments that it has made in the past since CMS packaged stress agents in CY 2014 (78 FR 74927 through 74930). The commenter believed that this packaging policy may create a financial incentive for hospitals to utilize a low-cost stress agent instead of a high-cost stress agent and/or encourage hospitals to reduce appropriate patient care. The commenter requested that CMS create separate APCs for diagnostic tests that use high cost drugs.

Response: We have responded to this comment in previous final rules (for example, the CY 2014 OPSS/ASC final rule with comment period (78 FR 74928 through 74929) and the CY 2016 OPSS/ASC final rule with comment period (80 FR 70347)). We have no reason to believe that any stress agent that a hospital chooses, regardless of the cost, will not be entirely medically appropriate for the patient. The commenter did not provide any specific information to suggest that a high-cost stress agent (for example, regadenoson) is more clinically appropriate than a low-cost stress agent (for example, adenosine) in certain patients. In fact, we are aware of some evidence that may suggest that the opposite is true (Brink, H.L., Dickerson, J.A., Stephens, J.A. and Pickworth, K.K. (2015), Comparison of the Safety of Adenosine and Regadenoson in Patients Undergoing Outpatient Cardiac Stress Testing. *Pharmacotherapy*, 35: 1117–1123. Available at: American College of Cardiology Web site at: <https://www.acc.org/latest-in-cardiology/journal-scans/2016/01/15/13/40/adenosine-versus-regadenoson-in-cardiac-stress>).

To the extent that this stress agent packaging policy encourages hospitals to utilize the cheaper stress agent—adenosine—instead of regadenoson (as the commenter speculated that it has), we believe that this is a positive effect of the stress agent packaging policy. One important purpose of these packaging policies is to provide hospitals with the financial incentive to choose less

expensive alternative drugs, devices, and supplies, as clinically appropriate. In the preambles of our past rulemakings, we have repeatedly stated the following axiom: “Where there are a variety of devices, drugs, items, supplies, etc. that could be used to furnish a service, some of which are more expensive 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 results if separate payment is provided for the items” (78 FR 74925). The potential effect of this policy that the commenter is concerned about (hospitals choosing a lower cost stress agent) is precisely the outcome that we hope to encourage through this packaging policy. Therefore, we believe that this packaging policy supports medically necessary and efficient patient care. We believe that creating separate APCs for diagnostic tests that use high-cost stress agents could undermine this goal and, therefore, is not warranted at this time.

Comment: One commenter, the manufacturer of the drug Omidria®, did not want CMS to package the drug Omidria® (described by HCPCS code C9447, with status indicator “N”) under § 419.2(b)(14) or (b)(16), after pass-through payment status expires at the end of CY 2017 (80 FR 70347). Specifically, the commenter opposed packaging this drug with cataract surgery effective beginning in CY 2018 and subsequent years. The commenter believed that the surgical supply packaging policy inadvertently conflicts with CMS’ broader policies targeting therapeutic products, unintentionally creates financial disincentives for hospitals and ASCs to use Omidria®, and is overly broad. The commenter pointed out that studies have shown that the use of Omidria® can reduce complications during cataract surgery, and therefore Omidria® provides a distinct therapeutic benefit independent of the procedural benefits achieved without Omidria®. The commenter recommended that CMS exclude from the surgical supply packaging policy all drugs and biologicals that have “a therapeutic indication that provides a benefit independent of the procedure performed without the drug or biological and that may substitute for one or more other subsequent interventions that would otherwise be separately paid by CMS.” Presumably, according to the commenter, if CMS adopted such an exclusion, it would result in the continued separate

payment for Omidria® after pass-through payment status expires.

Response: We appreciate the commenters' concerns and believe that some additional explanation might be of use. We believe that this comment reflects a misunderstanding of our OPPS packaging policy that packages drugs and biologicals that function as supplies when used in a surgical procedure. We have reviewed Omidria®'s indications and, based on those indications, it is unclear what the commenter means when it requested that CMS exclude drugs from the packaging policy that have "a therapeutic indication that provides a benefit independent of the procedure performed without the drug or biological and that may substitute for one or more other subsequent interventions that would otherwise be separately paid by CMS." Omidria® supplements the drugs delivered as preoperative eye drops to dilate the pupil to either improve or prolong dilation in certain cases. The benefit of Omidria® is the facilitation of cataract surgery. The surgical supply packaging policy for drugs and biologicals that function as surgical supplies is intended to apply broadly to drugs and biologicals that are used in surgery or that are used to achieve the surgical objective. In the CY 2014 OPPS/ASC final rule with comment period, in discussing the surgical supplies packaging policy as it applies to another drug used in an eye surgery, we stated that "we believe packaging is appropriate for items and services that are integral or ancillary or supportive or dependent or adjunctive to the primary procedure. Therefore, items and services that fall within any of these categories may be properly packaged in the OPPS" (78 FR 74938). Any and all of these descriptive terms apply to Omidria®, which is integral and ancillary and supportive and dependent and adjunctive to cataract surgery. The commenter believes that the packaging policy unintentionally creates financial disincentives for hospitals and ASCs to use Omidria®. We view the financial effect of the packaging policy differently. We believe this approach promotes efficient resource use in hospitals and ASCs. We believe that once its pass-through payment status expires, Omidria® should be packaged as are all of these other surgical supplies. In summary, in the CY 2016 OPPS/ASC final rule with comment period, we finalized a policy to package the drug Omidria® (described by HCPCS code C9447) after pass-through payment status expires under our policy that packages drugs and biologicals that

function as supplies when used in a surgical procedure. This policy will take effect on January 1, 2018.

Comment: One commenter, the manufacturer of the drug Cysview (described by HCPCS code C9275) requested that CMS withdraw the packaging policy described by 42 CFR 419.2(b)(15), which packages drugs, biologicals, and radiopharmaceuticals that function as supplies in a diagnostic test or procedure, and pay separately for its drug, Cysview. The commenter pointed out that CMS acknowledged in the CY 2004 OPPS proposed rule that "... packaging payments adversely affect beneficiary access to medically necessary services" (68 FR 47995). The commenter also asserted that this packaging policy has had a negative effect on the quality of patient care because it has created a significant financial disincentive for hospitals to purchase Cysview. In addition, the commenter stated that Cysview costs \$810, but because the APC payment amount for the cystoscopy procedures in which Cysview is used is based on the average costs of many different procedures (most of which do not use Cysview), the cost of Cysview is highly diluted and therefore the cystoscopy procedure payments do not fully reflect the cost of Cysview.

Response: We begin with the complete quote from the CY 2004 OPPS proposed rule from which the commenter extracted its partial quote described earlier. The full quote is as follows: "*Packaging costs into a single aggregate payment for a service, procedure, or episode of care is a fundamental principle that distinguishes a prospective payment system from a fee schedule.* In general, packaging the costs of items and services into the payment for the primary procedure or service with which they are associated encourages hospital efficiencies and also enables hospitals to manage their resources with maximum flexibility. Notwithstanding our commitment to package as many costs as possible, we are aware that packaging payments for certain drugs and radiopharmaceuticals, especially those that are particularly expensive or rarely used, might result in insufficient payments to hospitals, which could adversely affect beneficiary access to medically necessary services" (68 FR 47995) (emphasis added). Separate payment for all products, items, devices, among others, that are the components of a primary service furnished to a patient in the hospital would be inconsistent with a prospective payment system—doing so would make the OPPS essentially a fee schedule in which

every coded item resulted in additional payment. Furthermore, the latter part of the quoted statement refers only to particularly expensive or rarely used drugs, and Cysview is neither. Cysview has a fairly broad indication as an adjunct to white light cystoscopy, and \$810 is not "particularly expensive" for an OPPS drug (many of which cost several thousands of dollars). However, we do note that the price of Cysview has increased 38 percent in the last 5 years (from approximately \$588 in 2012). Finally, the commenter stated that the relevant bladder cancer APCs are APC 5373 (Level 3 Urology and Related Services) and APC 5374 (Level 4 Urology and Related Services), and that these APCs contain the procedure codes that primarily use Cysview when blue light cystoscopy is performed. Both of these APCs are being finalized as C-APCs for CY 2017. Part of the C-APC methodology is to package all drugs except for those in pass-through payment status, and this methodology would apply to Cysview because it is not in drug pass-through payment status. Therefore, aside from the diagnostic test supplies packaging policy, Cysview would be packaged when used with any procedure assigned to a C-APC.

In summary, We are not adopting any changes based on the comments received on these three policy-packaged drugs—Lexiscan®, Omidria®, and Cysview—for CY 2017.

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

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74938), we unconditionally packaged skin substitute products into their associated surgical procedures as part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure. As part of the policy to finalize the packaging of skin substitutes, we also finalized a methodology that divides the skin substitutes into a high cost group and a low cost group, in order to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures (78 FR 74933). We continued the high cost/low cost categories policy in CY 2015 and CY 2016, and in the CY 2017 OPPS/ASC proposed rule (81 FR 45661 through 45662), we proposed to continue it for CY 2017. Under this current policy, skin substitutes in the high cost category are reported with the skin substitute application CPT codes and skin substitutes in the low cost category are reported with the analogous skin substitute HCPCS C-codes. For a

discussion of the CY 2014 and CY 2015 methodologies for assigning skin substitutes to either the high cost group or the low cost group, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 74932 through 74935) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66882 through 66885).

For CY 2017, as in CY 2016, we proposed 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 a discussion of the CY 2016 high cost/low cost methodology, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434 through 70435). We proposed to assign skin substitutes that exceed either the MUC threshold or the PDC threshold to the high cost group. We proposed 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. For this CY 2017 OPPS/ASC final rule with comment period, we analyzed updated CY 2015 claims data to calculate the MUC threshold (a weighted average of all skin substitutes' MUCs) and the PDC threshold (a weighted average of all skin substitutes' PDCs). The final CY 2017 MUC threshold is \$33 per cm² (rounded to the nearest \$1) (proposed at \$25 per cm²) and the final CY 2017 PDC threshold is \$716 (rounded to the nearest \$1) (proposed at \$729).

For CY 2017, as in CY 2016, we proposed to continue to assign skin substitutes with pass-through payment status to the high cost category, and 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 stated in the proposed rule that we would use WAC+6 percent or 95 percent of AWP to assign a product to either the high cost or low cost category. We also stated in the proposed rule that new skin substitutes without pricing information would be assigned to the low cost category until pricing information is available to compare to the CY 2017 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). In addition, as in CY 2016, we proposed for CY 2017 that a skin substitute that is both assigned to the high cost group in CY 2016 and also exceeds either the MUC or PDC in the proposed rule for CY 2017 would be assigned to the high cost group for CY 2017, even if it no longer exceeds the MUC or PDC CY 2017 thresholds based on updated claims data and pricing information used in this CY 2017 final rule with comment period. Table 15 of the CY 2017 OPPS/ASC proposed rule (81 FR 45661 through 45662) displayed the proposed CY 2017 high cost or low cost category assignment for each skin substitute product.

Comment: One commenter notified CMS of an error in the calculation of the MUC threshold reported in the CY 2017 OPPS/ASC proposed rule (81 FR 45661), and stated that the values for the MUC threshold are different from the values for the PDC threshold. The commenter also requested that skin substitute products that were assigned to the high cost group because of the incorrect lower MUC threshold in the proposed rule, and that would have been classified in the low cost group if the corrected higher MUC threshold had been used in the proposed rule, be reassigned to the low cost group in the final rule.

Response: We reviewed our calculations and agreed with the commenter that the MUC threshold was incorrect in the proposed rule. We also found a calculation error with the PDC threshold. We have corrected our calculations and used more recent claims data from CY 2015 to revise the MUC threshold and the PDC threshold for this final rule with comment period.

We disagree with the request of the commenter to move skin substitute products back to the low cost group because of the erroneous calculation of a lower MUC threshold in the proposed rule. The policy we proposed to continue from CY 2016, and which we are finalizing for CY 2017, retains a skin substitute product in the high cost group if the product was assigned to the high cost group in CY 2016 and exceeded either the MUC threshold or the PDC threshold of the proposed rule for CY 2017. The policy does not make exceptions due to calculation errors or revisions by CMS. We will follow this policy and retain all skin substitute products in the high cost group that were assigned to the high cost group in CY 2016 and exceeded either the MUC threshold or the PDC threshold of the proposed rule for CY 2017.

Comment: One commenter provided information to support that HCPCS code Q4163 (Amnion bio and woundex sq cm) should be assigned to the high cost skin substitute group. The commenter stated that HCPCS code Q4163 is a relatively new skin substitute product and there was not sufficient claims data or pricing information available for the product when the CY 2017 OPPS/ASC proposed rule was released. The commenter stated that regulatory guidance requires CMS to assign a nonpass-through skin substitute product to the low cost group when there are no available cost data. The commenter supplied wholesale acquisition cost (WAC) and average wholesale price (AWP) data for HCPCS code Q4163 showing that HCPCS code Q4163 should be assigned to the high cost group.

Response: We reviewed WAC and ASP data for HCPCS code Q4163, and we agree with the findings of the commenter. After consideration of the public comment we received about HCPCS code Q4163, in this final rule with comment period, we are assigning HCPCS code Q4163 to the high cost skin substitute group for CY 2017.

Comment: One commenter requested that PuraPly (described by HCPCS code Q4172; previously HCPCS code C9349) have its pass-through payment status end as of December 31, 2016, and not continue through CY 2017. The commenter stated that PuraPly received its pass-through payment status in January 2015 and will have 2 full years of pass-through payment status by December 2016. The commenter also asserted that PuraPly was not a new skin substitute product when approved for pass-through payment status in the CY 2015 OPPS/ASC final rule with comment period. The commenter provided evidence that PuraPly, called by its previous name, FortaDerm, was introduced to the market as early as 2002.

Response: We disagree with the commenter. PuraPly (described by HCPCS code Q4172; previously HCPCS code C9349) was given pass-through payment status under the pass-through payment policy and process for drugs and biologicals that was in effect prior to CY 2015. Pass-through payment status products covered by the policy receive pass-through payments for at least 2 years but for no more than 3 years from the date the first OPPS payment for the product is generated. The assertion by the commenter that PuraPly will have reached 2 years of pass-through payment status by the end of December 2016 is incorrect. PuraPly will not achieve 2 years of pass-through

payment status until at least January 2017. The pass-through payment policy for drugs and biologicals that was in effect at the beginning of CY 2015 only allows changes to a pass-through payment designation for a product at the beginning of a calendar year. Therefore, PuraPly must continue to have pass-through status for all of CY 2017. The evidence presented by the commenter that PuraPly was available commercially in 2002 is not relevant, as the product (under any name) did not have pass-through payment status prior to 2015, and there was no newness criterion for drug and biological pass-through payment status eligibility at the time of the PuraPly (formerly FortaDerm) pass-through payment application evaluation.

After consideration of the public comment we received, we are finalizing our proposal, without modification, to continue pass-through status for PuraPly (HCPCS code Q4172; previously HCPCS code C9349) for CY 2017.

Comment: A few commenters supported the current methodology used by CMS to assign skin substitute products into high cost and low cost categories. Commenters appreciated that either the MUC threshold or the PDC threshold could be used to qualify skin substitute products as high cost. The commenter stated that including the PDC threshold reduces the risk that products with larger sizes would be assigned to the low cost category because of a low MUC. One commenter suggested that using the PDC threshold alone may improve on the current methodology. Another commenter supported the policy assigning skin substitute products to the high cost group that exceeded the MUC threshold or the PDC threshold in the CY 2016 final rule and in the CY 2017 proposed rule, even if analysis for the CY 2017 final rule indicate a product should be assigned to the low cost group.

Response: We appreciate the commenters' support. We agree that using either a MUC methodology or a PDC methodology along with the policy of automatically assigning skin substitute products to the high cost group if they were identified as high cost for both the CY 2016 final rule and the CY 2017 proposed rule stabilizes cost group assignments.

Comment: Several commenters expressed concerns about aspects of the current CMS methodology for payment

for the use of skin substitute products. The commenters stated that one issue is the accurate reporting of the cost of skin substitute products. The commenters believed that many providers report lower utilization of skin substitutes than what providers are actually using, which leads to lower payment rates. Some commenters were generally opposed to packaging or bundling skin substitute products with other services because of concerns that the cost of skin substitute products is not accurately accounted for in the packaged or bundled rates. Commenters continued to have concerns about the payment for wounds larger than 100 cm² that they believed are too low even after the addition of PDC methodology to determine if a skin substitute product should be in the high cost group.

Several commenters also suggested changes to the system of assigning skin substitutes to either a high cost or low cost category. Suggestions included creating a three-tiered system to more accurately reflect the prices of individual products, monitoring the current methodology to determine if it was leading to lower reimbursements, and improving transparency by making available MUC and PDC calculations and claims data by product.

Some commenters made a more general request for overall stability with skin substitute methodology and alternate ways to calculate the cost of products to compare to the MUC and PDC thresholds without using OPSS claims data. The most common suggestion was to use average sales price (ASP) + 6 percent as a primary source of cost data instead of using ASP + 6 percent when no claims data are available for a product.

Response: We appreciate the feedback we received from the commenters. However, we believe the current cost estimation and payment policies for skin substitutes reasonably reflect the costs incurred to administer these products. Therefore, after consideration of the public comments we received, we are finalizing our proposal to maintain current policies regarding the payment of skin substitute products for CY 2017 without additional modifications.

Comment: One commenter requested that CMS alter CPT coding instructions that prohibits wound healing products in the form of a gel, liquid, foam, ointment, powder, among others (a form other than a graft-type sheet) from using

the skin substitute application CPT codes or that CMS pay separately for these products in the OPSS.

Response: Skin substitutes and all of their variations and related wound products, regardless of the form or physical state, are packaged in the OPSS as surgical supplies under 42 CFR 419.2(b)(16). Skin substitutes is a broad class of wound products that includes all of the products in the HCPCS skin substitute Q code series and all related products. We cannot change AMA CPT coding guidance. We can (if we choose to do so) provide coding instructions or guidance specifically for Medicare coding and payment purposes. We believe that the AMA coding guidance for the skin substitute codes is sufficient as currently written. The skin substitute graft materials are applied to a wound in a manner that is different from how a liquid or particulate material is applied. In general, there are not very many codes for the application of topical medications such as liquids, creams or ointments because what the applier has to do to put the medication or other medical product on a patient's skin does not typically rise to the level of a service that would need to be described by a code depicting the professional services of a health care provider. In other words, it is generally a very minor activity that requires little time, effort or skill, and often such products are self-administered. Regarding the request that we pay separately for liquid, gel, particulate, powder, or other forms of skin substitutes, we do not agree with this request. It is common in the OPSS that the use of a surgical supply (whether expensive or not) does not correspond to a specific procedure code with a payment that covers the full cost of the supply. In this case, access to particular skin substitute products is generally not our concern because there are so many different skin substitute products available to Medicare beneficiaries in the HOPD that adequate treatment for wounds under the current payment scheme should always be available.

After consideration of the public comments we received, we are finalizing as proposed our high cost/low cost skin substitute methodology as described above. Table 37 below displays the CY 2017 high cost or low cost category assignment for each skin substitute product.

TABLE 37—SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2017

CY 2017 HCPCS code	CY 2017 short descriptor	CY 2017 High/low assignment
Q9363	Integra Meshed Bil Wound Mat	High.
Q4100	Skin Substitute, NOS	Low.
Q4101	Apligraf	High.
Q4102	Oasis Wound Matrix	Low.
Q4103	Oasis Burn Matrix	High.
Q4104	Integra BMWd	High.
Q4105	Integra DRT	High.
Q4106	Dermagraft	High.
Q4107	GraftJacket	High.
Q4108	Integra Matrix	High.
Q4110	Primatrix	High.
Q4111	Gammagraft	Low.
Q4115	Alloskin	Low.
Q4116	Alloderm	High.
Q4117	Hyalomatrix	Low.
Q4119	Matristem Wound Matrix	Low.
Q4120	Matristem Burn Matrix	High.
Q4121	Theraskin	High.
Q4122	Dermacell	High.
Q4123	Alloskin	High.
Q4124	Oasis Tri-layer Wound Matrix	Low.
Q4126	Memoderm/derma/tranz/integup	High.
Q4127	Talymed	High.
Q4128	Flexhd/Allopatchhd/Matrixhd	High.
Q4129	Unite Biomatrix	High.
Q4131	Epifix	High.
Q4132	Grafix Core	High.
Q4133	Grafix Prime	High.
Q4134	hMatrix	Low.
Q4135	Mediskin	Low.
Q4136	Ezderm	Low.
Q4137	Amnioexcel or Biodexcel, 1cm	High.
Q4138	Biodfence DryFlex, 1cm	High.
Q4140	Biodfence 1cm	High.
Q4141	Alloskin ac, 1cm	High.
Q4143	Repriza, 1cm	High.
Q4146	Tensix, 1CM	High.
Q4147	Architect ecm, 1cm	High.
Q4148	Neox 1k, 1cm	High.
Q4150	Allowrap DS or Dry 1 sq cm	High.
Q4151	AmnioBand, Guardian 1 sq cm	High.
Q4152	Dermapure 1 square cm	High.
Q4153	Dermavest 1 square cm	High.
Q4154	Biovance 1 square cm	High.
Q4156	Neox 100 1 square cm	High.
Q4157	Revitalon 1 square cm	High.
Q4158	MariGen 1 square cm	High.
Q4159	Affinity 1 square cm	High.
Q4160	NuShield 1 square cm	High.
Q4161	Bio-Connekt per square cm	Low.
Q4162	Amnio bio and woundex flow	Low.
Q4163	Amnio bio and woundex sq cm	High.
Q4164	Helicoll, per square cm	High.
Q4165	Keramatrix, per square cm	Low.
Q4166	Cytal, per square cm	Low.
Q4167	Truskin, per square cm	Low.
Q4168	Amnioband, 1 mg	Low.
Q4169	Artacent wound, per square cm	Low.
Q4170	Cygnus, per square cm	Low.
Q4171	Interfyl, 1 mg	Low.
Q4172*	PuraPly, PuraPly antimic	High.
Q4173	Palingen or palingen xplus, per sq cm	Low.
Q4175	Miroderm, per square cm	Low.

* Pass-through payment status in CY 2017.

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

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages because we believed that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others. We continue to believe that making packaging determinations on a drug-specific basis eliminates payment incentives for hospitals to report certain HCPCS codes for drugs and allows hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, in the CY 2017 OPPS/ASC proposed rule (81 FR 45662), we proposed to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2017.

For CY 2017, 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 2015 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 the CY 2017 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 2015 claims data to make the proposed packaging determinations for these drugs: HCPCS code J1840 (Injection, kanamycin sulfate, up to 500 mg), J1850 (Injection, kanamycin sulfate, up to 75 mg) and HCPCS code J3472 (Injection, hyaluronidase, ovine, preservative free, per 1000 usp units).

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 2017 drug packaging threshold of \$110 (so that all HCPCS codes for the same drug or biological would be packaged) or greater than the proposed CY 2017 drug packaging threshold of \$110 (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 2017 was displayed in Table 16 of the CY 2017 OPPS/ASC proposed rule (81 FR 45663).

We did not receive any public comments on this proposal. Therefore, for CY 2017, we are finalizing our CY 2017 proposal, without modification, to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages. Table 38 below displays the final packaging status of each drug and biological HCPCS code to which the finalized methodology applies for CY 2017.

TABLE 38—HCPCS CODES TO WHICH THE CY 2017 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2017 HCPCS code	CY 2017 long descriptor	CY 2017 SI
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K
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
J8520	Capecitabine, oral, 150 mg	N
J8521	Capecitabine, oral, 500 mg	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	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
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J1850	Injection, kanamycin sulfate, up to 75 mg	N
J1840	Injection, kanamycin sulfate, up to 500 mg	N
J7050	Infusion, normal saline solution, 250 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7030	Infusion, normal saline solution, 1000 cc	N
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N

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

a. Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable 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 OPPS payment rates for SCODs to take into account overhead and related expenses,

such as pharmacy services and handling costs. Section 1833(t)(14)(E)(i) of the Act required MedPAC to study pharmacy overhead and related expenses and to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for overhead and related expenses. Section 1833(t)(14)(E)(ii) of the Act authorizes the Secretary to adjust the weights for ambulatory procedure classifications for SCODs to take into account the findings of the MedPAC study.

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 the CY 2017 OPPS/ASC proposed rule (81 FR 45664), we proposed to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. Although we do not distinguish SCODs in this discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs, but we also are applying this provision to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

For a detailed discussion of our OPPS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68383 through 68385). In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386 through 68389), we first adopted the statutory default policy to pay for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act. We continued this policy of paying for separately payable drugs and biologicals at the statutory default for CY 2014, CY 2015, and CY 2016 (80 FR 70440).

b. CY 2017 Payment Policy

In the CY 2017 OPPS/ASC proposed rule (81 FR 45664), for CY 2017 and subsequent years, we proposed 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 proposed 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 proposed 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 scaler is not applied in determining payments for these separately paid drugs and biologicals.

Comment: The majority of commenters supported CMS’ proposal to continue to pay for separately payable drugs and biologicals based on the statutory default rate of ASP+6 percent. One commenter recommended that CMS increase payment for separately payable drugs and biologicals without pass-through payment status to adequately cover providers’ acquisition and pharmacy overhead costs.

Response: We thank commenters for their support. We continue to believe that ASP+6 percent based on the statutory default is appropriate for payment of separately payable drugs and biologicals for CY 2017 and that this percentage amount adequately covers acquisition and overhead cost. We see no evidence that an additional payment for overhead is required for separately payable drugs, biologicals, and therapeutic radiopharmaceuticals for CY 2017.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to pay for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). 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 for CY 2017. In addition, we are finalizing our proposal that payment for separately payable drugs and biologicals be included in the budget neutrality adjustments, under the requirements of section 1833(t)(9)(B) of the Act, and that the budget neutral weight scaler is not applied in determining payment of these separately paid drugs and biologicals.

We note that separately payable drug and biological payment rates listed in Addenda A and B to this final rule with comment period (available via the Internet on the CMS Web site), which illustrate the final CY 2017 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 October 1, 2016, or WAC, AWP, or mean unit cost from CY 2015 claims data and updated cost report information available for this final rule with comment period. In general, these published payment rates are not the same as the actual January 2017 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2017 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of 2016 (July 1, 2016 through September 30, 2016) will be used to set the payment rates that are released for the quarter beginning in January 2017 near the end of December 2016. In addition, payment rates for drugs and biologicals in Addenda A and B to this final rule with comment period for which there was no ASP information available for October 2016 are based on mean unit cost in the available CY 2015 claims data. If ASP information becomes available for payment for the quarter beginning in January 2017, 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 final rule with comment period (reflecting October 2016 ASP data) that do not have ASP information available for the quarter beginning in January 2017. As stated in the CY 2017 OPPS/ASC proposed rule (81 FR 45664), these drugs and biologicals will then be paid based on mean unit cost data derived from CY 2015 hospital claims. Therefore, the payment rates listed in Addenda A and B to this final rule with comment period are not for January 2017 payment purposes and are only illustrative of the CY 2017 OPPS payment methodology using the most recently available information at the time of issuance of this final rule with comment period.

c. Biosimilar Biological Products

For CY 2016, 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). In the CY 2017 OPPS/ASC proposed rule (81 FR 45664), for CY 2017, we proposed to continue this

same payment policy for biosimilar biological products.

We received several public comments on the proposed HCPCS coding and modifiers for biosimilar biological products. As proposed, under the OPPS, we will use the HCPCS codes and modifiers for biosimilar biological products based on the policy established under the CY 2016 MPFS final rule with comment period. Therefore, we are considering the public comments received on biosimilar biological product HCPCS coding and modifiers in response to the CY 2017 OPPS/ASC proposed rule to be outside the scope to the proposed rule and we are not addressing them in this CY 2017 OPPS/ASC final rule with comment period. We refer readers to the CY 2017 MPFS final rule with comment period.

We are finalizing our proposal, without modification, to pay for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act. In addition, we are finalizing our proposal, without modification, to subject nonpass-through biosimilar biological products to our annual threshold-packaged policy.

3. Payment Policy for Therapeutic Radiopharmaceuticals

In the CY 2017 OPPS/ASC proposed rule (81 FR 45664), for CY 2017, we proposed 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 from hospital claims. We believe that the rationale outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) for applying the principles of separately payable drug pricing to therapeutic radiopharmaceuticals continues to be appropriate for nonpass-through, separately payable therapeutic radiopharmaceuticals in CY 2017. Therefore, we proposed for CY 2017 to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent, based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520

through 60521). We also proposed to rely on CY 2015 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 available. For a complete history of the OPPS payment policy for therapeutic radiopharmaceuticals, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811), the CY 2006 OPPS final rule with comment period (70 FR 68655), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524). The proposed CY 2017 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals were in Addenda A and B to the proposed rule (which are available via the Internet on the CMS Web site).

Comment: Commenters supported CMS' proposal to pay for separately payable therapeutic radiopharmaceuticals under the statutory default payment rate of ASP+6 percent if ASP data are submitted to CMS.

Response: We appreciate the commenters' support. We continue to believe that providing payment for therapeutic radiopharmaceuticals based on ASP or mean unit cost if ASP information is not available would provide appropriate payment for these products. When ASP data are not available, we believe that paying for therapeutic radiopharmaceuticals using mean unit cost will appropriately pay for the average hospital acquisition and associated handling costs of non-pass-through separately payable therapeutic radiopharmaceuticals. As we stated in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60523), although using mean unit cost for payment for therapeutic radiopharmaceuticals when ASP data are not available is not the usual OPPS process (the usual process relies on alternative data sources such as WAC or AWP when ASP information is temporarily unavailable, prior to defaulting to the mean unit cost from hospital claims data), we continue to believe that WAC or AWP is not an appropriate proxy to provide OPPS payment for average therapeutic radiopharmaceutical acquisition cost and associated handling costs when manufacturers are not required to submit ASP data. Payment based on WAC or AWP under the established

OPPS methodology for payment of separately payable drugs and biologicals is usually temporary for a calendar quarter until a manufacturer is able to submit the required ASP data in accordance with the quarterly ASP submission timeframes for reporting under section 1847A of the Act. Because ASP reporting for OPPS payment of separately payable therapeutic radiopharmaceuticals is not required, a manufacturer's choice to not submit ASP could result in payment for a separately payable therapeutic radiopharmaceutical based on WAC or AWP for a full year, a result that we believe would be inappropriate.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue to pay all non-pass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent. We also are finalizing our proposal to continue to rely on CY 2015 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable. The CY 2017 final rule payment rates for nonpass-through separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site).

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

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

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

Therefore, beginning in CY 2013, we finalized a policy to provide an additional payment of \$10 for the marginal cost for radioisotopes

produced by non-HEU sources (77 FR 68323). Under this policy, hospitals report HCPCS code Q9969 (Tc-99m from non-highly enriched uranium source, full cost recovery add-on per study dose) once per dose along with any diagnostic scan or scans furnished using Tc-99m as long as the Tc-99m doses used can be certified by the hospital to be at least 95 percent derived from non-HEU sources (77 FR 68321).

We stated in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68321) that our expectation is that this additional payment will be needed for the duration of the industry's conversion to alternative methods to producing Tc-99m without HEU. We also stated that we would reassess, and propose if necessary, on an annual basis whether such an adjustment continued to be necessary and whether any changes to the adjustment were warranted (77 FR 68316). We have reassessed this payment for CY 2017 and did not identify any new information that would cause us to modify payment. Therefore, in the CY 2017 OPPS/ASC proposed rule (81 FR 45665), for CY 2017, we proposed to continue to provide an additional \$10 payment for radioisotopes produced by non-HEU sources.

Comment: Some commenters supported CMS' proposal to provide an additional \$10 payment for radioisotopes produced by non-HEU sources and asked that CMS work with stakeholders regarding a phase-out plan based on utilization and adoption of non-HEU technetium by the radiopharmaceutical manufacturers. Another commenter requested that CMS provide an explanation for not applying an annual inflation update to the \$10 payment for radioisotopes produced by non-HEU sources, provide details on plans to offset nuclear medicine procedures by the amount of cost paid through the non-HEU policy, and make available to the public data regarding claims submitted to date under this policy. The commenter also stated that CMS should assess whether the beneficiary copayment policy is adversely impacting patient access.

Response: We appreciate commenters' support. As stated earlier, we support efforts by all of the involved stakeholders to convert all medical radioisotope production to non-HEU sources. Regarding the comment requesting that we increase the \$10 payment for HCPCS code Q9969 (by an inflation update or some other amount) for CY 2017, we currently lack sufficient additional information to suggest that an add-on payment greater than \$10 would be more appropriate. Regarding the

request for payment information for services described by HCPCS code Q9969, the following are the most currently available total Medicare payments for services described by HCPCS code Q9969 for each year in which it has been in effect: CY 2013 (\$17,164); CY 2014 (\$66,609); and CY 2015 (\$106,584). Also, we do not believe that beneficiary copayments for services described by HCPCS code Q9969 are adversely impacting beneficiary access to any medically necessary services. The 20-percent copayment amount on the \$10 total payment for HCPCS code Q9969 is only \$2. Any Medicare beneficiary who is unable to afford this \$2 copayment would almost certainly have some form of government assistance that would cover this copayment amount. Therefore, we do not believe that the copayment requirements for services described by HCPCS code Q9969 are negatively impacting access to medical care for Medicare beneficiaries.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue the policy of providing an additional \$10 payment for radioisotopes produced by non-HEU sources for CY 2017, which will be the fifth year in which this policy is in effect in the OPPS. We will continue to reassess this policy annually, consistent with the original policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68321).

5. Payment for Blood Clotting Factors

For CY 2016, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee (80 FR 70441). That is, for CY 2016, we provided payment for blood clotting factors under the OPPS at ASP+6 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee is also applied to the payment. The CY 2016 updated furnishing fee was \$0.202 per unit.

In the CY 2017 OPPS/ASC proposed rule (81 FR 45665), for CY 2017, we proposed to pay for blood clotting factors at ASP+6 percent, consistent with our proposed payment policy for other nonpass-through, separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount. Our policy to pay for a furnishing fee for blood clotting factors under the OPPS is

consistent with the methodology applied in the physician's office and in the inpatient hospital setting. These methodologies were first articulated in the CY 2006 OPPTS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPPTS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update was 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 OPPTS/ASC proposed rules are published, we were 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 OPPTS/ASC final rule with comment period (72 FR 66765), we proposed to announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html>.

Comment: One commenter supported CMS' proposal to continue its longstanding policy for payment of the furnishing fee for blood clotting factors administered or dispensed in the hospital outpatient department at the same level as in the physician office setting.

Response: We appreciate the commenter's support.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to provide payment for blood clotting factors under the same methodology as other separately payable drugs and biologicals under the OPPTS and to continue payment of an updated furnishing fee. We will announce the actual figure of the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through the applicable program instructions and posting on the CMS Web site.

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

In the CY 2017 OPPTS/ASC proposed rule (81 FR 45665), for CY 2017, we proposed to continue to use the same payment policy as in CY 2016 for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS

codes but without OPPTS hospital claims data (80 FR 70443). The proposed CY 2017 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPTS hospital claims data was listed in Addendum B to the proposed rule, which is available via the Internet on the CMS Web site.

We did not receive any specific public comments regarding our proposed payment for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes, but without OPPTS hospital claims data. Therefore, we are finalizing our CY 2017 proposal without modification, including our proposal to assign drug or biological products status indicator "K" and pay for them separately for the remainder of CY 2017 if pricing information becomes available. The CY 2017 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPTS hospital claims data is listed in Addendum B to this final rule with comment period, which is available via the Internet on the CMS Web site.

VI. 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 an estimate of pass-through spending in CY 2017 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 2017. 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 2016 or beginning in CY 2017. The sum of the CY 2017 pass-through spending estimates for these two groups of device categories equals the total CY 2017 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 the CY 2017 OPPTS/ASC proposed rule (81 FR 45666), for CY 2017, we proposed to include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. Similarly, we finalized a policy in CY 2015 that applications for pass-through payment for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology (76 FR 66885 through 66888). Therefore, as we did beginning in CY 2015, for CY 2017, we also proposed to include an estimate of any skin substitutes and similar products in our estimate of pass-through spending for devices.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the

Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. Because we proposed to pay for most nonpass-through separately payable drugs and biologicals under the CY 2017 OPPS at ASP+6 percent, and because we proposed to pay for CY 2017 pass-through drugs and biologicals at ASP+6 percent, as we discussed in section V.A. of the proposed rule, our estimate of drug and biological pass-through payment for CY 2017 for this group of items was \$0, as discussed below.

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 the proposed rule and this final rule with comment period. In the CY 2017 OPPS/ASC proposed rule (81 FR 45666), we proposed that all of these policy-packaged drugs and biologicals with pass-through payment status would be paid at ASP+6 percent, like other pass-through drugs and biologicals, for CY 2017. Therefore, our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2017 was not \$0, as discussed below. In section V.A.5. of the proposed rule, we discussed our policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving pass-through payment, we proposed to offset the amount of pass-through payment for the policy-packaged drug or biological. For these drugs or biologicals, the APC offset amount is the portion of the APC

payment for the specific procedure performed with the pass-through drug or biological, which we refer to as the policy-packaged drug APC offset amount. If we determine that an offset is appropriate for a specific policy-packaged drug or biological receiving pass-through payment, we proposed to reduce our estimate of pass-through payments for these drugs or biologicals by this amount.

Similar to pass-through 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 2017. 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 2016 or beginning in CY 2017. The sum of the CY 2017 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2017 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. Estimate of Pass-Through Spending

In the CY 2017 OPPS/ASC proposed rule (81 FR 45666), we proposed to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2017, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004 through CY 2016 (80 FR 70446 through 70448).

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 2017, there are three active categories for CY 2017. For CY 2016, we established one new device category subsequent to the publication of the CY 2016 OPPS/ASC proposed rule, HCPCS code C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), that was effective January 1, 2016. We estimated that the device described by HCPCS code C1822 will cost \$1 million in pass-through expenditures in CY 2017. Effective April 1, 2015, we established that the device described by HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser) will be eligible for pass-through payment. We estimated that the device described by HCPCS code C2623 will cost \$97 million in pass-through expenditures in CY 2017. Effective July 1, 2015, we established that the device described by HCPCS code C2613 (Lung biopsy plug with

delivery system) will be eligible for pass-through payment. We estimated that the device described by HCPCS code C2613 will cost \$4.7 million in pass-through expenditures in CY 2017. Based on the three device categories of HCPCS codes C1822, C2623, and C2613, we proposed an estimate for the first group of devices of \$102.7 million.

We did not receive any public comments on our proposed estimate for the first group of devices that included HCPCS codes C1822, C2623 and C2613. Therefore, we are finalizing the proposed estimate for this first group of devices of \$102.7 million for CY 2017.

In estimating our proposed CY 2017 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 2017; 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, 2017; and contingent projections for new device categories established in the second through fourth quarters of CY 2017. In the CY 2017 OPPS/ASC proposed rule (81 FR 45667), we proposed to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. For the proposed rule, the estimate of CY 2017 pass-through spending for this second group of device categories was \$10 million.

We did not receive any public comments on our proposed estimate for the second group of devices. Therefore, we are finalizing the proposed estimate for this second group of devices of \$10 million for CY 2017.

To estimate proposed CY 2017 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 2017, we proposed to use the most recent Medicare physician 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 2017 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 2017, 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 proposed to include in the CY 2017 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 the proposed rule, using the proposed methodology described above, we calculated a CY 2017 proposed spending estimate for this first group of drugs and biologicals of approximately \$19.0 million.

We did not receive any public comments on our proposed spending estimate for this first group of drugs and biologicals. For this final rule with comment period, we calculated a CY 2017 spending estimate for this first group of drugs and biologicals of approximately \$20.2 million.

To estimate proposed CY 2017 pass-through spending for drugs and biologicals in the second group (that is, drugs and biologicals that we knew at the time of development of the proposed rule were newly eligible for pass-through payment in CY 2017, 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, 2016, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2017), we proposed to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2017 pass-through payment estimate. We also proposed to

consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2017 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 \$16.6 million.

We did not receive any public comments on our proposed methodology or the proposed spending estimate for this second group of drugs. Therefore, for CY 2017, we are continuing to use the general methodology described above. For this final rule with comment period, we calculated a CY 2017 spending estimate for this second group of drugs and biologicals of approximately \$17.7 million.

In summary, in accordance with the methodology described earlier in this section, for this final rule with comment period, 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 2017 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2017 is approximately \$150.6 million (approximately \$112.7 million for device categories and approximately \$37.9 million for drugs and biologicals), which represents 0.24 percent of total projected OPPS payments for CY 2017. Therefore, we estimate that pass-through spending in CY 2017 will not amount to 2.0 percent of total projected OPPS CY 2017 program spending.

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

In the CY 2017 OPPS/ASC proposed rule (81 FR 45667), for CY 2017, we proposed to continue with and did not propose 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 proposed to continue with and did not propose any change to our payment policy for critical care services for CY 2017. For a description of the current payment policy for critical care services, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70449), and for the history of the payment policy for critical care services, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78

FR 75043). In the proposed rule, we sought public comments on any changes to these codes that we should consider for future rulemaking cycles. We encouraged those parties who comment to provide the data and analysis necessary to justify any proposed changes.

We did not receive any public comments on this proposal. Therefore we are finalizing our CY 2017 proposal, without modification, to continue our current clinic and ED hospital outpatient visits and critical care services payment policies.

VIII. Payment for Partial Hospitalization Services

A. Background

A partial hospitalization program (PHP) is an intensive outpatient program of psychiatric services provided as an alternative to inpatient psychiatric care for individuals who have an acute mental illness. 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 defined in subparagraph (B)), and which is a distinct and organized intensive ambulatory treatment service offering less than 24-hour-daily care other than in an individual's home or in an 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, under 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 and policy and payment changes finalized in the CY 2008 OPSS/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 OPSS/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. 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 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 OPSS/ASC final rule with comment period (75 FR 71994 through 71994) for a full discussion.

For CY 2012, as discussed in the CY 2012 OPSS/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 OPSS/ASC final rule with comment period, we finalized our proposal to base the relative payment weights that underpin the OPSS APCs, including the four PHP APCs (APCs 0172, 0173, 0175, and 0176), on geometric mean costs rather than on the median costs. 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 OPSS/ASC final rule with comment period (77 FR 68406 through 68412).

In the CY 2014 OPSS/ASC proposed rule (78 FR 43621 through 43622), 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 OPSS/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 OPPTS/ASC final rule with comment period (78 FR 75050 through 75053).

In the CY 2015 OPPTS/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 OPPTS/ASC final rule with comment period (80 FR 70455 through 70465), we again 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. We also 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 an average cost per day that is above or below 2 (± 2) standard deviations from the mean. We also 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 OPPTS/ASC final rule with comment period (80 FR 70462 through 70467).

In the effort to increase the accuracy of the PHP per diem costs, in the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70455 through 70461), we completed an extensive analysis of the claims and cost data, which included provider service usage, coding practices, and the ratesetting methodology. This extensive analysis identified provider coding errors that were inappropriately removing costs from ratesetting, and aberrant data from several providers that were affecting the calculation of the proposed PHP geometric mean per diem costs. Aberrant data are claims and/or cost data that are so abnormal that they skew the resulting geometric mean per diem costs. For example, we found claims with 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. For an outpatient program like the PHP, which does not incur room and board costs such as an inpatient stay would, these costs per day were excessive. In addition, we found some CMHCs had very low costs per day (less than \$25 per day). We stated in the CY 2016 OPPTS/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. Further analysis of the data confirmed that there were a few providers with extreme cost per day values, which led us to propose and finalize a ± 2 standard deviation trim on CMHC costs per day.

During our claims and cost data analysis, we also found aberrant data from some hospital-based PHP providers. The existing OPPTS ± 3 standard deviation trim removed very extreme CCRs by defaulting two providers that failed this trim to their overall hospital ancillary CCR. However, the calculation of the ± 3 standard deviations used to define the trim was influenced by these two providers, which had extreme CCRs greater than 175. Because these two hospital-based PHP providers remained in the data when we calculated the boundaries of the OPPTS ± 3 standard deviation trim in the CY 2016 ratesetting, the upper limit of the trim boundaries was fairly high, at 28.3446. As such, some aberrant CCRs were not trimmed out, and still had high values ranging from 6.3840 to 19.996. We note that, as stated in the CY 2016 OPPTS/ASC proposed rule (80 FR 39242 and 39293) and reiterated in the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70456), OPPTS defines a biased CCR as one that falls outside the predetermined ceiling threshold for a valid CCR; using CY 2014 cost report data, that threshold is 1.5.

In order to reduce or eliminate the impact of aberrant data received from a few CMHCs and hospital-based PHP providers in the claims data used for ratesetting, we finalized the application of a ± 2 standard deviation trim on cost per day for CMHCs and a CCR>5 hospital service day trim for hospital-based PHP providers for CY 2016 and subsequent years (80 FR 70456 through 70459). In addition, in the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70459 through 70460), a cost inversion occurred in the final rule data with respect to hospital-based PHP providers. A cost inversion exists when the Level 1 PHP APC geometric mean per diem cost for providing exactly 3 services per day exceeds the Level 2 PHP APC geometric mean per diem cost for providing 4 or more services per day. 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.

For a comprehensive description on the background of PHP payment policy, we refer readers to the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70453 through 70455).

B. PHP APC Update for CY 2017

1. PHP APC Changes and Effects on Geometric Mean Per Diem Costs

For CY 2017, in the CY 2017 OPPTS/ASC proposed rule (81 FR 45669 through 45673), we proposed 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. However, as explained in greater detail below, we proposed 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 believe 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 by avoiding the cost inversions that hospital-based PHPs experienced in the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70459).

a. Changes to PHP APCs

In the CY 2017 OPPTS/ASC proposed rule (81 FR 45669 through 45673), we proposed to combine the existing two-tiered PHP APCs for CMHCs into a single PHP APC and the existing two-tiered hospital-based PHP APCs into a single PHP APC. Specifically, we proposed to replace existing CMHC APCs 5851 (Level 1 Partial Hospitalization (3 services) for CMHCs) and 5852 (Level 2 Partial Hospitalization (4 or more services) for CMHCs) with proposed new CMHC APC 5853 (Partial Hospitalization (3 or More Services Per Day)), and to replace existing hospital-based PHP 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) with proposed new hospital-based PHP APC 5863 (Partial Hospitalization (3 or More Services Per Day)). In conjunction with this proposal, we proposed to combine the geometric mean per diem costs for the existing Level 1 and Level 2 PHP APCs for

CMHCs (APC 5851 and APC 5852, respectively) to calculate the proposed geometric mean per diem costs for proposed new PHP APC 5853 for CMHCs using only CY 2015 CMHC claims data and the most recent cost data, and to combine the geometric mean per diem costs for the existing Level 1 and Level 2 PHP APCs for hospital-based PHPs (APC 5861 and APC 5862, respectively) to calculate the proposed geometric mean per diem costs for proposed new PHP APC 5863 for hospital-based PHPs using only CY 2015 hospital-based PHP claims data and the most recent cost data, for CY 2017 and subsequent years. We discuss these computations in section VIII.B.2 of this preamble. The proposed geometric mean per diem costs were shown in Table 19 in section VIII.B.2. of the proposed rule.

Comment: MedPAC supported the proposal to combine the existing Level 1 and Level 2 APCs into a single new APC for providing 3 or more services. MedPAC stated that the logic in payment rates is vital to having a meaningful payment system, and further added that payment rates that are higher for an APC that provides fewer of the same types of services as another APC is not reasonable. However, several commenters opposed the proposal.

One commenter stated that the proposal would violate the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA, Pub. L. 110–343) because it limits mental health care to a cap of 3 or fewer treatment groups per day and reduces payments to below payments for comparable acute care services.

One commenter urged CMS to monitor the effects of combining the existing two-tiered APCs into a single PHP APC, by provider type, to ensure that these changes do not cause or contribute to any unintended consequences such as reducing access to PHP services, or incentivizing reductions in services provided under the single APC.

Response: We appreciate the commenters' support. We agree that it is reasonable to combine similar costs and services into the same APC payment. It is also worth noting that in CY 2014, when we requested public comments on possible future initiatives, we received several public comments requesting a single APC payment for PHP services (78 FR 75051).

We also agree that it is possible that the combined PHP APCs could incentivize a reduction in services under a single APC, with PHP providers providing more days with only 3 services per day, but receiving an APC

payment that is heavily weighted toward providing 4 or more services. We have monitored utilization of 3-service days over the years, and found that 3-service days are appropriately infrequent. In the updated CY 2015 claims data reviewed for this final rule with comment period, we found that 5 percent of CMHC paid days and 12 percent of hospital-based PHP paid days indicated that exactly 3 services were provided. In addition, given the intensive nature of partial hospitalization services and that PHP services are provided in lieu of inpatient hospitalization, we have a longstanding eligibility requirement that PHP beneficiaries require at least 20 hours per week in services, as evidenced in their plan of care. We discuss this requirement more fully in section VIII.B.1.b. of this final rule with comment period. We will be monitoring PHP claims beginning in January 2017, to determine whether PHP participants are receiving at least 20 hours per week in partial hospitalization services. In particular, we will monitor whether the frequency of providing 3-service days increases now that the payment incentive to provide 4 or more services per day, as opposed to 3 services per day, has been removed through combining the two PHP APCs. Payments for claims will not be affected at this time. Rather, our goal is to implement claims edits in the future to ensure that eligible Medicare beneficiaries are receiving the intense level of services that the statute and regulations require PHPs to provide. We are soliciting public comments on what facility types, treatment patterns, and other indicators are most important to monitor to ensure adequate provision of services.

We disagree with the commenter who believed that combining the existing two-tiered PHP APCs would violate the provisions of the MHPAEA. The MHPAEA generally prevents group health plans and health insurance issuers that provide mental health or substance use disorder benefits from imposing less favorable benefit limitations on those benefits than on medical/surgical benefits. The mental health parity requirements of MHPAEA do not apply to Medicare. More information is available about the MHPAEA on the CMS Web site at: https://www.cms.gov/ccio/programs-and-initiatives/other-insurance-protections/mhpaea_factsheet.html.

In addition, we believe that the commenter is misinterpreting the proposal in stating that combining the two-tiered PHP APCs, by provider type, limits outpatient mental health care to a cap of 3 or fewer group therapy

treatments per day. The combined PHP APCs will generate payments for 3 or more services per day, not for 3 or fewer services provided per day. A different policy, the outpatient mental health treatment cap, limits the maximum payment for a day of individually billed outpatient mental health services to the highest hospital-based PHP APC per diem, and is derived from the most recent provider claims and cost data. It does not cap the number of services that can be provided to a beneficiary. Beneficiaries may receive as many services as are reasonable and necessary for their treatment. As noted in the April 7, 2000 OPPS final rule (65 FR 18454 through 18455), our rationale for implementing the mental health treatment cap was that the costs associated with administering a PHP represent the most resource-intensive of all outpatient mental health treatment services. Therefore, we do not believe it would be appropriate to pay more for a day of individually billed outpatient mental health services than what is paid for a day providing 3 or more partial hospitalization services. We also are concerned that a provider may disregard a patient's need for the intensive active treatment offered by a PHP and opt to bill for individual services. The geometric mean per diem payment amount represents the cost of an average day of partial hospitalization services (the data used to calculate the geometric mean per diem costs were derived from all of the PHP data and include the most and least intensive days). It would not be appropriate for a provider to obtain more payment through component billing.

For CY 2017, the outpatient mental health treatment cap will be equal to the combined PHP APC 5863 geometric mean per diem rate for hospital-based PHPs. Because 88 percent of hospital-based PHP service days provide 4 or more services, the mental health cap is heavily weighted toward the cost of providing 4 or more services per day. This cap is applied to each day of outpatient mental health treatment provided outside of the PHP benefit.

After consideration of the public comments we received, we are finalizing our proposal to replace existing CMHC APCs 5851 (Level 1 Partial Hospitalization (3 services) for CMHCs) and 5852 (Level 2 Partial Hospitalization (4 or more services) for CMHCs) with new CMHC APC 5853 (Partial Hospitalization (3 or More Services Per Day)), and to replace existing hospital-based PHP 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) with new hospital-based PHP APC 5863 (Partial Hospitalization (3 or More Services Per Day)). We also are finalizing our proposal to combine the geometric mean per diem costs for the existing Level 1 and Level 2 PHP APCs for CMHCs (APC 5851 and APC 5852, respectively) to calculate the final geometric mean per diem costs for new PHP APC 5853 for CMHCs using only CY 2015 CMHC claims data and the most recent cost data, and to combine the geometric mean per diem costs for the existing Level 1 and Level 2 PHP APCs for hospital-based PHPs (APC 5861 and APC 5862, respectively) to calculate the final geometric mean per diem costs for new PHP APC 5863 for hospital-based PHPs using only CY 2015 hospital-based PHP claims data and the most recent cost data, for CY 2017 and subsequent years.

As we previously noted, we believe that these finalized policies will best reflect actual geometric mean per diem costs in the future; provide more predictable geometric mean per diem costs, particularly given the small number of CMHCs; simplify and reduce administrative burden by only having one APC for each provider type; and generate more appropriate payments for these services by avoiding the cost inversions that hospital-based PHPs experienced in the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70459), and which were noted in the CY 2017 OPPTS/ASC proposed rule (81 FR 45670 through 45672), and occurred again in geometric mean per diem cost calculations for this final rule with comment period as described in section VIII.B.1.b. of this final rule with comment period. The CY 2017 final geometric mean per diem costs are shown in Table 41 in section VIII.B.2. of this final rule with comment period. As noted earlier, we are soliciting public comments on how we can best target monitoring efforts to ensure adequate provision of services by hospital-based PHPs and CMHC.

b. Rationale for Changes in PHP APCs

One of the primary reasons for our decision to replace the existing Level 1 and Level 2 PHP APCs with a single PHP APC, by provider type, is because the new PHP APCs will avoid any further issues with cost inversions and, therefore, generate more appropriate payment for the services provided by specific provider types. As previously stated, a cost inversion exists when the Level 1 PHP APC geometric mean per diem cost for providing exactly 3 services per day exceeds the Level 2 PHP APC geometric mean per diem cost

for providing 4 or more services per day, and, as we noted in last year's final rule with comment period, we do not believe that it is reasonable or appropriate to pay more for fewer services provided per day and to pay less for more services provided per day (80 FR 70459 through 70460).

To determine if the issue with hospital-based cost inversions that occurred in the data used for the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70459) would continue, we calculated the CY 2017 hospital-based PHP APC geometric mean per diem costs separately for Level 1 and Level 2 partial hospitalization services provided by hospital-based PHPs. After applying our established trims and exclusions, we determined that the CY 2017 Level 1 hospital-based PHP APC geometric mean per diem cost is \$281.35 (proposed at \$241.08) and the CY 2017 Level 2 hospital-based PHP APC geometric mean per diem cost is \$210.50 (proposed at \$187.06), which again demonstrates an inversion.

For the CY 2017 OPPTS/ASC proposed rule, we analyzed the CY 2015 hospital-based PHP claims data used for the CY 2017 proposed rule to determine the source of the inversion between the Level 1 and Level 2 hospital-based PHP APCs geometric mean per diem costs, and found that 13 hospital-based PHPs had high geometric mean per diem costs per day. Two of those providers account for 11.5 percent of Level 1 hospital-based PHP service days, but only 1.9 percent of Level 2 hospital-based PHP service days. Eleven of those 13 providers only reported costs for Level 1 hospital-based PHP service days, which increased the geometric mean per diem costs for the Level 1 hospital-based PHP APC. There also were 3 hospital-based PHP providers with very low geometric mean costs per day that accounted for approximately 28 percent of the Level 2 hospital-based PHP service days, which decreased the geometric mean per diem costs for the Level 2 hospital-based PHP APC.

For this CY 2017 final rule with comment period, we found that the inversion of the Level 1 and Level 2 hospital-based PHP geometric mean per diem costs was caused by 3 providers with high-cost Level 1 service days, accounting for 16 percent of all Level 1 service days, and 1 low-cost provider accounting for 15 percent of all Level 2 service days. High volume providers heavily influence the cost data, and we believe that the high volume providers with very low Level 2 hospital-based PHP geometric mean per diem costs per day and high volume providers with

very high Level 1 hospital-based PHP geometric mean per diem costs per day contributed to the inversion between the hospital-based PHP APCs Level 1 and Level 2 geometric mean per diem costs. In developing the policy to combine the Level 1 and Level 2 PHP APCs into one APC each for CMHCs and hospital-based providers, we reviewed the reasons why we structured the existing PHP APCs into a two-tiered payment distinguished by Level 1 and Level 2 services for both provider types in the CY 2009 OPPTS/ASC final rule with comment period (73 FR 68688 through 68693), to determine whether the rationales continued to be applicable. In the CY 2009 OPPTS/ASC final rule with comment period, we referenced the CY 2008 OPPTS/ASC final rule with comment period (72 FR 66672), which noted that a significant portion of PHP service days actually provided fewer than 3 services to Medicare beneficiaries. In our CY 2009 OPPTS/ASC final rule with comment period, we noted that PHP service days that provide exactly 3 services should only occur in limited circumstances. We were concerned about paying providers a single per diem payment rate when a significant portion of the PHP service days provided 3 services, and believed it was appropriate to pay a higher rate for more intensive service days.

We evaluated the frequency of claims reporting Level 1 and Level 2 PHP service days in Table 17 of the proposed rule to determine if a significant portion of PHP service days only provided exactly 3 services (81 FR 45671). Table 17 showed that the frequency of claims reporting PHP service days providing exactly 3 services (Level 1 services) has decreased greatly from 73 percent of CMHC service days in the CY 2009 rulemaking to 4 percent of CMHC service days in the CY 2017 proposed rule, and from 29 percent of hospital-based PHP service days in the CY 2009 rulemaking to 12 percent of hospital-based PHP service days in the CY 2017 proposed rule. We have updated this table, as shown below, to reflect updated CY 2015 claims data used for this final rule with comment period, and found that 5 percent of CMHC service days and 12 percent of hospital-based PHP service days have exactly 3 services provided. Level 1 PHP service days represent a small portion of PHP service days, particularly for CMHCs, as shown in Table 39 below. Based on this decline in the frequency of claims reporting Level 1 service days, we believe that the need for the PHP APC Level 1 and Level 2 payment tiers that was present in CY 2009 no longer exists.

The utilization data in Table 39 indicate that for the CY 2017 rulemaking year, the Level 2 CMHC service days and the hospital-based PHP Level 2 service days are 95 percent and 88 percent, respectively. Because Level 1 service days are now less common for both provider types, we believe it is no longer necessary to pay a separate rate when 4 or more services are provided compared to when only 3 services are provided. Our new PHP APCs 5853 and 5863 are based on cost data for 3 or

more services per day (by provider type). Therefore, the combined cost data used to derive new PHP APCs 5853 and 5863 result in appropriate per diems based on costs for providing 3 or more services per day. We are sensitive to the fact that our payment policy may have influenced this change in service provision because providers were able to obtain higher payment for providing 4 or more services than for providing only 3 services. Therefore, as discussed earlier, we remain concerned that

providers may inappropriately provide too few services to beneficiaries enrolled in PHPs, and we are working expeditiously to implement coding edits that will better monitor whether PHP providers are furnishing at least 20 hours of services per week, which eligible beneficiaries require.

Table 39 below reflects the utilization data used for this CY 2017 final rule with comment period, using the updated CY 2015 claims data.

TABLE 39—UTILIZATION OF PHP LEVEL 1 DAYS (PROVIDING EXACTLY 3 SERVICES PER DAY) AND PHP LEVEL 2 DAYS (PROVIDING 4 OR MORE SERVICES PER DAY), FROM CY 2007 THROUGH FINAL CY 2015 CLAIMS DATA

Rulemaking year	Claims year	CMHC Level 1 days (%)	CMHC Level 2 days (%)	Hospital-based PHP Level 1 days (%)	Hospital-based PHP Level 2 days (%)
CY 2009	CY 2007	73	27	29	71
CY 2010	CY 2008	66	34	25	75
CY 2011	CY 2009	2	98	18	82
CY 2012	CY 2010	2	98	19	81
CY 2013	CY 2011	3	97	11	89
CY 2014	CY 2012	4	96	11	89
CY 2015	CY 2013	6	94	11	89
CY 2016	CY 2014	5	95	11	89
CY 2017	CY 2015	5	95	12	88

When we implemented the PHP APCs Level 1 and Level 2 payment tiers in our CY 2009 rulemaking, we noted that we wanted to provide PHPs with flexibility in scheduling patients. Both the industry and CMS recognized that there may be limited circumstances when it is appropriate for PHPs to receive payment for days when exactly 3 units of service are provided (73 FR 68688 through 68689). Allowing PHPs to receive payment for a Level 1 service day where exactly 3 services are provided gives PHPs some flexibility in scheduling their patients. Our decision to replace the existing two-tiered PHP APCs with new PHP APCs 5853 and 5863 will provide payment for providing 3 or more services per day by CMHCs and hospital-based PHPs, respectively. Therefore, this flexibility in scheduling will remain.

Another primary reason for our decision to replace the Level 1 and Level 2 PHP APCs with a single PHP APC, by provider type, is the decrease in the number of PHPs, particularly CMHCs. With a small number of providers, data from large providers with a high percentage of all PHP service days and unusually high or low geometric mean costs per day will have a more pronounced effect on the PHP APCs geometric mean per diem costs, skewing the costs up or down. That effect would be magnified by continuing to split the geometric mean per diem

costs further by distinguishing Level 1 and Level 2 PHP services. Creating a single PHP APC for each provider type providing 3 or more partial hospitalization services per day will reduce these cost fluctuations and provide more stability in the PHP APC geometric mean per diem costs.

We also note that our decision to replace the existing Level 1 and Level 2 PHP APCs, by provider type, with a single PHP APC for each provider type is permissible under the applicable statute and regulatory provisions. 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. Moreover, the language that follows paragraph (t)(2) of section 1833 of the Act provides that, for purposes of subparagraph (B), items and services within a group shall not be treated as comparable with respect to use of resources if the highest mean cost for an item or service is more than two times greater than the lowest mean cost for an item or service within the group, with some exceptions. Section 419.31 of our regulations implements this statutory provision, providing that CMS classify outpatient services and procedures that are comparable clinically and in terms

of resource use into APC groups. We believe our policy to replace the existing Level 1 and Level 2 PHP APCs for both provider types with a single PHP APC, by provider type, is supported by the statute and regulations and will continue to pay for partial hospitalization services appropriately based upon actual provider costs.

Both of the existing Level 1 and Level 2 PHP APCs are comprised of services described by the same HCPCS codes. Therefore, the types of services provided under the two payment tiers are the same. The difference is in the quantity of the services provided, where the Level 1 PHP APCs provide for payment for providing exactly 3 services per day, while the Level 2 PHP APCs provide for payment for providing 4 or more services per day. Because the difference in the Level 1 and the Level 2 PHP APCs is in the quantity of the services provided, we expect that the resource use (that is, the geometric mean per diem cost) for providing partial hospitalization services under Level 1 will represent approximately 75 percent or less of the resource use for providing partial hospitalization services under Level 2, by provider type. Table 18 of the proposed rule showed a clear trend for hospital-based PHPs, where the geometric mean per diem costs for providing Level 1 partial hospitalization services have approached the geometric mean per

diem costs for providing Level 2 partial hospitalization services, until they exceed the geometric mean per diem costs for providing Level 2 partial hospitalization services beginning in CY 2016. As the percentages in Table 18 of the proposed rule approach 100 percent, the Level 1 and the Level 2 PHP APC geometric mean per diem costs become closer to each other, demonstrating similar resource use. The trend is less

clear for CMHCs, but the data still show the cost difference between the two tiers narrowing, except in CY 2016. We are not sure why the cost difference is wider among CMHCs in CY 2016. In the CY 2017 OPPS/ASC proposed rule, we welcomed public comments that could help explain the difference. However, we did not receive any public comments on this issue.

The data trends reflected in Table 40 below, which is an update of Table 18 in the proposed rule based on final CY 2015 claims data for this final rule with comment period, continue to support the proposals we made, and our decision to change from a two-tiered APC system for CMHCs and for hospital-based PHPs to a combined APC for providing 3 or more services per day for each provider type.

TABLE 40—TRENDS IN LEVEL 1 PER DIEM COSTS AS A PERCENTAGE OF LEVEL 2 PER DIEM COSTS

	CY 2013 (%)	CY 2014 (%)	CY 2015 (%)	CY 2016 (%)	CY 2017* (%)
CMHCs; Level 1 PHP APC per diem costs/Level 2 PHP APC per diem costs	77.5	88.6	84.4	66.1	94.4
Hospital-based PHPs; Level 1 PHP APC per diem costs/Level 2 PHP APC per diem costs	79.2	89.0	91.6	* 110.0	** 133.7

* Based on CY 2015 final claims data.

** Cost inversions occurred with the Level 1 PHP APC per diem costs exceeding the Level 2 PHP APC per diem costs.

We evaluated the provision of more costly individual therapy in our CY 2017 analyses to determine if there were differences in its provision for PHP APC Level 1 service days compared to PHP APC Level 2 service days, by provider type, because this could affect our expected difference in resource use (that is, geometric mean per diem costs) between the two payment tiers. Using the updated CY 2015 claims data for this final rule with comment period, we found that individual therapy was provided less frequently on days where exactly 3 services were provided by hospital-based PHPs (in 4.0 percent of PHP APC Level 1 service days and in 6.2 percent of PHP APC Level 2 service days). However, we found that individual therapy was provided more frequently under the Level 1 CMHC service days than under the Level 2 CMHC service days (7.9 percent versus 4.4 percent). The greater frequency of CMHCs' providing more costly individual therapy under Level 1 PHP service days should increase resource use for these service days, narrowing the cost difference between Level 1 and Level 2 CMHC service days. This result reflects the updated claims data used for this final rule with comment period.

As we described earlier, the services provided under the Level 1 and Level 2 PHP APC payment tiers are comparable clinically and in terms of resource use. Therefore, based on the authority provided under section 1833(t)(2)(B) of the Act and our regulations at § 419.31(a)(1), and to mitigate the policy concerns noted above, as we proposed, we are replacing the Level 1 and Level 2 PHP APCs, for each provider type,

with a single PHP APC by provider type for CY 2017 and subsequent years.

Our decision to replace the existing Level 1 and Level 2 PHP APCs for both provider types with a single PHP APC, by provider type, is designed to continue to pay for partial hospitalization services appropriately based upon actual provider costs. We believe that section 1833(t)(2)(B) of the Act and our regulations at § 419.31(a)(1) provide the Secretary with the authority to classify services that are comparable clinically and in terms of resource use under a single APC grouping, which is the basis for our decision to replace the existing Level 1 and Level 2 PHP APCs for CMHCs and hospital-based PHPs for providing partial hospitalization services with a single PHP APC for each specific provider type. In addition, we believe that our decision to combine the PHP APCs two-tiered payment structure by provider type will more appropriately pay providers for partial hospitalization services provided to Medicare beneficiaries and avoid cost inversions in the future. Our decision to combine the PHP APC payment tiers, by provider type, also will provide more predictable geometric mean per diem costs, particularly given the small number of CMHCs and the cost inversions that hospital-based PHPs have experienced. The cost inversions between PHP APC Level 1 and Level 2 service days in the hospital-based PHP claims data and the small number of CMHCs are the two primary reasons for our policy to replace the two-tiered PHP APCs with a single PHP APC for each provider type. The small percentage of all PHP service days for partial hospitalization services provided under

the Level 1 PHP APCs further supports our policy to replace the two-tiered PHP APCs with a single PHP APC for each provider type. As noted previously, we believe that the need for the PHP APC Level 1 and Level 2 payment tiers that was present in CY 2009 no longer exists.

In summary, we are creating new CMHC APC 5853 to pay CMHCs for partial hospitalization services provided to Medicare beneficiaries for providing 3 or more services per PHP service day to replace existing CMHC APCs 5851 and 5852 for CY 2017 and subsequent years. We also are creating new hospital-based PHP APC 5863 to pay hospital-based PHPs for partial hospitalization services provided to Medicare beneficiaries for providing 3 or more services per PHP service day to replace existing hospital-based PHP APCs 5861 and 5862 for CY 2017 and subsequent years. We discuss the final geometric mean per diem cost for new CMHC APC 5853 and the final geometric mean per diem cost for new hospital-based PHP APC 5863 in section VIII.B.2. of this final rule with comment period.

By finalizing these proposals, we will pay both CMHCs and hospital-based PHP providers the same payment rate for providing 3 partial hospitalization services in a single service day as is paid for providing 4 or more services in a single service day, by the specific provider type. We remind providers that because partial hospitalization services are intensive outpatient services, our regulations at §§ 410.43(a)(3) and (c)(1) require that PHP beneficiaries need at least 20 hours of services each week and that PHPs furnish services in accordance with the plan of care

reflecting that need. We reiterate that this 20 hour per week requirement is a minimum requirement, and have noted in multiple prior OPPS/ASC final rules with comment periods that a typical PHP would include 5 to 6 hours per day (70 FR 68548, 71 FR 67999, 72 FR 66671, and 73 FR 68687). We want providers to continue to have flexibility in providing PHP services, and we will continue to monitor the utilization of providing 3 services per service day for those limited circumstances when a 3-service day is appropriate. We are considering multiple options for enhancing monitoring of providers to ensure that they furnish appropriate services under PHPs which, according to our regulations at § 410.43(c), are intended for patients who require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care, and which, according to our regulations at § 424.24(e), require that the services be furnished in accordance with a plan of care that sets forth the frequency and duration of the services, taking into account a reasonable expectation of improvement in the patient's condition. We will communicate how we intend to undertake such enhanced monitoring in subregulatory guidance within the next year.

Finally, we are concerned about the low frequency of providing individual therapy, which we noted earlier in this section, and we will be monitoring its provision. The PHP is intensive by nature, and PHP services are provided in lieu of inpatient hospitalization. Furthermore, section 1861(ff) of the Act describes the items and services to be included in a PHP, including individual and group therapy. Therefore, we believe that appropriate treatment for PHP patients includes individual therapy. We encourage providers to examine their provision of individual therapy to PHP patients to ensure that patients are receiving all of the services that they may need.

Comment: One commenter believed that the combined PHP APCs do not appear to have included all of the data from the original Level 1 and Level 2 PHP APCs, and would result in a payment reduction because of implementation of the new policy.

Response: As described earlier, the combined PHP APCs' geometric mean costs used available CY 2015 claims data and were calculated by following the existing methodology for ratesetting, except that the geometric mean per diem costs for each provider type were calculated for days providing 3 or more partial hospitalization services, rather than calculated separately for days with

exactly 3 services, and for days with 4 or more services. The combined PHP APCs' geometric mean costs are similar to a weighted average of actual provider costs. Therefore, the total payments resulting from the combined PHP APC geometric mean per diem cost, by provider type, would be roughly equal to the total payments resulting from the two-tiered PHP APC per diem costs, by provider type. As such, combining the PHP APCs geometric mean per diem costs does not reduce total costs or total payments by provider type. We refer readers to section VIII.B.2. for more detailed specifics on the CY 2017 PHP geometric mean per diem cost calculations.

Comment: A few commenters stated that the current two-tiered payment structure fostered a continuum of care, and contended that CMS' current policy of distinguishing 3 services per day and 4 or more services per day offers the flexibility of intermediate levels of care between outpatient, office-based visits, and inpatient psychiatric care, and further are differentiated from each other by the provider community as "Intensive Outpatient Programs" (IOPs) and PHPs, respectively. The commenters believed that, consequently, replacing the two-tiered payment methodology with a single APC and calculating the geometric mean per diem costs for 3 or more services per day would not recognize the importance and need for the continuum of care.

Response: We are concerned about the potential misuse of the PHP benefit. A few commenters indicated that some in the provider community recognize an IOP level of care. However, there is no Medicare benefit category for IOPs. Therefore, we cannot recognize or pay for what providers term "IOPs" using the PHP benefit. If the individual services that make up these IOPs meet all applicable requirements for non-PHP outpatient services, including coding definitions, and are reasonable and necessary, then conceivably these services could be billed individually under the OPPS. IOPs are typically not only less intensive than PHPs, but, as previously noted, are also a nonexistent Medicare category. In equating IOPs with the statutorily mandated PHP benefit, we believe commenters misunderstood the purpose of the PHP benefit. Specifically, a PHP requires physician certification that the individual would need inpatient psychiatric care if the partial hospitalization services were not provided, as described in § 424.24(e) of the regulations. Furthermore, as required by section 1861(ff) of the Act and by § 424.24(e) of the regulations, a

PHP must be prescribed by a physician, and the services provided under the physician's care must be certified and recertified as being reasonable and necessary and under a plan of treatment that sets forth the duration and frequency of services, taking into account a reasonable expectation of improvement in the patient's condition. If a beneficiary is certified for PHP but provided services that meet some lesser level of care, this action could be some indication of fraud. We plan to work with the MACs in order to better educate providers on PHP requirements.

Finally, combining the PHP APCs does not affect the continuum of care available to Medicare beneficiaries seeking treatment for mental health issues. Our decision to combine the PHP APCs for Level 1 and Level 2 services into a single APC for 3 or more services per day, by provider type, is simply a change in how we pay for PHP services, and does not affect access to mental health care or the ways that non-PHP patients may receive mental health services.

Comment: One commenter stated that the requirement for a minimum of 20 hours per week of therapeutic services conflicts with accepted treatment parameters and other managed care options, where attendance and minimum hours are not required. The commenter believed that the 20 hour per week minimum imposes a burden on older patients, is not necessary to receive a positive outcome, provides no flexibility, would result in a patient attending the program 5 days a week and, therefore, creates a barrier to providing the most appropriate treatment for a patient's needs.

Response: When Congress established the PHP benefit in statute, it described a PHP as an *intensive* program that is provided *in lieu of inpatient treatment* (we refer readers to sections 1835(a)(2)(F), 1861(ff)(2), and 1861(ff)(3)(A) of the Act). Congress provided discretion to the Secretary to determine the frequency of PHP services. In our CY 2009 rulemaking, we promulgated regulations to establish an eligibility requirement at 42 CFR 410.43(c)(1), which states that PHPs are intended for patients who require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care. Under § 410.43(a)(3), we also require PHP services to be furnished in accordance with the plan of care and a physician certification.

Because a PHP is intended for patients who would otherwise be in an inpatient psychiatric setting, and who require an intensive level of services of at least 20 hours per week, it is not an

appropriate program for patients who need less intensive mental health services. Medicare provides a number of ways in which patients can receive covered mental health services, which range from inpatient psychiatric care, to PHPs, to other outpatient care provided by physicians or other health professionals in a variety of settings. Our Medicare Benefit Policy Manual (IOM 100–02, Chapter 6) states that PHP patients must be able to cognitively and emotionally participate in the active treatment process, and to tolerate the intensity of a PHP program (we refer readers to section 70.3, Chapter 6 of IOM 100–02, which is available via the Internet on the CMS Web site at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c06.pdf>). It is possible that mental health treatment provided outside of the PHP benefit may be a more appropriate venue for some patients for whom the 20 hour per week minimum requirement is deemed to be burdensome.

We are concerned that some PHPs are admitting patients who do not meet the eligibility requirements required by the statute. Many of these PHPs are not providing at least 20 hours per week of services to their patients. As such, in March 2016, we issued a MedLearn Special Edition article to notify PHPs of edits to the claims processing system, which would begin July 1, 2016, and would systematically enforce our existing regulations related to the 20-hour per week minimum requirement. However, in early July 2016, we inactivated the edits, effective July 1, 2016, so that we could consider adding more flexibility to the editing process. (We refer readers to MedLearn Matters SE1607, which is available via the Internet on the CMS Web site at: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1607.pdf>.)

In addition, we are considering proposing clarifications to our regulations in our CY 2018 rulemaking to more strongly tie a beneficiary's receipt of at least 20 hours per week of partial hospitalization services under a PHP to payment for those services. We are informing hospital-based PHPs and CMHCs so that they can review their admission procedures, and ensure that the patients they serve are truly eligible for the PHP benefit. In this final rule with comment period, we are requesting public comments on the advantages, disadvantages, and potential challenges of strengthening the tie between payment and furnishing at least 20 hours of services per week to eligible

beneficiaries, for consideration in our development of the CY 2018 rulemaking. Individuals should submit their comments as indicated under the **DATES** section of this final rule with comment period. Finally, as noted previously in this section, we will monitor PHP claims, beginning in January 2017, to determine whether PHP beneficiaries are receiving at least 20 hours per week of partial hospitalization services.

PHP services can be extremely beneficial to eligible patients and, at the same time, can provide a more cost-effective method for providing care outside of an inpatient setting. We are working to protect vulnerable beneficiaries with mental health conditions by helping to ensure that eligible beneficiaries receive the level of care that is appropriate to the PHP setting.

c. Alternatives Considered

As we discussed in the CY 2017 OPPI/ASC proposed rule (81 FR 45672 through 45673), we considered several alternatives to replacing the Level 1 and Level 2 PHP APCs with a single new APC for each PHP provider type. We investigated whether we could maintain the Level 1 and Level 2 PHP APCs if the PHP APC per diem costs were based upon unit costs. However, the same data issues that affected per diem costs also affected unit costs. The hospital-based unit cost data also were inverted such that a Level 1 service day would be more costly than a Level 2 service day. As we have previously noted, we do not believe that it is appropriate to pay more for providing Level 1 services than for providing Level 2 services because only 3 services are provided during Level 1 service days and 4 or more services are provided during Level 2 service days.

We also considered continuing the two-tiered PHP APC payment structure by provider type, and addressing future cost inversions as they arise. Under this alternative, we could have proposed to use a default methodology for handling cost inversions by only combining the two-tiered PHP APC structure for the provider type with inverted data, and only for the affected calendar year. However, we believe that it could be confusing if one provider type was paid for PHP services based on a two-tiered payment structure, while the other provider type was paid based on a single APC grouping. We also believe that providers would prefer the predictability of knowing whether they would be paid using a single PHP APC or using two-tiered PHP APCs for Level 1 and Level 2 services.

Another alternative for handling cost inversions could be to apply an equitable adjustment. However, the level of adjustment required would vary depending on the degree of the inversion, which also could fluctuate from year to year. Again, we believe, and providers and their representative associations have informed us, that providers would prefer the predictability afforded by avoiding cost inversions altogether, rather than being subject to an *ad hoc* adjustment as cost inversions arise.

We considered whether we should adjust our data trims, but we determined that the cause of the cost inversion was not due to providers with aberrantly high CCRs or costs per day. Rather, we believe that the cause of the cost inversion was largely the influence of high volume providers with high (but not inappropriately high) Level 1 service day costs and low (but not inappropriately low) Level 2 service day costs in the CY 2015 hospital-based PHP claims data used for the CY 2017 rulemaking. This suggested that adjusting data trims may not be an effective method for resolving the inversion. Nevertheless, we reconsidered our analysis of the preliminary CY 2015 claims data for hospital-based PHPs by testing a stricter trim on hospital-based PHP data using the published upper limit CCR that hospitals use for calculating outliers rather than the existing CCR>5 trim. This test of a stricter CCR trim did not remove the inversion, and as a result, we did not propose to change the existing CCR>5 trim on hospital-based PHP service days for our CY 2017 ratesetting.

Comment: One commenter recommended that CMS maintain the two-tiered system, but combine the APCs for CMHCs and hospital-based PHPs. The commenter noted that CMHCs and hospital-based PHPs provide the exact same services, but are paid differently, although the commenter acknowledged that hospital-based PHPs have higher costs, largely due to overhead allocation. The commenter believed that the APCs distinguished by provider type “punish” rather than reward CMHCs for being more cost-effective than hospital-based PHPs. The commenter believed that freestanding CMHCs should not be paid less than hospital-based PHPs, and noted that, in 2015, MedPAC recommended that Congress decrease or eliminate the payment differences between hospital outpatient departments and physician offices. The commenter stated that setting CMHCs’ payment rates based on the small

number of remaining CMHCs does not reflect the actual cost of providing these services.

Response: The OPSS system pays for outpatient services, including partial hospitalization services. This system bases payment on the geometric mean per diem costs of providing services using provider data from claims and cost reports. We calculate the PHP APC geometric mean per diem costs based on the data provided for each type of provider to determine payment for these services. We believe that this system provides appropriate payment for partial hospitalization services based on actual provider costs. The final PHP APC geometric mean per diem costs for CY 2017 reflect the costs of what providers expend to maintain such programs, as reported on their claims and cost reports.

We believe the commenter has misunderstood MedPAC's recommendation in its March 2015 Report to Congress. MedPAC recommended that payment rates be adjusted for more costly hospital outpatient departments so that they more closely align with those of less costly freestanding physician offices providing the same services (Medicare Payment Advisory Commission Report to the Congress: Medicare Payment Policy, Chapter 3, "Hospital Inpatient and Outpatient Services," page 51, March 2015). Congress has since addressed a portion of this recommendation in section 603 of the Bipartisan Budget Act of 2015. We refer readers to section X.A. of this final rule with comment period for a full discussion of the provisions of section 603. The provisions of section 603 do not apply to CMHCs because CMHCs are not a department of a hospital. The difference in payment between CMHCs and hospital-based PHPs is based upon differences in resource use (or costs). When Congress required the Secretary to implement an outpatient prospective payment system, it required that this payment system group clinically similar covered services with respect to resource use (section 1833(t)(2) of the Act). Because CMHCs and hospital-based PHPs resource uses are different, these two provider types are paid under different APCs, based on their actual resource use.

Because the cost of providing partial hospitalization services differs significantly by site of service, we established different PHP payment rates for hospital-based PHPs and CMHCs in the CY 2011 OPSS/ASC final rule with comment period (75 FR 71991 through 71994). However, we allowed a 2-year transition to CMHC payment rates based

solely on CMHC data. With respect to the continued use of PHP APC geometric mean per diem costs for determining payment rates by provider type (rather than median costs, which commenters mistakenly referenced), we refer readers to the CY 2013 OPSS/ASC final rule with comment period (77 FR 68406 through 68412) for a discussion of the implementation of this policy. The resulting payment rates reflect the geometric mean cost of what providers expend to maintain such programs, based on data provided by CMHCs and hospital-based PHPs, which we believe is an improvement over the two-tiered methodology calculated based on median costs using only hospital-based data.

Comment: One commenter suggested that CMS consider paying PHPs using a quality-based payment system, and that CMS use value-based purchasing.

Response: We responded to a similar public comment in the CY 2016 OPSS/ASC final rule with comment period (80 FR 70462) and refer readers to a summary of that comment and our response. To reiterate, sections 1833(t)(2) and 1833(t)(9) of the Act set forth the requirements for establishing and adjusting OPSS payment rates, which include PHP payment rates. Section 1833(t)(17) of the Act authorizes the Hospital OQR Program, which applies a payment reduction to subsection (d) hospitals that fail to meet program requirements. In the CY 2015 OPSS/ASC proposed rule (79 FR 41040), we considered future inclusion of, and requested comments on, the following quality measures addressing PHP issues that would apply in the hospital outpatient setting: (1) 30-day Readmission; (2) Group Therapy; and (3) No Individual Therapy. We also refer readers to the CY 2015 OPSS/ASC final rule with comment period (79 FR 66957 through 66958) for a more detailed discussion of PHP measures considered for inclusion in the Hospital OQR Program in future years. The Hospital OQR Program does not apply to CMHCs. Further, currently, there is no statutory language explicitly authorizing a value-based purchasing program for PHPs.

2. Development of the PHP APC Geometric Mean Per Diem Costs and Payment Rates

In the CY 2017 OPSS/ASC proposed rule (81 FR 45667 through 45678), for CY 2017 and subsequent years, we proposed to follow the detailed PHP ratesetting methodology described in section VIII.B.2. of the CY 2016 OPSS/ASC final rule with comment period (80 FR 70462 through 70466) to determine the PHP APCs' geometric mean per

diem costs and to calculate the payment rates for the new single hospital-based PHP APC and CMHC APC. However, as discussed in section VIII.B.1. of this CY 2017 final rule with comment period, in support of our CY 2017 policies to establish single PHP APCs for hospital-based PHPs and CMHCs, we also are combining the geometric mean per diem costs for the two existing hospital-based PHP APCs to calculate a geometric mean per diem cost for new hospital-based PHP APC 5863. Currently, hospital-based PHP service days with exactly 3 service units (based on allowable PHP HCPCS codes) are assigned to Level 1 PHP APC 5861, and hospital-based PHP service days with 4 or more service units (based on allowable PHP HCPCS codes) are assigned to Level 2 PHP APC 5862. Under our CY 2017 proposal, instead of separating the service days between these two APCs, we proposed to combine the service days so that hospital-based PHP service days that provide 3 or more service units per day (based on allowable PHP HCPCS codes) are assigned to new hospital-based PHP APC 5863. We then proposed to continue to follow the existing methodology described in section VIII.B.2.e. of the CY 2016 OPSS/ASC final rule with comment period (80 FR 70465 through 70466) to its end to calculate the geometric mean per diem cost for new hospital-based PHP APC 5863. Therefore, the geometric mean per diem cost for new 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, we proposed to combine the geometric mean per diem costs for the two existing CMHC APCs to calculate a geometric mean per diem cost for new CMHC APC 5853. Currently, CMHC service days with exactly 3 service units (based on allowable PHP HCPCS codes) are assigned to Level 1 CMHC APC 5851, and CMHC service days with 4 or more service units (based on allowable PHP HCPCS codes) are assigned to Level 2 CMHC APC 5852. Under our CY 2017 proposal, instead of separating the service days between these two APCs, we proposed to combine the service days so that CMHC service days that provide 3 or more service units (based on allowable PHP HCPCS codes) are assigned to proposed new CMHC APC 5853. We then proposed to continue to follow the existing PHP ratesetting methodology described in section VIII.B.2.e. of the CY 2016 OPSS/ASC final rule with comment period (80 FR 70465 through 70466) to its end to

calculate the geometric mean per diem cost for new CMHC APC 5853. Therefore, the geometric mean per diem cost for new CMHC APC 5853 would be based upon actual CMHC claims and costs for CMHC service days providing 3 or more services.

To prevent confusion, we referred to the per diem costs listed in Table 19 of the proposed rule as the proposed CMHC or hospital-based PHP APC per diem costs or the proposed CMHC or hospital-based PHP APC geometric mean per diem costs. We referred to the CMHC or hospital-based PHP per diem payment rates listed in Addendum A to the proposed rule (which is available via the Internet on the CMS Web site) as the proposed CMHC or hospital-based PHP APC per diem payment rates or the proposed CMHC or hospital-based PHP APC geometric mean per diem payment rates. The CMHC or hospital-based PHP APC per diem costs are the provider-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 OPSS budget neutrality adjustments described in section II.A.4. of this final rule with comment period.

We proposed to apply our established methodologies in developing the geometric mean per diem costs and payment rates under this proposal, 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 OPSS/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 the proposed rule, prior to calculating the proposed geometric mean per diem cost for new CMHC APC 5853, we prepared the data by first applying trims and data exclusions, and assessing CCRs as described in the CY 2016 OPSS/ASC final rule with comment period (80 FR 70463 through 70465), so that ratesetting is not skewed by providers with extreme 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 2017 ratesetting, in the proposed rule, three CMHCs with geometric mean per

diem costs per day below the trim's lower limit of \$42.83 were excluded from the proposed ratesetting for CY 2017 (81 FR 45674). We also applied the OPSS ± 3 standard deviation trim on CCRs to exclude any data from CMHCs with CCRs above or below this range. This trim resulted in the exclusion of one CMHC with a very low CCR of 0.001. Both of these standard deviation trims removed four providers from ratesetting whose data would have skewed the calculated proposed geometric mean per diem cost downward.

In accordance with our PHP ratesetting methodology, in the 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 our CY 2017 proposed rule ratesetting, one CMHC was excluded because it was missing wage index data for all of its 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 OPSS ratesetting methodology defaults any CMHC CCR >1 to the statewide hospital ancillary CCR (80 FR 70457). In our CY 2017 proposed rule ratesetting, we identified one CMHC that had a CCR >1 . This CMHC's CCR was 1.185 and was defaulted to its appropriate statewide hospital ancillary CCR for CY 2017 ratesetting purposes.

These data preparation steps adjusted the CCR for 1 CMHC and excluded 5 CMHCs, resulting in the inclusion of a total of 46 CMHCs in our CY 2017 proposed rule ratesetting modeling, and the removal of 643 CMHC claims from the 17,033 total CMHC claims used. We believe that excluding providers with extremely low geometric mean costs per day or extremely low 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.

For the CMHC final rule results, we used updated CY 2015 final claims data. The final CY 2015 Outpatient Standard Analytic File used for CY 2017 ratesetting showed that 52 CMHCs had claims in CY 2015. As described in the discussion of the PHP ratesetting process in the CY 2016 final rule (80 FR 70462 through 70467), in section II.A. of this final rule with comment period, and in the OPSS Claims Accounting

Document under supporting documentation "Downloads" for the CY 2017 OPSS/ASC final rule with comment period (available online at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html>), in developing the claims eligible for ratesetting we excluded CMHCs with outlier overall CCRs (1 CMHC). After making this exclusion, our updated CY 2015 claims data showed 51 CMHCs with claims that were eligible for ratesetting. We then applied our ratesetting trims and exclusions. Our ± 2 standard deviation trim policy excluded 3 CMHCs with geometric mean per diem costs per day below the trim's lower limit of \$39.77, and 1 CMHC with geometric mean per diem costs per day above the trim's upper limit of \$403.50. This ± 2 standard deviation trim removed 4 CMHCs from our final rule ratesetting whose data would have skewed the calculation of the final geometric mean per diem cost. For this final rule with comment period, we also applied the OPSS ± 3 standard deviation trim on CCRs to exclude any data from CMHCs with CCRs above or below this range, but no CMHCs were excluded as a result.

In accordance with our PHP ratesetting methodology, 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 2017 final rule ratesetting, 2 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 through 70464). Our longstanding PHP OPSS ratesetting methodology defaults any CMHC CCR >1 to the statewide hospital ancillary CCR (80 FR 70457). In this CY 2017 final rule ratesetting, we identified 1 CMHC that had a CCR >1 . This CMHC's CCR was 1.185 and was defaulted to its appropriate statewide hospital ancillary CCR for CY 2017 final rule ratesetting purposes.

These data preparation steps adjusted the CCR for 1 CMHC and excluded 6 CMHCs, resulting in the inclusion of a total of 45 CMHCs in our CY 2017 final rule ratesetting modeling, and the removal of 2,395 CMHC claims from the 18,990 total CMHC claims used.

After applying all of the above trims, exclusions, or adjustments, the geometric mean per diem cost for all

CMHCs for providing 3 or more services per day (new CMHC APC 5853) is \$124.92 (compared to the proposed \$135.30).

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

For the CY 2017 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 the proposed rule there were 404 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 8 hospital-based PHP providers with CCRs ranging from 5.8763 to 19.9996 from our proposed rule ratesetting. However, all of the service days for these eight 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, the OPPS ± 3 standard deviation trim on costs per day removed four providers from proposed rule ratesetting.

Finally, in our proposed rule ratesetting, we excluded 13 hospital-based PHP providers that reported zero daily costs on their claims, in accordance with our proposed rule PHP ratesetting policy (80 FR 70465). Therefore, we excluded a total of 25 hospital-based PHP providers, resulting in 379 hospital-based PHP providers in the data used for proposed rule ratesetting. After completing these data preparation steps, we calculated the geometric mean per diem cost for proposed new 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 (new hospital-based PHP APC 5863) was \$192.57.

The proposed CY 2017 PHP APC geometric mean per diem costs for the new CMHC and hospital-based PHP APCs were shown in Table 19 of the proposed rule (81 FR 45674). The proposed PHP APC payment rates were included in Addendum A to the proposed rule (which is available via the Internet on the CMS Web site).

For this final rule with comment period, for hospital-based PHPs, we used updated CY 2015 final claims data. The final CY 2015 Outpatient Standard Analytic File showed that 482 hospital-based PHPs had claims in CY 2015. As described in the discussion of the PHP ratesetting process in the CY 2016 final rule with comment period (80 FR 70462 through 70467), in section II.A. of this final rule with comment period, and in the OPPS Claims Accounting Document under supporting documentation “Downloads” for the CY 2017 OPPS/ASC final rule with comment period (available online at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html>), in developing the claims eligible for ratesetting, we excluded providers paid outside of the OPPS (39 hospital-based PHPs), providers without cost report data (9 hospital-based PHPs), and providers with outlier overall CCRs (14 hospital-based PHPs). After making those exclusions, the updated CY 2015 claims data for this final rule with comment period showed 420 hospital-based PHP providers that were eligible for ratesetting. We then applied our ratesetting trims and exclusions.

For hospital-based PHP providers, for this final rule with comment period, we applied a trim on hospital service days when the CCR was greater than 5 at the cost center level. Applying this trim removed service days from 8 hospital-based PHP providers with CCRs ranging from 5.411 to 17.603. However, all of the service days for these 8 hospital-based PHP providers had at least one service associated with a CCR>5, so the trim removed these providers entirely from ratesetting. Also, the OPPS ± 3 standard deviation trim on costs per day removed 1 provider with costs per day over \$4,000 from this final rule ratesetting.

For this final rule with comment period, we also excluded 15 hospital-based PHP providers that reported zero daily costs on all of their claims, in accordance with our PHP ratesetting policy (80 FR 70465). Finally, we excluded 1 hospital-based PHP without valid wage index data. Therefore, we excluded a total of 25 hospital-based PHP providers, resulting in 395

hospital-based PHP providers in the data used for ratesetting. After completing these data preparation steps, we calculated the geometric mean per diem cost for new hospital-based PHP APC 5863 for hospital-based PHP services. The final geometric mean per diem cost for hospital-based PHP providers that provide 3 or more services per service day (new hospital-based PHP APC 5863) is \$213.14 (compared to the proposed \$192.57).

Currently, the highest hospital-based PHP per diem rate, which for CY 2016 was the Level 2 hospital-based PHP per diem rate for APC 5862, serves as the cap for all non-PHP outpatient mental health services provided in a single service day. Because we are finalizing our proposal to replace the existing two-tiered PHP APCs structure with a single APC grouping for these services by specific provider type, the outpatient mental health treatment cap for CY 2017 is the geometric mean per diem rate for new hospital-based PHP APC 5863.

In the CY 2017 OPPS/ASC proposed rule, we solicited comments on our proposals related to CMHCs and hospital-based PHP APC geometric mean per diem cost calculations and data exclusions.

Comment: Several commenters expressed concern that the proposed CY 2017 PHP APC geometric mean per diem costs and payment rates were lower than the current CY 2016 PHP APC geometric mean per diem costs and payment rates, and stated that the proposed payment rates would not provide adequate payment of these services.

Several commenters suggested an alternative payment methodology. Some commenters suggested that CMS delay implementation of the CY 2017 PHP APC per diem payment rates until it can capture and adequately cover hospital-based PHP costs, or that CMS “freeze” the CY 2017 PHP APC per diem payment rates at the CY 2016 level. Several commenters recommended that CMS use a median cost phase-in of at least 3 years to allow PHP providers to assess their programs and make necessary changes, using a rolling average of the per diem costs. One commenter stated that this method could minimize the major fluctuations in the payment rates from year to year and provide a more stable basis for hospitals and CMHCs when budgeting and planning. Another commenter stated that the decrease in the PHP APC payment rate would discourage hospitals from offering the PHP benefit to Medicare beneficiaries, ultimately creating a barrier to access to these services, which could place the

population at risk. Some commenters stated that the payment rate reduction would impair services and affect the provider network of both service organization types, or that the lower payment rates will force providers to restructure their organization and programs. Other commenters stated that a payment reduction will force providers to cut costs, staff and programming, which would cause them to assist fewer people, and would lead to higher ED visits. Another commenter stated that providers would be unable to absorb the impact of the reduction. Some commenters noted that PHP costs had increased due to rising wages, the new CMHC conditions of participation (CoPs), and a reduction in bad debt reimbursement.

One commenter mentioned that since last year, another 11 CMHCs closed or discontinued PHP services, and the policy would further decrease valuable resources for the mentally ill. Several commenters believed that PHPs will continue to decrease in numbers without adequate payment. One commenter stated that establishing payment rates that are lower than geometric mean costs is a disincentive for PHPs to continue providing services. Another commenter stated that the 13 percent reduction in hospital-based PHP geometric mean per diem payment rates may prohibit high quality providers from continuing to provide PHP services and exacerbate existing access constraints. A number of commenters noted that PHPs are a vital part of the mental health care continuum, and noted the benefits of the program, which include providing needed care to a vulnerable population, avoiding more costly and less efficient emergency department visits and more costly inpatient stays, and increasing the time between readmission.

Response: We appreciate the commenters' input regarding the CY 2017 proposed PHP APC payment rates. The final hospital-based PHP APC geometric mean per diem cost for new APC 5863 is higher than the proposed hospital-based PHP per diem cost (\$213.14 for this final rule versus \$192.57 in the proposed rule). However, the final CMHC geometric mean per diem cost for new APC 5853 is lower than the proposed CMHC geometric mean per diem costs (\$124.92 for this final rule versus \$135.30 in the proposed rule). As we explained in the CY 2014 OPPTS/ASC final rule (78 FR 75049), our calculation of geometric mean per diem costs is based on the actual provider-reported claims and cost data and, therefore, represents the cost of providing PHP services, including,

for example, rising staff wages. The resulting PHP APC geometric mean per diem costs and specific payment amounts and the APC payment structure reflect the cost providers expend to maintain such programs. While we proposed the geometric mean per diem costs in this section, section 1833(t)(9)(B) of the Act requires that we apply a budget neutrality adjustment before determining final payment rates, as described in section II.A.4. of this final rule with comment period. That adjustment can result in geometric mean per diem payment rates that are higher or lower than the calculated geometric mean per diem costs. It is also important to note that the reduction to bad debt reimbursement was a result of provisions of section 3201 of the Middle Class Tax Extension and Job Creation Act of 2012. The reduction to bad debt impacted all providers eligible to receive bad debt reimbursement, as discussed in the CY 2013 ESRD final rule (77 FR 67518).

We remind PHPs that the services of physicians, clinical psychologists, clinical nurse specialists (CNSs), nurse practitioners (NPs), and physician assistants (PAs) furnished to partial hospitalization patients will continue to be billed separately as professional services and costs for these professional services are not considered to be partial hospitalization services. Therefore, payment for partial hospitalization services represents the provider's overhead costs, support staff, and the services of clinical social workers (CSWs) and occupational therapists (OTs), whose professional services are considered to be partial hospitalization services for which payment is made to the provider (65 FR 18452). We encourage CMHCs and hospital-based PHPs to review their cost reporting procedures, to ensure that they are accurately reporting PHP costs on their cost reports, and hospital-based PHPs to follow the revenue-code-to-cost-center hierarchy.

We recognize the commenters' concern regarding variance in payment rates from year to year. As we explained in the CY 2014 OPPTS/ASC final rule (78 FR 75049), payment rates for PHP services fluctuate from year to year based on a variety of factors, including direct changes to the PHP APC per diem payment rate, changes to the OPPTS, and provider-driven changes. Over the past several years, we have made changes to the PHP APC per diem payment rates to more accurately align the payments with costs. The changes have included establishing separate APCs and associated per diem payment rates for CMHCs and hospital-based providers

based on each provider's costs. We also believe that combining the two tiers into one payment tier for 3 or more services will reduce fluctuations and better stabilize the payment rate variance. Combining the tiers systematically addresses chronic issues with inverted costs leading to inverted payment rates and creates a more stable geometric mean per diem cost, given the small number of PHP providers.

Regarding the recommendation to use median cost, we note that, in the CY 2013 OPPTS/ASC final rule with comment period, we finalized our proposal to base the relative payment weights that underpin the OPPTS APCs, including the PHP APCs, on geometric mean costs rather than on the median costs (77 FR 68406 through 68412). The use of geometric mean data supports our goal of aligning resource use with appropriate payment.

In response to commenters' suggestions to delay implementation of the CY 2017 per diem payment rates, or to "freeze" the PHP APC per diem payment rates at the CY 2016 level, as we discussed in the CY 2014 OPPTS/ASC final rule with comment period (78 FR 75049), we cannot establish payment rates that do not accurately reflect current claims and cost report data. Providers attest to the accuracy of the cost reports from which we obtain PHP claims and cost data. In addition, the ratesetting methodology for calculating OPPTS APC payment rates as stated in the regulations at 42 CFR 419.31 does not allow us to take an average of prior year and current PHP per diem payment rate data to determine the PHP geometric mean per diem payment rates. Rather, the regulations at § 419.31(b)(1) require us to use the most current available cost data in ratesetting. Therefore, we cannot delay or "freeze" the CY 2017 PHP APC per diem payment rates, or base the calculations upon an average of multiple years of data.

We appreciate the commenters' input regarding the effect any reduction in PHP payment rates would have on access to care. As noted earlier, the final PHP geometric mean per diem cost increased for hospital-based PHPs, but decreased for CMHCs. Our calculated geometric mean per diem costs are based on the actual provider-reported claims and cost data and, therefore, represent the cost of providing PHP services.

We are working to strengthen continued access to the PHP benefit for eligible beneficiaries. For example, in CY 2016 ratesetting, we conducted an extensive analysis of the ratesetting process, and discovered errors providers

had made in claims coding of revenue and HCPCS codes that were leading to lower geometric mean per diem costs. In the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70462 through 70467), we also included a detailed description of the ratesetting process to help PHPs record costs correctly so that we can more fully capture PHP costs in ratesetting.

To address fluctuations in payments and to protect ratesetting from aberrant data, we also implemented trims on the PHP data used in ratesetting in the CY 2016 rulemaking. For example, the CMHC ±2 standard deviation trim has protected CMHCs by removing from ratesetting several providers with aberrantly low costs per day, which would have lowered total CMHC geometric mean per diem costs, and thus lowered CMHC geometric mean per diem payment rates.

We agree that PHPs serve a vulnerable population, and appreciate the care that PHPs provide to Medicare beneficiaries. We also believe that PHPs can help patients avoid emergency department

visits and inpatient stays in a cost-efficient fashion. We remain concerned about access to PHP services, and particularly about the declining numbers of CMHCs. We will continue to explore policy options for strengthening the PHP benefit.

Comment: A few commenters stated that the lack of a required standardized PHP cost center on the Medicare cost report may be creating some cost-finding nuances in the cost report itself (for example, inaccurate step-down of overhead cost allocations to the PHP program, diluted CCRs by the comingling of PHP and “Intensive Outpatient Program (IOP)” on the cost report, among others) that may have contributed to this decreased PHP median [sic] cost. These commenters believed that the cost decreases observed with hospital-based PHP costs may not be “real” cost decreases, but rather a result of Medicare cost accounting.

Response: We agree that if PHP costs are combined with other less intensive outpatient mental health treatment costs

in the same cost center, the CCR could be diluted, leading to lower geometric mean per diem costs being calculated. We will analyze this further and consider adding a cost center to the hospital cost report for PHP costs only.

After consideration of the public comments we received, we are finalizing our proposals to replace the four PHP APCs (5851, 5852, 5861, and 5862) with the two new PHP APCs (5853 and 5863) and to calculate the geometric mean per diem costs using the most recent claims and cost data for each provider type. The final CY 2017 PHP APC geometric mean per diem costs for the new CMHC and hospital-based PHP APCs are shown in Table 41 below. The final PHP APC payment rates are included in Addendum A to this final rule with comment period (which is available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html>).

TABLE 41—CY 2017 PHP APC GEOMETRIC MEAN PER DIEM COSTS

CY 2017 APC	Group title	PHP APC geometric mean per diem costs
5853	Partial Hospitalization (3 or more services per day) for CMHCs	\$124.92
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	213.14

3. PHP Ratesetting Process

While PHP services are part of the OPPTS, PHP ratesetting has some unique aspects. To foster understanding and transparency, we provided a detailed explanation of the PHP APC ratesetting process in the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70462 through 70466). The OPPTS ratesetting process includes various steps as part of its data development process, such as CCR determination and calculation of geometric mean per diem costs, identification of allowable charges, development of the APC relative payment weights, calculation of the APC payment rates, and establishment of outlier thresholds. We refer readers to section II. of this final rule with comment period and encourage readers to review these discussions to increase their overall understanding of the entire OPPTS ratesetting process. We also refer readers to the OPPTS Claims Accounting narrative, which is a supporting document to this final rule with comment period, available on the CMS Web site at: [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html)

[Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html); click on the link to this final rule with comment period to find the Claims Accounting narrative. We encourage CMHCs and hospital-based PHPs to review their accounting and billing processes to ensure that they are following these procedures, which should result in greater accuracy in setting the PHP payment rates.

C. Outlier Policy for CMHCs

1. Estimated Outlier Threshold

As discussed in the CY 2004 OPPTS final rule with comment period (68 FR 63469 through 63470), after examining the costs, charges, and outlier payments for CMHCs, we believed that establishing a separate OPPTS outlier policy for CMHCs would be appropriate. A CMHC-specific outlier policy would direct OPPTS outlier payments towards the genuine cost of outlier cases, and address situations where charges were being inflated to enhance outlier payments.

We created a separate outlier policy that would be specific to the estimated

costs and OPPTS payments provided to CMHCs. Beginning in CY 2004, we designated a portion of the estimated OPPTS outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPTS 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 OPPTS/ASC final rule with comment period, we also established an outlier reconciliation policy to address charging aberrations related to OPPTS outlier payments (73 FR 68594 through 68599).

In the CY 2017 OPPTS/ASC proposed rule (81 FR 45675 through 45678), we proposed to continue to designate a portion of the estimated 1.0 percent outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under

the OPSS in CY 2017, excluding outlier payments. CMHCs are projected to receive 0.03 percent of total OPSS payments in CY 2017, 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. Therefore, we proposed to designate less than 0.01 percent of the estimated 1.0 percent 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 2017, in the proposed rule, we proposed to continue to set the cutoff point for CY 2017 at 3.4 times the highest CMHC APC payment rate implemented for that calendar year, which for CY 2017 is the payment rate for new CMHC APC 5853. In addition, we proposed to continue to apply the same outlier payment percentage that applies to hospitals. Therefore, for CY 2017, we proposed to continue to pay 50 percent of CMHC APC geometric mean per diem costs over the cutoff point. For example, for CY 2017, if a CMHC's cost for partial hospitalization services paid under new CMHC APC 5853 exceeds 3.4 times the proposed payment rate for proposed new 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 new CMHC APC 5853.

In section II.G. of the proposed rule, for the hospital outpatient outlier payment policy, we proposed 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 OPSS, and is for providing a defined set of services which are relatively low cost when compared to other OPSS services. As such, it is not necessary to also impose a fixed dollar threshold on CMHCs. Therefore, we did not propose to set a dollar threshold for CMHC outlier payments.

In summary, in this section, we proposed to continue to calculate our CMHC outlier threshold and CMHC outlier payments according to our established policies.

We did not receive any public comments on these proposals, and are finalizing them without modification.

2. CMHC Outlier Cap

a. Summary of Proposal

As discussed in the CY 2017 OPSS/ASC proposed rule (81 FR 45675 through 45678), prior to receipt of CY

2015 preliminary claims data, we analyzed CY 2014 CMHC final claims data and found that CMHC outlier payments began to increase similarly to the way they had prior to CY 2004. While many CMHCs had small outlier payments or no outlier payments, three CMHCs had very high charges for their CMHC services, which resulted in their collecting large outlier payments that exceeded their total per diem payments. CMHC total per diem payments are comprised of the Medicare CMHC total per diem payments and the beneficiary share of those per diem payments. In total, Medicare paid CMHCs \$6.2 million in outlier payments in CY 2014, which was 36 percent of all CMHC total per diem payments. The 36 percent is a stark contrast to the OPSS outlier threshold of 1 percent of total OPSS payments, especially because the CMHC threshold is a fraction of that 1 percent, based on the percentage of projected per diem payments to CMHCs under the OPSS. In CY 2014, three CMHCs accounted for 98 percent of all CMHC outlier payments that year and received outlier payments that ranged from 104 percent to 713 percent of their total per diem payments.

When a CMHC's outlier payments approach or exceed its total per diem payments, it suggests that outlier payments are not being used as intended, specifically for exceptionally high-cost cases, but instead as a routine supplement to the per diem payment because outlier payments are being made for nearly all patients. The OPSS outlier policy is intended to compensate providers for treating exceptionally resource-intensive cases. As we noted in our CY 2004 OPSS/ASC final rule with comment period (68 FR 63470), outlier payments were never intended to be made for all patients and used as a supplement to the per diem payment amount. Sections 1833(t)(5)(A) and (B) of the Act specify that outlier payments are to approximate the marginal cost of care when charges, adjusted to cost, exceed a cutoff point established by the Secretary. As stated previously, for CMHCs, that cutoff point is 3.4 times the highest CMHC APC payment rate (PHP APC 0173). In the CY 2014 claims, that meant a CMHC was eligible for an outlier payment for a given day if the cost for that day was greater than 3.4 times the CMHC APC 0173 payment rate for Level II services, or 3.4 times \$111.73, which equals \$379.88 before wage adjustment.

We examined the total average cost per day for the three CMHCs with outlier payments that were more than 100 percent of their regular payments. In CY 2014, these three CMHCs had a

total average cost per day of \$1,065, which exceeded the FY 2014 unadjusted daily payment rate for inpatient psychiatric care of \$713.19. We do not believe that the cost of a day of intensive outpatient CMHC services, which usually comprises 4 hours of services (mostly group therapy), should equal or exceed the cost of a 24-hour period of inpatient care, which includes 24-hour nursing care, active psychiatric treatment, room and board, drugs, and laboratory tests. Because the outpatient PHP daily payment rate includes payment for fewer items and services than the inpatient psychiatric facility daily payment rate, we believe that the cost of a day of outpatient PHP services should be significantly less than the cost of a day of inpatient psychiatric care. Therefore, we believe that those three CMHCs with total average cost per day of \$1,065 demonstrated excessive outlier payments.

We believe that these excessive outlier payments to some CMHCs are the result of inflated costs, which result from artificially inflated charges. Costs are calculated by multiplying charges by the CCR. The CCR used for calculating outlier payments has established upper limits for hospitals and for CMHCs (we refer readers to the CY 2016 OPSS/ASC final rule with comment period (80 FR 70456) and the Medicare Claims Processing Internet-only Manual, Chapter 4, Section 10.11.9, available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf>). We also believe that these excessive outlier payments do not approximate the marginal cost of care when costs exceed the established cutoff point, as specified in sections 1833(t)(5)(A) and (B) of the Act. The resulting outlier payments would be inappropriate. We are entrusted with accurately paying CMHCs participating in Medicare. Therefore, we are addressing outlier payments resulting from inflated costs. By continuing this pattern of inflated charges for partial hospitalization services, CMHCs will receive a disproportionate share of outlier payments compared to other OPSS providers that do not artificially inflate their charges, thereby limiting outlier payments for truly deserving cases.

Based on our available claims data, we chose to apply 30 percent of total per diem payments as a cutoff point for reasonable outlier payments. In the CY 2014 claims data, the average charge per day for the 3 CMHCs that received outlier payments greater than or equal to 30 percent of their total per diem payments was \$3,233, which was nearly 8 times greater than the average charge

per day for the CMHCs that received outlier payments that were less than 30 percent of their total per diem payments. In our review of CY 2015 claims data for the CY 2017 OPPTS/ASC proposed rule, the average charge per day for the CMHCs that received outlier payments greater than or equal to 30 percent of their total per diem payments was \$1,583, which was more than 3 times greater than the average charge per day for the CMHCs that received outlier payments that were less than 30 percent of their total per diem payments.

In our review of CY 2015 claims data for the CY 2017 proposed rulemaking, Medicare paid CMHCs \$3.2 million in outlier payments, with over 99 percent of those payments made to 4 CMHCs. These outlier payments were 26 percent of all CMHC total per diem payments, and ranged from 39 percent to 179 percent of the individual CMHC's total per diem payments. Total outlier payments to CMHCs decreased from \$6.2 million in CY 2014 to \$3.2 million in CY 2015 because the CMHC that received the largest outlier payments in CY 2014 no longer had outlier payments in CY 2015. This CMHC revised its charge structure downward. However, two additional CMHCs that did not receive outlier payments in CY 2014 began receiving outlier payments in CY 2015 that were greater than or equal to 30 percent of their total payments, which suggests a continuing, if not growing problem.

Under the current outlier reconciliation process, a MAC will reconcile a CMHC's outlier payments at the time of final cost report settlement if the CMHC's CCR has changed by 0.10 or more and if the CMHC received any outlier payments. This process is described in Section 10.7.2, Chapter 4, of the Medicare Claims Processing Manual, which is available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf>. Typically, final cost report settlement occurs within 12 months of the MAC's acceptance of the cost report. However, because cost reports are filed up to 5 months after the CMHC's fiscal year end, CMHC outlier reconciliation can occur more than a year after outlier overpayments are made. Long timeframes between outlier payment and outlier reconciliation at final cost report settlement have also allowed cases with outlier overpayments to continue and to grow. For example, one CMHC with inflated charges in CY 2013 continued to have inflated charges in CY 2014, and received more than double its CY 2013 outlier payments in

CY 2014. This CMHC did not receive outlier payments in CY 2015 because it revised its charge structure downward and, therefore, no longer had costs qualifying for outlier payments.

Although efforts geared towards limiting very high outlier payments to CMHCs are occurring, such as the outlier reconciliation process, these efforts typically occur after the outlier payments are made. We would prefer to focus on stopping questionable outlier payments *before* they occur, to avoid the risk that a provider would be unable to repay Medicare after those overpayments occur. Therefore, we considered whether a broader, supplementary policy change to our CMHC outlier payment policy might also be warranted to mitigate possible billing vulnerabilities associated with very high outlier payments, while at the same time ensuring that we adhere to the existing statutory requirements related to covering the marginal cost of care for exceptionally resource-intensive cases. We want to ensure that CMHCs that provide services that represent the cost of care for legitimate high-cost cases are able to continue to receive outlier payments.

Given these program integrity concerns and our longstanding history of introducing CMHC-specific outlier policies when necessary (the CMHC-specific outlier threshold and the CMHC-specific reconciliation process), we proposed to implement a CMHC outlier payment cap to be applied at the provider level, such that in any given year, an individual CMHC would receive no more than a set percentage of its CMHC total per diem payments in outlier payments. This outlier payment cap would only affect CMHCs, and would not affect other provider types. This outlier payment cap would be in addition to and separate from the current outlier policy and reconciliation policy in effect. We proposed that the CMHC outlier payment cap be set at 8 percent of the CMHC's total per diem payments. As noted previously, each CMHC's total per diem payments are comprised of its Medicare CMHC total per diem payments plus the total beneficiary share of those per diem payments. If implemented, this proposal would mean that a CMHC's total outlier payments in a calendar year could not exceed 8 percent of its total per diem payments in that year.

To determine this CMHC outlier cap percentage, we performed analyses to model the impact that a variety of cap percentages would have on CMHC outlier payments. We want to ensure that any outlier cap policy would not disadvantage CMHCs with truly high-

cost cases that merit an outlier payment, while also protecting the benefit from making payments for outlier cases that exceed the marginal cost of care. In the CY 2017 OPPTS/ASC proposed rule, we used CY 2015 claims data to perform a detailed impact analysis of CMHC outlier payments. That analysis showed that out of 51 CMHCs with paid claims in CY 2015, 9 CMHCs received outlier payments. We separated these 9 CMHCs into 4 CMHCs that received outlier payments that were greater than or equal to 30 percent of their total CMHC payments in CY 2015, and 5 CMHCs that received outlier payments that were less than 30 percent of their total CMHC payments in CY 2015.

In the CY 2017 proposed rule, the 5 CMHCs that received outlier payments that were less than 30 percent of their total per diem payments received a total of \$11,496 in outlier payments. We believe that these 5 CMHCs are representative of the types of CMHCs we are most concerned about that would be disadvantaged with an outlier payment policy that includes a cap at the individual CMHC level. We tested the effects of CMHC outlier caps ranging from 3 percent to 10 percent on these two groups of CMHCs. Our analysis focused on total CMHC per diem payments, total CMHC outlier payments, and percentage reductions in payments if a CMHC outlier payment cap were imposed, as shown in Table 20 of the proposed rule (81 FR 45677).

Table 20 of the proposed rule showed that 4 out of the 5 CMHCs that received outlier payments that were less than 30 percent of their total per diem payments received outlier payments that were less than 1 percent of their total per diem payments and, therefore, would be unaffected by a CMHC outlier payment cap. The fifth CMHC received outlier payments that were 9.4 percent of its total per diem payments and is the only CMHC that would have been affected by a CMHC outlier payment cap applied at the provider level. The effect on this CMHC was shown under the various cap percentage options. At the 8 percent level, this CMHC's outlier payments would have been reduced by \$1,628. A 10-percent cap would have had no effect on this CMHC. The difference in total outlier payments to all CMHCs between the 8 percent and 10 percent cap levels was relatively small (approximately \$58,000).

We also conducted our CMHC outlier cap analysis using final CY 2014 claims data. When we evaluated the effect of the different CMHC provider-level outlier cap percentages on the CMHCs with outlier payments that were less than 30 percent of their total per diem

payments, using the final CY 2014 claims data, we found that 5 CMHCs would be affected by an 8-percent cap, and 4 CMHCs would be affected by a 10-percent cap, with a difference in outlier payments of only \$4,069. However, an 8-percent cap compared to a 10-percent cap saved more than \$37,000 in outlier payments to the CMHCs that were charging excessively (data not shown).

We considered both the CY 2014 and CY 2015 claims data as we sought to balance our concern about disadvantaging CMHCs with our interest in protecting the benefit from excessive outlier payments by proposing an 8-percent CMHC outlier payment cap. An 8-percent CMHC outlier payment cap would mitigate potential inappropriate outlier billing vulnerabilities by limiting the impact of inflated CMHC charges on outlier payments. The 8-percent cap would have reduced outlier payments to the 4 CMHCs that received outlier payments that were greater than or equal to 30 percent of their total per diem payments in CY 2015 by \$3.0 million dollars, or 93.3 percent.

Therefore, for CY 2017 and subsequent years, we proposed to apply a CMHC outlier payment cap of 8 percent to each CMHC's total per diem payments, such that in any given calendar year, an individual CMHC would not receive more than 8 percent of its CMHC total per diem payments in outlier payments.

We invited public comments on the CMHC provider-level outlier cap percentage. We also proposed to revise § 419.43(d) of the regulations by adding a paragraph (7) to require that CMHC outlier payments for the calendar year be subject to a CMHC outlier payment cap, applied at the individual CMHC level, that is, 8 percent of each CMHC's total per diem payments for that same calendar year.

We did not receive any public comments on these proposals.

b. CY 2017 Final Rule Update and Policy

Updated analysis using CY 2015 final claims data for this CY 2017 final rule with comment period continued to show that Medicare paid CMHCs \$3.2 million in outlier payments, with over 99 percent of those payments made to 4 CMHCs. These outlier payments were 23 percent of all CMHC total per diem payments, and ranged from 42 percent to 163 percent of the individual CMHC's total per diem payments. The updated CY 2015 data showed that out of 52 CMHCs with paid claims in CY 2015, 9 CMHCs received outlier payments.

Five CMHCs with outlier payments that were less than 30 percent of their total per diem payments received a total of \$11,643 in outlier payments. Four CMHCs with outlier payments that were greater than or equal to 30 percent of their total per diem payments received \$3.2 million in outlier payments, which was 99.6 percent of all CMHC outlier

payments made in CY 2015. The average charge per day for the 4 CMHCs that received outlier payments that were greater than or equal to 30 percent of their total per diem payments was \$1,566, which was 3 times greater than the average charge per day for the 5 CMHCs that received outlier payments that were less than 30 percent of their total per diem payments.

We tested the effects of CMHC outlier caps ranging from 3 percent to 10 percent on these two groups of CMHCs using the final CY 2015 claims data as shown in Table 42 below. Our analysis focused on total CMHC per diem payments, total CMHC outlier payments, and percentage reductions in payments if a CMHC outlier payment cap were imposed. Because 4 out of the 5 CMHCs that received outlier payments that were less than 30 percent of their total per diem payments received outlier payments that were less than 1 percent of their total per diem payments, Table 42 below shows that these providers would be unaffected by a CMHC outlier payment cap. The fifth CMHC with outlier payments that were less than 30 percent of its total per diem payments received outlier payments that were 8.0 percent of its total per diem payments. This CMHC would not have been affected by an 8 percent or 10 percent CMHC outlier payment cap applied at the provider level because its outlier payments did not exceed 8 or 10 percent.

TABLE 42—EFFECT OF CMHC OUTLIER CAP SIMULATION ON OUTLIER PAYMENTS

	Simulated CMHC outlier payments using final CY 2015 claims data						
	Total per diem payments	Actual outlier payments	3% cap	5% cap	6% cap	8% cap	10% cap
All 52 CMHCs	\$14,022,861	\$3,245,624
Outlier Payments <30% of Total Per Diem Payments							
Total Actual Payments (n = 5)	\$1,419,316	11,643
Simulated Outlier Payments	\$4,869	\$7,581	\$8,936	\$11,643	\$11,643
Reduction in Outlier Payments	\$6,775	\$4,063	\$2,707
% Reduction	58.2%	34.9%	23.2%	0.0%	0.0%
CMHCs Affected	1	1	1
Outlier Payments ≥30% of Total Per Diem Payments							
Total Actual Payments (n = 4)	\$3,154,279	\$3,233,981
Simulated Outlier Payments	\$94,628	\$157,714	\$189,257	\$252,342	\$315,428
Reduction in Outlier Payments	\$3,150,996	\$3,087,910	\$3,056,367	\$2,993,282	\$2,930,196
% Reduction	97.4%	95.5%	94.5%	92.6%	90.6%
CMHCs Affected	4	4	4	4	4

As noted in the CY 2017 OPPS/ASC proposed rule, we sought to balance our concern about disadvantaging CMHCs with our interest in protecting the

benefit from excessive outlier payments by proposing an 8-percent CMHC outlier payment cap. The updated CY 2015 claims data for this final rule with

comment period shows that an 8-percent CMHC outlier payment cap would mitigate potential inappropriate outlier billing vulnerabilities by limiting

the impact of inflated CMHC charges on outlier payments. The 8-percent cap would have reduced outlier payments to the CMHCs that received outlier payments that were greater than or equal to 30 percent of their total per diem payments in CY 2015 by \$3.0 million dollars, or 92.6 percent, without affecting any of the CMHCs that received outlier payments that were less than 30 percent of their CY 2015 total per diem payments.

We did not receive any public comments on our proposals and are finalizing them as proposed. As we noted in the proposed rule, our existing outlier reconciliation policy will continue to remain in effect with the final 8 percent CMHC outlier payment cap serving as a complement. We also are finalizing our proposed revision of § 419.43(d) of the regulations by adding a paragraph (7) to require that CMHC outlier payments for the calendar year be subject to a CMHC outlier payment cap, applied at the individual CMHC level, that is, 8 percent of each CMHC's total per diem payments for that same calendar year.

We will continue to monitor the trends in outlier payments and also monitor these policy effects. Also, we will analyze CMHC outlier payments at the provider level, relative to the 8 percent CMHC outlier cap. Finally, we will continue to utilize program integrity efforts, as necessary, for those CMHCs receiving excessive outlier payments.

3. Implementation Strategy for the 8-Percent Cap on CMHC Outlier Payments

CMS envisions that the 8-percent CMHC cap on outlier payments will be managed by the claims processing system. We will provide detailed information on our implementation strategy through sub-regulatory channels. However, to foster a clearer understanding of the CMHC outlier payment cap, we are providing the following high-level summary of the preliminary approach we envision.

For each CMHC, for a given calendar year, the claims processing system will maintain a running tally of year-to-date (YTD) total CMHC per diem payments (Medicare payments and the beneficiary share) and YTD actual CMHC outlier payments. YTD outlier payments for that calendar year could never exceed 8 percent of YTD CMHC total per diem payments for that CMHC for that calendar year. For example, we will determine whether or not a given provider-specific outlier payment exceeds the 8-percent cap on a "rolling" basis. Under such an implementation approach, for each CMHC, the claims

processing system will maintain a running tally of the YTD total CMHC per diem payments. The claims processing system will ensure that each time an outlier claim for a CMHC is processed, actual outlier payments will never exceed 8 percent of the CMHC's YTD total payments. While a CMHC will receive its per diem payment timely, the outlier portion of the claim will be paid as the CMHC's YTD payments support payment of the outlier. As part of our routine claims processing, we will utilize a periodic review process under which outlier payments that were withheld will subsequently be paid if the CMHC's total payments have increased to the point that its outlier payments can be made. This process will result in additional cash flow to CMHCs. As noted previously, we will also maintain our existing outlier reconciliation policy, which is applied at the time of cost report final settlement if the CMHC's CCR changed by 0.10 or more. With regard to revenue tracking by CMHCs, distinct coding will be used on the CMHC's remittance advice when outlier payments are withheld, assisting receivables accountants in identifying and accounting for the differences between expected and actual payments.

4. Summary of Policies

In summary, for CY 2017, we are finalizing our proposals to:

- Continue to designate a portion of the estimated 1.0 percent outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPSS in CY 2017, excluding outlier payments;
- Implement an 8-percent cap on CMHC outlier payments at the individual CMHC provider level for CY 2017 and subsequent years and change the regulations at § 419.43(d) accordingly;
- Continue to set the cutoff point for CMHC outlier payments in CY 2017 at 3.4 times the highest CMHC APC payment rate implemented for that calendar year, which for CY 2017 is new CMHC APC 5853; and
- Continue to pay 50 percent of CMHC APC geometric mean per diem costs over the cutoff point in CY 2017.

We believe that these CMHC outlier policies will minimize the impact of inflated CMHC charges on outlier payments, result in a better approximation of the marginal cost of care beyond the applicable cutoff point compared to the current process, and better target outlier payments to truly exceptionally high-cost cases.

IX. Procedures That Will Be Paid Only as Inpatient Procedures

A. Background

We refer readers to the CY 2012 OPSS/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 OPSS, and on the criteria that we use to review the IPO list each year to determine whether or not any procedures should be removed from the list. The complete list of codes (IPO list) that will be paid by Medicare in CY 2017 as inpatient only procedures is included as Addendum E to this final rule with comment period (which is available via the Internet on the CMS Web site).

B. Changes to the Inpatient Only (IPO) List

In the CY 2017 OPSS/ASC proposed rule (81 FR 45678 through 45679), for CY 2017, we proposed 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. The established criteria upon which we make such a determination are as follows:

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 proposed to remove the following six codes (four spine procedure codes and two laryngoplasty codes) from the IPO list for CY 2017:

- CPT code 22840 (Posterior non-segmental instrumentation (e.g., Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List

separately in addition to code for primary procedure));

- CPT code 22842 (Posterior segmental instrumentation (eg., pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments (List separately in addition to code for primary procedure));
- CPT code 22845 (Anterior instrumentation; 2 to 3 vertebral segments (List separately in addition to code for primary procedure));
- CPT code 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));
- CPT code 31584 (Laryngoplasty; with open reduction of fracture); and
- CPT code 31587 (Laryngoplasty, cricoid split).

We reviewed the clinical characteristics of the four spine procedure codes and related evidence, including input from multiple physician specialty societies whose members specialize in spine surgery, and determined the four spine procedure codes listed above to be appropriate candidates for removal from the IPO list. These four spine procedure codes are add-on codes to procedures that are currently performed in the HOPD and describe variations of (including additional instrumentation used with) the base code procedure. Therefore, we believe these spine procedures satisfy criterion 3 listed above as they are related to codes that we have already removed from the IPO list. Because these four spine procedure codes are add-on codes, in accordance with the regulations at 42 CFR 419.2(b)(18), we proposed to package them with the associated procedure and assign them status indicator "N."

We also reviewed the clinical characteristics of the two laryngoplasty procedure codes and related evidence, and determined that the two laryngoplasty procedure codes listed above are appropriate candidates for removal from the IPO list because we believe they satisfy criterion 3 listed above (that is, the procedure is related to codes that we have already removed from the IPO list). These two codes are related to and clinically similar to CPT code 21495 (Open treatment of hyoid fracture), which is currently not on the IPO list. We proposed that the two laryngoplasty procedure codes would be assigned to APC 5165 (Level 5 ENT Procedures) with status indicator "J1."

Comment: Several commenters supported the proposal to remove CPT codes 22840, 22842, 22845, 22858, 31584, and 31587 from the IPO list for CY 2017. One commenter opposed the proposal to remove these codes from the IPO list, stating that although the spine codes were add-on codes for procedures currently performed in the HOPD, these codes represented variations in the instrumentation used which made them more complex than the base code procedures. The commenter also believed that the two laryngoplasty codes were too complex to be performed in the HOPD.

Another commenter opposed the removal of CPT codes 31584 and 31587 from the IPO list, stating that these procedures often require prolonged use of intravenous pain medications and close monitoring of drainage tubes. The commenter also stated that both procedures frequently involve patient admission to the intensive care unit postoperatively, as they warrant assessments of respiratory status and oxygenation at frequent intervals to evaluate for postoperative swelling.

Response: We appreciate the commenters' support. We disagree with the commenter that CPT codes 22840, 22842, 22845, 22858, 31584, and 31587 should remain on the IPO list. As discussed in the CY 2017 OPPS/ASC proposed rule (81 FR 45678 through 45679), we believe that these codes satisfy criterion 3 for removal from the IPO list; that is, being a procedure that is related to codes that we have already removed from the IPO list. We remind the commenter and the public that removal of a code from the IPO list does not mean that all procedures described by the code or even a majority of procedures must or should be performed in the outpatient setting. Removal of a procedure from the IPO list only means that the procedure is no longer precluded from being paid under the OPPS if it is performed in the outpatient setting. The cases that the commenters are concerned about can all still be performed on an inpatient basis if appropriate.

Comment: Several commenters disagreed with the proposal to package the four spine codes proposed to be removed from the IPO list with associated procedure and assign them status indicator "N." The commenters requested that CMS allow for separate payment for these procedures.

Response: As specified in 42 CFR 419.2(b)(18), services described by add-on codes are packaged costs that are integral, ancillary, supportive, dependent, or adjunctive to performing a procedure or furnishing a service on

an outpatient basis. The procedures described by the four spine codes are all procedures described by add-on codes. The costs for the procedures described by these codes are included in the payment rate for the related procedure or service. Therefore, we will not provide separate payment for these codes.

Comment: Other commenters requested that the following additional codes be removed from the IPO list:

- CPT code 22585 (Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophyctomy, and decompression of spinal cord and/or nerve roots; each additional interspace (List separately in addition to code for primary procedure));
- CPT code 22633 (Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar);
- CPT code 22850 (Removal of posterior nonsegmental instrumentation (eg., Harrington rod);
- CPT code 23472 (Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (eg., total shoulder); and
- CPT code 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft).

Response: We agree with the commenter at this time only for removal of the procedure described by CPT code 22585, which is an add-on code, from the IPO list. The base code for CPT code 22585, CPT code 22554 (Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2), is assigned to APC 5115 (Level 5 Musculoskeletal Procedures). We believe that cases involving CPT codes 22554 and 22585 are sufficiently comparable to cases involving only CPT code 22554, such that it is appropriate to remove CPT code 22585 from the IPO list. Because CPT code 22585 is an add-on code, it is being assigned status indicator "N." After reviewing the clinical characteristics of these procedures described by CPT codes 22633, 22850, 23472, and 27130, we do not believe that removal from the IPO list is warranted at this time.

After consideration of the public comments we received, we are removing CPT codes 22585, 22840, 22842, 22845, 22858, 31584, and 31587 from the IPO

list for CY 2017. The complete list of codes (the IPO list) that will be paid by Medicare in CY 2017 as inpatient only procedures is included as Addendum E to this final rule with comment period (which is available via the Internet on the CMS Web site).

C. Response To Solicitation of Public Comments on the Possible Removal of Total Knee Arthroplasty (TKA) Procedure From the IPO List

1. Background

Total knee arthroplasty (TKA) or total knee replacement, CPT code 27447 (Arthroplasty, knee, condyle and plateau; medial and lateral compartments with or without patella resurfacing (total knee arthroplasty)), has traditionally been considered an inpatient surgical procedure. The procedure described by CPT code 27447 was placed on the original IPO list in the 2000 OPSS final rule (65 FR 18781). 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 18443 and 18455). In 2000, the geometric mean average length of stay for the DRG to which an uncomplicated TKA procedure was assigned was 4.6 days, and in 2016, the average length of stay for a current uncomplicated TKA procedure for the MS-DRG is 2.8 days.

Recent innovations have enabled surgeons to perform TKA on an outpatient basis on non-Medicare patients (both in the HOPD and in the ASC). In this context, "outpatient" services include both same day outpatient surgery (that is, the patient goes home on the same day that the outpatient surgery was performed) and outpatient surgery that includes one overnight hospital stay for recovery from the surgery. These innovations in TKA care include minimally invasive techniques, improved perioperative anesthesia, alternative postoperative pain management, and expedited rehabilitation protocols. Patients generally benefit from a shorter hospital stay. Some of these benefits 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, TKA needs 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 would likely be good candidates for an outpatient TKA procedure. On the other hand, patients with severe illnesses 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 TKA procedures with us have emphasized the importance of careful patient selection and strict protocols to optimize outpatient TKA 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 and ambulation.

In the CY 2013 OPSS/ASC proposed rule (77 FR 45153), we proposed to remove the procedure described by CPT code 27447 from the IPO list. We proposed to remove the procedure described by CPT code 27447 from the IPO list because we believed that the procedure could be appropriately provided and paid for as a hospital outpatient procedure for some Medicare beneficiaries, based upon the five evaluation criteria for removal from the IPO list discussed earlier. The public comments we received on the CY 2013 proposal varied. There were several surgeons and other stakeholders who supported the proposal. They believed that, given thorough preoperative screening by medical teams with significant experience and expertise involving knee replacement procedures, the TKA procedure could be provided on an outpatient basis for some Medicare beneficiaries. These commenters discussed recent advances in total knee replacement technology and surgical care protocols, including improved perioperative anesthesia, and expedited rehabilitation protocols, as well as significant enhancements to the postoperative process, such as improvements in pain management, early mobilization, and careful monitoring. These commenters also stated that early preventive intervention for the most common medical complications has decreased the average length of hospital stays to the point that a TKA procedure can now be performed on an outpatient basis in certain cases. The 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 furnishing a TKA procedure on an outpatient basis will lead to significant enhancements in patient well-being and cost savings to the Medicare program, including shorter hospital stays resulting in fewer medical complications, improved results, and enhanced patient satisfaction. However, the majority of the commenters disagreed with the CY 2013 proposal and believed that it would be unsafe to perform outpatient TKA for Medicare beneficiaries. (We refer readers to 77 FR 68419 for a discussion of these comments.) After consideration of these public comments, we decided not to finalize the proposal, and the procedure described by CPT code 27447 remains on the IPO list.

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. Discussion of TKA and the IPO List

Since 2000, when the IPO list was established, there have been significant developments in both TKA technique and patient care. The advances in TKA technique and patient care are discussed in general terms above. As noted above, in 2000, the criteria by which procedures were reviewed to determine IPO list assignment 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.

In order to discuss the possibility of removing TKA procedures from the IPO list, we believe it is helpful to explore each of these criteria in turn as they apply to present-day TKA. In the CY 2017 OPPS/ASC proposed rule (81 FR 45680), we solicited comment from the public on a list of questions that relate to considering removing TKA from the IPO list in the future.

The first criterion was “the invasive nature of the procedure.” We elaborated on this criterion in the 2000 OPPS final rule by stating: “We believe that certain surgically invasive procedures on the brain, heart, and abdomen, such as craniotomies, coronary artery bypass grafting, and laparotomies, indisputably require inpatient care, and therefore are outside the scope of outpatient services” (65 FR 18456). TKA does not invade the brain, heart, or abdomen; instead, like several other outpatient orthopedic surgeries, it is an operation on the knee joint. A similar procedure described by CPT code 27446 (Arthroplasty, knee, condyle and plateau; medical OR lateral compartment) (unicompartmental knee replacement) was removed from the IPO list on January 1, 2002, and also was added to the ASC covered surgical procedures list in 2008. The degree of invasiveness of TKA as compared to other major surgical procedures would not appear to prohibit its removal from the IPO list.

The second IPO list criterion from the 2000 OPPS final rule is “the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged.” Currently, for procedures that are not on the IPO list, services furnished to patients requiring 24 hours of postoperative recovery time may be payable as either outpatient services or inpatient services, depending on the condition of the patient. Therefore, the need for at least 24 hours of postoperative recovery time or monitoring in many cases should not require IPO list placement.

The third criterion is “the underlying physical condition of the patient who would require the surgery.” For this criterion to be the basis of an IPO list assignment seems to presume a relatively homogeneous and morbid patient population undergoing the surgical procedure. Otherwise, patients with a good underlying physical condition could be considered for outpatient surgery while those with a poor underlying physical condition might be more appropriate for inpatient admission. TKA candidates, although they all have osteoarthritis severe enough to warrant knee replacement, are a varied group in which the anticipated length of hospitalization is

dictated more by comorbidities and diseases of other organ systems. Some patients may be appropriate for outpatient surgery while others may be appropriate for inpatient surgery.

3. Topics and Questions for Public Comment

In the CY 2017 OPPS/ASC proposed rule (81 FR 45680), we sought public comments on whether we should remove the procedure described by CPT code 27447 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 TKA procedures; hospitals and hospital trade associations; and any other interested stakeholders. We sought public comments on any of the topics discussed earlier in addition to the following questions:

1. Are most outpatient departments equipped to provide TKA to some Medicare beneficiaries?

2. Can the simplest procedure described by CPT code 27447 be performed in most outpatient departments?

3. Is the procedure described by CPT code 27447 sufficiently related to or similar to the procedure described by CPT code 27446 such that the third criterion listed at the beginning of this section for identifying procedures that may be removed from the IPO list, that is, the procedure under consideration for removal from the IPO list is related to codes that we have already removed from the IPO, is satisfied?

4. How often is the procedure described by CPT code 27447 being performed on an outpatient basis (either in an HOPD or ASC) on non-Medicare patients?

5. 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 a TKA procedure as a hospital outpatient, which may or may not include a 24-hour period of recovery in the hospital after the operation?

6. CMS is currently testing two episode-based payment models that include TKA: The Comprehensive Care for Joint Replacement (CJR) Model and the Bundled Payment for Care Improvements (BPCI) Model. These models hold hospitals and, in the case of the BPCI, physicians and postacute care providers, responsible for the quality and cost of an episode of care. Providers participating in the CJR model or BPCI Models 2 and 4 initiate episodes

with admission to the hospital of a beneficiary who is ultimately discharged under an included MS-DRG. Both initiatives include MS-DRGs 469 (Major Joint Replacement or Reattachment of Lower Extremity with MCC) and 470 (Major Joint Replacement or Reattachment of Lower Extremity without MCC). Depending on the model, the episode ends 30 to 90 days postdischarge in order to cover the period of recovery for beneficiaries. Episodes include the inpatient stay and all related items and services paid under Medicare Part A and Part B for all Medicare fee-for-service (FFS) beneficiaries, with the exception of certain exclusions.

In the BPCI and CJR models, services are paid on an FFS basis with a retrospective reconciliation for all episodes included in a defined time period (quarterly in BPCI and annually in CJR). At reconciliation, actual spending is compared to a target price. The target price is based on historical episode spending. If CMS were to remove the procedure described by CPT code 27447 from the IPO list and pay for outpatient TKA procedures, the historical episode spending data may no longer be an accurate predictor of episode spending for beneficiaries receiving inpatient TKA procedures. As such, establishing an accurate target price based on historical data would become more complicated. This is because some patients who previously would have received a TKA procedure in an inpatient setting may receive the procedure on an outpatient basis if the procedure is removed from the IPO list.

We sought public comment on how CMS could modify the CJR and BPCI models if the TKA procedure were to be moved off the IPO list. Specifically, we sought public comment on how to reflect the shift of some Medicare beneficiaries from an inpatient TKA procedure to an outpatient TKA procedure in the BPCI and CJR model pricing methodologies, including target price calculations and reconciliation processes. Some of the issues CMS faces include the lack of historical data on both the outpatient TKA episodes and the average episode spending for beneficiaries who would continue to receive the TKA procedure on an inpatient basis. Because historically the procedure described by CPT code 27447 has been on the IPO list, there is no claims history for beneficiaries receiving TKA on an outpatient basis. In addition, we sought public comment on the postdischarge care patterns for Medicare beneficiaries that may receive an outpatient TKA procedure if it were removed from the IPO list and how this

may be similar or different from these beneficiaries' historical postdischarge care patterns. For example, Medicare beneficiaries who are appropriate candidates for an outpatient TKA procedure may be those who, in the past, would have received outpatient physical therapy services as follow-up care after an inpatient TKA procedure. CMS would need to develop a methodology to ensure model target prices account for the potentially higher risk profiles of Medicare beneficiaries who would continue to receive TKA procedures in inpatient settings.

Comment: Numerous comments responded to CMS' solicitation for discussion of the removal of TKA from the IPO list. The overwhelming majority of the commenters (which included organizations and individuals) supported removing TKA from the IPO list. The commenters who supported the removal of TKA from the IPO list included ASCs, therapeutic professional associations, hospital associations, as well as many surgeons. 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. Several organizations cited innovations such as less invasive surgical techniques, improved perioperative anesthesia, alternative postoperative pain management, expedited rehabilitation protocols, and the similarity of the TKA procedure to other procedures currently being performed as outpatient services (namely CPT code 27446 (Unicompartmental Knee Arthroplasty)) as reasons to remove the procedure from the IPO list. Most organizations in support of the removal of TKA from the IPO list noted that an appropriate patient selection protocol should be used to determine the patients who are best suited for outpatient joint replacement. Some commenters requested that total hip arthroplasty and total shoulder replacement procedures also be removed from the IPO list.

A few commenters representing professional organizations, health systems, and hospital associations, opposed the removal of a TKA procedure from the IPO list. These commenters believed that the increased likelihood that Medicare patients have comorbidities that require the need for intensive rehabilitation after a TKA procedure preclude this procedure from being performed in the outpatient setting. They also stated that most outpatient departments are not currently equipped to provide TKA procedures to Medicare beneficiaries, which require exceptional patient selection,

exceptional surgical technique, and a carefully constructed postoperative care plan. One commenter opined that only exceptional surgeons can perform outpatient TKA procedures, and, for this reason, CMS should not pay for TKA procedures performed in an outpatient setting. One commenter believed that the procedure described by CPT code 27446 can be performed through a much smaller and limited incision than required by CPT code 27447 and, therefore, was a less complex procedure.

Other commenters were concerned about the implications that the removal of the TKA procedure from the IPO list would have for the pricing methodologies, target pricing, and reconciliation process of the procedure in certain Medicare payment models (that is, the Comprehensive Care for Joint Replacement and the Bundled Payments for Care Improvement models). They requested modifications to these models if the TKA procedure is removed from the IPO list.

Response: We thank the stakeholder public for the many detailed comments on this topic. We will consider all of these comments in future policy making.

X. Nonrecurring Policy Changes

A. Implementation of Section 603 of the Bipartisan Budget Act of 2015 Relating to Payment for Certain Items and Services Furnished by Off-Campus Provider-Based Departments of a Hospital

1. Background

When a Medicare beneficiary receives services in an off-campus department of a hospital, the total payment amount for the services made by Medicare is generally higher than the total payment amount made by Medicare when the beneficiary receives those same services in a physician's office. Medicare pays a higher amount for services furnished to beneficiaries in the off-campus department of a hospital because it generally pays two separate claims for these services—one under the OPSS for the institutional services and one under the MPFS for the professional services furnished by a physician or other practitioner. Medicare beneficiaries are responsible for the cost-sharing liability, if any, for both of these claims, often resulting in higher total beneficiary cost-sharing than if the service had been furnished in a physician's office.

In the CY 2017 OPSS/ASC proposed rule (81 FR 45681), we discussed the provision of section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted on November 2, 2015, which amended section 1833(t) of the

Act. Specifically, this provision amended the OPSS statute at section 1833(t) 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 OPSS and will instead be paid “under the applicable payment system” under Medicare Part B if the requirements for such payment are otherwise met. We note that, in order to be considered part of a hospital, an off-campus department of a hospital must meet the provider-based criteria established under 42 CFR 413.65. Accordingly, in the proposed rule and this final rule with comment period, we refer to an “off-campus outpatient department of a provider,” which is the term used in section 603, as an “off-campus outpatient provider-based department” or an “off-campus PBD.”

As noted earlier, section 603 of Public Law 114–74 made two amendments to section 1833(t) of the Act—one amending paragraph (1)(B) and the other adding new paragraph (21). The provision amended section 1833(t)(1)(B) by adding a new clause (v), which excludes from the definition of “covered OPD services” applicable items and services (defined in paragraph (21)(A) of such section) that are furnished on or after January 1, 2017 by an off-campus PBD, as defined in paragraph (21)(B) of such section. The second amendment added a new paragraph (21) to section 1833(t) of the Act, which defines the terms “applicable items and services” and “off-campus outpatient department of a provider,” requires the Secretary to make payments for such applicable items and services furnished by an off-campus PBD under an applicable payment system (other than OPSS), provides that hospitals shall report on information as needed for implementation of the provision, and establishes a limitation on administrative and judicial review on certain determinations for applicable items and services, applicable payment system, and off-campus outpatient department of a provider, and information required to be reported.

In defining the term “off-campus outpatient department of a provider,” section 1833(t)(21)(B)(i) of the Act specifies that the term means a department of a provider (as defined at 42 CFR 413.65(a)(2) as that regulation was in effect on November 2, 2015, the

date of enactment of Pub. L. 114–74) that is not located on the campus of such provider, or within the distance from a remote location of a hospital facility. Section 1833(t)(21)(B)(ii) of the Act excepts from the definition of “off-campus outpatient department of a provider,” for purposes of paragraphs (1)(B)(v) and (21)(B) of such section, an off-campus PBD that was billing under section 1833(t) with respect to covered OPD services furnished prior to the date of enactment of Public Law 114–74, that is, November 2, 2015. In the CY 2017 OPPTS/ASC proposed rule, we proposed to refer to this exception as providing “excepted” status to certain off-campus PBDs and certain items and services furnished by such excepted off-campus PBDs, which would continue to be paid under the OPPTS. Moreover, because the definition of “applicable items and services” specifically excludes items and services furnished by a dedicated emergency department as defined at 42 CFR 489.24(b) and the definition of “off-campus outpatient department of a provider” does not include PBDs located on the campus of a hospital or within the distance (described in the definition of campus at 413.65(a)(2)) from a remote location of a hospital facility, the items and services furnished by these excepted off-campus PBDs on or after January 1, 2017 will continue to be paid under the OPPTS.

In the CY 2017 OPPTS/ASC proposed rule (81 FR 45681), we proposed to make a number of proposals to implement section 603 of Public Law 114–74. Broadly, we proposed to do three things: (1) Define applicable items and services in accordance with section 1833(t)(21)(A) of the Act for purposes of determining whether such items and services are covered OPD services under section 1833(t)(1)(B)(v) of the Act or whether payment for such items and services shall instead be made under section 1833(t)(21)(C) of the Act; (2) define off-campus PBD for purposes of sections 1833(t)(1)(B)(v) and (t)(21) of the Act; and (3) establish policies for payment for applicable items and services furnished by an off-campus PBD (nonexcepted items and services) under section 1833(t)(21)(C) of the Act. To do so, we proposed policies that would define whether certain items and services furnished by a given off-campus PBD may be considered excepted and, thus, continue to be paid under the OPPTS; establish the requirements for the off-campus PBDs to maintain excepted status (both for the excepted off-campus PBD and for the items and services furnished by such excepted off-campus PBDs); and

describe the applicable payment system for nonexcepted items and services. In addition, we solicited public comments on information collection requirements for implementing this provision in accordance with section 1833(t)(21)(D) of the Act.

There is no legislative history on record regarding section 603 of Public Law 114–74. However, the Congressional Budget Office estimated program savings for this provision of approximately \$9.3 billion over a 10-year period. In January 2016, we posted a notice on the CMS Web site that informed stakeholders that we expected to present our proposals for implementing section 603 of Public Law 114–74 in the CY 2017 OPPTS/ASC proposed rule. Because we had already received several inquiries or suggestions from stakeholders regarding implementation of the section 603 provision, we provided a dedicated email address for stakeholders to provide information they believed was relevant in formulating the proposals in the proposed rule. We stated in the proposed rule that we had considered this stakeholder feedback in developing the proposed policies.

Comment: Numerous commenters urged CMS to delay implementation of the section 603 provisions to allow the agency additional time to develop policies that would not impose undue burden on CMS and hospitals. The commenters stated that if all of the proposals related to section 603 are adopted as final without modification, hospitals may not be able to continue to provide the current level of health care necessary in their communities. Commenters who support a delay posited that the delay would provide additional time to collect data that would inform “implementation” of section 603. In addition, commenters stated that there is precedence for CMS to delay implementation of legislative provisions, even if the legislation includes a deadline for enactment. The commenters cited the following as examples of CMS delaying implementation of legislative provisions:

- Hospital Outpatient Prospective Payment System for 18 months, from January 1, 1999 to July 1, 2000;
- Ambulance Fee Schedule for 27 months, from January 1, 2000 to April 1, 2002; and
- Medicare Clinical Diagnostic Laboratory Tests Payment System for 12 months, from January 1, 2017 to January 1, 2018.

Response: As discussed in detail later in this final rule with comment period, we are not delaying implementation of

the section 603 provisions of Public Law 114–74, and are finalizing implementation of the provisions, effective January 1, 2017, in this final rule with comment period. In addition, in an interim final rule with comment period presented under section X.B. of this document, we are establishing payment rates under the MPFS to be used by hospitals for billing for nonexcepted items and services. With respect to the comment that a delay would enable CMS to collect appropriate data; we disagree. As discussed in section X.A.3.b.(2) of this final rule with comment period and also in the interim final rule with comment period in section X.B. of this document, we are establishing a modifier for use by hospitals to bill on their claim to identify nonexcepted items and services beginning January 1, 2017. These claims-based data will prove useful for making payment for nonexcepted items and services under the MPFS beginning in January 2017 and will be helpful over time as Medicare is able to collect and analyze hospital data on nonexcepted items and services and use that information to refine payment for nonexcepted items and services. Accordingly, we do not agree with commenters that a delay is appropriate. Moreover, we note that the law requires the section 603 provisions to take effect January 1, 2017.

Comment: MedPAC commended CMS’ effort to “rigorously implement” section 603 and further stated that if CMS finalized the proposed policies, it believed the policies would have the potential to reduce the financial burden on taxpayers and beneficiaries, although there would likely be substantial administrative burdens on the agency, its contractors and providers. Other commenters generally supported the proposed policies and believed that the proposals would reduce the incentive for hospitals to purchase physician’s offices and convert them to HOPDs without changing their location or patient population.

Response: We appreciate the commenters’ support. We summarize and respond to public comments on specific proposals within the appropriate sections below.

2. Defining Applicable Items and Services and an Off-Campus Outpatient Department of a Provider as Set Forth in Sections 1833(t)(21)(A) and (B) of the Act

a. Background on the Provider-Based Status Rules

Since the beginning of the Medicare program, some hospitals, which we refer

to as “main providers,” have functioned as a single entity while owning and operating multiple departments, locations, and facilities. Having clear criteria for provider-based status is important because this designation can result in additional Medicare payments under the OPSS for services provided at the provider-based facility and may also increase the coinsurance liability of Medicare beneficiaries receiving those services versus if those same services were furnished in a physician’s office. The current criteria for provider-based status are located in the regulations at 42 CFR 413.65.

When a facility or organization has provider-based status, it is considered to be part of the hospital. The hospital as a whole, including all of its PBDs, must meet all Medicare conditions of participation and conditions of payment that apply to hospitals. In addition, a hospital bills for services furnished by its provider-based facilities and organizations using the CMS Certification Number of the hospital. One type of facility or organization that a hospital may treat as provider-based is an off-campus outpatient department. In order for the hospital to do so, the off-campus outpatient department must meet certain requirements under 42 CFR 413.65, including, but not limited to:

- It generally must be located within a 35-mile radius of the campus of the main hospital;
- Its financial operations must be fully integrated within those of the main provider;
- Its clinical services must be integrated with those of the main hospital (for example, the professional staff at the off-campus outpatient department must have clinical privileges at the main hospital, the off-campus outpatient department medical records must be integrated into a unified retrieval system (or cross reference) of the main hospital), and patients treated at the off-campus outpatient department who require further care must have full access to all services of the main hospital;
- It is held out to the public as part of the main hospital.

Section 603 of Public Law 114–74 makes certain distinctions with respect to whether a department of the hospital is “on” campus or “off” campus and also excludes from the definition of “off-campus outpatient department of a provider” a department of a provider within the distance from a remote location of a hospital facility. Below we provide some details on the definitions of the terms “campus” and “remote locations.”

Section 413.65(a)(2) of the regulations defines a “campus” as “[T]he physical area immediately adjacent to the provider’s main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS Regional Office, to be part of the provider’s campus.”

In developing the provider-based rules, CMS also recognized that many hospitals operated fully integrated, though geographically separate, inpatient facilities. While the initial scope of provider-based rulemaking primarily concerned situations with outpatient departments, we believed the policies set forth were equally applicable to inpatient facilities. Therefore, CMS also finalized a regulatory definition for a “remote location of a hospital” at 42 CFR 413.65(a)(2) as “a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A remote location of a hospital comprises both the specific physical facility that serves as the site of services for which separate payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. The Medicare conditions of participation do not apply to a remote location of a hospital as an independent entity. For purposes of this part, the term ‘remote location of a hospital’ does not include a satellite facility as defined in §§ 412.22(h)(1) and 412.25(e)(1) of this chapter.”

Under the provider-based rules, we consider these inpatient “remote locations” to be “off-campus,” and CMS reiterated this position in the FY 2003 IPPS/LTCH PPS final rule (67 FR 50081 through 50082). Hospitals that comprise several sites at which both inpatient and outpatient care are furnished are required to designate one site as its “main” campus for purposes of the provider-based rules. Thus, any facility not located on that main campus (generally within 250 yards) is considered “off-campus” and must satisfy the provider-based rules in order to be treated by the main hospital as provider-based. For Medicare purposes, a hospital that wishes to add an off-campus PBD must submit an amended Medicare provider enrollment form detailing the name and location of the

provider-based facility within 90 days of adding the new facility to the hospital. In addition, a hospital may ask CMS to make a determination that a facility or organization has provider-based status by submitting a voluntary attestation to its MAC, for final review by the applicable CMS Regional Office, attesting that the facility meets all applicable provider-based criteria in the regulations. If no attestation is submitted and CMS later determines that the hospital treated a facility or organization as provider-based when the facility or organization did not meet the requirements for provider-based status, CMS will recover the difference between the amount of payments actually made to the hospital and the amount of payments that CMS estimates should have been made for items and services furnished at the facility in the absence of compliance with the provider-based requirements for all cost reporting periods subject to reopening. However, if the hospital submits a complete attestation of compliance with the provider-based status requirement for a facility or organization that has not previously been found by CMS to have been inappropriately treated as provider based, but CMS subsequently determines that the facility or organization does not meet the requirements for provider-based status, CMS will recover the difference between the amount of payments actually made to the hospital since the date the attestation was submitted and the amount of payments that CMS estimates should have been made in the absence of compliance with the provider-based requirements.

Historically, PBDs billed as part of the hospital and could not be distinguished from the main hospital or other PBDs within the claims data. In CY 2015 OPSS/ASC final rule with comment period (79 FR 66910 through 66914), CMS adopted a voluntary claim modifier “PO” to identify services furnished in off-campus PBDs (other than emergency departments, remote locations and satellite locations of the hospital) to collect data that will help identify the type and costs of services typically furnished in off-campus PBDs. Based on the provision in the CY 2015 OPSS/ASC final rule with comment period, use of this modifier became mandatory beginning in CY 2016. While the modifier identifies that the service was provided in an off-campus PBD, it does not identify the type of off-campus PBD in which services were furnished, nor does it distinguish between multiple off-campus PBDs of the same hospital. As discussed in section X.A.2.e. of this

final rule with comment period, in the CY 2017 OPPS/ASC proposed rule, we solicited public comments on the type of information that would be needed to identify nonexcepted off-campus PBDs for purposes of section 603, although we did not propose to collect such information for CY 2017.

b. Exemption of Items and Services Furnished in a Dedicated Emergency Department or by an Off-Campus PBD as Defined at Sections 1833(t)(21)(B)(i)(I) and (II) of the Act (Excepted Off-Campus PBD)

(1) Dedicated Emergency Departments (EDs)

Section 1833(t)(21)(A) of the Act specifies that, for purposes of paragraph (1)(B)(v) and this paragraph 21 of section 1833(t), the term “applicable items and services” means items and services *other* than items and services furnished by a dedicated emergency department (as defined in 42 CFR 489.24(b)). Existing regulations at § 489.24(b) define an ED as any department or facility of the hospital, regardless of whether it is located on or off the main hospital campus, that meets at least one of the following requirements:

- It is licensed by the State in which it is located under applicable State law as an emergency room or emergency department;
- It is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or
- During the calendar year immediately preceding the calendar year in which a determination under this section is being made, based on a representative sample of patient visits that occurred during that calendar year, it provides at least one-third of all of its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.

Accordingly, based on existing regulations, an ED may furnish both emergency and nonemergency services as long as the requirements under § 489.24(b) are met. In accordance with section 1833(t)(21)(A) of the Act and regulations at § 489.24(b), in the CY 2017 OPPS/ASC proposed rule (81 FR 45683), we proposed that all services furnished in an ED, whether or not they are emergency services, would be exempt from application of sections 1833(t)(1)(B)(v) and 1833(t)(21) of the Act, and thus continue to be paid under the OPPS. Moreover, we proposed to

define “applicable items and services” to which sections 1833(t)(1)(B)(v) and (t)(21)(A) of the Act apply to include all items and services not furnished by an ED as described in the regulations at 42 CFR 489.24(b).

Comment: Many commenters supported CMS’ proposal to exempt application of the section 603 payment provisions to EDs. These commenters stated that CMS correctly interpreted the statutory provisions and agreed with the CMS proposal to exclude all services, emergency and nonemergency, furnished in a dedicated ED of a hospital.

Response: We appreciate the commenters’ support.

After consideration of the public comments we received, we are adopting as final, without modification, our proposal to exempt all items and services (emergency and nonemergency) furnished in an ED from the provisions of section 603, as long as the department maintains its status as an ED under the regulation at § 489.24(b).

(2) On-Campus Locations

As noted earlier, section 1833(t)(21)(B)(i) of the Act defines the term “off-campus outpatient department of a provider” for purposes of paragraphs (1)(B)(v) and (21) of such section as a department of a provider (as defined at 42 CFR 413.65(a)(2) *as that term is in effect as of the date of enactment of Public Law 114–74*), that is not located on the campus of that provider or within the distance (described in the definition of campus at § 413.65(a)(2)) from a remote location of a hospital facility (as defined in § 413.65(a)(2)). We stated in the CY 2017 OPPS/ASC proposed rule that we believe the statutory language refers to such departments as defined by the regulations at § 413.65 as they existed as of the date of enactment of Public Law 114–74, which was November 2, 2015. The existing regulatory definition at § 413.65(a)(2) of a “department of a provider” includes both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. We used the existing regulatory definition of a department of a provider as a guide in designing our proposals to implement section 603 of Public Law 114–74.

In the proposed rule, we did not propose to change the existing definition of “campus” located at § 413.65(a)(2) of our regulations. We stated that we believe hospitals can adequately determine whether their

departments are on-campus, including by using the current provider-based attestation process described in § 413.65(b) to affirm their on-campus status. Currently, the CMS Regional Offices review provider-based attestations to determine whether a facility is within full compliance of the provider-based rules, and hospitals that ask for a provider-based determination are required to specify whether they are seeking provider-based status for an on-campus or off-campus facility or organization. If a CMS Regional Office determines that a department is not in full compliance with the provider-based rules, hospitals may utilize the reconsideration process described under § 413.65(j) and the administrative appeal process described at 42 CFR part 498.

In accordance with section 1833(t)(21)(B)(i)(I) of the Act, in the CY 2017 OPPS/ASC proposed rule (81 FR 45683), we proposed that on-campus PBDs and the items and services provided by such a department would be excepted from application of sections 1833(t)(1)(B)(v) and (t)(21) of the Act.

Comment: Several commenters supported the decision by CMS to not modify existing provider-based regulations. They stated that it is advisable to continue to use the current definition of facilities that are considered to be on-campus versus off-campus, including the use of both the 250 yards rule, as well as allowing the CMS Regional Offices to continue to provide case-specific discretion for making such determinations. Other commenters requested revisions to the definitions at § 413.65(a)(2). Many of these commenters suggested using a “reasonable proximity” test for “campus” or to emphasize the ability of CMS Regional Offices to allow for expanded campuses. Other commenters requested that certain types of providers be exempted from the general 250 yard limitation. Some commenters requested that CMS remove the Regional Office’s discretion and not consider any location outside the 250 yard radius as part of a campus. Several commenters requested that CMS provide additional subregulatory guidance concerning the existing definition of “campus” and “main building.”

Response: We continue to believe that the current regulatory definition of campus at § 413.65(a)(2), including the ability for the CMS Regional Offices to exercise discretion, allows a flexible and realistic approach to the configurations a hospital may adopt. Because we did not propose any changes to the existing definition of “campus,” we are not changing the definition at this time.

While implementation of the provisions of section 603 has added significantly more focus and attention on provider-based criteria, we note that the CMS Regional Offices have been making on-campus and off-campus provider-based determinations for many years, with relatively few instances where there has not been consensus as to whether a facility was on-campus or off-campus. As we gain experience with the implementation of section 603, our preference is to make any necessary adjustments to provider-based policies at § 413.65 through separate notice-and-comment rulemaking.

After consideration of the public comments we received, we are finalizing the proposed policy that on-campus PBDs and the items and services provided by such departments would be excepted from application of sections 1833(t)(1)(B)(v) and (t)(21) of the Act.

(3) Within the Distance From Remote Locations

In addition to the statutory exception for PBDs located on the campus of a provider, section 1833(t)(21)(B)(i)(II) of the Act excludes off-campus PBDs that are not located within the distance (as described in the definition of campus at § 413.65(a)(2)) from a “remote location” (as also defined at § 413.65(a)(2)) of a hospital facility. The “distance” described in the definition of “campus” at § 413.65(a)(2) is 250 yards. While hospitals that operate remote locations are referred to as “multi-campus” hospitals, as discussed previously, under current provider-based rules, a hospital is not allowed to have more than one single “main” campus for each hospital. Therefore, in the CY 2017 OP/ASC proposed rule (81 FR 45683 through 45684), when determining whether an off-campus PBD meets the exception set forth at section 1833(t)(21)(B)(i)(II) of the Act, we proposed that the off-campus PBD must be located at or within the distance of 250 yards from a remote location of a hospital facility. We stated that hospitals should use surveyor reports or other appropriate documentation to ensure that their off-campus PBDs are within 250 yards (straight-line) from any point of a remote location for this purpose.

Comment: A number of commenters requested specific clarifications of remote-location definitions. In particular, the commenters requested that CMS better define the exact methodology a hospital should use to determine the 250 yard criterion. Commenters also requested verification that if any portion of an outpatient

facility is within 250 yards of the remote location, the entire facility can be considered excepted from section 603 payment implications.

Response: We note that all remote locations of a hospital, as well as any nearby outpatient departments, continue to be considered as “off-campus” under regulations at § 413.65. A remote location is not a “campus” as that term is currently defined in § 413.65, and we did not propose any changes to the definitions in § 413.65. Therefore, as stated in the proposed rule, we interpreted the distance (described in such definition of campus) from a remote location of a hospital facility (as defined in § 413.65(a)(2)) to be 250 yards. Because neither section 1833(t)(21)(B)(i)(II) of the Act, as added by section 603 of Public Law 114–74, nor the provider-based regulations specify the specific point from which to measure (for example, the main entrance), we interpret this to mean that a hospital may measure 250 yards from any point of the physical facility that serves as the site of services of the remote location to any point in the PBD. We believe this implementation is consistent with how CMS has historically implemented the 250-yard criterion when making on-campus determinations under § 413.65.

After consideration of the public comments we received, we are finalizing the policy as proposed. Off-campus PBDs that are located at or within 250 yards of a remote location of a hospital facility, as defined in § 413.65(a)(2), will be excepted from application of sections 1833(t)(1)(B)(v) and (t)(21) of the Act.

c. Applicability of Exception at Section 1833(t)(21)(B)(ii) of the Act

Section 1833(t)(21)(B)(ii) of the Act states that, for purposes of sections 1833(t)(1)(B)(v) and 1833(t)(21) of the Act, the term “off-campus outpatient department of a provider” shall not include a department of a provider (that is, an off-campus PBD) (as so defined) that was billing under this subsection, that is, the OP/ASC, with respect to covered OPD services furnished prior to November 2, 2015. In the CY 2017 OP/ASC proposed rule (81 FR 45684), we proposed that, as provided in section 1833(t)(21)(B)(ii) of the Act, if an off-campus PBD meets this exception, sections 1833(t)(1)(B)(v) and 1833(t)(21) of the Act do not apply to that department or to the types of items and services furnished by that department (discussed in greater detail below) that were being billed under the OP/ASC prior to November 2, 2015.

A major concern with determining the scope of the exception set forth at section 1833(t)(21)(B)(ii) of the Act for purposes of applying sections 1833(t)(1)(B)(v) and 1833(t)(21) of the Act is determining how relocation of the physical location or expansion of services lines furnished at the “excepted” off-campus PBD affects the excepted status of the off-campus PBD itself and the items and services furnished by that excepted off-campus PBD.

In the proposed rule, we noted that we had heard from some providers that they believe that section 1833(t)(21)(B)(ii) of the Act specifically excepted off-campus PBDs billing for covered OPD services furnished before November 2, 2015, and that these excepted departments should remain excepted, regardless of whether they relocate or expand services, or both. These providers noted that the exception for certain off-campus PBDs states that section 1833(t)(21)(B)(ii) of the Act does not include an off-campus PBD (as so defined) that was billing under this subsection with respect to covered OPD services furnished prior to the date of the enactment of this paragraph. These providers argued that, because the statute does not include a specific limitation on relocation or expansion of services, no limitation should be applied.

We also noted that providers also suggested that off-campus PBDs should be able to relocate and maintain excepted status as long as the structure of the PBD is substantially similar to the PBD prior to the relocation and that some stakeholders have suggested that the criteria for defining substantially similar could be based on maintaining similar personnel, space, patient population, or equipment, or a combination of these factors. In the proposed rule, we stated our belief 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, including those items and services furnished and billed by such a PBD prior to that time. Thus, as noted above, we developed our proposals in defining the scope of the excepted off-campus PBD and the items and services it furnishes based on the existing regulatory definition of department of a provider, which speaks to both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program and the personnel and equipment needed to deliver the services at that facility.

Below we discuss the proposals we made in the proposed rule regarding the scope of the exception at section 1833(t)(21)(B)(ii) of the Act for purposes of applying sections 1833(t)(1)(B)(v) and (t)(21) of the Act.

(1) Relocation of Off-Campus PBDs Excepted Under Section 1833(t)(21)(B)(ii) of the Act

In the proposed rule, we stated that in considering how relocation of an excepted off-campus PBD could affect application of sections 1833(t)(1)(B)(v) and (t)(21) of the Act, we were concerned that if we proposed to permit excepted off-campus PBDs to relocate and continue such status, hospitals would be able to relocate excepted off-campus PBDs to larger facilities, purchase additional physician practices, move these practices into the larger relocated facilities, and receive OPPS payment for services furnished by these physicians, which we believe section 603 of Public Law 114–74 intended to preclude.

As stated in the proposed rule, we believe that section 603 of Public Law 114–74 applies to off-campus PBDs as they existed at the time of enactment and excepts those items and services that were being furnished and billed by off-campus PBDs prior to November 2, 2015.

After reviewing the statutory authority, and the concerns noted earlier, we proposed that, for purposes of paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act, excepted off-campus PBDs and the items and services that are furnished by such departments would no longer be excepted if the excepted off-campus PBD moves or relocates from the physical address that was listed on the provider's hospital enrollment form as of November 1, 2015. In the case of addresses with multiple units, such as a multi-office building, the unit number is considered part of the address; in other words, an excepted hospital PBD could not purchase and expand into other units in its building, and remain excepted under our proposal. Once an excepted off-campus PBD has relocated, we proposed that both the off-campus PBD itself and the items and services provided at that off-campus PBD would no longer be excepted, and instead, would be subject to paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act.

In the proposed rule, we noted that hospitals had expressed concern that there may be instances when an excepted off-campus PBD may need to relocate, including, for example, to meet Federal or State requirements, or due a natural disaster. We recognize that there

may be circumstances beyond the hospital's control where an excepted off-campus PBD must move from the location in which it existed prior to November 2, 2015. In the CY 2017 OPPS/ASC proposed rule, we solicited public comments on whether we should develop a clearly defined, limited relocation exception process, similar to the disaster/extraordinary circumstance exception process under the Hospital VBP program (as implemented in the FY 2014 IPPS/LTCH PPS final rule; 78 FR 50704) for hospitals struck by a natural disaster or experiencing extraordinary circumstances that would allow off-campus PBDs to relocate in very limited situations, and that would mitigate the potential for the hospital to avoid application of sections 1833(t)(1)(B)(v), and (t)(21)(C) of the Act. In addition, we sought public comments on whether we should consider exceptions for any other circumstances that are completely beyond the control of the hospital, and, if so, what those specific circumstances would be.

Comment: Numerous commenters opposed CMS' proposal to limit excepted off-campus PBDs to the physical address on the provider's hospital enrollment form as of November 1, 2015. The commenters stated that a PBD that moves or relocates from its physical address after November 2, 2015, should not lose its excepted status, given the many circumstances that may necessitate a hospital to move or relocate, temporarily or permanently, such as lease expiration, building safety code compliance, building deterioration, population shifts, natural disaster, seismic requirements, and other situations beyond a hospital's control. Many commenters stated that CMS' proposal is overly restrictive and that CMS does not have the authority to apply payment reductions to hospitals that move or relocate because section 603 does not explicitly discuss or address relocation. These commenters believed that Congress intended the section 603 provisions to apply to new off-campus PBDs and not to relocation of existing off-campus PBDs. The commenters requested that CMS allow flexibility such that excepted off-campus PBDs could move or relocate for any reason without jeopardizing payment under the OPPS. Several commenters opposed CMS' consideration of a disaster/extraordinary circumstance exception process similar to the Hospital VBP Program because they believed excepted off-campus PBDs should be allowed to relocate for any

reason without permission or approval from CMS.

Some commenters were opposed to the relocation proposal and suggested that, if CMS moves forward with adopting a limitation on relocation of existing PBDs, CMS clearly define relocation exceptions. In particular, the commenters recommended that CMS allow excepted PBDs to relocate without the loss of excepted status under the following circumstances:

- Relocation to comply with Federal and State requirements;
- Relocation of an HOPD that has been destroyed or substantially damaged in a disaster or emergency;
- Temporary relocation of an HOPD in order to allow rebuilding, updating or retrofitting of its infrastructure;
- Relocation due to the HOPD losing its lease;
- Relocating a HOPD in order to provide access to care in an underserved area; and
- Relocation due to a shifting/growing patient population.

Response: We disagree that, in the context of section 603, an off-campus PBD should be allowed to relocate for any reason and continue to be paid under the OPPS. In the proposed rule, we cited our concern that without limitations on relocation, hospitals would be able to relocate excepted off-campus PBDs to larger facilities, purchase additional physician practices, and move these practices into the larger relocated facilities that would continue to be paid under the OPPS.

As previously stated, we believe that section 603 applies to off-campus PBDs as they existed at the time the law was enacted. That is, we believe that the statutory language provides for payment to continue under the OPPS for such departments as defined by the regulations at § 413.65 as they existed at the time of enactment of Public Law 114–74. The existing regulatory definition at § 413.65 of a “department of a provider” includes both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. To allow excepted off-campus PBDs to relocate under every circumstance and continue to be paid OPPS rates would allow hospitals to continue the practices we believe section 603 was intended to curb. Allowing unlimited relocation of an off-campus PBD would potentially result in relocation to larger facilities, with different equipment and staff and unbridled expansion of service lines. Among other changes, its composition

could result in an off-campus PBD that is remarkably different than it was prior to November 2, 2015, the date of enactment of Public Law 114–74.

With respect to exercising flexibility in interpreting the statute, we are adopting an exceptions process to our relocation proposal that is limited to extraordinary circumstances outside a hospital's control, which is described later in this section. We believe that this final policy adds some additional flexibility from what we proposed, which was excepted off-campus PBDs and the items and services that are furnished by such departments would no longer be excepted if the excepted off-campus PBD moves or relocates from the physical address that was listed on the provider's hospital enrollment form as of November 1, 2015. In addition, with respect to the comment about defining criteria under which exceptions for relocation might be made, we note that it is not feasible to establish criteria that would apply to every type of extraordinary circumstance that may arise. Accordingly, we believe providing an exhaustive list of scenarios for which relocation is necessary would be contrary to the notion of added flexibility.

Comment: Several commenters suggested two alternatives to CMS' relocation proposal that would grant more flexibility to hospitals that may need to relocate for reasons seen and unforeseen. One suggested alternative was to allow relocation so long as the total number of off-campus PBDs for a hospital did not increase relative to the number prior to enactment of section 603. A second suggested alternative was that CMS develop a "substantially similar" test to determine if a relocated location is actually new. Commenters suggested that the substantially similar test could be similar to the critical access hospital (CAH) relocation requirements as defined in regulations at 42 CFR 485.610(d).

Response: We appreciate the commenters' feedback. As discussed earlier in section X.A.1. of this final rule with comment period, we believe that one of the primary goals of section 603 of Public Law 114–74 is to remove the difference in payment for outpatient services furnished in freestanding facilities and nonexcepted off-campus PBDs. Also, in the proposed rule, we stated our concern with establishing relocation policies that could result in an unintentional loophole and therefore undermine what we believe is the intent of the law. We disagree with the commenters' recommendation to allow relocation based on CAH relocation

requirements because it could allow fairly unlimited relocation and expansion as long as 75 percent of the services/staff continue to be present in the expanded service area. In addition, this recommendation has significant operational and enforcement challenges and would require significant administrative resources to evaluate exception requests, including data analysis to ensure criteria are met. Likewise, while "capping and freezing" the total number of off-campus PBDs a hospital could have to the number of off-campus PBDs the hospital had prior to enactment of section 603 would limit the total number of off-campus PBDs to those that existed prior to enactment, we believe it would not address the previously stated concerns that a hospital could use relocation to expand to a new type of department that furnishes a higher volume and a wider variety of services with staff, personnel, and equipment that the off-campus PBD that was billing prior to enactment of section 603 previously did not have. Therefore, we do not agree with either suggestion.

Comment: Several commenters and MedPAC supported CMS' relocation proposal but recommended that CMS allow excepted off-campus PBDs to relocate for acts of nature, either temporarily or permanently, without loss of excepted status.

Response: We appreciate the commenters' support and agree that excepted off-campus PBDs should be permitted to relocate for extraordinary circumstances outside their control, such as natural disasters, significant seismic building codes, or significant public health and public safety issues, without loss of excepted status. Accordingly, we are adopting a policy in this final rule with comment period to allow an excepted off-campus PBD to relocate in the limited instances of extraordinary circumstances outside of the hospital's control, such as natural disasters, significant seismic building code requirements, or significant public health and public safety issues, that necessitate moving to a new building (either temporarily or permanently) without losing its excepted status. Exceptions to the relocation policy will be evaluated on a case-by-case basis by the appropriate CMS Regional Office. We note that such exceptions will be both limited and rare because we do not wish to allow this extraordinary circumstances exception to undermine the goal of limiting the growth and expansion of excepted off-campus PBDs. We intend to issue subregulatory guidance on the extraordinary circumstances process. Technical

details will be addressed in that guidance.

Comment: Some commenters raised the question of whether an on-campus PBD that was billing under the OPSS prior to November 2, 2015, would maintain excepted status if the PBD moved off-campus after the date of enactment of Public Law 114–74.

Response: In this scenario, an on-campus PBD that relocates off-campus would be subject to sections 1833(t)(1)(B)(v) and (t)(21) of the Act in CY 2017 and subsequent years. We believe that section 603 applies to off-campus PBDs as they existed at the time the law was enacted. Therefore, while an on-campus PBD as of November 2, 2015 would be treated as an excepted off-campus PBD, the subsequent relocation of that PBD off-campus would result in the PBD no longer being paid under the OPSS.

Comment: Several commenters recommended that, if CMS were to adopt a relocation exceptions process, the process to obtain an exception be administratively simple and timely. Specifically, the commenters suggested two approaches to establishing a relocation exceptions process: First, CMS could modify the Medicare 855 enrollment form and the online Medicare Provider Enrollment, Chain, and Ownership System (PECOS) so that the hospital would notify CMS of the reason for a relocation of an excepted off-campus PBD by choosing among the list of preapproved exceptions. Second, CMS Regional Offices could have discretionary authority to approve additional relocation exceptions for excepted off-campus PBDs in other reasonable, but unforeseen, circumstance.

Response: We agree that the relocation exceptions process should be as administratively simple as possible. As mentioned earlier, the appropriate CMS Regional Office will evaluate relocation requests on a case-by-case basis. We will take these comments into consideration prior to issuing subregulatory technical guidance.

After consideration of the public comments received, we are finalizing our proposed policy on relocation, with modification to allow excepted off-campus PBDs to relocate temporarily or permanently, without loss of excepted status, for extraordinary circumstances outside of the hospital's control, such as natural disasters, significant seismic building code requirements, or significant public health and public safety issues. This policy is intended to be applied in a limited and rare manner to ensure that excepted off-campus PBDs do not leverage these

requirements to subvert the intent of section 603. CMS Regional Offices will evaluate and approve or deny these relocation requests. We will provide instruction through subregulatory guidance on the process to request a relocation exception. CMS Regional Offices will make determinations for relocation exception requests.

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

In the CY 2017 OPPS/ASC proposed rule, we noted that we had received questions from some hospitals regarding whether an excepted off-campus PBD can expand the number or type of services the department furnishes and maintain excepted status for purposes of paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act. As mentioned earlier in the relocation discussion, we have heard that some providers believe that section 1833(t)(21)(B)(ii) of the Act specifically excepted *departments*, and that excepted departments should remain excepted, regardless of whether these departments expand either the number of services or the types of services they provide. Under this interpretation, section 1833(t)(21)(B)(ii) of the Act would limit only the number of excepted off-campus PBDs a hospital can have to the number of off-campus PBDs that were billing Medicare for covered OPD services furnished prior to enactment of Public Law 114–74.

In the proposed rule, we stated that we believe section 1833(t)(21)(B)(ii) of the Act excepts off-campus PBDs and the items and services that are furnished by such excepted off-campus PBDs for purposes of paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act as they were being furnished on the date of enactment of section 603 of Public Law 114–74, as guided by our regulatory definition at § 413.65(a)(2) of a department of a provider. Thus, we proposed that the excepted off-campus PBD items and services that would continue to be paid under the OPPS 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 only. 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 OPPS.

As noted earlier, 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 OPPS rates. One issue we contemplated in considering how expanded services should affect excepted status is how it could affect payment to newly acquired physicians' offices or new off-campus PBDs established *after* the date of enactment of section 603. In the 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 OPPS rates for these new types of services, hospitals may be able to purchase additional physician practices and add those physicians to existing excepted off-campus PBDs. This could result in newly purchased physician practices furnishing services that are paid at OPPS rates, which we believe these amendments to section 1833(t) of the Act are intended to address.

After reviewing the statutory authority and the concerns raised by commenters noted above, we proposed, 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 is 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 OPPS 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 thus 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 as described in section X.A.1.c. of the proposed rule. We note that we proposed not to limit the volume of excepted items and services within a clinical family of services that an excepted off-campus PBD could furnish.

In summary, our proposals related to expansion of clinical families of services are as follows: We proposed that service types be defined by the 19 clinical families of hospital outpatient service types described in Table 21 of the proposed rule (81 FR 45685 through 45686). Moreover, we proposed that if an excepted off-campus PBD furnished and billed for any specific service within a clinical family of services prior to November 2, 2015, such clinical family of services would be excepted and be eligible to receive payment

under the OPPS. However, we proposed that if an excepted off-campus PBD furnishes services from a clinical family of services that such department did not furnish and bill for prior to November 2, 2015, those services would be subject to sections 1833(t)(1)(B)(v) and (t)(21) of the Act in CY 2017 and subsequent years. We referred readers to Addendum B to the proposed rule (which is available via the Internet on the CMS Web site) for which HCPCS codes mapped to each clinical family of services. We stated that if we added a new HCPCS code or APC in future years, we would provide mapping to these clinical families of services, where relevant.

In addition, we considered, but did not propose, to specify a specific timeframe in which service lines had to be billed under the OPPS for covered OPD services furnished prior to November 2, 2015. We sought public comment 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 proposal, while excepted off-campus PBDs would not be eligible to receive OPPS payments for expanded clinical families of services, such excepted off-campus PBDs would continue to be eligible to receive OPPS payment for clinical families of services that were furnished and billed prior to that date. We discuss later in this section how we proposed to pay for expanded items and services that are furnished at excepted off-campus PBDs, that is, are nonexcepted items and services.

We sought public comments on these proposals. In addition, we sought public comments on our proposed categories of clinical families of services, and our proposal not to limit the volume of services furnished within a clinical family of services that the hospital was billing prior to November 2, 2015.

Comment: A large number of commenters opposed CMS' proposals related to service expansion. The commonly cited concerns among the commenters who opposed the proposed policy were as follows:

- The statutory language included in section 603 does not address changes in service-mix by excepted off-campus PBDs. These commenters stated that CMS exceeded its authority to state that Congress established both excepted facilities and excepted items and services that those facilities may provide.

- Limitations on service line expansion does not reflect that health care is ever evolving and new therapies and services may be developed that do

not fit squarely in the proposed clinical families. Commenters stated that CMS' proposal would hinder beneficiary access to innovative technologies if an excepted off-campus PBD is penalized financially for keeping up with the practice of medicine.

- The term "clinical families of service" appears to be a new term created by CMS for the purpose of implementing section 603. Commenters expressed concern that, because the clinical families are defined by APC groupings, it would be difficult for CMS and hospitals to manage changes in the composition of APCs and HCPCS code changes contained in those APCs.

- Operational challenges and administrative burden seem significant for both CMS and hospitals. Commenters believed that CMS' proposal is unnecessarily complex and will create challenges for CMS to operationalize, track, manage, and enforce particularly because hospitals do not report or attest to the types of services furnished at each off-campus PBD.

In addition, MedPAC recommended an alternative approach that it suggested would also meet the intent of section 603 by minimizing the incentive of hospitals to purchase independent physician practices and convert them to off-campus PBDs. MedPAC recommended that CMS establish a baseline service volume for each applicable off-campus PBD and cap services, regardless of clinical family, at that limit. When the hospital reaches the annual cap for that location, CMS would no longer pay OPPS rates for those services. The annual cap could be updated based on the annual updates to the OPPS payment rates. However, MedPAC noted that, in order for CMS to implement this approach, CMS would have to collect information on OPPS payments to each excepted off-campus PBD from November 2, 2014 through November 1, 2015 to establish a baseline.

Response: We appreciate the detailed comments that were submitted. We disagree that section 603 does not provide us the authority to adopt a policy that would limit OPPS payment to the type of services that had been furnished and billed at an off-campus PBD prior to enactment of Public Law 114–74. Further, we believe the statute gives us the authority to limit the volume of services furnished to the level that was furnished prior to the date of enactment; however, we did not propose to do so. However, we are interested in feedback from stakeholders in this final rule with comment period about how such a policy would work,

and we intend to monitor for potential shifting of services to excepted off-campus PBDs, including on-campus PBDs. As mentioned in the proposed rule, we were concerned that if excepted off-campus PBDs could expand the types of services provided at the excepted off-campus PBDs and also be paid OPPS rates for these new types of services, hospitals may be able to purchase additional physician practices and add those physicians to existing excepted off-campus PBDs. This could result in newly purchased physician practices furnishing services that are paid at OPPS rates, which we believe these amendments to section 1833(t) of the Act are intended to prevent. Nonetheless, we agree with commenters, including MedPAC, that our proposed policy could be operationally complex and could pose an administrative burden to hospitals, CMS, and our contractors to identify, track, and monitor billing for clinical services. Further, we believe that the relocation policy for excepted off-campus PBDs, when coupled with the final service expansion policy we are adopting in this final rule with comment period, will help ensure that off-campus PBDs excepted from application of sections 1833(t)(1)(B)(v) and (t)(21) of the Act will not be able to circumvent applicability of payment under section 1833(t)(21) of the Act. In response to the comments about the need to allow services to evolve over time to meet community needs, we recognize that community needs may evolve over time. However, to the extent that the community needs are of the service type that could be furnished by either a hospital or a different provider supplier type, we do not believe that our proposed policy would have hindered access to needed services in the community. Accordingly, we are not finalizing this proposal at this time. However, we intend to monitor service line growth and, if appropriate, may propose to adopt a limitation on the expansion of services or service lines in future rulemaking. In that event, we will consider the commenters' concerns expressed in comments received on the proposed clinical families of service in development of any future rulemaking on service expansion.

After consideration of the public comments we received, we are not finalizing our proposed policy to limit service line expansion. Therefore, an excepted off-campus PBD will receive payments under the OPPS for all billed items and services, regardless of whether it furnished such 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 this final rule with comment period. As mentioned earlier in this section, we intend to monitor this issue and continue to consider how a potential limitation on expansion would work. To that end, we would appreciate receiving feedback from stakeholders 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, would work in practice. Specifically, we are interested in what data are currently available or could be collected that would allow us to implement a limitation on service expansion. We also are interested in suggestions for changes to the clinical families of services that we set forth in Table 21 of the proposed rule as we move forward (81 FR 45685 through 45686).

(3) Other Related Public Comments

Comment: A few commenters requested clarification on whether the section 603 provisions apply to Federally Qualified Health Centers (FQHCs) that meet provider-based criteria set forth in 42 CFR 413.65(n) and are paid under the OPPS. In addition, the commenters stated that even if the section 603 policies would apply, CMS has the authority to exempt FQHCs from policies related to implementation of section 603 using equitable adjustment authority as defined in section 1833(t)(2)(E) of the Act. Commenters requested that CMS invoke the equitable adjustment authority and continue to pay FQHCs that meet the criteria at § 413.65(n) under the OPPS in spite of the section 603 provisions.

Response: Section 603 of Public Law 114–74 generally provides that 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 OPPS and will instead be paid "under the applicable payment system" under Medicare Part B if the requirements for such payment are otherwise met.

Under existing regulations at 42 CFR 413.65(n), a FQHC or FQHC look-alike facility that has, since April 7, 1995, furnished only services that were billed as if they had been furnished by a department of a provider will continue to be treated, for purposes of the provider-based regulations, as a

department of a provider without regard to whether it complies with the criteria for provider-based status, as long as it was qualified as an FQHC (not including tribal/Indian facilities which are subject to 413.65(m)) or FQHC look-alike on or before April 7, 2000. (An “FQHC look-alike” is an organization that has been identified by HRSA as meeting the definition of “Health Center” under section 330 of the PHS Act, but does not receive grant funding under section 330.)

Section 603 does not apply to FQHCs that are paid under the FQHC Prospective Payment System methodology at section 1834(k) of the Act. However, section 603 provisions would apply to any entity that is paid under section 1833(t), including a provider-based FQHC under § 413.65(n), because a provider-based FQHC is considered a department of a provider under the OPSS.

The commenter mentioned section 1833(t)(2)(E) of the Act, which provides that the Secretary shall establish, in a budget neutral manner, other adjustments under the OPSS as determined to be necessary to ensure equitable payments. In other words, section 1833(t)(2)(E) of the Act provides the authority to make a payment adjustment under the OPSS. While section 1833(t)(2)(E) of the Act does provide fairly broad authority to make such a payment adjustment, we do not believe this authority extends to exempting a class of off-campus PBDs from application of a separate statutory provision that specifically prohibits payment under the OPSS itself; that is, there would be no OPSS payment to which a payment adjustment could be made.

Comment: Several commenters requested clarification on whether the section 603 provisions apply to off-campus PBDs of hospitals operated by the Indian Health Service (IHS) or by a tribe or tribal organization.

Response: Hospitals that are operated by the IHS, tribes, or tribal organizations are paid under section 1880 of the Act. As mentioned, section 603 of Public Law 114–74 amended sections 1833(t)(1)(B) and (t)(21) of the Act and only applies to those entities paid under section 1833(t) of the Act. Section 603 does not change payment to the IHS, tribes, and tribal organization eligible for payment under section 1880 of the Act.

Comment: Numerous commenters acknowledged that the CY 2017 OPSS/ASC proposed rule did not include a proposal for the treatment of off-campus PBDs mid-build or under development at the time Public Law 114–74 was

enacted on November 2, 2015. Commenters contended that PBDs under construction or in the development phase could not have reasonably foreseen the restrictions put in place by section 603. The commenters further believed that, in the absence of reasonable knowledge or notice that such restrictions would ever be put in place at the time plans were completed for and construction begun on the new off-campus departments, these facilities will be inadvertently disadvantaged financially because they will not be paid under the OPSS. As such, commenters requested that CMS either delay implementation of section 603 to allow Congress time to pass H.R. 5273—Helping Hospitals Improve Patient Care Act of 2016 or add “mid-build” or “under development” PBDs to the types of excepted off-campus PBDs.

Response: While we understand the commenters’ concerns that hospitals could not have reasonably predicted or expected that new off-campus PBDs would not be paid under the OPSS, section 603 does not provide an exception for off-campus PBDs that were mid-build at the time of enactment. Therefore, we did not propose to include mid-build or under development off-campus PBDs among the types of excepted off-campus PBDs. In addition, we are required to implement the provisions of section 603 to provide payments for nonexcepted items and services furnished by nonexcepted off-campus PBDs under the applicable payment system other than the OPSS beginning January 1, 2017.

Comment: Several commenters believed that CMS misinterpreted the statute when the agency proposed to limit the definition of an excepted off-campus PBD to those that submitted a bill for covered outpatient services under the OPSS furnished prior to November 2, 2015. Commenters believed that CMS’ proposal is based on a narrow read of the statute and that Congress did not intend the billing function to be the deciding factor in determining the exceptions requirement. Instead, the commenters requested that CMS consider a more flexible interpretation and except off-campus PBDs that satisfy any of the following scenarios:

- Off-campus PBDs fully operational but not yet treating patients on or before November 2, 2015;
- Off-campus PBDs fully operational and treating patients on or before November 2, 2015, but billing department not yet fully functional; and
- Off-campus PBDs fully operational and treating patients on or before

November 2, 2015, but internal process for billing claims includes a standard review period before the claims are submitted to Medicare.

Response: We disagree with the commenters’ request to except off-campus PBDs that were operational and not yet treating patients by November 2, 2015. We believe that the exception under section 1833(t)(21)(B)(ii) of the Act, as added by section 603, is limited to those off-campus PBDs that were “billing under this subsection with respect to covered OPD services furnished prior to [November 2, 2015].” However, we agree with commenters’ that one interpretation of the statute could allow for an exception for off-campus PBDs that furnished a covered OPD service prior to November 2, 2015, but had not submitted a bill to Medicare for such service prior to November 2, 2015. We are finalizing our interpretation as proposed, with modification, which means that off-campus PBDs would be eligible to receive OPSS payment as excepted off-campus PBDs for services that were furnished prior to November 2, 2015, and billed under the OPSS in accordance with timely filing limits.

d. Change of Ownership and Excepted Status

Under current policy, provider-based status is defined as the relationship between a facility and a main provider. If a Medicare-participating hospital, in its entirety, is sold or merges with another hospital, a PBD’s provider-based status generally transfers to new ownership as long as the transfer does not result in any material change of provider-based status. A provider-based approval letter for such a department will be considered valid as long as the new owners accepted the prior hospital’s provider agreement, consistent with other hospital payment policies.

We have received inquiries regarding whether excepted off-campus PBDs would maintain excepted status if a hospital were purchased by a new owner, if a hospital merged with another provider, or if only an excepted off-campus PBD were sold to another hospital.

In the CY 2017 OPSS/ASC proposed rule (81 FR 45686), we proposed that excepted status for the off-campus PBD would be transferred to new ownership only if ownership of the main provider is also transferred and the Medicare provider agreement is accepted by the new owner. Under our proposal, if the provider agreement is terminated, all excepted off-campus PBDs and the excepted items and services furnished

by such off-campus PBD would no longer be excepted for purposes of paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act. We proposed that individual excepted off-campus PBDs cannot be transferred from one hospital to another and maintain excepted status. We solicited public comments on these proposals.

Comment: A few commenters supported CMS' proposal that an excepted off-campus PBD would continue to be excepted after a change in ownership in which the buyer accepts assignment of the provider agreement. However, many commenters opposed the proposals regarding change of ownership on the grounds that the section 603 provisions do not specifically address change of ownership. The commenters asserted that, had Congress intended payment reductions for purchases or acquisitions of existing off-campus PBDs by a different hospital, Congress would have included it in the law. Several commenters stated that hospitals in financial difficulty that plan to close their inpatient hospital beds will offer to transfer their HOPDs to better-performing hospitals in order to ensure that critical hospital-based outpatient services are still accessible to patients in the community. Similarly, commenters expressed concern that the change of ownership proposals could have an unintended consequence for hospitals that downsize from providing inpatient and outpatient services to outpatient services only or that close inpatient hospital beds but want to retain the outpatient off-campus PBD.

Commenters believed that such acquisitions or reconfigurations within a health system may not be financially feasible if the excepted off-campus PBD were to lose payment under the OPSS. To remedy their concerns, the commenters requested that CMS permit individual off-campus PBDs to retain their excepted status even if bought individually by another provider.

Response: We disagree with the commenters who believe that we do not have the authority or are prohibited from addressing change of ownership as part of our implementation of section 603. For hospitals that participate in Medicare, CMS has a longstanding policy codified in regulation at 42 CFR 489.18 and Manual Publication 100-07, Chapter 3, Sections 3210 through 3210.5(C) that addresses change of ownership including merger/acquisitions and consolidations, and the effect on the Medicare provider agreement. Our change of ownership proposals to implement the section 603 provisions are modeled after

longstanding payment policy across several payment systems in which assets/liabilities are transferred to the new owner only if the new owner accepts the existing provider agreement. If a hospital is sold or merges with another hospital, a PBD's provider-based status generally transfers to the new ownership as long as the transfer would not result in any material change of provider-based status. In addition, provider-based status is defined as the relationship between a facility and a main hospital provider, not an asset that can be transferred from one provider to another. Therefore, because provider-based status is a relationship with the main hospital provider, it is not practical to allow the sale of an individual PBD even if the main hospital is closing or downsizing. For example, a hospital owner that decides to combine two certified hospitals under one Medicare provider agreement, with one CMS Certification Number (CCN) would lose excepted status if the off-campus PBD was not enrolled as a provider-based department of the resulting combined hospital and billing under the OPSS for covered items and services furnished prior to November 2, 2015.

After consideration of the public comments we received, we are finalizing our proposals without modification. Specifically, we are allowing excepted status for the off-campus PBD to be transferred to new ownership only if ownership of the main provider is also transferred and the Medicare provider agreement is accepted by the new owner. If the provider agreement is terminated, all excepted off-campus PBDs will no longer be excepted for purposes of paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act. Finally, an individual excepted off-campus PBDs cannot be transferred from one hospital to another and maintain excepted status.

e. Comment Solicitation for Data Collection Under Section 1833(t)(21)(D) of the Act

Hospitals are required to include all practice locations on the CMS 855 enrollment form. Beginning in March 2011 and ending in March 2015, in accordance with section 1866(j) of the Act, CMS conducted a revalidation process where all actively enrolled hospitals were required to complete a new CMS 855 enrollment form to (1) initially enroll in Medicare, (2) add a new practice location, or (3) revalidate existing enrollment information.

Collection and retention of Medicare enrollment data have been authorized through a Paperwork Reduction Act

notice in the **Federal Register**. The authority for the various types of data to be collected is found in multiple sections of the Act and the Code of Federal Regulations; specifically, in sections 1816, 1819, 1833, 1834, 1842, 1861, 1866, and 1891 of the Act, and 42 CFR Chapter IV, Subchapter A.

As we discussed in the CY 2017 OPSS/ASC proposed rule, sections 1833(t)(21)(A) and (B) of the Act exempt both certain off-campus PBDs and the items and services furnished in certain types of off-campus PBDs from application of sections 1833(t)(1)(B)(v) and (21) of the Act. However, while the Medicare enrollment process requires that a hospital identify the name and address of each of its off-campus PBDs, such departments bill under the CMS Certification Number of the hospital, rather than a separate identifier. Accordingly, at the time of development of the proposed rule, we were unable to automate a process by which we could link hospital enrollment information to claims processing information to identify items and services to specific off-campus PBDs of a hospital. In order to accurately identify items and services furnished by each off-campus PBD (exempt or not) and to actively monitor the expansion of clinical family of services at excepted off-campus PBDs, we sought public comments on whether to require hospitals to self-report this information to us (via their MAC) using the authority under section 1833(t)(21)(D) of the Act to collect information as necessary to implement the provision.

Specifically, we sought public comments on whether hospitals should be required to separately identify all individual excepted off-campus PBD locations, the date that each excepted off-campus PBD began billing and the clinical families of services (shown in Table 21 of the proposed rule) that were provided by the excepted off-campus PBD prior to the November 2, 2015 date of enactment. We indicated that if we were to require hospitals to report this information, we would expect to collect this information through a newly developed form which would be available for download on the CMS Web site.

Comment: Commenters believed that CMS would not be able to distinguish between individual off-campus PBDs of a hospital nor would CMS be able to determine if an individual off-campus PBD billed for certain services prior to enactment based on currently available data. Some commenters believed that an additional data collection would be needed to ascertain this information before CMS could effectively implement

its proposed policy. Another commenter suggested that CMS collect information to separately identify each off-campus PBD location, the date that each off-campus PBD began billing Medicare, the provider number of the parent hospital, and the clinical family of services the off-campus PBD was providing before enactment. This commenter suggested that this information should be made public for use by oversight agencies and policy analysts.

Some commenters asked CMS to analyze whether additional data collection is necessary given the burden for providers. Other commenters believed that the CMS proposals on relocation and expansion of services would require significant data collection to implement. Commenters believed the data collection burden provided good reason for CMS to alter its proposals for relocation and expansion of services.

Response: We thank the commenters for their input. As with OPSS payments generally, we rely on hospitals to bill all HCPCS codes accurately in accordance with their code descriptors and CPT and CMS instructions, and to report charges on claims and charges and costs on their Medicare hospital cost report appropriately. We note that hospital billing, in general, relies upon hospitals to appropriately identify items and services for which they are claiming payment under the Medicare program, including use of modifiers as appropriate. From a monitoring and enforcement perspective, we intend to follow traditional practices, including prepayment and postpayment reviews to the extent applicable to ensure that hospitals are correctly identifying nonexcepted items and services. We expect that existing protocols used by program integrity entities will continue to be used to monitor and enforce appropriate billing of nonexcepted items and services. Hospitals will be expected to maintain documentation sufficient to prove that an off-campus PBD is an excepted off-campus PBD; that is, was an off-campus PBD billing for covered OPD services furnished prior to November 2, 2015. We note that, because multiple off-campus PBDs may bill under the same CMS Control Number (CCN), Medicare billing data may not be sufficient to prove that an off-campus PBD was billing Medicare for covered OPD services furnished prior to November 2, 2015.

In addition, we plan to issue instructions to the Medicare contractors to update their systems using enrollment data that would identify each off-campus PBD by physical address and by the date it was added to the hospital's enrollment.

Comment: One commenter suggested that CMS wait to require additional data collection until after it had the opportunity to analyze data provided by the mandatory use of the "PO" modifier to indicate off-campus OPSS services that began in CY 2016.

Response: We appreciate the commenter's feedback. As the commenter mentioned, use of the "PO" modifier became mandatory for services furnished on or after January 1, 2016 (it was voluntary in 2015) for all off-campus PBDs other than remote locations, satellite facilities, and EDs. We are monitoring data that include the "PO" modifier and intend to continue to monitor the data. In addition, we are establishing a new modifier "PN" that will be required to be billed with nonexcepted items and services. This new modifier is discussed in greater detail later in this section, is also discussed in the interim final rule with comment period in section X.B. of this document, and will be discussed in subregulatory guidance.

Comment: MedPAC and other commenters suggested that CMS create new claim line modifiers to indicate when an item or service is an excepted or nonexcepted service. MedPAC suggested that such modifiers would help ensure program integrity. In addition, MedPAC suggested that CMS establish modifiers to indicate when a service is provided in a dedicated ED and whether the dedicated ED is on-campus or off-campus, citing its June 2016 report in which it quantified the recent growth in the number of off-campus EDs billing Medicare and the inability of the Medicare program to distinguish between on-campus and off-campus ED services. In addition, MedPAC suggested that CMS seek legislative authority to impose strict penalties on hospitals that inappropriately bill for nonexcepted services under the OPSS and that these claims should be subject to the False Claims Act.

Response: We appreciate MedPAC's detailed comments on these issues. We have established a new claim line modifier for nonexcepted items and services ("PN") that can be used to identify and pay nonexcepted items and services billed on an institutional claim. This modifier will be effective for items and services furnished on or after January 1, 2017, and is discussed in more detail in section X.A.3.b.(2) of this final rule with comment period. We have not established a modifier specific to services provided at an off-campus dedicated ED at this time and note that EDs, whether they are on-campus or off-campus, are excepted from section

603. The comment suggesting that we seek legislative authority to impose penalties against hospitals that inappropriately bill for nonexcepted services is outside the scope of the proposed rule.

3. Payment for Items and Services Furnished in Off-Campus PBDs to Which Sections 1833(t)(1)(B)(v) and 1833(t)(21) of the Act Apply (Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus PBDs)

a. Background on Medicare Payment for Services Furnished in an Off-Campus PBD

As previously noted, under existing policies, Medicare generally makes two types of payments for items and services furnished in an off-campus PBD: (1) Payment for the items and services furnished by the off-campus PBD (that is, the facility) where the procedure is performed (for example, surgical supplies, equipment, and nursing services); and (2) payment for the physician's professional services in furnishing the service(s).

The first type of payment is made under the OPSS. Items and services furnished in an off-campus PBD are billed using HCPCS codes and paid under the OPSS according to the APC group to which the HCPCS code of the item or service is assigned. The OPSS includes payment for most hospital outpatient services, except those identified in section I.C. of this final rule. Section 1833(t)(1)(B) of the Act generally outlines what are covered OPD services eligible for payment under the OPSS. Sections 1833(t)(1)(B)(i) through (iii) of the Act provide for Medicare payment under the OPSS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by community mental health centers (CMHCs)), certain items and services that are furnished to inpatients who have exhausted their Part A benefits or who are otherwise not in a covered Part A stay, and certain implantable items. Section 1833(t)(1)(B)(iv) and new subsection (v) of the Act, as added by section 603 of Public Law 114-74, list those items and services that are not covered OPD services and, therefore, not eligible for Medicare payment under the OPSS.

The second type of payment for items and services furnished in an off-campus PBD is for physicians' services and is made under the MPFS at the MPFS "facility rate." For most MPFS services, Medicare maintains two separate payment rates: One that assumes a

payment is also made to the facility (*i.e.*, the facility rate); and another that assumes the professional furnishes and incurs the full costs associated with furnishing the service (that is, the nonfacility rate). The MPFS facility rate is based on the relative resources involved in furnishing a service when separate Medicare payment is also made to the facility, usually through an institutional payment system, like the OPSS. The MPFS nonfacility rate, which reflects all of the direct and indirect practice expenses involved in furnishing the particular services, is paid in a variety of settings such as physician offices, where Medicare does not make a separate, institutional payment to the facility.

Under Medicare Part B, the beneficiary is responsible for paying cost-sharing, which is generally about 20 percent of both the OPSS hospital payment amount and the MPFS facility allowed amount. Because the sum of the OPSS payment and the MPFS facility payment is greater than the MPFS nonfacility payment for most services, there is generally a greater cost to both the beneficiary and the Medicare program for services furnished in facilities and paid through both an institutional payment system like the OPSS and the MPFS.

The incentives for hospital acquisition of physician practices and the resultant higher payments for the same types of services when those physician practices are converted to PBDs have been the topic of several reports in the popular media and by governmental agencies. For example, MedPAC stated in its March 2014 Report to Congress that Medicare pays more than twice as much for a level II echocardiogram in an outpatient facility (\$453) as it does in a freestanding physician office (\$189) (based on CY 2014 payment rates). The report determined that the payment difference creates a financial incentive for hospitals to purchase freestanding physicians' offices and convert them to HOPDs without changing their location or patient-mix. (MedPAC March 2014 Report to Congress, Chapter 3.) The Government Accountability Office (GAO) also published a report in response to a Congressional request about hospital vertical consolidation. Vertical consolidation is a transaction (or combination of transactions) through which a hospital acquires a physician practice. In addition, the Office of Inspector General (OIG) published a report in June 2016 entitled "CMS Is Taking Steps To Improve Oversight of Provider-Based Facilities, But Vulnerabilities Remain" (OEI-04-12-

00380), in which it highlighted concerns about provider-based status in light of the higher costs to both the Medicare program and Medicare beneficiaries relative to when the same services are furnished at a freestanding facility such as a physician's office. These types of reports highlight the types of concerns we believe Congress may have been trying to address with section 603 of Public Law 114-74.

As we stated in the CY 2017 OPSS/ASC proposed rule, as we developed our proposal to implement section 603, we took into consideration the concerns described above, the specific statutory language, and the discretion provided in that statutory language. As described in detail earlier and below, paragraphs (1)(B)(v) and (21) of section 1833(t), as added by section 603 of Public Law 114-74, provide that certain items and services furnished by certain off-campus PBDs (that is, nonexcepted items and services furnished by nonexcepted off-campus PBDs) are not covered OPD services under the OPSS, and that payment shall be made for those applicable items and services under the applicable payment system if the requirements for such payment are otherwise met. However, the statutory amendments do not reference or define a specific applicable payment system under which payment shall be made.

We have established and maintained institutional Medicare payment systems based on specific statutory requirements and on how particular institutions provide particular kinds of services and incur particular kinds of costs. The rules regarding provider and supplier enrollment, conditions of participation, coverage, payment, billing, cost reporting, and coding vary across these institutional payment systems. While some of the requirements are explicitly described in statute and others are captured in CMS regulatory rules or subregulatory guidance, the requirements are unique to the particular type of institution.

Section 1833(t)(21)(C) of the Act provides for the availability of payment under other payment systems for "nonexcepted items and services." Section 1833(t)(21)(C) of the Act provides that payments for these nonexcepted items and services furnished by a nonexcepted off-campus PBD shall be made under the applicable payment system under Medicare Part B (other than under this subsection, that is OPSS), if the requirements for such payment are otherwise met.

While we noted our intention to provide a mechanism for a hospital to bill and receive payment for nonexcepted items and services

furnished by an off-campus PBD under an applicable payment system that is not the OPSS in the proposed rule, we further noted that there was no straightforward way to do that before January 1, 2017. As discussed elsewhere in this final rule with comment period, we also proposed the MPFS to be the applicable payment system for nonexcepted items and services furnished and billed by off-campus PBDs. We stated in the proposed rule that, at a minimum, numerous complex systems changes would need to be made to allow an off-campus PBD to bill and be paid as another provider or supplier type. For example, currently, off-campus PBDs bill under the OPSS for their services on an institutional claim, whereas physicians and other suppliers bill under the MPFS on a practitioner claim; and there are numerous systems edits designed to be sure that entities enrolled in Medicare bill for their services only within their own payment systems. The Medicare system that is used to process professional claims (the Multi-Carrier System or "MCS") was not designed to accept nor process institutional OPSS claims. Rather, OPSS claims are processed through an entirely separate system referred to as the Fiscal Intermediary Standard System or "FISS" system. To permit an off-campus PBD to bill under a different payment system than the OPSS would require significant changes to these complex systems as well as other systems involved in the processing of Medicare Part B claims. In the proposed rule, we did not suggest these operational issues are insurmountable, but we indicated that they are multifaceted and will require time and care to resolve. As such, we did not propose a mechanism for an off-campus PBD to bill and receive payment for nonexcepted items and services furnished on or after January 1, 2017, under an applicable payment system that is not the OPSS.

As described in greater detail below, in order to begin implementing the requirements of section 603 of Public Law 114-74, we proposed to specify that the applicable payment system for purposes of section 1833(t)(21)(C) of the Act is the MPFS. We indicated that while we did not believe there is a way to permit off-campus PBDs to bill for nonexcepted items and services they furnish under the MPFS beginning January 1, 2017, we were actively exploring options that would allow off-campus PBDs to bill for these services under another payment system and be paid at the applicable rate under such system beginning in CY 2018. We solicited public comment on the

changes that might need to be made to enrollment forms, claim forms, the hospital cost report, as well as any other operational changes that might need to be made in order to allow an off-campus PBD to bill for nonexcepted items and services under a payment system other than the OPSS in a way that provides accurate payments under such payment system and minimizes burden on both providers and Medicare beneficiaries. Accordingly, we stated that we intended the policy we proposed to be a temporary, 1-year solution until we could adapt our systems to accommodate payment to off-campus PBDs for the nonexcepted items and services they furnish under the applicable payment system, other than OPSS. The public comments we received on this proposal will be discussed in the following sections that discuss each aspect of the proposed payment policy in detail.

b. Payment for Applicable Items and Services Furnished in Off-Campus PBDs That Are Subject to Sections 1833(t)(1)(B)(v) and (21) of the Act

(1) Definition of “Applicable Payment System” for Nonexcepted Items and Services

In the CY 2017 OPSS/ASC proposed rule (81 FR 45688), we describe our interpretation and proposed implementation of section 1833(t)(21)(C) of the Act, as it applies to nonexcepted items and services for CY 2017. Section 1833(t)(21)(C) of the Act requires that payments for nonexcepted items and services be made under the applicable payment system under Medicare Part B (other than under this subsection; that is, the OPSS) if the requirements for such payment are otherwise met. While section 1833(t)(21)(C) of the Act clearly specifies that payment for nonexcepted items and services shall not be made under section 1833(t) (that is, the OPSS), it does not define the term “applicable payment system.” In analyzing the term “applicable payment system,” we considered whether and how the requirements for payment could be met under alternative payment systems in order to pay for nonexcepted items and services, and considered several other payment systems under which payment is made for similar items and services, such as the ASC payment system, the MPFS, or the CLFS.

As noted above, many off-campus PBDs were initially enrolled in Medicare as freestanding physician practices, and were converted as evidenced by the rapid growth of vertical hospital consolidation and hospital acquisition of physician

practices.⁵ We believe that this trend has continued. In September 2016, the Physicians Advocacy Institute collaborated with Avalere Health to study recent physician employment trends.⁶ Avalere analyzed a database that contains physician and practice location information on hospital/health system ownership and linked data with the CMS National Plan & Provider Enumeration System. The findings showed that hospital ownership of physician practices has increased by 86 percent and the percent of hospital-employed physicians increased by almost 50 percent from July 2012 to July 2015.

Before these physician practices were converted to off-campus PBDs, the services furnished in these locations were paid under the MPFS using an appropriate place of service code that identified the location as a nonfacility setting. This would trigger Medicare payment under the MPFS at the nonfacility rate, which includes payment for the “practice expense” resources involved in furnishing services. Many physician practices that were acquired by a hospital became provider-based to the hospital in accordance with the regulations at 42 CFR 413.65. Once a hospital-acquired physician practice became provider-based, the location became an off-campus PBD eligible to bill Medicare under the OPSS for its facility services, while physicians’ services furnished in the off-campus PBD were paid at the facility rate under the MPFS. Because many of the services furnished in off-campus PBDs are identical to those furnished in freestanding physician practices, as discussed later in this section, in the CY 2017 OPSS/ASC proposed rule, we proposed to designate the applicable payment system for the payment of the majority of nonexcepted items and services to be the MPFS. Specifically, we proposed that, because we currently do not have a mechanism to pay the off-campus PBD for nonexcepted items and services, the physician or practitioner would bill and be paid for items and services in the off-

campus PBD under the MPFS at the nonfacility rate instead of the facility rate.

When items and services similar to those often furnished by off-campus PBDs are furnished outside of a setting with an applicable Medicare institutional payment system, Medicare payment is generally made under the MPFS under one of several different benefit categories of Medicare benefit such as physician’s services, diagnostic tests, preventive services, or radiation treatment services. Although section 1833(t)(1)(B)(v) of the Act specifically carves out from the definition of covered OPD services those items and services defined at section 1833(t)(21)(A) of the Act furnished by certain off-campus PBDs defined by section 1833(t)(21)(B) of the Act, the amendments to section 1833(t) of the Act do not specify that the off-campus outpatient departments of a provider are no longer considered a PBD part of the hospital. We stated in the proposed rule that this nuance made it difficult for us to determine how to provide payment for the hospital-based portion of the services under MPFS because, as previously noted, Medicare payment processing systems were not designed to allow these off-campus PBDs to bill for their hospital services under a payment system other than OPSS.

Currently, a hospital (including a PBD) does not meet the requirements to bill under another payment system; that is, a hospital and its departments are enrolled as such in the Provider Enrollment, Chain and Ownership System (PECOS) and may only submit institutional claims for payment of covered OPD services under the hospital OPSS under the CMS Certification Number of the hospital. As explained above, there are several other Medicare payment systems for other types of providers and suppliers. Many of these are designed for particular kinds of institutional settings, are specifically authorized by law, and have their own regulations, payment methodologies, rates, enrollment and billing requirements, and in some cases, cost reporting requirements. While the services furnished in a PBD may be the same or similar to those that are furnished in other sites of service, for Medicare purposes, an off-campus PBD is considered to be part of the hospital that meets the requirements for payment under the OPSS for covered OPD services. There currently is no mechanism for it to be paid under a different payment system. In order to allow an off-campus PBD to bill under the MPFS for nonexcepted items and services, we indicated in the proposed

⁵ The number of vertically consolidated hospitals and physicians increased from 2007 through 2013. Specifically, the number of vertically consolidated hospitals increased from about 1,400 to 1,700, while the number of vertically consolidated physicians nearly doubled from about 96,000 to 182,000. This growth occurred across all regions and hospital sizes, but was more rapid in recent years. (Government Accountability Office; GAO 16–189, December 2015; <http://www.gao.gov/products/GAO-16-189>).

⁶ Avalere Health Study. Physician Practice Acquisition Study: National and Regional Employment Changes. Prepared for Physicians Advocacy Institute. September 2016.

rule that we believe it would be necessary to establish a new provider/supplier type (for nonexcepted off-campus PBDs) that could bill and be paid under the MPFS for nonexcepted items and services using the professional claim. At the time of the proposed rule, we did not propose new mechanisms to allow an off-campus PBD to bill and receive payment from Medicare for these nonexcepted items and services as currently enrolled as a hospital based department. However, as described in detail later in this section, we solicited comments on changes that would need to be made in order to allow an off-campus PBD to bill for nonexcepted items services it furnishes under a payment system other than the OPSS.

Accordingly, we proposed the MPFS to be the applicable payment system for nonexcepted items and services that, but for section 603, would have otherwise been paid under the OPSS; and that payment would be made for applicable nonexcepted items and services to the physician or practitioner under the MPFS at the nonfacility rate because no separate facility payment would be made to the hospital. We also noted that, for CY 2017, no mechanism would allow an off-campus PBD to bill under the MPFS for nonexcepted items and services for which coding and billing rules would otherwise allow payment (such as the technical component of diagnostic tests or radiation treatment delivery services). We sought comment on the kinds of changes that would need to be made in order to allow off-campus PBDs to bill for these kinds of services in the future. We noted that the hospital may continue to bill for services that are not paid under the OPSS, such as laboratory services.

Comment: Many commenters disagreed that the MPFS should be the applicable payment system and suggested that the ASC payment system, a combination of the ASC payment system and the MPFS, or an entirely new Part B payment system should be the applicable payment system for nonexcepted items and services. Many of these commenters believed that the applicable payment system could be an entirely new payment system that is an amalgamation of current Part B payment systems (the ASC payment system, the MPFS, and the OPSS) that selects whichever current system best applies for the applicable service. Commenters noted that, for many surgical services, the ASC payment system would better reflect facility costs than the MPFS. MedPAC discouraged CMS from creating a new provider/supplier type.

MedPAC and other commenters agreed with the proposal to establish the MPFS as the applicable payment system for nonexcepted services. Other commenters suggested that the MPFS is an appropriate applicable payment system because it reduces cost of services for beneficiaries and creates more equitable payments between off-campus PBDs and nonprovider-based clinics that bill under the MPFS instead of the OPSS.

Response: We thank commenters for their feedback. After considering the public comments on the proposed rule, we continue to believe that the MPFS is the appropriate applicable payment system for nonexcepted items and services. As previously mentioned, many of the services furnished in off-campus PBDs are also furnished in the physician office setting. We reiterate that many off-campus PBDs were initially enrolled in Medicare as freestanding physician practices, and were converted as evidenced by the rapid growth of vertical hospital consolidation and hospital acquisition of physician practices. In addition, the findings of the recent Avalere Health study mentioned earlier showed that hospital ownership of physician practices has increased by 86 percent and the percent of hospital-employed physicians increased by almost 50 percent from July 2012 to July 2015. As mentioned previously in this section, MedPAC commended CMS for the effort to rigorously implement section 603 and stated that, if finalized, the proposals would have the potential to reduce the financial burden on taxpayers and beneficiaries, although there would likely be substantial administrative burdens on the agency and its contractors and providers. Furthermore, preliminary data billed by off-campus departments with the "PO" modifier indicate that most items and services furnished in those departments are the types of services that are also commonly furnished in the physician office setting. The most commonly billed item or service was for an evaluation and management visit, followed by diagnostic and imaging services, drugs or biologicals and drug administration. We believe that adopting the MPFS as the applicable payment system is the most appropriate system for these nonexcepted off-campus PBDs items and services and is appropriate to implement section 603. However, we are modifying our proposal regarding payment for nonexcepted items and services, as discussed in section X.A.3.a.(2) of this final rule with comment period.

(2) Definition of Applicable Items and Services and Section 603 Amendment to Section 1833(t)(1)(B) of the Act and Payment for Nonexcepted Items and Services for CY 2017

(a) Background

Section 1833(t)(21)(A) of the Act defines the term "applicable items and services" for purposes of paragraph (1)(B)(v) and paragraph (21) of section 1833(t) to mean items and services (other than those furnished by a dedicated emergency department). Paragraph (1)(B)(v) of such section then specifically carves out from the definition of covered OPD services, that is, those applicable items and services that are furnished on or after January 1, 2017, by an off-campus PBD, as defined in paragraph (21)(B) of such section. Thus, such applicable items and services are not eligible for payment under the OPSS because they are not covered OPD services. Under our proposals in the CY 2017 OPSS/ASC proposed rule, we explained that this would mean that all items and services furnished by a nonexcepted off-campus PBD and those nonexcepted items and services furnished by an excepted off-campus PBD (collectively references as nonexcepted items and services) are applicable items and services under the statute. Therefore, we stated in the proposed rule that instead of being eligible for payment under the OPSS as covered OPD services, paragraph (21)(C) of section 1833(t) of the Act requires that, for nonexcepted items and services, payment shall be made under the applicable payment system, other than OPSS, if the requirements for such payment are otherwise met. In other words, under our proposed rule, the payment requirement under paragraph (21)(C) of section 1833(t) of the Act applies to items and services furnished by nonexcepted off-campus PBDs and for expanded clinical families of services furnished by excepted off-campus PBDs (nonexcepted items and services). However, we note here that the proposed payment policy will not apply to expanded items and services because we are not finalizing our proposal with respect to expanded clinical families of services furnished by excepted off-campus PBDs.

(b) Payment Policy for CY 2017

In accordance with sections 1833(t)(1)(B)(v) and 1833(t)(21)(C) of the Act, we specified in the CY 2017 OPSS/ASC proposed rule that payment for nonexcepted items and services as defined in section X.A.2. of the proposed rule will no longer be made under the OPSS, effective January 1,

2017. Instead, we proposed that, for items and services for which payment can be made to a billing physician or practitioner under the MPFS, the physician or practitioner furnishing such services in the off-campus PBD would bill under the MPFS at the nonfacility rate. As discussed in the proposed rule, we do not believe that, under current systems, an off-campus PBD could be paid for its facility services under the MPFS, but we noted that we would actively explore options that would allow for this beginning in CY 2018. Alternatively, we noted that an off-campus PBD continues to have the option to enroll as a freestanding facility or supplier in order to bill for the nonexcepted items and services it furnishes (which is different from billing only for reassigned physicians' services) under the MPFS.

At the time of development of the proposed rule, we did not propose a change in payment policy under the MPFS regarding these nonexcepted items and services. However, in the CY 2017 MPFS proposed rule, we proposed to amend our regulations and subregulatory guidance to specify that physicians and nonphysician practitioners furnishing professional services would be paid the MPFS nonfacility rate when billing for such services because there will be no accompanying Medicare facility payment for nonexcepted items and services furnished in that setting. (We refer readers to the CY 2017 MPFS final rule with comment period for a discussion of the final policies for CY 2017.) The MPFS nonfacility rate is calculated based on the full costs of furnishing a service, including, but not limited to, space, overhead, equipment, and supplies. Under the MPFS, there are many services that include both a professional component and a technical component. Similarly, there are some services that are defined as either a "professional-only" or "technical-only" service. The professional component is based on the relative resource costs of the physician's work involved in furnishing the service and is generally paid at a single rate under the MPFS, regardless of where the service is performed. The technical component portion of the service is based on the relative resource costs of the nonphysician clinical staff who perform the test, medical equipment, medical supplies, and overhead expenses. When the service is furnished in a setting where Medicare makes a separate payment to the facility under an institutional payment system, the technical component is not paid under

the MPFS because the practitioner/supplier did not incur the cost of furnishing the technical component. Rather, it is paid to the facility under the applicable institutional payment system.

As we noted in the proposed rule, if an off-campus PBD that furnishes nonexcepted items and services wishes to bill Medicare for those services, it could choose to meet the requirements to bill and receive payment under a payment system other than the OPFS by enrolling the off-campus PBD as another provider/supplier type. For example, an off-campus PBD could enroll in Medicare as an appropriate alternative provider or supplier type (such as an ASC or physician group practice). The enrolled provider/supplier would then be able to bill and be paid under the payment system for that type of Medicare enrolled entity. For example, if an off-campus PBD were to enroll as a group practice, it would bill on the professional claim and be paid under the MPFS at the nonfacility rate in accordance with laws and regulations that apply under the MPFS.

We recognize that our proposal in the CY 2017 OPFS/ASC proposed rule to pay under the MPFS for all nonexcepted items and services furnished to beneficiaries could result in hospitals establishing business arrangements with the physicians or nonphysician practitioners who bill under the MPFS. In the proposed rule, we solicited public comments regarding the impact of other billing and claims submission rules, the fraud and abuse laws, and other statutory and regulatory provisions on our proposals. Specifically, we solicited public comments regarding the limitations of section 1815(c) of the Act and 42 CFR 424.73 (the reassignment rules); the limitations of section 1842(n) of the Act and 42 CFR 414.50 (the anti-markup prohibition); the application of section 1877 of the Act and 42 CFR 411.350 through 411.389 (the physician self-referral provisions) to any compensation arrangements that may arise; and the application of section 1128B(b) of the Act (the Federal anti-kickback statute) to arrangements between hospitals and the physicians and other nonphysician practitioners who refer to them. We stated that we will consider these laws and regulations as well, and look forward to reviewing public comments on the anticipated impact of these provisions on our proposed policy and any possible future proposals.

In the proposed rule, we noted that there are some services that off-campus departments may furnish that are not billed or paid under the OPFS. For

example, although laboratory tests are generally packaged under the OPFS, there are some circumstances in which hospitals are permitted to bill for certain laboratory tests and receive separate payment under the CLFS. These circumstances include:

- Outpatient laboratory tests are the only services provided. If the hospital provides outpatient laboratory tests only and no other hospital outpatient services are reported on the same claim.

- Unrelated outpatient laboratory tests. If the hospital provides an outpatient laboratory test on the same claim as other hospital outpatient services that is clinically unrelated to the other hospital outpatient services (that is, the laboratory test is ordered by a different practitioner than the practitioner who ordered the other hospital outpatient services and for a different diagnosis than the other hospital outpatient services). We note that this exception was proposed for deletion for CY 2017, and this deletion is being finalized in this final rule with comment period. We refer readers to section II.A.3.b.(2) of this final rule with comment period for a discussion of this policy.

- Molecular pathology laboratory tests and advanced diagnostic laboratory tests (ADLTs) (section II.A.3.b.(3) of this final rule with comment period).

- Laboratory tests that are preventive services.

Under our proposal, if a laboratory test furnished by a nonexcepted off-campus PBD is eligible for separate payment under the CLFS, the hospital may continue to bill for it and receive payment under the CLFS. In addition, a bill may be submitted under the MPFS by the practitioner (or hospital for physicians who have reassigned their benefit), provided that the practitioner meets all the MPFS requirements. Consistent with cost reporting guidance and the Medicare Provider Reimbursement Manual, Part 1, Chapter 23, Section 2302.8, hospitals should report these laboratory services on a reimbursable cost center on the hospital cost report.

In addition, with respect to partial hospitalization programs (PHP) (intensive outpatient psychiatric day treatment programs furnished to patients as an alternative to inpatient psychiatric hospitalization or as a stepdown to shorten an inpatient stay and transition a patient to a less intensive level of care), 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 CMHC. Because CMHCs also furnish PHP services and are ineligible to be

provider-based to a hospital, we noted in our proposal that a nonexcepted off-campus PBD would be eligible for PHP payment if the entity enrolls and bills as a CMHC. We noted that a hospital may choose to enroll a nonexcepted off-campus PBD as a CMHC, provided it meets all Medicare requirements and conditions of participation. While a hospital could still choose this option, we are modifying this proposal in order to provide for payment for PHP services furnished by a nonexcepted off-campus PBD under the MPFS as explained later in this interim final rule with comment period.

Comment: Many commenters opposed the payment proposal for nonexcepted items and services because they believed it would make no payment to hospitals for the nonexcepted items and services they furnish to Medicare beneficiaries. These commenters specifically noted that, under the proposal, no payment would be made to the nonexcepted off-campus PBD of the hospital for the nursing, laboratory, imaging, chemotherapy, surgical services, and many other reasonable and necessary services they provide to Medicare beneficiaries. The commenters believed that such a payment policy is unjustified. In addition, these commenters believed that CMS has a mechanism at its disposal that it could use to pay hospitals directly for nonexcepted services under the MPFS and urged CMS to work to be able to use this, or another, mechanism to provide reasonable payment to hospitals. The commenters stated that CMS must delay implementation of its site-neutral policies until it does so. In addition, the commenters objected to the notion that an off-campus PBD would have to enroll as a different provider/supplier type in order to bill for its services.

Many commenters raised concerns regarding the impact of the fraud and abuse laws on hospitals and physicians in the event that CMS finalizes the proposals. Commenters identified perceived legal and operational impediments associated with the payment policies as they affect nonexcepted off-campus OPDs. Specifically, the commenters were concerned that the proposed payment policies, if finalized, would require hospitals to enter into financial relationships with referring physicians that cannot satisfy the requirements of an applicable exception to the physician self-referral law, resulting in a violation of that law's referral and claims submission prohibitions and subjecting hospitals to False Claims Act liability. Some commenters expressed doubt that, even if hospitals and physicians could

structure their business arrangements to avoid noncompliance with the physician self-referral law and Federal anti-kickback statute, they could do so by January 1, 2017 when the payment policies would go into effect. As a result, according to the commenters, beneficiary access could be limited if off-campus PBDs were forced to close or remain "frozen" as of November 2, 2015 due to their inability to comply with the physician self-referral law or Federal anti-kickback statute. A few commenters believed that the impact and effect of the proposals would be particularly burdensome in rural areas where, often, the only available services are provided by hospitals. Other commenters expressed concerns about the impact of certain State laws, such as fee-splitting and corporate practice of medicine prohibitions, on the ability of hospitals and physicians to implement changes in their business and employment arrangements in order to comply with the proposed payment policies if finalized. One commenter expressed concerns about potential False Claims Act liability if a physician were to submit a claim with the place of service noted as "non-facility" (in accordance with the CMS billing and claims submission rules under the proposed payment policy) when the service was, in fact, furnished in a nonexcepted off-campus PBD.

Response: We appreciate the commenters' consideration of our proposals regarding the impact of the Federal fraud and abuse laws on hospitals and physicians should we finalize our proposals. We reiterate our belief that our proposal to make payment under the MPFS at the nonfacility rate for CY 2017 only would result in site neutral payment between physician offices and hospitals for furnished nonexcepted items and services, and we disagree that our proposal was "unjustified." However, we agree with the commenters that our proposed payment policies could have required hospitals and physicians to establish financial relationships that implicate the physician self-referral law and Federal anti-kickback statute for CY 2017 only. Further, we recognize the difficulties that would be faced by hospitals and physicians in establishing financial relationships that comply with the physician self-referral law and other fraud and abuse laws (mentioned earlier) under our proposed payment methodology for nonexcepted items and services. Therefore, we are not finalizing our proposal. Instead, we are issuing an interim final rule with comment period under section X.B. of this document

(and in conjunction with this final rule with comment period) to establish rates under the MPFS that will be paid for nonexcepted items and services furnished by off-campus PBDs, effective for services furnished on or after January 1, 2017. Because we are providing for payment directly to hospitals that furnish services to beneficiaries in nonexcepted off-campus PBDs, we believe that the commenters' concerns regarding the application of the Federal fraud and abuse laws are moot. Specifically, we refer readers to our commentary in the CY 2016 MPFS final rule with comment period (80 FR 71321) where we discuss the application of the physician self-referral law in "split billing" arrangements under which a hospital bills the Medicare program under the OPPS for the resources and services that it furnishes to a beneficiary in a PBD (that is, the facility fee) and the referring physician bills the Medicare program under the MPFS for only the professional services that he or she furnishes to the beneficiary in a PBD.

Details about the specific payment that will be made for these services are included in the interim final rule with comment period under section X.B. of this document.

Comment: Many commenters who did not support the proposed payment policy and who suggested that CMS delay implementation of the section 603 provisions requested that CMS convene a stakeholder workgroup or gather stakeholder input and expert advice on an alternative payment policy. Some commenters suggested that CMS pay providers the technical component of services from the MPFS. Many hospital commenters believed that the MPFS nonfacility rate is insufficient to pay for services provided at hospital facilities. Some commenters objected to the idea of nonexcepted off-campus PBDs having to enroll as another provider/supplier type to receive Medicare payment, especially if the CY 2017 policy is a transition to a more permanent policy in CY 2018. Some commenters suggested paying hospitals through the institutional claim at MPFS rates. Other commenters suggested adopting the ASC payment system as the applicable payment system instead of the MPFS.

Some commenters recommended that CMS adopt an alternative payment policy that would allow the off-campus PBD to bill under the OPPS using a modifier that would trigger payment based on the practice expense for the service under the MPFS. Commenters believed that this alternative would allow facility payment for services provided until CMS develops a new

payment system or billing mechanism. Other commenters noted that hospital-billed therapy and laboratory services are currently paid under other fee schedules and stated that Medicare already has the ability to pay for nonexcepted items and services billed on the institutional claim.

Response: We thank commenters for their feedback. We do not believe a delay in implementation is necessary. We also note that delaying the provision for a year would not only result in not meeting the statutory deadline for implementing section 603, but also a year's loss of savings to the Medicare Part B program, which the CMS Office of the Actuary estimates to be \$50 million for CY 2017 in this final rule.

We are issuing an interim final rule with comment period under section X.B. of this document to establish new MPFS rates for nonexcepted items and services furnished in an off-campus PBD. Providers will be able to bill for nonexcepted items and services on the institutional claim utilizing new claim line modifier "PN" to indicate that an item or service is a nonexcepted item or service. We consider these rates to be site-of-service specific rates for the technical component of MPFS services.

As described in the interim final rule with comment period, for CY 2017, the newly established MPFS rate for nonexcepted items and services will be based upon OPPS rates. That is, several payment policies that apply under the OPPS, including C-APCs and OPPS packaging logic, are being adopted under the newly established site-of-service MPFS rates. Because we do not currently have site-of-service specific data from nonexcepted off-campus PBDs on which to base these rates for CY 2017, we conducted an analysis of off-campus PBD payment data from 2016 and compared these payment data to MPFS rates. As discussed in detail in the interim final rule with comment period under section X.B. of this document, we are using a rate that is 50 percent of the OPPS rate for each nonexcepted item or service, with some exceptions, as the interim technical component of MPFS services for items or services provided at a nonexcepted PBD. We are seeking public comments on the new payment mechanisms and rates detailed in the interim final rule with comment period and, based on these comments, will make adjustments as necessary to the payment mechanisms and rates through rulemaking that could be effective in CY 2017.

We agree with the commenters who recommended that we pay for nonexcepted items and services using

the technical component of the facility MPFS rate. Specifically, we are establishing, under the interim final rule with comment period, policies under the MPFS that will allow nonexcepted off-campus PBDs to be paid the site-specific technical component for services beginning in CY 2017. As discussed in the interim final rule with comment period, the initial payment rates will be made based on the general relationship between OPPS and MPFS rates for comparable services. Therefore, we note that payments under our interim final rule policy may not be exactly equal to payment under the technical component of MPFS for any specific item or service. Over time, we believe this billing and payment mechanism will provide information that will help us to refine and improve the accuracy of payment for these services under the MPFS. We will continue to pay for therapy and preventive services, as well as separately payable drugs, at the MPFS rate because nonexcepted off-campus PBDs would bill under the MPFS.

The new rates under the MPFS will incorporate several important exceptions to the general payment methodologies. These exceptions are described in the interim final rule with comment period. Briefly, because payment for Part B drugs is prescribed under section 1842(o) and 1847A of the Act and separately payable Part B drugs are paid at the same rate under the OPPS and the MPFS, which is a longstanding policy determination rather than a statutory requirement, we are not reducing the payment rate for separately payable Part B drugs. Similarly, we will use the existing MPFS rate for items and services that are currently paid the MPFS rate under the OPPS, including the majority of therapy and preventive services.

We believe that these payment policies address the majority of issues and concerns raised by commenters. Accordingly, we do not believe it is necessary to establish a formal stakeholder workgroup. However, we continue to be interested in feedback and comments from all interested parties on the payment policies we have set forth in the interim final rule with comment period, especially comments related to stakeholders' preference for the approach being adopted in the interim final rule with comment period as well as potential other approaches, or ratesetting methodologies based on readily available data.

Comment: Many commenters noted that, under the proposed rule, there would be services for which no payment would be available because there is no

payment rate for these services under the MPFS or because these services are furnished "incident to" physician services. Commenters noted that these services included drug administration, Part B drugs, clinical laboratory services, observation services, partial hospitalization services, and services that do not have nonfacility RVUs under the MPFS. Commenters expressed concern that the proposed payment policy would result in impracticable payment options for these services would lead to access issues for beneficiaries.

Commenters specifically noted that outpatient services furnished "incident-to" physicians' services are only priced in the nonfacility setting under the MPFS. The commenters added that payment for these services is provided under the OPPS, not the MPFS, when these services are provided in an outpatient setting. The commenters suggested that payment to the practitioner for "incident to" services furnished in a nonexcepted off-campus PBD would run counter to CMS' "incident to" regulations at 42 CFR 410.26 (b)(1), which state that services and supplies must be furnished in a noninstitutional setting to noninstitutional patients. The commenters suggested that these regulations indicated that there would be no payment for "incident-to" services provided by non-accepted PBDs under the proposed policy, as payment could not be made to the PBD nor the practitioner for these services.

Response: We thank the commenters for their feedback. As discussed in the interim final rule with comment period, we are implementing a policy that will allow hospitals to bill for nonexcepted items and services, including many of the types of services that commenters mentioned, under newly established rates under the MPFS that are being adopted in the interim final rule with comment period.

Comment: Several commenters disagreed with the payment proposal as it relates to PHP services. These commenters stated that the proposal would provide no payment for PHP services which would disrupt the continuity of care that is provided by hospital-based PHPs and restrict access to PHP services. Several commenters urged CMS to apply the authority under section 1833(t)(2)(E) of the Act, thereby allowing nonexcepted off-campus PBD PHPs to continue being paid under OPPS. Many commenters believed that Congress did not intend for PHP to no longer be paid when furnished at nonexcepted off-campus PBDs. In addition, the commenters noted that

application of the MPFS to nonexcepted off-campus PBDs would require hospitals to hire additional physicians in order to meet the MPFS supervision requirements and completely restructure residency programs so that attending physicians meet the requirements to provide “personally performed services” to obtain payment under the MPFS. The commenters believed this would radically alter the residency training programs and impose extraordinary new costs to hire attending supervisors to attend to patients with trainees.

Several commenters disagreed with the notion of enrolling as a CMHC in order to receive payment, stating that hospital-based PHPs and CMHCs are inherently different in structure, operation, and reimbursement, and noting that the conditions of participation for hospital departments and CMHCs are different.

Response: Sections 1833(t)(1)(B)(v) and (t)(21) do not exempt PHP services from application of section 603. In response to the commenters who requested that we apply section 1833(t)(2)(E) of the Act to exclude PHP services from application under section 603, while section 1833(t)(2)(E) of the Act does provide fairly broad authority to make “other adjustments as determined to be necessary to ensure equitable payments,” we do not believe this authority extends to exempting a class of hospital off-campus PBDs from application of a separate statutory provision specifically prohibiting payment under the OPFS itself. In other words, for these PHP services provided by hospital-based PHPs to which sections 1833(t)(1)(B)(v) and (t)(21) of the Act apply, there would be no OPFS payment to which a payment adjustment could be made.

In addition, we are adopting as final our proposal that the applicable payment system is the MPFS. As noted in the interim final rule with comment period in section X.B. of this document, PHP services are payable to hospitals only under the OPFS. As we have for certain other nonexcepted items and services, we are identifying the MPFS as the applicable payment system for PHP services furnished by a nonexcepted off-campus PBD, and we are setting the MPFS payment rate for these PHP services as the rate that would be paid to a CMHC. Therefore, hospital-based PHPs to which sections 1833(t)(1)(B)(v) and (t)(21) of the Act apply will continue to be able to bill and be paid for the furnishing of those services. Alternatively, as we proposed, these PBDs may choose to enroll as a CMHC in order to continue to provide PHP

services and receive Medicare payment. We acknowledge that CMHCs and hospital-based PHPs have differences in structure, operation, and payment, and that there can be advantages to providing PHP care through a hospital-based PHP. In the CY 2017 OPFS/ASC proposed rule (81 FR 45681), we noted that when a beneficiary receives services in an off-campus department of a hospital, the Medicare payment for those services is generally higher than when those same services are provided in a physician’s office. Similarly, when partial hospitalization services are provided in a hospital-based PHP, Medicare pays more than when those same services are provided by a CMHC. CMHCs are freestanding providers that are not part of a hospital, and that have lower cost structures than hospital-based PHPs. This is similar to the differences between freestanding entities paid under the MPFS that furnish other services also provided by hospital-based entities. We believe that paying for nonexcepted hospital-based partial hospitalization services at the lower CMHC per diem rate is in alignment with section 603 of Public Law 114–74, while also preserving access to the PHP benefit. As we noted in section VIII.B.1 of this final rule with comment period, Medicare beneficiaries with mental health needs can access outpatient care in a variety of ways, including individual mental health services that are reasonable and medically necessary. Therefore, we believe that beneficiaries will still have access to mental health care.

In regards to the comment that the application of the MPFS to nonexcepted off-campus PBDs would require hospitals to hire additional physicians in order to meet the MPFS supervision requirements, the requirements for supervision are the same whether the PHP is on-campus or off-campus. The amendments made by section 603 of Public Law 114–74 did not change the status of these PBDs; only the status of and payment mechanisms for the services they furnished changed.

Comment: Many commenters stated that it was important that hospitals be able to bill for the facility portion of payment on the institutional claim. These commenters noted that hospital claim systems are designed to utilize the institutional claim and suggested that if CMS proposed that hospitals utilize the practitioner claim for these services, it would represent a significant burden for providers. Some commenters noted that the statute that amended section 1833(t)(21)(D) of the Act to allow the Secretary to collect information from hospitals to implement this provision

included the parenthetical phrase “(which may include reporting of information on a hospital claim using a code or modifier)”; these commenters suggested that this parenthetical phrase indicates that Congress envisioned that nonexcepted items and services would be billed on a hospital claim. Commenters inquired whether and how nonexcepted items and services would be included in the 3-day payment window if the nonexcepted items and services were billed on a practitioner claim. Commenters suggested that supplemental payers may have difficulty processing claims that have hospital outpatient services billed on both an institutional claim and a practitioner claim. Commenters also suggested there may be implications for the Health Insurance Portability and Accountability Act (HIPAA) transaction standards if institutional services are billed on a professional claim. Some commenters noted that if nonexcepted items and services are not billed on an institutional claim, these services would not appear on Provider Statistical and Reimbursement reports. MedPAC and other commenters suggested that nonexcepted items and services should be included on hospital cost reports because CMS has indicated that it will view nonexcepted off-campus PBDs as part of the hospital.

Response: We thank commenters for their feedback. We do not interpret section 1833(t)(21)(D) of the Act to mean that the statute requires that nonexcepted items and services be billed on an institutional claim. Rather, it explicitly provides the Secretary the authority to collect data from hospitals for purposes of implementing section 603 through means such as a modifier on the hospital claim. As discussed in the interim final rule with comment period, we are implementing a policy that will allow hospitals to identify and bill for nonexcepted items and services on the institutional claim with HCPCS modifier “PN”. Hospital outpatient services identified with the modifier will continue to be reflected on Provider Statistical and Reimbursement reports. We believe implementation of this policy will obviate the commenters’ concerns with the possibility that facility costs for nonexcepted items and services would not be billed and reflected as reimbursable costs on the Medicare hospital cost report.

Comment: Several commenters requested that specific services paid under the OPFS be exempt from application of this provision, either because the service is most commonly performed in the outpatient setting or because of the importance of the service.

Response: We thank the commenters for their feedback. We do not believe the statute allows us to exempt items and services from application of this provision unless the items or services are specifically mentioned in section 1833(t)(21) of the Act as exempt from application of this provision, such as those furnished in a dedicated ED. We reiterate that we are adopting MPFS rates for nonexcepted items and services in the interim final rule with comment period in section X.B. of this document. We refer readers to the interim final rule with comment period for details on payment for various categories of items and services.

Comment: Many commenters requested that CMS clarify how payment for laboratory services and Part B drugs would be made for nonexcepted items and services.

Response: As discussed in the interim final rule with comment period in section X.B. of this document, laboratory services that are separately paid under the CLFS under standard OPFS policy will be separately paid under the CLFS. Laboratory services that are packaged under standard OPFS policy will continue to be packaged under the newly established MPFS rate for nonexcepted items and services. Part B drugs that are separately payable under the OPFS will still be paid separately under the newly established policy using the Part B drug pricing methodologies under sections 1842(o) and 1847A of the Act. That is, in accordance with a longstanding policy rather than a statutory requirement, we generally pay separately payable Part B drugs at ASP + 6 percent. Drugs that are packaged into OPFS services are not separately paid under the current OPFS rates and will not be separately paid under the newly established MPFS rates.

Comment: Many commenters noted that the proposed rule did not specifically address whether nonexcepted off-campus PBDs would be eligible as “child sites” under HRSA’s 340B drug program. These commenters noted that, under the proposal, most nonexcepted items and services would not be billed on the institutional claim and therefore would not automatically be recorded as a reimbursable cost center on the cost report, which under HRSA’s methodology would make them eligible for the 340B drug program. Most of these commenters indicate that nothing in section 603 mentions the 340B drug program and that, as a result, the 340B drug program should not be affected by the implementation of section 603. These commenters suggested that CMS specifically indicate

in the final rule that we do not intend for implementation of section 603 to affect the 340B drug program. Other commenters suggested that the intention of the statute was to remove incentives to provide care in the outpatient setting that could be provided in a physician’s office, and thus that CMS indicate that nonexcepted off-campus PBDs should not be eligible for the 340B drug program. Some commenters suggested that nonexcepted off-campus PBDs should be considered PBDs of hospitals, but that their costs should not show up as payable on a cost report, and that, as such, they should not be eligible for the 340B drug program.

Response: We note that, under our finalized policy, services provided at nonexcepted off-campus PBDs will continue to be reported on the hospital cost report. We refer interested parties to HRSA for questions on when drugs qualify for discounts under the 340B program. To the extent that our final payment policies necessitate a change for hospital cost reporting, we will issue guidance, as applicable, in subregulatory guidance.

(3) Comment Solicitation on Allowing Direct Billing and Payment for Nonexcepted Items and Services in CY 2018

In the CY 2017 OPFS/ASC proposed rule (81 FR 45690), for nonexcepted items and services furnished in an off-campus PBD, we solicited public comments on developing a new billing and payment policy proposal for CY 2018. Specifically, we solicited comments regarding whether an off-campus PBD should be allowed to bill nonexcepted items and services on the professional (not institutional) claim and receive payment under the MPFS, provided the off-campus PBD meets all the applicable MPFS requirements. Under this scenario, we envisioned that the PBD would still be considered to be part of the hospital and that the hospital as a whole would continue to be required to meet all applicable conditions of participation and regulations governing its provider-based status, but, for payment purposes, the off-campus PBD would be considered a nonhospital setting that is similar to a freestanding physician office or clinic and that is paid the same rate that is paid to freestanding offices or clinics under the MPFS. We noted that there are other nonpractitioner entities that bill these kinds of services under the MPFS (for example, Independent Diagnostic Testing Facilities, Radiation Treatment Centers), and we sought public comments on whether or not there are administrative impediments

for hospitals billing for such services. We sought public comments on whether making the necessary administrative changes that would allow the hospital to bill for these kinds of services under the MPFS would provide any practical benefit to the hospitals relative to the current requirements for billing under the MPFS. We also solicited public comments on other implications or considerations for allowing the hospital to do this, such as how the cost associated with furnishing such services might be reflected on the hospital cost report.

Comment: MedPAC recommended that CMS not create a new provider/supplier type for nonexcepted off-campus PBDs because this would add unnecessary complexity. MedPAC suggested that, instead, CMS continue its proposed 2017 policy of paying the practitioner under the MPFS at the nonfacility rate. Many commenters noted the difficulty providers would have in implementing the proposed temporary payment policy for CY 2017, then adapting their systems to receive facility payments for nonexcepted items and services under the practitioner claim process in CY 2018. Other commenters suggested that CMS include a proposed CY 2018 payment policy for nonexcepted items and services in the CY 2017 final rule, in order for providers to have a better idea of what the CY 2018 payment policy would require while providers are adapting their systems for the CY 2017 payment policy.

Response: We thank commenters for their feedback. As discussed in the interim final rule with comment period in section X.B. of this document, we are implementing a policy that will allow providers to bill for nonexcepted items and services on the institutional claim. We appreciate commenters’ feedback about billing for facility costs for nonexcepted items and services on the professional claim. We intend to continue open communication with stakeholders on an ongoing basis and will take these comments into consideration for future rulemaking as we develop and refine the payment mechanisms under the newly established MPFS policies.

4. Beneficiary Cost-Sharing

Under our proposed policy in the CY 2017 OPFS/ASC proposed rule, payment for most nonexcepted items and services under section 1833(t)(21)(C) of the Act would be made under the MPFS to the physician at the nonfacility rate. As a result, the beneficiary cost-sharing for such nonexcepted items and services would

generally be equal to the beneficiary cost-sharing if the service was provided at a freestanding facility.

Comment: Some commenters suggested that if, in CY 2018, CMS provided a way for providers to bill for nonexcepted items and services utilizing a practitioner claim, this may prove to be confusing to beneficiaries, who could then receive up to three bills for copayments: One from the provider for excepted services billed on the institutional claim; one from the provider for nonexcepted services billed on the practitioner claim; and one from the practitioner billed on the practitioner claim.

Response: We thank commenters for their feedback. As discussed earlier, we are implementing a policy that will allow providers to bill for nonexcepted items and services on the institutional claim, and we believe implementation of this policy will obviate the concerns the commenters noted above. We note that, under the interim final rule with comment period in section X.B. of this document, beneficiary cost-sharing will generally be equal to that which applies under the MPFS.

5. Summary of Finalized Policies

Under our finalized policy, all excepted off-campus PBDs will be permitted to continue to bill for the furnishing of excepted items and services under the OPSS. These excepted items and services include those furnished in an ED, in an on-campus PBD, or within the distance from a remote location of a hospital facility. In addition, excepted items and services include those furnished by an off-campus PBD that was billing Medicare for covered OPD services furnished prior to November 2, 2015, the date of enactment of Public Law 114–74, provided that the excepted off-campus PBD does not impermissibly relocate from the same physical address of the PBD on the provider enrollment form as of November 2, 2015 (with limited exceptions for extraordinary circumstances), or experience an impermissible change of ownership (CHOW). That is, an excepted off-campus PBD will lose its status as excepted (that is, the off-campus PBD will be considered a new nonexcepted off-campus PBD) if the excepted off-campus PBD changes location or changes ownership. An off-campus PBD that experiences a CHOW will continue its excepted status only if the new hospital owners acquire the main hospital and adopt the existing Medicare provider agreement.

Items and services furnished in a new nonexcepted off-campus PBD (that is,

one that was not billing under the OPSS for covered OPD services furnished prior to November 2, 2015) will be nonexcepted items and services, no longer eligible for payment under the OPSS.

Beginning in CY 2017, the MPFS will be the “applicable payment system” for the majority of nonexcepted items and services furnished in an off-campus PBD. Physicians furnishing services in these nonexcepted departments will be paid based on the professional claim and will be paid at the facility rate for services for which they are permitted to bill, consistent with the established policy of applying the MPFS facility rate to the professional when Medicare makes a corresponding payment to the facility for the same service. Provided it can meet all Federal and other requirements, a hospital continues to have the option of enrolling the nonexcepted off-campus PBD as the type of provider/supplier for which it wishes to bill in order to meet the requirements of that payment system (such as an ASC or a group practice).

In response to public comments and due to concerns that our proposed payment policy may result in beneficiaries being unable to access needed medical services and administrative complexities for hospitals and physicians, we have decided to issue an interim final rule with comment period (in section X.B. of this document) to establish new MPFS rates for nonexcepted items and services. Under this final policy, a hospital will bill for nonexcepted items and services on the institutional claim and must identify that such items and services are nonexcepted through use of claim line modifier “PN.” This “PN” modifier will be used to trigger payment under the newly adopted PFS rates for nonexcepted items and services. Additional details about these payment rates are included in the interim final rule with comment period in section X.B. of this document.

As we and our contractors conduct audits of hospital billing, we and our contractors will examine whether nonexcepted off-campus PBDs are billing correctly for nonexcepted items and services. We expect hospitals to maintain proper documentation showing which individual off-campus PBDs were billing Medicare prior to November 2, 2015, and to make this documentation available to us and our contractors upon request.

6. Changes to Regulations

To implement the provisions of section 1833(t) of the Act, as amended by section 603 of Public Law 114–74, in

the CY 2017 OPSS/ASC proposed rule (81 FR 45691), we proposed to amend the Medicare regulations by (a) adding a new paragraph (v) to § 419.22 to specify that, effective January 1, 2017, for cost reporting periods beginning January 1, 2017, excluded from payment under the OPSS are items and services that are furnished by an off-campus provider-based department that do not meet the definition of excepted items and services; and (b) adding a new § 419.48 that sets forth the definition of excepted items and services, and also the definition of “excepted off-campus provider-based department”.

In response to public comments, we are modifying paragraph (v) of § 419.22 as specified in the interim final rule with comment period under section X.B. of this document and finalizing the addition of a new § 419.48 that sets forth the definition of excepted items and services and off-campus PBDs and codifies the MPFS, generally, as the applicable payment system.

7. Other Technical Clarification Requests

Comment: Several hospitals with high Medicaid populations expressed concern that State Medicaid programs may adopt site neutral payment policies. The commenters acknowledged that the site neutral policies included in the CY 2017 OPSS/ASC proposed rule are focused on the Medicare program, but urged CMS to direct States not to apply site neutral payment policies to State Medicaid programs.

Response: We appreciate the commenters’ concern with protecting access to hospital services for Medicaid recipients. As noted earlier, the section 603 provisions amended section 1833(t) of the Act, which authorizes Medicare payment to hospital outpatient departments. Our final policies to implement the amendments made by section 603 will provide a Medicare payment for nonexcepted items and services furnished by nonexcepted off-campus PBDs. We refer commenters to the Center for Medicaid and CHIP Services for questions on similar section 603 provisions for State Medicaid programs.

B. Interim Final Rule With Comment Period: Establishment of Payment Rates Under the Medicare Physician Fee Schedule for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital

1. Background

This interim final rule with comment period is being issued in conjunction with a final rule discussed under section X.A. of this document which implements section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74). Specifically, this provision amended the OPPS statute at section 1833(t) by amending paragraph (1)(B) and adding a new paragraph (21). Sections 1833(t)(1)(B)(v) and (t)(21) of the Act require that certain items and services furnished in certain off-campus provider-based departments (PBDs) (collectively referenced here as nonexcepted items and services furnished by nonexcepted off-campus PBDs) shall not be considered covered OPD services for purposes of OPPS, and payment for those nonexcepted items and services shall be made “under the applicable payment system” beginning January 1, 2017. In the CY 2017 OPPS/ASC proposed rule (81 FR 45681), we proposed to implement section 603, and we proposed that the MPFS would be the “applicable payment system” for the majority of the items and services furnished by nonexcepted off-campus PBDs. In this final rule with comment period, we are finalizing that proposal. As such, for purposes of payment for nonexcepted items and services, the applicable payment system is the MPFS. In the CY 2017 OPPS/ASC proposed rule, we noted that, due to concerns with the significant changes that would need to be made to complex Medicare billing and claims systems, we would not be able to operationalize a mechanism to make payment to the off-campus PBD for nonexcepted items and services under a payment system other than the OPPS by January 1, 2017. Therefore, in that proposed rule, we noted that we intended the payment proposal to be a temporary 1-year policy, applicable in CY 2017 only, while we continued to explore operational changes that would allow nonexcepted items and services to be billed by the off-campus PBD under the applicable payment system, which, in the majority of cases, would be the MPFS (81 FR 45687 through 45689).

We are finalizing, with modifications, our proposal to implement section 603 of Public Law 114–74 in the CY 2017 OPPS/ASC final rule with comment period and refer readers to section X.A.

of that final rule with comment period for a detailed discussion. As part of that discussion, we indicate that, in response to public comments received on the proposed payment policies for nonexcepted items and services, we are issuing this interim final rule with comment period to establish payment policies under the MPFS for nonexcepted items and services furnished on or after January 1, 2017. We thank commenters for their insightful comments during the proposed rule process and intend to continue open communication with stakeholders on an ongoing basis as we develop and refine the payment mechanisms for CY 2017 and for future years.

The following discussion establishes policies for nonexcepted items and services furnished by nonexcepted off-campus PBDs and billed by hospitals for payment under the MPFS. We are seeking public comments on the new payment mechanisms and rates detailed in this interim final rule with comment period and, based on these comments, will make adjustments as necessary to the payment mechanisms and rates through rulemaking that could be effective in CY 2017.

2. Payment Mechanisms

a. Relevance of the MPFS for Payment for Nonexcepted Items and Services

Under the MPFS, Medicare makes payment to physicians, nonphysician practitioners, and other suppliers for physicians’ services as specified in section 1848 of the Act. In accordance with section 1848(b) and (c) of the Act, MPFS payment is based on the relative value of the resources involved in furnishing particular services. Because Medicare makes separate payment under institutional payment systems (such as the OPPS) for the facility costs associated with many of the same services, we establish two different MPFS payment rates for many of these services—one that applies when the service is furnished in a location where a facility bills and is paid for the service under a Medicare payment system other than the MPFS (the facility rate), and another that applies when the billing practitioner or supplier furnishes and bills for the entire service (the nonfacility rate). The nonfacility rate is developed based on the assumption that the practitioner or other supplier typically bears the practice expense costs such as labor, medical supplies, and medical equipment associated with the service. The facility rate is developed based on the assumption that the practitioner or other supplier is not

typically bearing the cost of these direct practice expenses, and that the costs of resources such as labor, medical supplies, and medical equipment are borne by another entity to which Medicare makes payment under a different payment system.

When services are furnished in a facility that is paid under the MPFS, other coding and billing mechanisms are used to distinguish between the portion of the service furnished by the practitioner and the portion furnished by the facility. For example, both radiologists and independent diagnostic testing facilities (IDTFs) furnish and are paid for diagnostic imaging tests under the MPFS. Payment under the MPFS for most codes that describe diagnostic imaging tests is, consequently, “split” into the professional component and the technical components of the service. The payment for the professional component is based on the practitioner’s work involved in furnishing the service and is generally paid at a single rate under the MPFS, regardless of where the service is performed. The payment for the technical component of the service is based on the relative cost of the other resources involved in furnishing the service, such as clinical staff who perform the test, medical equipment, medical supplies, and overhead expenses involved with imaging acquisition; and the technical component payment is only billed and paid when the service is furnished in a setting in which Medicare does not make an institutional payment for the service through another payment system.

For example, an MRI for a beneficiary may be furnished by an IDTF that owns and operates the capital equipment required to furnish the service. This IDTF would bill under the MPFS for its portion of the service furnished (acquiring the image), by submitting a claim using the appropriate HCPCS code describing the test with the “–TC” modifier, signifying a bill for the technical component of the service. The interpretation of the same test for the same patient might be furnished by a radiologist who would bill separately under the MPFS for the professional component of the test by submitting a claim using the HCPCS code with the “26” modifier, signifying a bill for the professional component of the service. Alternatively, both the professional and the technical components of the test could be furnished at the office of a radiologist who owns and operates the capital equipment. In this case, the radiologist would bill under the MPFS using the same HCPCS code without either of the modifiers, signifying a

“global” bill for the service that includes both the professional and the technical components of the service. Under the MPFS ratesetting process, this global payment rate is automatically valued as the sum of the relevant professional and technical components. When the imaging acquisition (technical component) is furnished in a setting to which Medicare makes a separate payment to the facility under a payment system other than the MPFS, the technical component is not paid under the MPFS because the practitioner or supplier did not incur the cost of furnishing the technical component. Rather, payment for this component of the service is paid through the other applicable payment system.

Similar to IDTFs, radiation treatment centers are a type of supplier paid under the MPFS for the kinds of services they furnish. However, billing for radiation treatment services hinges on different coding conventions. For radiation treatment services, there are separate HCPCS codes that describe and distinguish the professional aspects of radiation treatment services (such as treatment planning) and the technical aspects of radiation treatment (such as application of the therapeutic radiation). When the radiation treatment delivery is furnished in a setting where Medicare makes a separate payment to the facility under a different payment system, these services are generally not paid under the MPFS because the practitioner or supplier did not incur the cost of furnishing the technical aspects of the service. Rather, payment is made for these services to the facility under the other applicable payment system. In both cases, the coding and billing mechanisms allow for practitioners to be paid for their professional services under the MPFS, and for other billing entities to be paid for their facility services under either the MPFS or another applicable payment system for the portion of the service they furnish.

b. Operational Considerations

When we developed our proposal to identify the MPFS as the applicable payment system for nonexcepted items and services furnished by nonexcepted off-campus PBDs, we recognized that these nonexcepted off-campus PBDs, similar to IDTFs and radiation treatment centers currently paid under the MPFS, furnish certain components of services that are sometimes paid under the MPFS. In addition, similar to IDTFs and radiation treatment centers, these nonexcepted off-campus PBDs likely incur costs that are, in many cases, complementary to the costs of the practitioners who furnish professional

services. Consequently, we surveyed the necessary operational changes that would be necessary to allow hospitals to bill directly under the MPFS for these nonexcepted items and services using the same billing mechanisms currently available to IDTFs and radiation treatment centers. We sought to identify the scope of changes that would be required that would allow nonexcepted off-campus PBDs to bill in the same manner as these entities currently bill. After examining the claims processing, cost reporting, and enrollment records changes that would be necessary, we concluded that it would not be possible to implement these billing process modifications for nonexcepted items and services furnished by nonexcepted off-campus PBDs for CY 2017.

After we considered the public comments we received on the payment proposal for CY 2017 which did not provide for direct billing by, or payment to, the nonexcepted off-campus PBDs for their services, we recognized that establishing the MPFS as the “applicable payment system” for nonexcepted items and services furnished by nonexcepted off-campus PBDs without implementing simultaneous billing mechanisms for nonexcepted items and services furnished by hospitals under the MPFS may result in significant negative consequences, such as implications under the physician self-referral and anti-kickback laws and existing “incident to” regulations, thereby leading to an inability for either the physician or the hospital to bill for certain nonexcepted items and services. While we believe that many of these issues would only be present in the context of the temporary payment policy that we proposed for CY 2017, we were concerned that if we were to finalize the payment proposal without modification, the potential implications of the issues raised by commenters could result in possible access to care issues for Medicare beneficiaries in CY 2017. At the same time, we recognize that many off-campus PBDs that would bill for nonexcepted items and services incur costs involved in furnishing a broader range of services paid under the MPFS than those services provided in IDTFs and radiation therapy centers. Therefore, we determined that it was necessary, for CY 2017, to establish MPFS rates for the technical component of nonexcepted items and services furnished by nonexcepted off-campus PBDs, in order to provide hospitals a mechanism to bill and be paid.

c. General MPFS Coding and Billing Mechanisms

Coding and payment policies under the MPFS have long recognized the differences between the portions of services for which direct costs generally are incurred by practitioners and the portions of services for which direct costs generally are incurred by facilities. At present, the coding and relative value units (RVUs) established for particular groups of services under the MPFS generally reflect such direct cost differences. As described earlier, we establish separate nonfacility and facility RVUs for many HCPCS codes describing particular services paid under the MPFS. For many other services, we establish separate RVUs for the professional component and the technical component of the service described by the same HCPCS code. For yet other services, we establish RVUs for the different HCPCS codes that segregate and describe the discrete professional and technical aspects of particular services.

After consideration of the public comments we received in response to our proposed payment policies for nonexcepted items and services that are subject to sections 1833(t)(1)(B)(v) and (21) of the Act (81 FR 45688 through 45690), we continue to believe that it is currently operationally infeasible for nonexcepted off-campus PBDs to bill under the MPFS for the subset of MPFS services for which there is a separately valued technical component (either through a “TC” value or through unique HCPCS codes). In addition, we believe that hospitals that furnish nonexcepted items and services are likely to furnish a broader range of services than other provider or supplier types for which there is currently a separately valued technical component under the MPFS. Therefore, we believe it is necessary for CY 2017 to establish a new set of payment rates under the MPFS that reflects the relative resource costs of furnishing the technical component of a broad range of services to be paid under the MPFS specific to one site of service (the off-campus PBD of a hospital) with packaging (bundling) rules that are significantly different from current MPFS rules.

The variety of coding and billing mechanisms used under the MPFS evolved over time based on the practice patterns of the practitioners and suppliers paid under the MPFS, and we believe that the change in policy to shift payment to these nonexcepted off-campus PBDs from the OPFS to the MPFS similarly requires accommodation of their practice

patterns under the MPFS. Because we are finalizing our proposal to establish the MPFS as the applicable payment system for nonexcepted items and services furnished by nonexcepted off-campus PBDs in section X.A. of the CY 2017 OPPS/ASC final rule with comment period, we believe that it is necessary to establish a mechanism for CY 2017 under the MPFS for these entities to bill and be paid under the MPFS for the component of the services they furnish to Medicare beneficiaries. We also believe that, in accordance with the effective date specified in section 603 of Public Law 114–74, this billing mechanism must be effective for January 1, 2017. In accordance with the MPFS, the payment rates under this mechanism should reflect the estimated relative resource costs involved in furnishing these services compared to other MPFS services based on the information we have available to us at this time.

The changes implemented through this interim final rule with comment period are intended to provide a billing mechanism for hospitals to report and be paid for nonexcepted items and services furnished by nonexcepted off-campus PBDs to Medicare beneficiaries in CY 2017. In principle, the coding and billing mechanisms required to make appropriate payment to hospitals are parallel to those currently used to make payment for the technical component of diagnostic tests and for codes that describe technical radiation treatment services. However, hospitals are generally more likely to furnish a wider range of items and services than those items and services for which there currently are separate values for the professional component and the technical component of services under the MPFS. Therefore, the new payment rates for the nonexcepted items and services billed by hospitals under the MPFS will establish a means to report the technical aspect of all applicable items and services under the MPFS, not merely the ones with currently separate values for the component rates.

However, we do not believe that the establishment of these payment mechanisms and rates should be disruptive to other practitioners and suppliers paid under the MPFS for CY 2017. In addition, we note that there is no current payment rate under the MPFS that is based on the existing packaging (bundling) rules for hospitals paid under the OPPS. Therefore, we are not implementing any change to the current payment rules, rates, or mechanisms used by other practitioners and suppliers that bill under the MPFS. Instead, the rates and policies

established by this interim final rule with comment period implement a payment mechanism under the MPFS intended to reflect the relative resource costs incurred in furnishing the technical component of services in a specific site of service (the nonexcepted off-campus PBD) using the current packaging policies used in the hospital outpatient setting.

In concept, this new payment rate parallels the current technical component for diagnostic tests furnished under the MPFS and the technical component codes currently used under the MPFS, as well as the facility fees paid under a Medicare institutional payment system, such as the OPPS. However, the payment amounts established under this interim final rule with comment period are intended to reflect the estimated relative resource costs of furnishing services only under the MPFS using the packaging rules unique to the hospital outpatient setting.

Because section 603 of Public Law 114–74 did not change the fact that nonexcepted off-campus PBDs are still departments of a hospital, despite no longer being able to be paid under the OPPS for nonexcepted items and services, and in order to implement the statutory payment changes by the effective date of section 603 of Public Law 114–74 of January 1, 2017, we believe it is appropriate to establish a mechanism to allow nonexcepted off-campus PBDs that furnish nonexcepted items and services to bill in the same way as other hospital outpatient departments through use of the institutional claims processing systems in order to be paid under the MPFS for CY 2017. That is, nonexcepted off-campus PBDs will continue to bill on the institutional claim that will pass through the Outpatient Code Editor and into the OPPS PRICER for calculation of payment under the MPFS. It is not operationally feasible to revise the Multi-Carrier System (MCS), which is used to process professional claims, to accept and process institutional claims by January 1, 2017. We also considered adopting a mechanism whereby the hospital would bill under the MPFS on the professional claim, but due to operational challenges that are not possible to adequately address by January 1, 2017, we are not adopting such a policy in this interim final rule with comment period. In addition, as described later in this interim final rule with comment period, we believe it is necessary for now to apply to the payments for nonexcepted items and services the same hospital wage index that would otherwise apply if the off-

campus PBD was billing for excepted items and services. Therefore, we are implementing a set of MPFS payment rates that are specific to and can only be reported by hospitals reporting nonexcepted items and services on the institutional claim form in CY 2017.

We also are making a conforming change to our regulations at 42 CFR 414.22(b)(5)(ii) by deleting the paragraph that limits the number of practice expense RVUs that can be applied for services that have only technical component practice expense RVUs or only professional component practice expense RVUs; evaluation and management services, such as hospital or nursing facility visits, that are furnished exclusively in one setting; and major surgical services.

3. Establishment of Payment Rates

We have long acknowledged our concerns regarding some of the information currently used to develop RVUs for payment rates under the MPFS (for example, in the CY 2015 MPFS final rule with comment period (79 FR 67568)). We believe that, for nonexcepted items and services furnished by an off-campus PBD, the quality of the data currently used to develop payment rates under the OPPS, including hospital claims data and cost reporting, far exceeds the quality of data currently used for MPFS payments. In fact, the narrower the gap between the OPPS and MPFS packaging and billing rules and/or the better we are able to estimate the effect of that gap, the greater the potential would be to utilize the OPPS data in the MPFS ratesetting in future years. Nevertheless, it is not currently appropriate to use the OPPS data for services furnished, for example, in physicians' offices, given the significant differences in packaging and billing rules that remain in place, and the fact that we have not yet sufficiently been able to estimate the effect of those differences.

However, given that for CY 2017 we are implementing a set of MPFS payment rates that are specific to and can only be reported by hospitals reporting nonexcepted items and services on the institutional claim form, we do believe it would be appropriate to use the OPPS data to establish code-level relativity between these services when furnished in hospital outpatient departments. Given the current superiority of the OPPS data for these services, and its straightforward applicability when used in conjunction with the OPPS packaging and billing rules, we are establishing a payment mechanism for CY 2017 under the MPFS that, at the code level, is based on

the relative payment rates and packaging and billing rules for these services as paid under the OPSS. However, the mechanism will only use the OPSS payment rates to the extent that they serve to establish appropriate payment under the MPFS based on the relative resources involved, in accordance with those packaging rules. Similarly, there are specific policies and adjustments that currently apply under the OPSS that we are incorporating into the MPFS, exclusively for this site-specific payment rate. In other words, in order to maintain the integrity of the code-specific relativity of current payments under the OPSS as we shift payment for services furnished by nonexcepted off-campus PBDs to the MPFS, we are adopting under the MPFS a set of OPSS payment adjustments as MPFS policies for these payments. We believe this will maintain the code-level relativity that is essential to the MPFS and provide an operational means to implement the amendments made by section 603 of Public Law 114–74 by making payment to hospitals for these nonexcepted items and services furnished.

However, establishing the relativity among the nonexcepted items and services billed by hospitals under the MPFS is only one aspect of establishing the necessary relativity of these services under the MPFS more broadly. We still need to estimate the relativity of these services compared to MPFS services furnished in other settings. In other words, we need to make our current best estimate of the more general relativity between the technical component of MPFS services furnished in nonexcepted off-campus PBDs and all other MPFS services furnished in other settings. As described more fully below, using the limited information available to us at this time, we estimate that, for CY 2017, scaling the OPSS payment rates by 50 percent will strike an appropriate balance that avoids potentially underestimating the relative resources involved in furnishing services in nonexcepted off-campus PBDs as compared to the services furnished in other settings for which payment is made under the MPFS. Specifically, we are establishing site-specific rates under the MPFS for the technical component of the broad range of nonexcepted items and services furnished by nonexcepted off-campus PBDs to be paid under the MPFS that will be based on the OPSS payment amount for these same services, scaled downward by 50 percent. We discuss below how we arrived at this adjustment percentage for CY 2017.

a. Methodology

We began by analyzing hospital outpatient claims data from January 1 through August 26, 2016, that contained the “PO” modifier signifying that they were billed by an off-campus department of a hospital paid under the OPSS other than a remote location, a satellite facility, or a dedicated emergency department (ED). We note that the use of the “PO” modifier was a new mandatory reporting policy for CY 2016. In development of this interim final rule with comment period, we analyzed available “PO” modifier claims data billed from January through August 2016. We limited our analysis to those claims billed on the 13X Type of Bill because those claims are used for Medicare Part B billing under the OPSS. We then identified the top (most frequently billed) 25 “major codes” that were billed by claim line; that is, items and services that were separately payable or conditionally packaged. Specifically, we restricted our analysis to codes with OPSS status indicators “J1”, “J2”, “Q1”, “Q2”, “Q3”, “S”, “T”, or “V”. We did not include separately payable drugs or biologicals in this analysis because those drugs or biologicals are paid the same rate whether they are furnished in the physician office setting or the hospital setting, and because we are not adopting a percentage reduction to separately payable drugs and biologicals under this interim final rule with comment period. Similarly, we excluded codes assigned an OPSS status indicator “A” because the services described by these codes are already paid at a rate under a fee schedule other than the OPSS and payment for those nonexcepted items and services will not be changed under the rates being established under this interim final rule with comment period. Next, for the same major codes (or analogous codes in the rare instance that different coding applies under the OPSS than the MPFS), we compared the CY 2016 payment rate under the OPSS to a CY 2016 payment rate under the MPFS attributable to the nonprofessional resource costs involved in furnishing the services.

The most frequently billed service with the “PO” modifier is described by HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), which is paid under APC 5012; the total number of CY 2016 claim lines for this service is approximately 6.7 million as of August 2016. In CY 2016, the OPSS payment rate for APC 5012 is \$102.12. Because there are multiple CPT codes (CPT codes 99201 through 99215) used under

the MPFS for billing this service, an exact comparison between the \$102.12 OPSS payment rate for APC 5012 and the payment rate for a single CPT code billed under the MPFS is not possible. However, for purposes of this analysis, we examined the difference between the nonfacility payment rates and the facility payment rates under the MPFS for CPT codes 99213 and 99214, which are the billing codes for a Level III and a Level IV office visit. While we do not have data to precisely determine the equivalent set of MPFS visit codes to use for the comparison, we believe that, based on the distribution of services billed for the visit codes under the MPFS and the distribution of the visit codes under the OPSS from the last time period the CPT codes were used under the OPSS in CY 2014, these two codes provide reliable points of comparison. For CPT code 99213, the difference between the nonfacility payment rate and the facility payment rate under the MPFS in CY 2016 is \$21.86, which is 21 percent of the OPSS payment rate for APC 5012 of \$102.12. For CPT code 99214, the difference between the nonfacility payment rate and the facility payment rate under the MPFS in CY 2016 is \$29.02, which is 28 percent of the OPSS payment rate for APC 5012. However, we recognize that, due to the more extensive packaging that occurs under the OPSS for services provided along with clinic visits relative to the more limited packaging that occurs under the MPFS for office visits, these payment rates are not entirely comparable.

We then assessed the next 24 major codes most frequently billed on the 13X claim form by hospitals. We removed HCPCS code 36591 (Collection of blood specimen from a completely implantable venous access device) because, under current MPFS policies, the code is used only to pay separately under the MPFS when no other service is on the claim. We also removed HCPCS code G0009 (Administration of Pneumococcal Vaccine) because there is no payment for this code under the MPFS. For the remaining 22 major codes most frequently billed, we estimated the amount that would have been paid to the physician in the office setting under the MPFS for practice expenses not associated with the professional component of the service. As indicated in Table X.B.1. below, this amount reflects (1) the difference between the MPFS nonfacility payment rate and the MPFS facility rate, (2) the technical component, or (3) in instances where payment would have been made only to the facility or only to the

physician, the full nonfacility rate. This estimate ranged from 0.0 percent to 137.8 percent of the OPPS payment rate for a code. Overall, the average (weighted by claim line volume times rate) of the nonfacility payment rate estimate for the MPFS compared to the estimate for the OPPS for the 22 remaining major codes is 45 percent.

TABLE X.B.1—COMPARISON OF CY 2016 OPPS PAYMENT RATE TO CY 2016 MPFS PAYMENT RATE FOR TOP HOSPITAL CODES BILLED USING THE “PO” MODIFIER

HCPCS Code	Code Description	Total Claim Lines	CY 2016 OPPS Payment Rate	CY 2016 Applicable MPFS Technical Payment Amount Estimate	Col (5) as a Percent of OPPS (%)	MPFS Estimate
(1)	(2)	(3)	(4)	(5)	(6)	
96372	Injection beneath the skin or into muscle for therapy, diagnosis, or prevention.	338,444	\$42.31	\$25.42	60.1	Single rate paid exclusively to either practitioner or facility: Full nonfacility rate.
71020	X-ray of chest, 2 views, front and side.	333,203	60.80	16.83	27.7	Technical component: Full nonfacility rate.
93005	Routine electrocardiogram (EKG) with tracing using at least 12 leads.	318,099	55.94	8.59	15.4	Technical component: Full nonfacility rate.
96413	Infusion of chemotherapy into a vein up to 1 hour.	254,704	280.27	136.41	48.7	Single rate paid exclusively to either practitioner or facility: Full nonfacility rate.
93798	Physician services for outpatient heart rehabilitation with continuous EKG monitoring per session.	203,926	103.92	11.10	10.7	Nonfacility rate—Facility rate.
96375	Injection of different drug or substance into a vein for therapy, diagnosis, or prevention.	189,140	42.31	22.56	53.3	Single rate paid exclusively to either practitioner or facility: Full nonfacility rate.
93306	Ultrasound examination of heart including color-depicted blood flow rate, direction, and valve function.	179,840	416.80	165.77	39.8	Technical component: Full nonfacility rate.
77080	Bone density measurement using dedicated X-ray machine.	155,513	100.69	31.15	30.9	Technical component: Full nonfacility rate.
77412	Radiation treatment delivery.	137,241	194.35	267.86	137.8	Technical component (Full nonfacility rate) based on weighted averages for the following MPFS codes: G6011; G6012; G6013; and G6014.
90853	Group psychotherapy	123,282	69.65	0.36	0.5	Nonfacility rate—Facility rate.
96365	Infusion into a vein for therapy, prevention, or diagnosis up to 1 hour.	122,641	173.18	69.82	40.3	Nonfacility rate—Facility rate.
20610	Aspiration and/or injection of large joint or joint capsule.	106,769	223.76	13.96	6.2	Nonfacility rate—Facility rate.
11042	Removal of skin and tissue first 20 sq cm or less.	99,134	225.55	54.78	24.3	Nonfacility rate—Facility rate.
96367	Infusion into a vein for therapy prevention or diagnosis additional sequential infusion up to 1 hour.	98,930	42.31	30.79	72.8	Single rate paid exclusively to either practitioner or facility: Full nonfacility rate.
93017	Exercise or drug-induced heart and blood vessel stress test with EKG tracing and monitoring.	96,312	220.35	39.74	18.0	Technical component: Full nonfacility rate.
77386	Radiation therapy delivery	81,925	505.51	347.30	68.7	Technical component: Nonfacility rate for CPT code G6015 (analogous code used under the MPFS).

TABLE X.B.1—COMPARISON OF CY 2016 OPPTS PAYMENT RATE TO CY 2016 MPFS PAYMENT RATE FOR TOP HOSPITAL CODES BILLED USING THE “PO” MODIFIER—Continued

HCPCS Code	Code Description	Total Claim Lines	CY 2016 OPPTS Payment Rate	CY 2016 Applicable MPFS Technical Payment Amount Estimate	Col (5) as a Percent of OPPTS (%)	MPFS Estimate
(1)	(2)	(3)	(4)	(5)	(6)	
78452	Nuclear medicine study of vessels of heart using drugs or exercise.	79,242	1,108.46	412.82	37.2	Technical component: Full nonfacility rate.
74177	multiple studies CT scan of abdomen and pelvis with contrast.	76,393	347.72	220.20	63.3	Technical component: Full nonfacility rate.
71260	CT scan chest with contrast.	75,052	236.86	167.21	70.6	Technical component: Full nonfacility rate.
71250	CT scan chest	74,570	112.49	129.61	115.2	Technical component: Full nonfacility rate.
73030	X-ray of shoulder, minimum of 2 views.	71,330	60.80	19.33	31.8	Technical component: Full nonfacility rate.
90834	Psychotherapy, 45 minutes with patient and/or family member.	70,524	125.04	0.36	0.3	Nonfacility rate—Facility rate.
Weighted Average (claim line volume*rate) of the MPFS payment compared to OPPTS payment for the 22 major codes:						45.

As noted with the clinic visits, we recognize that there are limitations to our data analysis including that OPPTS payment rates include the costs of packaged items or services billed with the separately payable code, and therefore the comparison to rates under the MPFS will not be a one-to-one comparison. Also, we include only a limited number of services, and additional services may have different patterns than the services described here. After considering the payment differentials for major codes billed by off-campus departments of hospitals with the “PO” modifier and based on the data limitations of our analysis, we are adopting, with some exceptions noted below, a set of MPFS payment rates that are based on a 50-percent reduction to the OPPTS payment rates (inclusive of packaging) for nonexcepted items and services furnished in nonexcepted off-campus PBDs in this interim final rule with comment period. Generally speaking, we arrived at 50 percent by examining the 45-percent rate noted above, the ASC payment rate—which is roughly 55 percent of the OPPTS payment rate on average—and the payment rate for the large number of OPPTS and MPFS evaluation and management services, as described above. We recognize the equivalent MPFS nonfacility rate may be higher or lower than the percentage reduction we are applying to the OPPTS payment rates on a code specific basis. However, we believe that, on the whole, this percentage reduction will not underestimate the overall relativity

between the OPPTS and the MPFS based on the limited data currently available. We are concerned, however, that this percentage reduction might be too small. For example, if we were able at this time to sufficiently estimate the effect of the packaging differences between the OPPTS and MPFS, we suspect that the equivalent portion of MPFS payments for evaluation and management codes, and for MPFS services on average, would likely be less than 50 percent for the same services. We consider this percentage reduction for CY 2017 to be a transitional policy until such time that we have more precise data to better identify and value nonexcepted items and services furnished by nonexcepted off-campus PBDs and billed by hospitals.

There are several significant exceptions to this standard adjustment. For example, for services that are currently paid under the OPPTS based on payment rates from other Medicare fee schedules (including the MPFS) on an institutional claim, we will not adjust the current payment rates. These are the items and services assigned status indicator “A” in Addendum B to the CY 2017 OPPTS/ASC final rule with comment period (which is available via the Internet on the CMS Web site) that will continue to be reported on an institutional claim and paid under the MPFS, the CLFS, or the Ambulance Fee Schedule without a payment reduction. Similarly, drugs and biologicals that are separately payable under the OPPTS (identified by status indicator “G” or “K” in Addendum B to the CY 2017

OPPTS/ASC final rule with comment period) will be paid in accordance with section 1847A of the Act (that is, typically ASP + 6 percent), consistent with payment rules in the physician office setting. Drugs and biologicals that are unconditionally packaged under the OPPTS and are not separately payable (that is, those drugs and biologicals assigned status indicator of “N” in Addendum B to the CY 2017 OPPTS/ASC final rule with comment period) will be bundled into the MPFS payment and will not be separately paid to hospitals billing for nonexcepted items and services. The full range of exceptions and adjustments to the otherwise applicable OPPTS payment rate that are being adopted in the new MPFS site-of-service payment rates in this interim final rule with comment period are displayed in Table X.B.2. below.

All nonexcepted items and services billed by a hospital on an institutional claim with modifier “PN” (Nonexcepted service provided at an off-campus, outpatient, provider-based department of a hospital) will be paid under the MPFS at the rate established in this interim final rule with comment period. Specifically, nonexcepted off-campus PBDs must report modifier “PN” on each UB-04 claim line to indicate a nonexcepted item or service, but should otherwise continue to bill as they currently do. There are no billing changes for excepted items and services provided at an off-campus PBDs because these items and services remain covered outpatient department services that are paid under the OPPTS.

b. MPFS Relativity Adjuster

If we were to use the payment mechanisms described in this interim final rule with comment period over several years, we would anticipate using Medicare claims data to compare the services paid in this nonexcepted off-campus PBD setting to a similar set of services otherwise paid under the MPFS in other sites of service (office or freestanding center, among others) in order to develop a MPFS relativity adjuster that incorporates the specific mix of services furnished in nonexcepted off-campus PBDs. However, given the lack of data regarding the mix of services currently being furnished in nonexcepted off-campus PBDs, we examined the data that were available to us to estimate a first year MPFS relativity adjuster that we believe best approximates the appropriate measure of relativity without underestimating it. In other words, we conducted several analyses in order to develop a MPFS relativity adjuster that we believe would, in the aggregate, approximate the payment under MPFS rates that would otherwise be applicable without underestimating it, were the necessary alternative coding and billing mechanisms under the MPFS present. In this interim final rule with comment period, we discuss two analyses that were considered in determination of the MPFS relativity adjuster for CY 2017. First, we examined the payment differential between the OPPS and the ASC payment system. Under the ASC payment system, covered surgical procedures furnished in an ASC are paid approximately 55 percent of the amount paid to hospital outpatient departments for performing the same services. Second, we considered the CY 2016 claims reported with the "PO" modifier (used to report services at off-campus PBDs under the OPPS). We compared overall payment under the OPPS and the MPFS for clinic visits from a list of the most frequently billed HCPCS codes reported with the "PO" modifier and determined the weighted average payment differential for these services. Using the ASC differential and the "PO" modifier as points of reference, and taking into account our desire not to underestimate the relativity adjuster for CY 2017, we determined the initial year (CY 2017) MPFS-relativity adjuster to be 50 percent. We intend to continue to study this issue and welcome comments regarding potential future refinements as we gain more experience with these new site-of-service MPFS rates.

c. Geographic Adjustments

For 2017, we are establishing class-specific geographic practice cost indices (GPCIs) under the MPFS exclusively used to adjust these site-specific, technical component rates for nonexcepted items and services furnished in nonexcepted off-campus PBDs. These class-specific GPCIs are parallel to the geographic adjustments made under the OPPS based on the hospital wage index. We believe it is appropriate to adopt the hospital wage index areas for purposes of geographic adjustment because nonexcepted off-campus PBDs are still considered to be part of a hospital and the MPFS payments to these entities will be limited to the subset of PFS services furnished by hospitals. We also believe it is appropriate, as an initial matter for CY 2017, to adopt the actual wage index values for these hospitals in addition to the wage index areas. The MPFS GPCIs that would otherwise currently apply are not based on the hospital wage index areas. Pending further study of this issue for future years, for CY 2017, we are using the authority under section 1848 (e)(1)(B) of the Act to establish a new set of GPCIs for these site-specific, technical component rates that are based both on the hospital wage index areas and the hospital wage index value themselves.

d. Coding Consistency

For most services, the same HCPCS codes are used to describe services paid under both the MPFS and the OPPS. There are two notable exceptions that describe high-volume services. The first of these are evaluation and management services, which are reported under the MPFS using the 5 levels of CPT codes describing new or established patient visits (for a total of 10 codes). However, since CY 2014, these visits have been reported under the OPPS using the single HCPCS code G0463 (Hospital Outpatient Clinic Visit) (78 FR 75042). We are establishing the MPFS payment rate for HCPCS code G0463 based on the OPPS payment rate reduced by the 50 percent MPFS relativity adjuster. Second, several radiation treatment delivery and imaging guidance services also are reported using different codes under the MPFS and the OPPS. CMS established HCPCS Level II "G" codes to describe radiation treatment delivery services when furnished in the physician office setting (79 FR 67666 through 67667). However, these HCPCS "G" codes are not recognized under the OPPS; rather, CPT codes are used to describe these services when furnished in the HOPD. Both sets of codes were

implemented for CY 2015 and were maintained for CY 2016. Under the MPFS, there is a particular statutory provision under section 1848(c)(2)(K) of the Act that requires maintenance of the CY 2016 coding and payment inputs for these services for CY 2017 and CY 2018. Accordingly, the finalized CY 2017 MPFS rates for these services were calculated based on the maintenance of the CY 2016 coding payment inputs. On that basis, we are establishing payment amounts for nonexcepted items and services consistent with the payments that would be made to other facilities under the MPFS. That is, an off-campus PBDs submitting claims for nonexcepted items and services will bill the HCPCS "G" codes established under the MPFS to describe radiation treatment delivery procedures. However, the off-campus PBD must append modifier "PN" to each applicable claim line for nonexcepted items and services. The payment amount for these services will be set to reflect the technical component rate for the code under the MPFS.

4. OPPS Payment Adjustments

In this interim final rule with comment period, we are adopting the packaging payment rates and multiple procedure payment reduction (MPPR) percentage that apply under the OPPS to establish the MPFS payment rates for nonexcepted items and services furnished by nonexcepted off-campus PBDs and billed by hospitals. That is, the claims processing logic that is used for payments under the OPPS for comprehensive APCs (C-APCs), conditionally and unconditionally packaged items and services, and major procedures will be incorporated into the newly established MPFS rates. We believe it is necessary to incorporate these OPPS payment policies for C-APCs, packaged items and services, and the MPPR in order to effectuate a mechanism for payment for nonexcepted items and services furnished by off-campus PBDs by January 1, 2017. We also believe that this is necessary in order to maintain the integrity of the MPFS relativity adjuster because the adjuster intends to incorporate the differences in these rules under the OPPS and the MPFS rates that would otherwise apply. Hospitals will continue to bill on an institutional claim form that will pass through the Outpatient Code Editor and into the OPPS PRICER for calculation of payment. This approach will yield data based on reported charges for nonexcepted items and services furnished by nonexcepted off-campus PBDs, which can be used to refine MPFS payment rates for these services

in future years should we ultimately determine to continue this policy in future years.

There are several OPPS payment adjustments that we are not adopting in this interim final rule with comment period, including, but not limited to, outlier payments, the rural sole community hospital (SCH) adjustment, the cancer hospital adjustments, transitional outpatient payments, the hospital outpatient quality reporting payment adjustment, and the inpatient hospital deductible cap to the cost-sharing liability for a single hospital outpatient service. We believe these payment adjustments are expressly authorized for, and should be limited to, hospitals that are paid under the OPPS for covered OPD services in accordance with section 1833(t) of the Act.

5. Partial Hospitalization Services

With respect to partial hospitalization programs (PHP) (intensive outpatient psychiatric day treatment programs furnished to patients as an alternative to inpatient psychiatric hospitalization or as a stepdown to shorten an inpatient stay and transition a patient to a less intensive level of care), 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 CMHC. In the CY 2017 OPPS/ASC proposed rule (81 FR 45681), in the discussion of the proposed implementation of section 603 of Public Law 114–74, we noted that because CMHCs also furnish PHP services and are ineligible to be provider-based to a hospital, a nonexcepted off-campus PBD would be eligible for PHP payment if the entity enrolls and bills as a CMHC for payment under the OPPS. We further noted that a hospital may choose to enroll a nonexcepted off-campus PBD as a CMHC, provided it meets all Medicare requirements and conditions of participation (81 FR 45690).

Commenters expressed concern that without a clear payment mechanism for PHP services furnished by nonexcepted off-campus PBDs, access to partial hospitalization services would be limited, and pointed out the critical role PHPs play in the continuum of mental health care. Many commenters believed that Congress did not intend for partial hospitalization services to no longer be paid for by Medicare when such services are furnished by nonexcepted off-campus PBDs. Several commenters disagreed with the notion of enrolling as a CMHC in order to receive payment for PHP services. These commenters stated that hospital-based PHPs and CMHCs are inherently different in structure, operation, and payment, and noted that

the conditions of participation for hospital departments and CMHCs are different. Several commenters requested that CMS find a mechanism to pay hospital-based PHPs in nonexcepted off-campus PBDs. Because we share the commenters' concerns, we are adopting payment for nonexcepted items and services furnished by PHP under the MPFS. When billed in accordance with this interim final rule with comment period, these items and services will be paid at the CMHC per diem rate for APC 5853, for providing 3 or more partial hospitalization services per day.

In the CY 2017 OPPS/ASC proposed rule (81 FR 45681), we noted that when a beneficiary receives outpatient services in an off-campus department of a hospital, the total Medicare payment for those services is generally higher than when those same services are provided in a physician's office. Similarly, when partial hospitalization services are provided in a hospital-based PHP, Medicare pays more than when those same services are provided by a CMHC. Our rationale for adopting the CMHC per diem rate for APC 5853 as the MPFS payment amount for nonexcepted PBDs providing PHP services is because CMHCs are freestanding entities that are not part of a hospital, but they provide the same PHP services as hospital-based PHPs. This is similar to the differences between freestanding entities paid under the MPFS that furnish other services also provided by hospital-based entities. Similar to other entities currently paid for their technical component services under the MPFS, we believe CMHCs would typically have lower cost structures than hospital-based PHPs, largely due to lower overhead costs and other indirect costs such as administration, personnel, and security. We believe that paying for nonexcepted hospital-based partial hospitalization services at the lower CMHC per diem rate aligns with section 603 of Public Law 114–74, while also preserving access to PHP services. In addition, nonexcepted off-campus PBDs will not be required to enroll as CMHC in order to bill and be paid for providing partial hospitalization services. However, a nonexcepted off-campus PBD that wishes to provide PHP services may still enroll as a CMHC if it chooses to do so and meets the relevant requirements. Finally, we recognize that because hospital-based PHPs are providing partial hospitalization services in the hospital outpatient setting, they can offer benefits that CMHCs do not have, such as an easier patient transition to and

from inpatient care, and easier sharing of health information between the PHP and the inpatient staff.

6. Supervision Rules

The supervision rules that apply for hospitals will continue to apply for off-campus PBDs that furnish nonexcepted items and services. The amendments made by section 603 of Public Law 114–74 did not change the status of these PBDs, only the status of and payment mechanism for the services they furnish. These supervision requirements are defined in 42 CFR 410.27.

7. Beneficiary Cost-Sharing

Under the MPFS, the beneficiary copayment is generally 20 percent of the fee schedule amount, unless it is waived in accordance with the statute. All cost-sharing rules that apply under the MPFS in accordance with section 1848(g) of the Act and section 1866(a)(2)(A) of the Act will continue to apply for all nonexcepted items and services furnished by off-campus PBDs, regardless of the cost-sharing obligation under the OPPS.

8. CY 2018, CY 2019, and Future Years

In this interim final rule with comment period, we are finalizing MPFS payment amounts for a new site of service—nonexcepted off-campus PBDs—for CY 2017. We are seeking public comments on the new payment mechanisms and rates detailed in this interim final rule with comment period and, based on these comments, will make adjustments as necessary to the payment mechanisms and rates through rulemaking that could be effective in CY 2017. Unless we significantly modify the policies set forth in this interim final rule with comment period in response to public comments, we anticipate continuing to use this same method to determine MPFS payment amounts for nonexcepted items and services furnished by nonexcepted off-campus PBDs for CY 2018 in order to allow for the operational changes necessary to design and implement a long-term payment approach for nonexcepted off-campus PBDs under the MPFS.

As we note elsewhere in this interim final rule with comment period and in section X.A. of the CY 2017 OPPS/ASC final rule with comment period, we believe the amendments made to the statute by section 603 of Public Law 114–74 intended to eliminate the Medicare payment incentive for hospitals to purchase physician offices, convert them to off-campus PBDs, and bill under the OPPS for services furnished there. Therefore, we believe the payment policy under this provision

should ultimately equalize payment rates between nonexcepted off-campus PBDs and physician offices to the greatest extent possible, while allowing nonexcepted off-campus PBDs to bill in a straight-forward way for services furnished.

We intend, for CY 2019 and beyond, to adopt an approach similar to the approach that we initially proposed for CY 2017. Under this approach, we would pay nonexcepted off-campus PBDs for their nonexcepted items and services at a MPFS-based rate that would reflect the relative resources involved in furnishing the services. We anticipate that payment amounts under this approach would approximate the amount Medicare would pay under the MPFS to cover facility overhead costs if the same services were furnished in a physician's office. For most services, this MPFS-based rate would equal the nonfacility payment rate under the MPFS minus the facility payment rate under the MPFS for the service in question. For other services for which we do not provide separate payment under the MPFS, if payment is made under OPPS, this MPFS-based rate would equal the MPFS nonfacility rate. For still other services, the technical component rate under the MPFS would serve as the MPFS-based rate. We recognize that certain services are billable under OPPS but not under MPFS; for such services, we would consider the relative resources involved in furnishing them, and we envision a rate similar to the rate that we pay ASCs for similar services. We note that the key advantage to this payment approach is that payment amounts would be nearly equal whether the service is furnished in a nonexcepted off-campus PBD or a physician office. This would address the differences in payment between the two sites of service that now create an incentive for hospitals to purchase and convert physician offices to off-campus PBDs in order to bill under the OPPS. However, to implement such a change, we would need to undertake substantial systems changes in order to both calculate and pay at these MPFS-based rates, and we would need to undertake such systems changes before we could require nonexcepted off-campus PBDs to bill using either the professional or facility claims forms for CY 2019 and beyond. We are seeking public comment on this intended payment approach, which we believe would best accomplish the goal of the section 603 provisions set out for us under the statute as amended by section 603 of Public Law 114–74.

Alternatively, we are seeking public comment on the possibility of

continuing to make payment using a methodology similar to that described under this interim final rule with comment period. Under such a methodology, we would pay nonexcepted off-campus PBDs under the MPFS at a percentage of standard OPPS rates that we believe reflects the relative resources involved in furnishing the services; we note that this percentage could be lower or higher than the percentage adopted in this interim final rule with comment period, and we would utilize billing data to the extent they are available, initially from CY 2017 and CY 2018, to determine the appropriate percentage adjustment, and then update the percentage adjustment annually based on the most recently available data, for future years. While in the aggregate we would seek to equalize payment rates between physician offices and nonexcepted off-campus PBDs to the extent appropriate, the rates would not be equal on a procedure-by-procedure basis. Therefore, for certain specialties, service lines, and nonexcepted off-campus PBD types, total Medicare payments for the same services might be either higher or lower when furnished in a nonexcepted off-campus PBD rather than in a physician office. We are concerned that such specialty-specific patterns in payment differentials could result in continued incentives for hospitals to buy certain types of physician offices and convert them to nonexcepted off-campus PBDs. In other words, we are concerned that continuing this type of payment approach indefinitely could create incentives to undertake exactly the behavior we believe Congress intended to avoid. However, continuing a policy similar to the one we are adopting in this interim final rule with comment period would allow hospitals to continue billing through a facility claim form and would allow for continuation of the packaging rules and cost report-based relative payment rate determinations under OPPS, which we believe are preferable to using the current valuation methodologies under the MPFS for nonexcepted items and services furnished by nonexcepted off-campus PBDs. In the future, we also will need to determine how rates established for nonexcepted off-campus PBDs will interact with the MPFS ratesetting methodology, rules, and statutory requirements because these rates would continue to be rates under the MPFS.

We recognize that nonexcepted off-campus PBDs would benefit from knowing our preliminary thoughts regarding a long-term payment approach for CY 2018 and beyond, so that they

can conduct long-term planning and begin considering possible operational or organizational changes in response. We are seeking public comment on both the policies established in this interim final rule with comment period and the intended and alternative approaches described above that may be used in future rulemaking.

9. Waiver of Proposed Rulemaking

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rule in the **Federal Register** before the provisions of a rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment. Section 553(b)(B) of the APA provides for exceptions from the notice and comment requirements; in cases in which these exceptions apply, section 1871(b)(2)(C) of the Act provides for exceptions from the notice and 60-day comment period requirements of the Act as well. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal rulemaking requirements for good cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest.

We find that there is good cause to waive the notice and comment requirements under sections 553(b)(B) of the APA and section 1871(b)(2)(C). Section 603 of Public Law 114–74, enacted on November 2, 2015, amended section 1833(t) of the Act. In general, section 603 of Public Law 114–74 provides that certain items and services furnished in certain off-campus PBDs will not be considered covered OPD services for which payment may be made under the OPPS and instead provides that those items and services shall be paid “under the applicable payment system” beginning January 1, 2017. Because the amendments to section 1833(t) of the Act at paragraphs (1)(B)(v) and (21) are effective for items and services that would have otherwise been paid through the OPPS beginning January 1, 2017, we proposed to implement these amendments in the CY 2017 OPPS/ASC proposed rule.

We received a significant number of public comments raising concerns with our proposals in the CY 2017 OPPS/ASC proposed rule. Specifically, commenters raised concerns with our proposing the “applicable payment system” to be the MPFS, proposing to make no payment to the hospital, and

proposing to make payment only to the physician or practitioner under the MPFS for the services they furnish. We thank the many commenters and acknowledge their valued input throughout the proposed rule process. After consideration of the public comments we received on these proposals included in the CY 2017 OPPS/ASC proposed rule, we have determined that establishing the MPFS as the applicable payment system for nonexcepted items and services furnished by nonexcepted off-campus PBDs without simultaneously implementing billing mechanisms to enable hospitals to bill and be paid under the MPFS may result in a number of negative consequences, such as implications under the physician self-referral and anti-kickback statutes and existing “incident to” regulations, thereby possibly leading to an inability for either the physician or the hospital to bill for certain nonexcepted items and services, and potentially, in effect, failing to fully implement the statutory language providing for payment for nonexcepted items and services under the applicable payment system. In addition, the public comments raised concerns that if we chose to finalize the payment proposal without modification, those final policies could result in possible access to care issues for Medicare beneficiaries in CY 2017. Commenters suggested that many nonexcepted off-campus PBDs would have chosen to cease operations rather than attempting to navigate the issues and resolve concerns raised in public comments, and that some of these may have been in otherwise underserved areas. After considering the gravity of concerns raised in public comments on our proposed policy on billing and payment for nonexcepted items and services, we conclude that it is not feasible to finalize the policy we proposed for CY 2017, and for which we provided detailed notice and an opportunity to comment in the CY 2017 OPPS/ASC proposed rule. At the same time, the amendments made by section 603 of Public Law 114–74 require that payment shall be made for these nonexcepted items and services under the applicable payment system other than the OPPS beginning January 1, 2017. As such, because of the potential implications of finalizing some of our proposed policies related to payment for nonexcepted items and services furnished by nonexcepted off-campus PBDs on hospitals, physicians, and beneficiaries, and the statutory requirement that payment shall be made for these items and services under the

applicable payment system other than OPPS beginning January 1, 2017, we find that it would be impracticable and contrary to the public interest to undergo notice and comment procedures before finalizing, on an interim basis subject to public comment, a payment policy for these items and services for CY 2017. Therefore, we find good cause to waive the notice of proposed rulemaking as provided under section 1871(b)(2)(C) of the Act and section 553(b)(B) of the APA and to issue this final rule on an interim basis subject to public comment. We are providing a 60-day public comment period as specified in the **DATES** section of this document.

10. Collection of Information Requirements

This document does not impose information collection requirements; that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

11. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

12. Regulatory Impact Statement

We estimate that the implementation of section 603 of Public Law 114–74 in this interim final rule with comment period will reduce Medicare Part B expenditures by roughly \$50 million in CY 2017. While this is a significantly lower impact than the \$330 million reduction estimated for the CY 2017 OPPS proposed rule, this lower impact is primarily the result of changes in technical assumptions regarding the services affected by this provision, and not a result of the change in payment policy. For this interim final rule with comment period, we analyzed OPPS claims data through the first 6 months of CY 2016 that were coded with the “PO” modifier to indicate that the service was performed off-campus. Based on this analysis, we have significantly reduced the volume of services that we expect to be affected by this provision. Additionally, the proposed rule estimate included an

impact in CY 2017 for lower Medicare Advantage payments due to lower fee-for-service expenditures that result from this provision. For this interim final rule with comment period, we have removed the associated Medicare Advantage impact for CY 2017, as the 2017 Medicare Advantage payment rates were set well before this provision will be implemented. For comparison purposes, if we had finalized the proposed rule policy using these revised assumptions, we would now estimate that the provision would reduce Medicare Part B expenditures by \$70 million in CY 2017.

C. Changes for Payment for Film X-Ray

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)(i) of the Act provides that, effective for services furnished during 2017 or any subsequent year, the payment under the OPPS 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 OPPS (without application of subparagraph (F)(i) and before application of any other adjustment) shall be reduced by 20 percent. New section 1833(t)(16)(F)(ii) of the Act provides that payments for imaging services that are X-rays taken using computed radiography (including the X-ray component of a packaged service) furnished during CY 2018, 2019, 2020, 2021, or 2022, that would otherwise be made under the OPPS (without application of subparagraph (F)(ii) and before application of any other adjustment), be reduced by 7 percent, and similarly, if such X-ray services are furnished during CY 2023 or a subsequent year, by 10 percent. New section 1833(t)(16)(F)(iii) of the Act provides that the reductions made under section 1833(t)(16)(F) 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. New section 1833(t)(16)(F)(iv) of the Act instructs the implementation of the reductions in payment set forth in subparagraph (F) through appropriate mechanisms which may include use of modifiers. Below we discuss the implementation of the reduction in payment for imaging services that are X-rays taken using film provided for in section 1833(t)(16)(F)(i) of the Act. We will address the reductions in OPPS payment for imaging services that are X-rays taken using computed radiography technology (including the imaging portion of a service) in future rulemaking.

To implement the provisions of sections 1833(t)(16)(F)(i) of the Act relating to the payment reduction for imaging services that are X-rays taken using film that are furnished during CY 2017 or a subsequent year, in the CY 2017 OPPS/ASC proposed rule (81 FR 45691), we proposed to establish a new modifier to be used on claims, as allowed under the provisions of new section 1833(t)(16)(F)(iv) of the Act. The applicable HCPCS codes describing imaging services that are X-rays taken using film were included in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site). We proposed that, beginning January 1, 2017, hospitals would be required to use this modifier on claims for imaging services that are X-rays taken using film.

Comment: Several commenters requested that the proposal for the new modifier be revised to include language that required registered radiologic technologists to perform all radiography procedures billed within the Medicare system.

Response: We proposed to adopt the new modifier to implement the statutory provisions of sections 1833(t)(16)(F)(i) of the Act relating to the payment reduction for imaging services that are X-rays taken using film that are furnished during CY 2017 or a subsequent year. The statute does not address, nor did we propose to change, the type of professional that is eligible to perform radiography procedures. Accordingly, we believe this comment is outside the scope of the proposed rule.

Comment: Commenters questioned whether facilities such as CAHs and hospitals in the State of Maryland are required to use the modifier to identify imaging services that are X-rays taken using film.

Response: In accordance with section 1833(t)(16)(F)(i) of the Act, the payment under the OPPS for imaging services that are X-rays taken using film that would otherwise be made under the OPPS (without application of subparagraph (F)(i) and before application of any other adjustment) shall be reduced by 20 percent. The reduction in payment is not applicable to hospitals that do not bill for payments for services under the OPPS. Therefore the modifier is not required to be used by hospitals that do not receive payments under the OPPS, such as CAHs or hospitals exempted from payment under the OPPS in accordance with section 1814(b)(3) of the Act.

Comment: One commenter requested that certain types of X-ray services, including radiographic-fluoroscopic

(R&F) services that combine both radiology and radiography in a single examination, vascular imaging services which use radiology and do not use CR or film technologies, and mammography imaging services which largely involve the use of digital technology, be considered exempt from payment reductions because these services are not typically performed using traditional X-ray systems.

Response: Section 1833(t)(16)(F)(i) of the Act specifically identifies imaging services that are X-rays and states that payment under the OPPS for imaging services that are X-rays taken using film shall be reduced by 20 percent in CY 2017. Therefore, the use of the proposed modifier is required for all imaging services that are X-rays receiving payment under the OPPS if those X-rays are taken using film. The statute does not provide exemptions to this policy for any imaging services that are X-rays. Therefore, we are not adopting any exemptions in this final rule with comment period.

Comment: One commenter noted that the text of the legislation did not specify which CPT codes will be affected by the proposed policy and that without this information the scope of the policy is ambiguous.

Response: Section 1833(t)(16)(F)(i) of the Act references imaging services that are X-rays taken using film. The use of the proposed modifier and subsequent reduction in payment under the OPPS is applicable to all imaging services that are X-rays taken using film as opposed to other methods. Each of the imaging services that are X-rays, along with all other codes payable under the OPPS, are included in Addendum B to this final rule with comment period.

After consideration of the public comments we received, we are finalizing the use of new modifier, FX, for use on claims for imaging services that are X-rays taken using film that are furnished during CY 2017 and subsequent years. The use of this modifier will result in a 20-percent payment reduction for an imaging service that is an X-ray service taken using film (including the X-ray component of a packaged service), as specified under section 1833(t)(16)(F)(i) of the Act, of the determined OPPS payment amount (without application of subparagraph (F)(i) and before any other adjustments under section 1833(t) of the Act). We note that 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 taken using film is made. Accordingly, the payment reduction in this instance

would be 0 percent (that is, 20 percent of \$0).

D. Changes to Certain Scope-of-Service Elements for Chronic Care Management (CCM) Services

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70450 through 70453), we finalized the CCM scope-of-service elements (as described in the CY 2015 MPFS final rule with comment period (79 FR 67721)) required in order for hospitals to bill and receive OPPS payment for furnishing CCM services. These scope-of-service elements are the same as those required for CCM under the MPFS. In the CY 2017 OPPS/ASC proposed rule (81 FR 45691), we discussed that in the CY 2017 MPFS proposed rule, we proposed some minor changes to certain CCM scope-of-service elements. We proposed that these proposed changes also would apply to CCM services furnished to hospital outpatients under the OPPS. All of the fundamental scope-of-service requirements are remaining intact. An example of these proposed minor changes are that the electronic sharing of care plan information would need to be timely but not necessarily on a 24 hour a day/7 days a week basis, as is currently required. We refer readers to the CY 2017 MPFS final rule with comment period for a detailed discussion of the proposed changes to the scope of service elements for CCM, the public comments received, and the finalized policies.

Comment: Commenters supported CMS' proposed changes to certain CCM scope-of-service elements under the OPPS. One commenter, in support of the proposal, suggested limiting billing for CCM under the OPPS to only those providers who use systems that do not limit information exchange.

Response: We thank commenters for their support. In response to the commenter's suggestion to limit billing for CCM under the OPPS to providers who use systems that do not limit information exchange, we note that we did not propose such a limitation on billing. Therefore, we are not accepting this suggestion but may consider it in future years' rulemaking.

After consideration of the public comments we received, we are finalizing our CY 2017 proposal, without modification, for CY 2017, to apply the changes to certain scope-of-service elements finalized in the CY 2017 MPFS final rule with comment period to CCM services furnished to hospital outpatients under the OPPS.

E. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Section 218(b) of the Protecting Access of Medicare Act of 2014 (PAMA, Pub. L. 113–93) amended section 1834 of the Act by adding paragraph (q) which directs the Secretary to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. The CY 2016 MPFS final rule with comment period (80 FR 71102 through 71116) addressed the initial component of the Medicare AUC program, including specifying applicable AUC and establishing CMS authority to identify clinical priority areas for making outlier determinations. The regulations governing the Medicare AUC program are codified at 42 CFR 414.94. The program's criteria and requirements were established and are being updated as appropriate through the MPFS rulemaking process. While the MPFS is the most appropriate vehicle for this practitioner-based program, we note that ordering practitioners will be required to consult AUC at the time of ordering advanced diagnostic imaging, and imaging suppliers will be required to report information related to such consultations on claims, for all applicable advanced diagnostic imaging services paid under the MPFS, the OPSS, and the ASC payment system. In the CY 2017 OPSS/ASC proposed rule (81 FR 45691), we noted that the CY 2017 MPFS proposed rule included proposed requirements and processes for the second component of the Medicare AUC program, which is the specification of qualified clinical decision support mechanisms (CDSMs) under the program. The CDSM is the electronic tool through which the ordering practitioner consults AUC. It also proposed specific clinical priority areas and exceptions to the AUC consultation and reporting requirements. We refer readers to the CY 2017 MPFS final rule with comment period for further information, including a summarization of any public comments received and the finalized policies for CY 2017.

XI. CY 2017 OPSS Payment Status and Comment Indicators

A. CY 2017 OPSS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs serve an important role in determining payment for services under the OPSS. They indicate whether a service represented by a HCPCS code is payable under the OPSS or another payment

system and also whether particular OPSS policies apply to the code. The complete list of the payment status indicators and their definitions that we are applying for CY 2017 is displayed in Addendum D1 to this final rule with comment period, which is available on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>. The CY 2017 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this final rule with comment period, which are available on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

In the CY 2017 OPSS/ASC proposed rule (81 FR 45692), we proposed revising the current definition of status indicator “E” by creating two status indicators, “E1” and “E2,” to replace status indicator “E.” We proposed that status indicator “E1” would be specific to items and services not covered by Medicare and status indicator “E2” would be exclusive to those items and services for which pricing information or claims data are not available.

Comment: Several commenters supported the proposal to differentiate between Medicare noncovered services (status indicator “E1”) and services that have not been assigned a payment rate due to lack of pricing information and claims data (status indicator “E2”). The commenters also recommended that CMS not assign the noncovered I/OCE edit to status indicator “E2” services because noncoverage is not the reason for nonpayment of these services.

Response: We appreciate the commenters' support for the proposal. In response to the commenters' recommendation regarding the I/OCE edit, we are assigning edit 13 to status indicator “E2” items and services. This edit will result in a line item rejection. A line item rejection is when a line has reached a final disposition with no payment for a reason other than medical necessity under section 1862(a)(1) of the Act.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to use new status indicators “E1” and “E2” to differentiate between Medicare noncovered services and services that have not been assigned a payment rate due to lack of pricing information and claims data.

B. CY 2017 Comment Indicator Definitions

In the CY 2017 OPSS/ASC proposed rule (81 FR 45692), we proposed to use four comment indicators for the CY 2017 OPSS. Three of these comment indicators, “CH”, “NI,” and “NP,” are in effect for CY 2016 and we proposed to continue their use in CY 2017. In the proposed rule, we also proposed to create new comment indicator “NC” that would be used in the final rule to flag the HCPCS codes that were assigned to comment indicator “NP” in the proposed rule. Codes assigned the “NC” comment indicator in the final rule will not be subject to comments to the final rule. We stated in the proposed rule that we believe that this new comment indicator “NC” would help hospitals easily identify new HCPCS codes that would have a final payment assignment effective January 1, 2017. The proposed CY 2017 OPSS comment indicators are as follows:

- “CH”—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.
- “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.
- “NC”—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year for which we requested comments in the proposed rule, final APC assignment; comments will *not* be accepted on the final APC assignment for the new code.

We did not receive any public comments regarding the proposed CY 2017 OPSS comment indicators. Therefore, we are adopting, as final, our proposal to continue to use for CY 2017 comment indicators “CH”, “NI,” and “NP” that are in effect for CY 2016, and to create new comment indicator “NC” that will be used in the final rule to flag the HCPCS codes that were assigned to comment indicator “NP” in the proposed rule. The definitions of the

OPPS comment indicators for CY 2017 are listed in Addendum D2 to this final rule with comment period, which is available on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

XII. 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 CY 2012 OPPS/ASC final rule with comment period (76 FR 74378 through 74379), the CY 2013 OPPS/ASC final rule with comment period (77 FR 68434 through 68467), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75064 through 75090), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66915 through 66940), and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70474 through 70502).

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). CMS releases new and revised Level II HCPCS codes and recognizes the release of new and revised CPT codes by the AMA and makes these codes effective (that is, the codes are recognized on Medicare

claims) via these ASC quarterly update CRs. CMS releases 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 is used to update HCPCS and CPT codes (76 FR 42291).

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.

B. Treatment of New and Revised Codes

1. Background on Current Process for Recognizing New and Revised Category I and Category III CPT Codes and Level II HCPCS Codes

Category I CPT, Category III CPT, and Level II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims:

- Category I CPT codes, which describe surgical procedures and vaccine codes;
- Category III CPT codes, which describe new and emerging

technologies, services, and procedures; and

- Level II HCPCS codes, which are used primarily to identify items, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 final rule (72 FR 42533 through 42535) to evaluate each year all new and revised Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures. In addition, we identify new and revised codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. In prior rulemakings, we refer to this process as recognizing new codes; however, this process has always involved the recognition of new and revised codes. We consider revised

codes to be new when they have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator. To clarify, we refer to these codes as new and revised in this CY 2017 OPPS/ASC final rule with comment period.

We have separated our discussion below based on when the codes are released and whether we proposed to solicit public comments in the CY 2017 OPPS/ASC proposed rule (and respond to those comments in this CY 2017 OPPS/ASC final rule with comment period) or whether we are soliciting public comments in this CY 2017 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2018 OPPS/ASC final rule with comment period).

We note that we sought public comments in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70371 through 70372) on the new and revised Category I and III CPT and Level II HCPCS codes that were effective January 1, 2016. We also sought public comments in the CY 2016 OPPS/ASC

final rule with comment period (80 FR 70371) on the new and revised Level II HCPCS codes effective October 1, 2015, or January 1, 2016. These new and revised codes, with an effective date of October 1, 2015, or January 1, 2016, were flagged with comment indicator “NI” in Addenda AA and BB to the CY 2016 OPPS/ASC final rule with comment period to indicate that we were assigning them an interim payment status and payment rate, if applicable, which were subject to public comment following publication of the CY 2016 OPPS/ASC final rule with comment period. We are responding to public comments and finalizing the treatment of these codes under the ASC payment system in this CY 2017 OPPS/ASC final rule with comment period.

In Table 43 below, we summarize our process for updating codes through our ASC quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the OPPS.

TABLE 43—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

ASC Quarterly update CR	Type of code	Effective date	Comments sought	When finalized
April 1, 2016	Level II HCPCS Codes	April 1, 2016	CY 2017 OPPS/ASC proposed rule.	CY 2017 OPPS/ASC final rule with comment period.
July 1, 2016	Level II HCPCS Codes	July 1, 2016	CY 2017 OPPS/ASC proposed rule.	CY 2017 OPPS/ASC final rule with comment period.
	Category I (certain vaccine codes) and III CPT codes.	July 1, 2016	CY 2017 OPPS/ASC proposed rule.	CY 2017 OPPS/ASC final rule with comment period.
October 1, 2016	Level II HCPCS Codes	October 1, 2016	CY 2017 OPPS/ASC final rule with comment period.	CY 2018 OPPS/ASC final rule with comment period.
January 1, 2017	Level II HCPCS Codes	January 1, 2017	CY 2017 OPPS/ASC final rule with comment period.	CY 2018 OPPS/ASC final rule with comment period.
	Category I and III CPT Codes	January 1, 2017	CY 2017 OPPS/ASC proposed rule.	CY 2017 OPPS/ASC final rule with comment period.

Note: In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that would be effective January 1. We refer readers to section XII.A.3. of this CY 2017 OPPS/ASC final rule with comment period for further discussion of this issue.

2. Treatment of New and Revised Level II HCPCS Codes and Category III CPT Codes Implemented in April 2016 and July 2016 for Which We Solicited Public Comments in the CY 2017 OPPS/ASC Proposed Rule

In the April 2016 and July 2016 CRs, we made effective for April 1, 2016 and July 1, 2016, respectively, a total of 19 (incorrectly referenced in the proposed rule as 20) new Level II HCPCS codes and 9 new Category III CPT codes that describe covered ASC services that were not addressed in the CY 2016 OPPS/ASC final rule with comment period.

In the April 2016 ASC quarterly update (Transmittal 3478, CR 9557, dated March 11, 2016), we added 10 new drug and biological Level II HCPCS

codes to the list of covered ancillary services. Table 23 of the proposed rule listed the new Level II HCPCS codes that were implemented April 1, 2016, along with their proposed payment indicators for CY 2017.

In the July 2016 ASC quarterly update (Transmittal R3531CP, CR 9668, dated May 27, 2016), we added nine new drug and biological Level II HCPCS codes to the list of covered ancillary services. Table 24 of the proposed rule listed the new Level II HCPCS codes that were implemented July 1, 2016. The proposed payment rates, where applicable, for these April and July codes can be found in Addendum BB to the proposed rule (which is available via the Internet on the CMS Web site).

Through the July 2016 quarterly update CR, we also implemented ASC payment for nine new Category III CPT codes as ASC covered surgical procedures, effective July 1, 2016. These codes were listed in Table 25 of the proposed rule, along with their proposed payment indicators. The proposed payment rates for these new Category III CPT codes can be found in Addendum AA to the proposed rule (which is available via the Internet on the CMS Web site).

In the CY 2017 OPPS/ASC proposed rule, we invited public comments on these proposed payment indicators and the proposed payment rates for the new Category III CPT codes and Level II HCPCS codes that were newly

recognized as ASC covered surgical procedures or covered ancillary services in April 2016 and July 2016 through the quarterly update CRs, as listed in Tables 23, 24, and 25 of the proposed rule. We also proposed to finalize their payment indicators and their payment rates in this CY 2017 OPPS/ASC final rule with comment period.

We did not receive any public comments regarding the proposed ASC payment indicators and payment rates. Therefore, we are adopting as final the

CY 2017 proposed ASC payment indicators and payment rates for the ASC covered surgical procedures and covered ancillary services described by the new Level II HCPCS codes implemented in April 2016 and July 2016 through the quarterly update CRs as shown below in Tables 44, 45, and 46, respectively. We note that, for the CY 2017 update, the HCPCS Workgroup replaced the temporary drug HCPCS C-codes that were listed in Table 23, 24, and 25 of the proposed rule with

permanent HCPCS J-codes effective January 1, 2017. Therefore, we are assigning the replacement HCPCS J-codes to the same payment indicators as their predecessor HCPCS C-codes, as shown in Tables 44, 45, and 46 below. The final CY 2017 ASC payment rates for these codes, where applicable, can be found in ASC Addendum AA and BB of this OPPS/ASC final rule with comment period.

TABLE 44—FINAL CY 2017 PAYMENT INDICATORS FOR THE NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES OR COVERED ANCILLARY SERVICES IMPLEMENTED ON APRIL 1, 2016

CY 2016 HCPCS Code	CY 2017 HCPCS Code	CY 2017 Long descriptor	Final CY 2017 payment indicator
C9137	J7207	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U ..	K2
C9138	J7209	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), 1 I.U	K2
C9461	A9515	Choline C 11, diagnostic, per study dose	K2
C9470	J1942	Injection, aripiprazole lauroxil, 1 mg	K2
C9471	J7322	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg	K2
C9472	J9325	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)	K2
C9473	J2182	Injection, mepolizumab, 1 mg	K2
C9474	J9205	Injection, irinotecan liposome, 1 mg	K2
C9475	J9295	Injection, necitumumab, 1 mg	K2
J7503	J7503	Tacrolimus, extended release, (Envarsus XR), oral, 0.25 mg	K2

TABLE 45—FINAL CY 2017 PAYMENT INDICATORS FOR THE NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2016

CY 2016 HCPCS Code	CY 2017 HCPCS Code	CY 2017 Long descriptor	Final CY 2017 payment indicator
C9476	J9145	Injection, daratumumab, 10 mg	K2
C9477	J9176	Injection, elotuzumab, 1 mg	K2
C9478	J2840	Injection, sebelipase alfa, 1 mg	K2
C9479	C9479	Instillation, ciprofloxacin otic suspension, 6 mg	K2
C9480	J9352	Injection, trabectedin, 0.1 mg	K2
Q9981	J8670	Rolapitant, oral, 1 mg	K2
Q5102	Q5102	Injection, infliximab, biosimilar, 10 mg	K2
Q9982 *	Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	K2
Q9983 **	Q9983	Florbetaben f18, diagnostic, per study dose, up to 8.1 millicuries	K2

* HCPCS code C9459 (Flutemetamol f18, diagnostic, per study dose, up to 5 millicuries) was deleted on June 30, 2016, and replaced with HCPCS code Q9982 effective July 1, 2016.

** HCPCS code C9458 (Florbetaben f18, diagnostic, per study dose, up to 8.1 millicuries) was deleted on June 30, 2016, and replaced with HCPCS code Q9983 effective July 1, 2016.

TABLE 46—FINAL CY 2017 PAYMENT INDICATORS FOR THE NEW CATEGORY III CPT CODES FOR COVERED SURGICAL PROCEDURES OR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2016

CY 2016 HCPCS Code	CY 2017 HCPCS Code	CY 2017 Long descriptor	Final CY 2017 payment indicator
0437T	0437T	Implantation of non-biologic or synthetic implant (e.g., polypropylene) for fascial reinforcement of the abdominal wall (List separately in addition to primary procedure).	N1
0438T *	0438T	Transperineal placement of biodegradable material, peri-prostatic (via needle), single or multiple, includes image guidance.	G2
0439T	0439T	Myocardial contrast perfusion echocardiography; at rest or with stress, for assessment of myocardial ischemia or viability (List separately in addition to primary procedure).	N1
0440T	0440T	Ablation, percutaneous, cryoablation, includes imaging guidance; upper extremity distal/peripheral nerve.	G2

TABLE 46—FINAL CY 2017 PAYMENT INDICATORS FOR THE NEW CATEGORY III CPT CODES FOR COVERED SURGICAL PROCEDURES OR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2016—Continued

CY 2016 HCPCS Code	CY 2017 HCPCS Code	CY 2017 Long descriptor	Final CY 2017 payment indicator
0441T	0441T	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve.	G2
0442T	0442T	Ablation, percutaneous, cryoablation, includes imaging guidance; nerve plexus or other truncal nerve (e.g., brachial plexus, pudendal nerve).	G2
0443T	0443T	Real time spectral analysis of prostate tissue by fluorescence spectroscopy	G2
0444T	0444T	Initial placement of a drug-eluting ocular insert under one or more eyelids, including fitting, training, and insertion, unilateral or bilateral.	N1
0445T	0445T	Subsequent placement of a drug-eluting ocular insert under one or more eyelids, including re-training, and removal of existing insert, unilateral or bilateral.	N1

* HCPCS code C9743 (Injection/implantation of bulking or spacer material (any type) with or without image guidance (not to be used if a more specific code applies) was deleted on June 30, 2016, and replaced with CPT code 0438T effective July 1, 2016.

3. Process for Recognizing New and Revised Category I and Category III CPT Codes That Will Be Effective January 1, 2017 for Which We Are Responding to Comments in This CY 2017 Final Rule With Comment Period

For new and revised CPT codes effective January 1 that were received in time to be included in the CY 2017 OPSS/ASC proposed rule, we proposed APC and status indicator assignments (81 FR 45695). We are responding to comments and finalizing the APC and status indicator assignments in this OPSS/ASC final rule with comment period. For those new/revised CPT codes that were received too late for inclusion in the OPSS/ASC proposed rule, we indicated that 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 2017 ASC update, the new and revised CY 2017 Category I and III CPT codes will be effective on January 1, 2017, and can be found in ASC Addendum AA and Addendum BB to this final rule with comment period (which are available via the Internet on the CMS Web site). The new and revised CY 2017 Category I and III CPT codes that were not received in time for inclusion in the proposed rule 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 included the 5-digit placeholder codes and their long descriptors for the new and revised CY 2017 CPT codes in Addendum O to the proposed rule (which is available via the Internet on the CMS Web site) so that the public could have time to adequately comment on our proposed payment indicator assignments. The 5-digit placeholder codes were included in Addendum O, specifically under the column labeled "CY 2017 OPSS/ASC Proposed Rule 5-Digit Placeholder Code," to the proposed rule. We indicated that the final CPT code numbers would be included in the CY 2017 OPSS/ASC final rule with comment period. We also noted that not every code listed in Addendum O was subject to comment. For the new/revised Category I and III CPT codes, we requested comments on only those codes that are assigned to comment indicator "NP."

Comment: One commenter objected to the proposed assignment of the procedure described by HCPCS code 05X1T (Suprachoroidal injection of a pharmacologic agent (does not include supply of medication)) to payment indicator "G2." The commenter believed that the procedure is similar in procedural complexity, resource utilization, and clinical application to the procedure described by CPT code 67028 (Intravitreal injection of a pharmacologic agent (separate procedure)), which is assigned to payment indicator "P3."

Response: We agree with the commenter that the procedure described by HCPCS code 05X1T (which is

finalized as CPT code 0465T in this final rule with comment period) is similar to the procedure described by CPT code 67028. Therefore, we are modifying our proposal to assign CPT code 0465T to payment indicator "P3" for CY 2017.

After consideration of the public comments we received, we are finalizing, with one modification, the proposed CY 2017 ASC payment indicator assignments for new and revised CPT codes, effective January 1, 2017. We are modifying our proposal and are assigning CPT code 0465T to payment indicator "P3." These final CPT codes with short descriptors only and their final payment indicators are listed in Addendum AA and Addendum BB to this final rule with comment period (which is available via the Internet on the CMS Web site). We also list these CPT codes with long descriptors in Addendum O to this final rule with comment period (which is available via the Internet on the CMS Web site).

4. Process for New and Revised Level II HCPCS Codes That Will Be Effective October 1, 2016 and January 1, 2017 for Which We Are Soliciting Public Comments in This CY 2017 OPSS/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 OPSS 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 OPSS quarterly update CRs. In the past, we also released new and revised Level II HCPCS codes that are effective October 1 through the October OPSS quarterly update CRs and

incorporated these new codes in the final rule with comment period, thereby updating the OPSS and the ASC payment system for the following calendar year.

In the CY 2017 OPSS/ASC proposed rule (81 FR 45696), for CY 2017, we proposed to continue our established policy of assigning comment indicator “NI” in Addendum B to the OPSS/ASC final rule with comment period to those new and revised Level II HCPCS codes that are effective October 1 and January 1 to indicate that we are assigning them an interim payment status, which is subject to public comment. Specifically, the Level II HCPCS codes that will be effective October 1, 2016, and January 1, 2017, would be flagged with comment indicator “NI” in Addendum B to this CY 2017 OPSS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPSS payment status for CY 2017. We are inviting public comments in this CY 2017 OPSS/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 2018 OPSS/ASC final rule with comment period.

C. Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services

1. Covered Surgical Procedures

a. Covered Surgical Procedures Designated as Office-Based

(1) Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as “office-based” those procedures that are added to the ASC 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 OPSS 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 OPSS relative payment weight), depending on whether we estimated the procedure would be paid according to the standard ASC payment methodology based on its OPSS 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) Changes for CY 2017 to Covered Surgical Procedures Designated as Office-Based in developing the CY 2017

OPSS/ASC proposed rule, we followed our policy to annually review and update the covered surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment, including their potential designation as office-based. We reviewed CY 2015 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 OPSS 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 2016 OPSS/ASC final rule with comment period (80 FR 70480 through 70482).

Our review of the CY 2015 volume and utilization data resulted in our identification of one covered surgical procedure, CPT code 0377T (Anoscopy with directed submucosal injection of bulking agent for fecal incontinence), that we believe meets the criteria for designation as office-based. The data indicate that this procedure is 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 code that we proposed to permanently designate as office-based for CY 2017 was listed in Table 26 of the proposed rule (81 FR 45697).

We invited public comment on this proposal.

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal, without modification, to designate the procedures described by CPT code 0377T as permanently office-based for CY 2017, as set forth in Table 47 below.

TABLE 47—ASC COVERED SURGICAL PROCEDURE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2017

CY 2017 CPT Code	CY 2017 Long descriptor	CY 2016 ASC payment indicator	Final CY 2017 ASC payment indicator*
0377T	Anoscopy with directed submucosal injection of bulking agent for fecal incontinence Esophagoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure).	G2	R2

*Final payment indicators are based on a comparison of the 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 2017. For a discussion of the MPFS rates, we refer readers to the CY 2017 MPFS final rule with comment period.

We also reviewed CY 2015 volume and utilization data and other information for eight procedures

designated as temporary office-based in Tables 64 and 65 in the CY 2016 OPSS/ASC final rule with comment period (80

FR 70480 through 70482). Of these eight procedures, there were very few claims in our data or no claims data for all

eight procedures: CPT code 0299T (Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound); 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 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); 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); and CPT code C9800 (Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies), which is being replaced by CPT code G0429 (Dermal filler injection(s) for the treatment of facial lipodystrophy syndrome (lds) (e.g., as a result of highly active antiretroviral therapy)) in this final rule with comment period. Consequently, in the CY 2017 OP/PS/

ASC proposed rule (81 FR 45697), we proposed to maintain the temporary office-based designations for these eight codes for CY 2017. We listed all of these codes for which we proposed to maintain the temporary office-based designations for CY 2017 in Table 27 of the proposed rule. The procedures for which the proposed office-based designations for CY 2017 are temporary also were indicated by asterisks in Addendum AA to the proposed rule (which is available via the Internet on the CMS Web site).

We invited public comment on this proposal.

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal, without modification, to designate the eight procedures listed in Table 48 below as temporary office-based for CY 2017.

TABLE 48—CY 2017 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARY OFFICE-BASED IN THE CY 2016 OP/PS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2017 CPT Code	CY 2017 Long descriptor	CY 2016 ASC payment indicator*	Final CY 2017 ASC payment indicator**
0299T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound.	R2*	R2**
0402T	Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed).	R2*	R2**
10030	Image-guided fluid collection drainage by catheter (e.g., abscess, hematoma, seroma, lymphocele, cyst), soft tissue (e.g., extremity abdominal wall, neck), percutaneous.	P2*	P2**
64461	Paravertebral block (PVB) (paraspinous block), thoracic; single injection site (includes imaging guidance, when performed).	P3*	P3**
64463	Continuous infusion by catheter (includes imaging guidance, when performed)	P3*	P3**
65785	Implantation of intrastromal corneal ring segments	R2*	P2**
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*	R2**
G0429***	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies.	R2*	R2**

* If designation is temporary.

** Final payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the MPFS final rates. Current law specifies a 0.5 percent update to the MPFS payment rates for CY 2017. For a discussion of the MPFS rates, we refer readers to the CY 2017 MPFS final rule with comment period.

*** HCPCS code G0429 replaces HCPCS code C9800, effective January 1, 2017.

In the CY 2017 OP/PS/ASC proposed rule (81 FR 45698), for CY 2017, we proposed to designate certain new CY 2017 codes for ASC covered surgical procedures as temporary office-based, as displayed in Table 28 of the proposed rule. After reviewing the clinical characteristics, utilization, and volume of related procedure codes, we determined that the procedures described by these new CPT codes would be predominantly performed in

physicians' offices. However, because we had no utilization data for the procedures specifically described by these new CPT codes, we proposed to make the office-based designations temporary rather than permanent and we will reevaluate the procedures when data become available. The procedures for which the proposed office-based designations for CY 2017 are temporary also were indicated by asterisks in Addendum AA to the proposed rule

(which is available via the Internet on the CMS Web site).

We invited public comments on these proposals.

We did not receive any public comments on our proposal. Therefore, for CY 2017, we are finalizing our proposal, without modification, to designate the two new CY 2017 codes for ASC surgical procedures listed in Table 49 as temporary office-based.

TABLE 49—CY 2017 PAYMENT INDICATORS FOR NEW CY 2017 CPT CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARY OFFICE-BASED

CY 2017 OPSS/ASC proposed rule 5-digit CMS placeholder code	CY 2017 OPSS/ASC final rule CPT code	CY 2017 Long descriptor	Final CY 2017 ASC payment indicator**
369X1	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*
36X41	36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated.	P2*

* If designation is temporary.

** Final payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the MPFS final rates. Current law specifies a 0.5 percent update to the MPFS payment rates for CY 2017. For a discussion of the MPFS rates, we refer readers to the CY 2017 MPFS final rule with comment period.

b. ASC Covered Surgical Procedures Designated as Device-Intensive—Finalized Policy for CY 2016 and Final Policy for CY 2017

(1) Background

As discussed in the August 2, 2007 final rule (72 FR 42503 through 42508), we adopted a modified payment methodology for calculating the ASC payment rates for covered surgical procedures that are assigned to the subset of OPSS device-dependent APCs with a device offset percentage greater than 50 percent of the APC cost under the OPSS, in order to ensure that payment for the procedure is adequate to provide packaged payment for the high-cost implantable devices used in those procedures. According to that modified 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 then calculate the service (nondevice) portion of the ASC payment for device-intensive procedures by applying the uniform ASC conversion factor to the service 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. For CY 2015, we implemented a comprehensive APC policy under the OPSS under which we created C-APCs to replace most of the then-current device-dependent APCs and a few

nondevice-dependent APCs under the OPSS, which discontinued the device-dependent APC policy (79 FR 66798 through 66810). We did not implement C-APCs in the ASC payment system.

Therefore, in the CY 2015 OPSS/ASC final rule with comment period (79 FR 66925), we provided that all separately paid covered ancillary services that are provided integral to covered surgical procedures that mapped to C-APCs continue to be separately paid under the ASC payment system instead of being packaged into the payment for the C-APC as under the OPSS. To avoid duplicating payment, we provided that the CY 2015 ASC payment rates for these C-APCs were based on the CY 2015 OPSS relative payments weights that had been calculated using the standard APC ratesetting methodology for the primary service instead of the relative payment weights that were based on the comprehensive bundled service. For the same reason, under the ASC payment system, we also used the standard OPSS APC ratesetting methodology instead of the C-APC methodology to calculate the device offset percentage for C-APCs for purposes of identifying device-intensive procedures and to calculate payment rates for device-intensive procedures assigned to C-APCs. Because we implemented the C-APC policy and, therefore, eliminated device-dependent APCs under the OPSS in CY 2015, we revised our definition of ASC device-intensive procedures to be those procedures that are assigned to any APC (not only an APC formerly designated as device-dependent) with a device offset percentage greater than 40 percent based on the standard OPSS APC ratesetting methodology.

We also provided that we would update the ASC list of covered surgical

procedures that are eligible for payment according to our device-intensive procedure payment methodology, consistent with our modified definition of device-intensive procedures, reflecting the APC assignments of procedures and APC device offset percentages based on the CY 2013 OPSS claims and cost report data available for the CY 2015 OPSS/ASC proposed rule and final rule with comment period.

(2) ASC Device-Intensive Designation by HCPCS Code

In CY 2016, we restructured many of the APCs under the OPSS, which resulted in some procedures with significant device costs not being designated device-intensive. In the CY 2016 OPSS/ASC proposed rule (80 FR 39310), we specifically recognized that, in some instances, there may be a surgical procedure that uses a high-cost device but is not assigned to a device-intensive APC. When an ASC covered surgical procedure is not designated as device-intensive, it will be paid under the ASC methodology established for that covered surgical procedure, through either an MPFS nonfacility PE RVU based amount or an OPSS relative payment weight based methodology, depending on the ASC payment indicator assignment.

In response to stakeholder concerns regarding circumstances where procedures with high-cost devices are not classified as device-intensive under the ASC payment system, we solicited public comments in the CY 2016 OPSS/ASC proposed rule, specifically requesting suggestions for alternative methodologies for establishing device-intensive status for ASC covered surgical services (80 FR 39310). We received several comments, which we summarized in the CY 2016 OPSS/ASC

final rule with comment period, and we indicated we would take them into consideration for future rulemaking (80 FR 70484). Among the comments we received, several commenters requested that we calculate device intensity at the HCPCS level because the commenters believed the current method of calculating device intensity at the APC level does not take into account device similarity within an APC.

We believe that it is no longer appropriate to designate ASC device-intensive procedures based on APC assignment because APC groupings of clinically similar procedures do not necessarily factor in device cost similarity. This means that there are some surgical procedures that include high-cost implantable devices that are assigned to an APC with procedures that include the cost of significantly lower-cost devices or no device at all. As a result, the proportion of the APC geometric mean unit cost attributed to implantation of a high-cost device can be underrepresented due to higher claim volume and the lower costs of relatively low-cost device implantation procedures or procedures that do not use an implantable device.

We believe that a HCPCS code-level device offset would be a better representation of a procedure's device cost than an APC-wide average device offset based on the device offset of many procedures. 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 would result in a more accurate representation of the cost attributable to implantation of a high-cost device, which would ensure consistent device-intensive designation of procedures with a significant device cost. Further, we believe that a HCPCS code-level device offset would remove an inappropriate device-intensive status for procedures without a significant device cost, but which are granted such status because of the APC assignment.

Therefore, in the CY 2017 OPPS/ASC proposed rule (81 FR 45698 through 45699), for CY 2017, we proposed that a procedure with a HCPCS code-level device offset of greater than 40 percent of the APC costs when calculated according to the standard OPPS APC ratesetting methodology would be designated as ASC device-intensive and would 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. We proposed to revise the regulations at 42 CFR 416.171(b)(2) to redefine device-intensive procedures in accordance with this proposal.

Comment: The majority of commenters supported CMS' proposal to revise the device-intensive procedure designation methodology such that an individual HCPCS code with a device offset greater than 40 percent, regardless of the APC assignment, would be designated as a device-intensive procedure. Among the commenters who supported the proposal, a few requested that CMS lower the ASC device offset threshold to 30 percent to qualify a larger number of ASC procedures as device-intensive.

Response: We appreciate the commenters' support. However, we do not believe that lowering the device offset percentage from 40 percent to 30 percent in the ASC setting only is appropriate. As discussed in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66924), the intent of the device-intensive policy is to align significant device cost percentage in the OPPS with the device-intensive procedures in the ASC payment system. That is, we should not pay more for a device when it is implanted in an ASC than if the same device were implanted in an HOPD. Lowering the ASC device-intensive procedure offset to 30 percent would create a disparity in the number of procedures designated device-intensive in the ASC setting, when compared to the HOPD setting. A lower device offset percentage in the ASC setting would result in more device-intensive procedures, when compared to the HOPD setting and, therefore, would result in a financial incentive to perform certain device-intensive procedures in the ASC setting rather than the HOPD setting. Therefore, for CY 2017, we believe it is not appropriate to lower the ASC device-intensive offset percentage to 30 percent when the OPPS device-intensive offset percentage is 40 percent. We refer readers to section IV.B. of this final rule with comment period for background on the OPPS device-intensive procedure policy.

After consideration of the public comments we received, we are finalizing our proposal, without modification, for CY 2017, to designate all procedures that involve the implantation of a device and that have an individual HCPCS code-level device offset of greater than 40 percent, regardless of the APC assignment, as device-intensive. In addition, we are revising the regulations under 42 CFR

416.171(b)(2) to reflect this finalized policy.

In addition, for new HCPCS codes describing procedures involving the implantation of medical devices that do not yet have associated claims data, we proposed to designate these procedures as device-intensive with a default device offset set at 41 percent until claims data are available to establish the HCPCS code-level device offset for the procedures. This default device offset amount of 41 percent 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 would be applied to the code if the HCPCS code device offset is greater than 40 percent, according to our proposed policy of determining device-intensive status by calculating the HCPCS code-level device offset. The complete listing of ASC device-intensive procedures was included in Addendum AA to the proposed rule (which is available via the Internet on the CMS Web site).

Comment: Several commenters supported CMS' proposal to apply a default device offset of at least 41 percent to new implant procedures, with the possibility for a higher device offset if supported by device cost. Some commenters asked that CMS specify how additional information can be submitted to CMS, including the deadline for submission and the type of information that can be submitted, for consideration of a higher device offset percentage for a new implant procedure.

Response: We appreciate the commenters' support. Additional information for CMS consideration of an offset percentage higher than the default of 41 percent for new HCPCS codes describing procedures involving 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, may be directed to CMS staff in 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 ASCPPS@cms.hhs.gov. Additional information can be submitted prior to the issuance of an OPPTS/ASC proposed rule or as a public comment in response to the proposed rule. Device offset percentages for a given year will be established in each year's OPPTS/ASC final rule.

After consideration of the public comments we received, we are finalizing our proposal, without modification, for CY 2017 to designate as device-intensive all procedures described by new HCPCS codes involving the implantation of a medical device that do not yet have associated claims data with a default device offset set at 41 percent, until claims data are available to establish the HCPCS code-level device offset for the procedure. For CY 2017, we also are finalizing our proposal, without modification, to temporarily assign a higher offset percentage if warranted by additional information. The complete listing of ASC device-intensive procedures for CY 2017 is included in Addendum AA to this final rule with comment period (which is available via the Internet on the CMS Web site).

(3) Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2017

For CY 2017, in the CY 2017 OPPTS/ASC proposed rule (81 FR 45699), we proposed to revise our methodology for designating ASC covered surgical procedures as device-intensive. Specifically, for CY 2017, we proposed to update the ASC list of covered surgical procedures that are eligible for payment according to our device-intensive procedure payment methodology, consistent with our proposed revised definition of device-intensive procedures, reflecting the proposed individual HCPCS code device offset percentages based on CY 2015 OPPTS claims and cost report data available for the proposed rule.

The ASC covered surgical procedures that we proposed to designate as device-intensive and would be subject to the device-intensive procedure payment methodology for CY 2017 were included in Addendum AA to the proposed rule (which is available via the Internet on the CMS Web site). The CPT code, the CPT code short descriptor, the proposed CY 2017 ASC payment indicator, the proposed CY 2017 HCPCS code device offset percentage, and an indication of whether the full credit/partial credit (FB/FC) device adjustment policy would

apply also were included in Addendum AA to the proposed rule.

We invited public comments on the proposed list of ASC device-intensive procedures.

Comment: One commenter requested that CMS review the proposed device offset percentage for CPT code 43284 (proposed as CPT code 432X1) (Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (*i.e.*, magnetic band), including cruroplasty when performed). CPT code 43284 is the replacement code for predecessor HCPCS codes C9737 (Laparoscopy, surgical, esophageal sphincter augmentation with device (*e.g.*, magnetic band)) and 0392T (laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (*e.g.*, magnetic band)). Therefore, the commenter believed that CY 2015 claims data for HCPCS codes C9737 and 0392T should be used to determine the device offset percentage for CPT code 43284. However, the commenter suggested that CMS used CY 2015 claims data for HCPCS code 0392T only when determining the device offset percentage for CPT code 43284.

Response: We agree with the commenter. Accordingly, for this CY 2017 OPPTS/ASC final rule with comment period, we used CY 2015 claims data for HCPCS codes C9737 and 0392T to determine the device offset percentage for CPT code 43284.

Comment: One commenter supported CMS' proposed designation of the procedure described by HCPCS code C9739 (cystourethroscopy with insertion of transprostatic implant; 1 to 3 implants) as device-intensive based on the proposed methodology change to device-intensive designations.

Response: We appreciate the commenter's support.

After consideration of the public comments we received, we are designating the ASC covered surgical procedures displayed in Addendum AA as device-intensive and subject to the device-intensive procedure payment methodology for CY 2017. The CPT code, the CPT code short descriptor, the final CY 2017 ASC payment indicator, the final CY 2017 HCPCS code device offset percentage, and an indication of whether the full credit/partial credit (FB/FC) device adjustment policy will apply, are included in the ASC policy file labeled "CY 2017 ASC Procedures to which the No Cost/Full Credit and Partial Credit Device Adjustment Policy Applies," which is available via the Internet on the CMS Web site at: [\[for-Service-Payment/ASCPayment/ASC-Policy-Files.html\]\(#\).](https://www.cms.gov/Medicare/Medicare-Fee-</p>
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c. 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 OPPTS policy that was in effect until CY 2014. 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 OPPTS to which this policy applies. We refer readers to the CY 2009 OPPTS/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 OPPTS/ASC final rule with comment period (78 FR 75005 through 75006), we finalized our proposal to modify our former policy of reducing OPPTS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. Formerly, under the OPPTS, our policy was to reduce OPPTS 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 OPPTS 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 OPPTS, 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 OPPTS, 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.

In the CY 2017 OPPS/ASC proposed rule (81 FR 45699 through 456700) we proposed to update the list of ASC covered device-intensive procedures, based on the proposed CY 2017 device-intensive definition, which would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2017. 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 proposed 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 OPPS/ASC final rule with comment period (79 FR 66926), to ensure our policy covers any situation involving a device-intensive procedure where an ASC may receive a device at no cost/full credit or partial credit, we apply our FB/FC policy to all device-intensive procedures.

We invited public comments on our proposals to adjust ASC payments for no cost/full credit and partial credit devices.

We did not receive any public comment on these proposals. Therefore, we are finalizing these proposals without modification. Specifically, we will apply the HCPCS FB/FC modifier policy to all device-intensive procedures in CY 2017. The device-intensive procedures for CY 2017 are listed in the ASC policy file labeled "CY 2017 ASC Procedures to which the No Cost/Full Credit and Partial Credit Device Adjustment Policy Applies" (referred to as "ASC device adjustment file" below), which is available via the Internet on the GMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Policy-Files.html>. For CY 2017, we will reduce the payment for the procedures listed in the ASC device adjustment file by the full device offset amount if a device is furnished without cost or with full credit. ASCs must append the HCPCS modifier "FB" to the HCPCS code for a surgical procedure listed in the ASC device adjustment file previously mentioned when the device is furnished without cost or with full credit. In addition, for CY 2017, we will reduce the payment for the procedures listed in the ASC device adjustment file by one-half of the device offset amount if a device is provided with partial credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the device cost. The ASC must append the HCPCS "FC" modifier to the HCPCS code for a surgical procedure listed in the ASC device adjustment file when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device.

d. Additions to the List of ASC Covered Surgical Procedures

We conducted a review of HCPCS codes that currently are paid under the OPPS, but not included on the ASC list

of covered surgical procedures, 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, in the CY 2017 OPPS/ASC proposed rule (81 FR 45700 through 45701), we proposed to update the list of ASC covered surgical procedures by adding eight procedures to the list for CY 2017. We determined that these eight procedures would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. These codes are add-on codes to procedures that are currently performed in the ASC and describe variations of (including additional instrumentation used with) the base code procedure. Therefore, we proposed to include them on the list of ASC covered surgical procedures for CY 2017.

The eight procedures that we proposed to add to the ASC list of covered surgical procedures, including their HCPCS code long descriptors and proposed CY 2017 payment indicators, were displayed in Table 29 of the proposed rule.

Comment: Several commenters supported the proposal to add the eight codes that were displayed in Table 29 of the proposed rule to the list of ASC covered surgical procedures for CY 2017.

Response: We appreciate the commenters' support.

Comment: Commenters noted that CPT code 22851 (Application of intervertebral biomechanical device(s) (e.g., synthetic cage(s), methacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure)), which was proposed to be added to the list of ASC covered surgical procedures (81 FR 45701) was deleted by the AMA Editorial Panel in April 2016. These commenters indicated that this code was replaced with the following three new CPT codes, effective January 1, 2017: 22853 (Insertion of interbody biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)); 22854 (Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed,

to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure); and 22859 (Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)). The commenters requested that the replacement codes for CPT code 22851 be included on the list of ASC covered surgical procedures.

Response: The commenters are correct. CPT code 22851 was deleted effective April 13, 2016, and replaced with CPT codes 22853, 22854, and 22859, effective January 1, 2017. CPT code 22851 was included on the list of codes proposed to be added to the ASC covered surgical procedures list in error. Instead of CPT code 22851, which will be deleted on December 31, 2016, we intended to propose to add CPT codes 22853, 22854, and 22859 to the list of ASC covered surgical procedures. We have included these codes with a payment indicator of “N1” in Table 51 below as well as Addendum AA to this final rule with comment period (which is available via the Internet on the CMS Web site). We also have removed these codes from Addendum EE to this final rule with comment period (which is available via the Internet on the CMS Web site) for CY 2017.

Comment: Some commenters requested that CMS establish separate payment for the instrumentation codes, CPT codes 22552, 22840, 22842, and 22845 that were proposed to be added to the list of ASC covered surgical procedures. Commenters also requested separate payment for CPT code 22851, which will be replaced with CPT codes 22853, 22854, and 22859, effective January 1, 2017.

Response: Each of these codes are add-on services to procedures and describe variations of (including additional instrumentation used with) the base code procedure. These codes are assigned to status indicator “N” under the OPPS. This status indicator is used to identify items and services packaged into APC payment rates. As noted in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70495), we update the ASC payment rates and 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. Therefore, these services are assigned

payment indicator “N1” under the ASC payment system, which identifies a packaged service where no separate payment is made.

Comment: Some commenters requested that CMS include several additional codes that were not proposed in the CY 2017 OPPS/ASC proposed rule on the list of ASC covered surgical procedures for CY 2017. These codes are shown in Table 50 below. One commenter also requested that CMS revise existing ASC regulations to allow unlisted codes to be payable in the ASC setting.

TABLE 50—PROCEDURES REQUESTED BY COMMENTERS FOR ADDITION TO THE CY 2017 LIST OF ASC COVERED SURGICAL PROCEDURES

CY 2017 CPT/HCPCS Code	Short descriptor
00142	Anesth lens surgery.
00170	Anesth procedure on mouth.
00810	Anesth low intestine scope.
0232T	Njx platelet plasma.
17999	Skin tissue procedure.
19307	Mast mod rad.
20930	Sp bone algrft morsel add-on.
21470	Treat lower jaw fracture.
22558*	Lumbar spine fusion.
22585	Additional spinal fusion.
22600*	Neck spine fusion.
22630*	Lumbar spine fusion.
22632*	Spine fusion extra segment.
22633*	Lumbar spine fusion combined.
22634*	Spine fusion extra segment.
22830*	Exploration of spinal fusion.
22846*	Insert spine fixation device.
22849*	Reinsert spinal fixation.
22850*	Remove spine fixation device.
22852*	Remove cerv fixation device.
22856	Cerv artific diskectomy.
22858	Second level cer diskectomy.
22864*	Remove cerv artif disc.
22899	Spine surgery procedure.
23470	Reconstruct shoulder joint.
23472*	Reconstruct shoulder joint.
27130*	Total hip arthroplasty.
27132*	Total hip arthroplasty.
27176*	Treat slipped epiphysis.
27412	Autochondrocyte implant knee.
27447*	Total knee arthroplasty.
27457*	Realignment of knee.
27477	Surgery to stop leg growth.
27485	Surgery to stop leg growth.
27486*	Revise/replace knee joint.
27487*	Revise/replace knee joint.
27535*	Treat knee fracture.
27540*	Treat knee fracture.
27702*	Reconstruct ankle joint.
28805	Amputation thru metatarsal.
28899	Foot/toes surgery procedure.
29799	Casting/strapping procedure.
29867	Allgrft implnt knee w/scope.
29868	Meniscal trnspl knee w/scpe.
29999	Arthroscopy of joint.
31599	Larynx surgery procedure.
32551	Insertion of chest tube.
33244	Remove elctrd transvenously.
37191	Ins endovas vena cava filtr.
37193	Rem endovas vena cava filter.
37244	Vasc embolize/occlude bleed.
37799	Vascular surgery procedure.
38207	Cryopreserve stem cells.
38214	Volume deplete of harvest.
38999	Blood/lymph system procedure.
41899	Dental surgery procedure.

TABLE 50—PROCEDURES REQUESTED BY COMMENTERS FOR ADDITION TO THE CY 2017 LIST OF ASC COVERED SURGICAL PROCEDURES—Continued

CY 2017 CPT/HCPCS Code	Short descriptor
43280	Laparoscopy fundoplasty.
43281	Lap paraesophag hern repair.
43499	Esophagus surgery procedure.
43775*	Lap sleeve gastrectomy.
43999	Stomach surgery procedure.
44180	Lap enterolysis.
44705	Prepare fecal microbiota.
44799	Unlisted px small intestine.
44950	Appendectomy.
44970	Laparoscopy appendectomy.
46999	Anus surgery procedure.
47379	Laparoscopy procedure liver.
47600*	Removal of gallbladder.
49329	Laparo proc abdm/per/oment.
49659	Laparo proc hernia repair.
49999	Abdomen surgery procedure.
53899	Urology surgery procedure.
54411	Remov/replc penis pros comp.
54417	Remv/replc penis pros compl.
55899	Genital surgery procedure.
57282	Colpopexy extraperitoneal.
57283	Colpopexy intraperitoneal.
57425	Laparoscopy surg colpopexy.
58300	Insert intrauterine device.
60252	Removal of thyroid.
60260	Repeat thyroid surgery.
61782	Scan proc cranial extra.
63035	Spinal disk surgery add-on.
63048	Remove spinal lamina add-on.
63057	Decompress spine cord add-on.
63081*	Remove vert body dcmprn crvl.
64999	Nervous system surgery.
67904	Repair eyelid defect.
90870	Electroconvulsive therapy.
91110	Gi tract capsule endoscopy.
C9600	Perc drug-el cor stent sing.
C9601	Perc drug-el cor stent bran.
C9602	Perc d-e cor stent ather s.
C9604	Perc d-e cor revasc t cabg s.
C9605	Perc d-e cor revasc t cabg b.
C9606	Perc d-e cor revasc w ami s.
C9607	Perc d-e cor revasc chro sin.
G0455	Fecal microbiota prep instil.
L8699	Prosthetic implant nos

*CPT codes on the OPPS inpatient list for CY 2017.

Response: We reviewed all of the codes that the commenters requested for addition to the ASC list of covered surgical procedures. Of the 102 codes requested for addition to the ASC list, we did not consider procedures that are reported by CPT codes that are on the inpatient only list (identified with an asterisk in Table 50 above). The 27 codes that are on the inpatient list for CY 2017 are not eligible for addition to the ASC list of covered surgical procedures (72 FR 42476 through 42486; 42 CFR 416.166).

We do not believe that the remaining 75 procedures described by codes listed in Table 50 should be added to the list for CY 2017 because they do not meet our criteria for inclusion on the list. Under §§ 416.2 and 416.166 of our 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 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. The criteria used under the revised ASC payment system to identify procedures that would be expected to pose a significant safety risk when performed in an ASC include, but are not limited to, those procedures that: (1) Generally result in extensive blood loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; (4) are generally emergent or life threatening in nature; (5) commonly require systemic thrombolytic therapy; (6) are designated as requiring inpatient care under 42 CFR 419.22(n); (7) can only be reported using a CPT unlisted surgical procedure code; or (8) are otherwise excluded under 42 CFR 411.15 (42 CFR 416.166). Procedures that do not meet the criteria set forth in § 416.166 would not be added to the list of ASC covered surgical procedures. We note that we have evaluated many of these procedures in previous years (79 FR 66918 through 66921; 78 FR 75067 through 75070) and did not add the procedures to the ASC list because of similar concerns regarding beneficiary safety. The commenters provided no

specific information regarding the safety of these procedures in the ASC setting.

In response to the request to allow other unlisted codes to be payable in the ASC setting, we note that we have addressed this comment several times in prior rulemaking. We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70489) for the most recent response. Our longstanding ASC policy under § 416.166 is that procedures described by all unlisted codes are noncovered in the ASC because we are unable to determine (due to the nondescript nature of unlisted procedure codes) if a procedure that would be reported with an unlisted code would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. We continue to believe that it would not be appropriate to provide ASC payment for procedures described by unlisted CPT codes in the surgical range, even if payment may be provided under the OPPS. Therefore, we are not adding procedures described by unlisted CPT codes to the list of ASC covered surgical procedures for CY 2017.

After consideration of the public comments we received, we are finalizing our proposal with respect to seven of the eight CPT codes that we

proposed to add to the list of ASC covered surgical procedures for CY 2017. We are not adding CPT code 22851 to the list of ASC covered surgical procedures for CY 2017. Instead, in response to public comments, we are adding three additional procedures described by CPT codes 22853, 22854, and 22859 to the list of ASC covered surgical procedures for CY 2017 in this final rule with comment period. In addition, as discussed below, in response to public comments, we removed CPT code 22585 (Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophyctectomy, and decompression of spinal cord and/or nerve roots; each additional interspace (List separately in addition to code for primary procedure)) from the OPPS inpatient list for CY 2017. CPT code 22585 is also an add-on code to procedures that are currently performed in the ASC and describes a variation of (including additional instrumentation used with) the base code procedure. Therefore, we are including the procedure described by CPT code 22585 on the list of ASC covered surgical procedures for CY 2017 as well. Table 51 below displays the 11 procedures that we are adding to the ASC list of covered surgical procedures, including their CPT code long descriptors and final CY 2017 payment indicators.

TABLE 51—ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2017

CY 2017 CPT code	CY 2017 long descriptor	CY 2017 ASC payment indicator
20936	Autograft for spine surgery only (includes harvesting the graft); local (e.g., ribs, spinous process, or laminar fragments) obtained from the same incision (List separately in addition to code for primary procedure).	N1
20937	Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision) (List separately in addition to code for primary procedure).	N1
20938	Autograft for spine surgery only (includes harvesting the graft); structural, biocortical or tricortical (through separate skin fascial incision).	N1
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophyctectomy and decompression of spinal cord and/or nerve roots; cervical C2, each additional interspace (List separately in addition to code for separate procedure).	N1
22840	Posterior non-segmental instrumentation (e.g., Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation).	N1
22842	Posterior non-segmental instrumentation (e.g., Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation).	N1
22845	Anterior instrumentation; 2 to 3 vertebral segments	N1
22853*	Insertion of interbody biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure).	N1
22854*	Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure).	N1
22859*	Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure).	N1

* Effective January 1 2017, CPT codes 22853, 22854, and 22859 replaced CPT code 22851, which was deleted April 13, 2016 by the AMA Editorial Panel.

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 proposed to remove the following six procedures described by CPT codes from the OPPS inpatient list for CY 2017: CPT codes 22840, 22842, 22845, 22858, 31584, and 31587. The long descriptors for each of these six CPT procedure codes were included in the proposed rule (81 FR 45678). We evaluated each of the six procedures we proposed to remove for the OPPS inpatient list for CY 2017 according to the criteria for exclusion from the list of ASC covered surgical procedures. After reviewing these procedures, we also proposed to add the procedures described by CPT codes 22840, 22842, and 22845 listed in Table 29 of the proposed rule to the list of ASC covered surgical procedures for CY 2017 (81 FR 45700 through 45701). We proposed to add these three procedures to the list of ASC covered surgical procedures (as well as proposed to remove them from the OPPS inpatient list) for CY 2017 because these procedures are described by add-on codes for procedures that are currently performed in the ASC and describe variations of (including additional instrumentation used with) the base code procedure. Therefore, we expect that the procedures described by these codes can be safely performed in an ASC without the need for an overnight stay.

Regarding the other three procedures that we proposed to remove from the OPPS inpatient list, we believe that procedures described by CPT codes 22858 (Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophylectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure)), 31584 (Laryngoplasty; with open reduction of fracture), and 31587 (Laryngoplasty, cricoid split) should continue to be excluded from the list of ASC covered surgical procedures. We invited public comments on the continued exclusion of these procedures from the list of ASC covered surgical procedures.

In response to public comments (as discussed in section IX.B. of this final rule with comment period), we also are removing CPT code 22585 from the OPPS inpatient list for CY 2017

(discussed in section IX.B. of this final rule with comment period). CPT code 22585 is also an add-on code to procedures that are currently performed in the ASC and describes a variation of (including additional instrumentation used with) the base code procedure. We also expect that the procedure described by CPT code 22585 can be safely performed in an ASC without the need for an overnight stay. Therefore, we are including the procedure described by CPT code 22585 on the list of ASC covered surgical procedures for CY 2017 as well.

Comment: Commenters supported the proposal to add the procedures described by CPT codes 22840, 22842, and 22845 to the list of ASC covered surgical procedures. Commenters also requested that CMS add the procedure described by CPT code 22858 to the list of ASC covered surgical procedures.

Response: We appreciate the commenters' support. As discussed earlier, we continue to believe that the procedure described by CPT code 22858 does not meet our criteria for inclusion on the list of ASC covered surgical procedures because this procedure would generally be expected to require at least an overnight stay.

After consideration of the public comments we received, we are finalizing the proposal to add the procedures described by CPT codes 22585, 22840, 22842, and 22845, which are being removed from the OPPS inpatient list for CY 2017, to the list of ASC covered surgical procedures for CY 2017. We also are including the procedure described by CPT code 22585 on the list of ASC covered surgical procedures for CY 2017.

2. Covered Ancillary Services

Consistent with the established ASC payment system policy, in the CY 2017 OPPS/ASC proposed rule (81 FR 45701), we proposed to update the ASC list of covered ancillary services to reflect the payment status for the services under the CY 2017 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 2017. For example, a covered ancillary service that was separately paid under the revised ASC payment system in CY 2016 may be proposed for packaged status under the CY 2017 OPPS and, therefore, also under the ASC payment system for CY 2017.

To maintain consistency with the OPPS, we proposed that these services also would be packaged under the ASC payment system for CY 2017. We

proposed to continue this reconciliation of packaged status for subsequent calendar years. Comment indicator "CH," discussed in section XII.F. of the proposed rule, was used in Addendum BB to the proposed rule (which is available via the Internet on the CMS Web site) to indicate covered ancillary services for which we proposed a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2017.

All ASC covered ancillary services and their proposed payment indicators for CY 2017 were included in Addendum BB to the proposed rule. We invited public comments on this proposal.

We did not receive any public comments on these proposals. Therefore, we are finalizing, without modification, our proposal to update the ASC list of covered ancillary services to reflect the payment status for the services under the OPPS. All CY 2017 ASC covered ancillary services and their final payment indicators are included in Addendum BB to this final rule with comment period (which is available via the Internet on the CMS Web site).

D. ASC Payment for Covered Surgical Procedures and Covered Ancillary Services

1. ASC Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are fully described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy for the revised ASC payment system, 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 OPSS, and only the service portion of the rate is subject to the ASC standard ratesetting methodology. In the CY 2016 OPSS/ASC final rule with comment period (80 FR 70474 through 70502), we updated the CY 2015 ASC payment rates for ASC covered surgical procedures with payment indicators of “A2,” “G2,” and “J8” using CY 2014 data, consistent with the CY 2016 OPSS update. We also updated payment rates for device-intensive procedures to incorporate the CY 2016 OPSS 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 2017 MPFS proposed rule) or the amount calculated using the ASC standard ratesetting methodology for the procedure. In the CY 2016 OPSS/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 OPSS data. We compared the estimated CY 2016 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 2016 payment rate for the procedure under our final policy for the revised ASC payment system (§ 416.171(d)).

In the CY 2014 OPSS/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 OPSS. Under the OPSS, 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 OPSS are always packaged (payment indicator “N1”) under the ASC payment system. Under the OPSS, 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 OPSS (status indicator “Q2”), we assigned the current ASC payment indicators associated with these procedures and continued to provide separate payment in CYs 2014, 2015, and 2016.

b. Update to ASC Covered Surgical Procedure Payment Rates for CY 2017

In the CY 2017 OPSS/ASC proposed rule (81 FR 45702), we proposed to update ASC payment rates for CY 2017 and subsequent years using the established rate calculation methodologies under § 416.171 and using our proposed modified definition of device-intensive procedures, as discussed in section XI.C.1.b. of the proposed rule. Because the proposed OPSS relative payment weights were based on geometric mean costs for CY 2017 and subsequent years, the ASC system would use geometric means to determine proposed relative payment weights under the ASC standard methodology. We proposed to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators “A2” and “G2.”

We proposed that payment rates for office-based procedures (payment indicators “P2,” “P3,” and “R2”) and device-intensive procedures (payment indicator “J8”) be calculated according to our established policies and, for device-intensive procedures, using our proposed modified definition of device-intensive procedures, as discussed in section XI.C.1.b. of the proposed rule. Therefore, we proposed 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 2017 OPSS device offset percentages that have been calculated using the standard OPSS APC ratesetting methodology. Payment for office-based procedures would be at the lesser of the proposed CY 2017 MPFS nonfacility PE RVU-based amount or the proposed CY 2017 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014, 2015, and 2016, for CY 2017, we proposed to continue our policy for device removal

procedures such that device removal procedures that are conditionally packaged in the OPSS (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 invited public comments on these proposals.

Comment: Several commenters disagreed with the proposed CY 2017 ASC payment rates for the surgical procedures described by the following CPT codes:

- CPT code 29882 (Arthroscopy, knee, surgical; with meniscus repair (medial OR lateral));
- CPT code 29883 (Arthroscopy, knee, surgical; with meniscus repair (medial and lateral));
- CPT code 28293 (Correction, hallux valgus (bunion), with or without sesamoidectomy; resection of joint with implant);
- CPT code 43239

(Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple);

- CPT code 45378 (Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure));
- CPT code 66982 (Extracapsular cataract extraction removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, 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) or performed on patients in the amblyogenic developmental stage); and

- CPT code 66984 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification)).

Commenters believed that the proposed CY 2017 payment rates for these procedures are inadequate and would not cover overhead costs or other standard supplies utilized during surgery. Commenters requested that CMS reconsider the data and methodology used to determine ASC payment rates.

Response: As discussed earlier, the ASC payment is dependent upon the APC assignment for the procedure. Based on our analysis of the latest hospital outpatient and ASC claims data used for this final rule with comment period, we updated ASC payment rates

for CY 2017 using the established rate calculation methodologies under § 416.171 and using our finalized modified definition of device-intensive procedures, as discussed in section XII.C.1.b. of this final rule with comment period. We do not make additional payment adjustments to specific procedures.

After consideration of the public comments we received, we are finalizing our proposed policies, without modification, to calculate the CY 2017 payment rates for ASC covered surgical procedures according to our established methodologies using the modified definition of device-intensive procedures. For those covered surgical procedures where the payment rate is the lower of the final rates under the ASC standard ratesetting methodology and the MPFS final rates, the final payment indicators and rates set forth in this final rule with comment period are based on a comparison using the MPFS rates effective January 1, 2017. For a discussion of the MPFS rates, we refer readers to the CY 2017 MPFS final rule with comment period.

2. Payment for Covered Ancillary Services

a. Background

Our final payment policies under the revised ASC payment system for covered ancillary services vary according to the particular type of service and its payment policy under the OPSS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPSS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators “N,” “Q1,” and “Q2”) under the OPSS. In the CY 2013 OPSS/ASC rulemaking (77 FR 45169 and 77 FR 68457 through 68458), we further clarified our policy regarding the payment indicator assignment of codes that are conditionally packaged in the OPSS (status indicators “Q1” and “Q2”). Under the OPSS, 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 OPSS are always packaged (payment indicator “N1”) under the ASC payment system (except for device removal codes as

discussed in section IV. of this final rule with comment period). Thus, our final policy generally aligns ASC payment bundles with those under the OPSS (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 OPSS at the OPSS 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 OPSS/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, 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 OPSS 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 OPSS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPSS or, if OPSS 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 OPSS.

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 OPSS. These categories do not have prospectively established ASC payment rates according to the final policies for the revised ASC payment

system (72 FR 42502 and 42508 through 42509; 42 CFR 416.164(b)). Under the revised ASC payment system, we have designated corneal tissue acquisition and hepatitis B vaccines as contractor-priced. Corneal tissue acquisition is contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplantation. Hepatitis B vaccines are contractor-priced based on invoiced costs for the vaccine.

Devices that are eligible for pass-through payment under the OPSS are separately paid under the ASC payment system and are contractor-priced. Under the revised ASC payment system (72 FR 42502), payment for the surgical procedure associated with the pass-through device is made according to our standard methodology for the ASC payment system, based on only the service (nondevice) portion of the procedure’s OPSS relative payment weight if the APC weight for the procedure includes other packaged device costs. We also refer to this methodology as applying a “device offset” to the ASC payment for the associated surgical procedure. This ensures that duplicate payment is not provided for any portion of an implanted device with OPSS pass-through payment status.

In the CY 2015 OPSS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized that, beginning in CY 2015, certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPSS are covered ancillary services when they are integral to an ASC covered surgical procedure. We finalized that diagnostic tests within the medicine range of CPT codes include all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT. In the CY 2015 OPSS/ASC final rule with comment period, we also finalized our policy to pay for these tests at the lower of the 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. Payment for Covered Ancillary Services for CY 2017

For CY 2017 and subsequent years, in the CY 2017 OPPS/ASC proposed rule (81 FR 45702 through 45704), we proposed to update the ASC payment rates and to make changes to ASC payment indicators as necessary to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2017 OPPS and ASC payment rates and subsequent year payment rates. We also proposed to continue to set the CY 2017 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 2017 and subsequent year payment rates.

Consistent with established ASC payment policy (72 FR 42497), we proposed that the CY 2017 payment for separately payable covered radiology services be based on a comparison of the proposed CY 2017 MPFS nonfacility PE RVU-based amounts (we refer readers to the CY 2017 MPFS proposed rule) and the proposed CY 2017 ASC payment rates calculated according to the ASC standard ratesetting methodology and then set at the lower of the two amounts (except as discussed below for nuclear medicine procedures and radiology services that use contrast agents). For CY 2017 and subsequent years, we proposed that payment for a radiology service would be packaged into the payment for the ASC covered surgical procedure if the radiology service is packaged or conditionally packaged under the OPPS. The payment indicators in Addendum BB to the proposed rule (which is available via the Internet on the CMS Web site) indicated whether the proposed payment rates for radiology services are based on the MPFS nonfacility PE RVU-based amount or the ASC standard ratesetting methodology; or whether payment for a radiology service is packaged into the payment for the covered surgical procedure (payment indicator “N1”). Radiology services that we proposed to pay based on the ASC standard ratesetting methodology in CY 2017 and subsequent years are assigned payment indicator “Z2” (Radiology or diagnostic service paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS relative payment weight), and those for which the proposed payment is based on the MPFS nonfacility PE

RVU-based amount are assigned payment indicator “Z3” (Radiology or diagnostic service paid separately when provided integral to a surgical procedure on ASC list; payment based on MPFS nonfacility PE RVUs).

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 for these procedures will be based on the OPPS relative payment weight using the ASC standard ratesetting methodology (rather than the MPFS nonfacility PE RVU-based amount, regardless of which is lower) and, therefore, will include the cost for the diagnostic radiopharmaceutical. We proposed to continue this modification to the payment methodology for CY 2017 and subsequent years and, therefore, proposed to assign payment indicator “Z2” to nuclear medicine procedures.

As finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74429 through 74430), payment indicators for radiology services that use contrast agents are assigned to “Z2” 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. We proposed to continue this modification to the payment methodology for CY 2017 and subsequent years and, therefore, proposed to assign the payment indicator “Z2” to radiology services that use contrast agents.

As finalized in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70471 through 70473), we proposed to continue to not make separate payment as a covered ancillary service for procurement of corneal tissue when used in any noncorneal transplant procedure under the ASC payment system for CY 2017. We also proposed for CY 2017 ASC payments to continue to designate hepatitis B vaccines as contractor-priced based on the invoiced costs for the vaccine, and corneal tissue acquisition as contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplant.

Consistent with our established ASC payment policy, we proposed that the CY 2017 payment for devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and would be contractor-priced. Currently, the four

devices that are eligible for pass-through payment in the OPPS are described by HCPCS code C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system); HCPCS code C2613 (Lung biopsy plug with delivery system); HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser); and HCPCS code C2624 (Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components). Consistent with our current policy, we proposed for CY 2017 that 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 similar packaged device costs.

Consistent with our current policy, we proposed that certain diagnostic tests within the medicine range of CPT codes (that is, 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) for which separate payment is allowed under the OPPS are covered ancillary services when they are provided integral to an ASC covered surgical procedure. We would 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). There are no additional codes that meet this criterion for CY 2017.

In summary, for CY 2017 and subsequent years, we proposed to continue the methodologies for paying for covered ancillary services established for CY 2016. Most covered ancillary services and their proposed payment indicators for CY 2017 were listed in Addendum BB to the proposed rule (which is available via the Internet on the CMS Web site).

We did not receive public comments on our proposals regarding payment for covered ancillary services and, therefore, are finalizing these policies as proposed for CY 2017 and subsequent years. For those covered ancillary services where the payment rate is the lower of the final rates under the ASC standard ratesetting methodology and the MPFS final rates, the final payment indicators and rates set forth in this final rule with comment period are

based on a comparison using the MPFS rates effective January 1, 2017. For a discussion of the MPFS rates, we refer readers to the CY 2017 MPFS final rule with comment period.

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 OPFS 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 OPFS 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 2017

We did not receive any requests for review to establish a new NTIOL class for CY 2017 by March 1, 2016, the due date published in the CY 2016 OPFS/ASC final rule with comment period (80 FR 70497).

3. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is \$50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we did not propose to revise the payment adjustment amount for CY 2017. The final ASC payment adjustment amount for NTIOLs in CY 2017 is \$50.

4. Announcement of CY 2018 Deadline for Submitting Requests for CMS Review of Applications for a New Class of NTIOLs

In accordance with § 416.185(a) of our regulations, CMS announces that in order to be considered for payment effective beginning in CY 2018, requests for review of applications for a new class of new technology IOLs must be received at CMS by 5:00 p.m. EST, on March 01, 2017. Send requests to ASC/NTIOL, Division of Outpatient Care, Mailstop C4–05–17, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850. To be considered, requests for NTIOL reviews must include the information requested on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html>.

F. ASC Payment and Comment Indicators

1. Background

In addition to the payment indicators that we introduced in the August 2, 2007 final rule, we created final comment indicators for the ASC payment system in the CY 2008 OPFS/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, OPFS 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 OPFS/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 OPFS/ASC final rule with comment period (74 FR 60622). In this CY 2017 OPFS/ASC final rule with comment period, we respond to public comments and finalize the ASC treatment of all codes that are labeled with comment indicator “NP” in Addenda AA and BB to the CY 2016 OPFS/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.

2. ASC Payment and Comment Indicators

For CY 2017 and subsequent years, in the CY 2017 OPFS/ASC proposed rule (81 FR 45705), we proposed to continue using the current comment indicators of “NP” and “CH.” For CY 2017, there are new and revised Category I and III CPT codes as well as new and revised Level

II HCPCS codes. Therefore, we proposed that 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 2017 compared to the CY 2016 descriptors that are included in ASC Addenda AA and BB to the CY 2017 OPPTS/ASC proposed rule would be labeled with proposed new comment indicator “NP” to indicate that these CPT and Level II HCPCS codes are open for comment as part of the CY 2017 OPPTS/ASC 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 stated that we would respond to public comments on ASC payment and comment indicators and finalize their ASC assignment in this CY 2017 OPPTS/ASC final rule with comment period. We referred readers to Addenda DD1 and DD2 to the 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 2017 update.

We did not receive any public comments on the ASC payment and comment indicators and therefore are finalizing their use as proposed without modification.

G. Calculation of the ASC Conversion Factor and the 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 OPPTS 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 OPPTS, 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 OPPTS/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 OPPTS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPTS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPTS 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 final rule with comment period), 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 OPPTS/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: <http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.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 OPPTS/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 2017.

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/omb/bulletins_default.

OMB Bulletin No. 15–01 made the following changes that are relevant to the IPPS and ASC wage index:

- Garfield County, OK, with principal city Enid, OK, which was a Micropolitan (geographically rural) area, now qualifies as an urban new CBSA 21420 called Enid, OK.
- The county of Bedford City, VA, a component of the Lynchburg, VA CBSA 31340, changed to town status and is added to Bedford County. Therefore, the county of Bedford City (SSA State county code 49088, FIPS State County Code 51515) is now part of the county of Bedford, VA (SSA State county code 49090, FIPS State County Code 51019). However, the CBSA remains Lynchburg, VA, 31340.
- The name of Macon, GA, CBSA 31420, as well as a principal city of the Macon-Warner Robins, GA combined statistical area, is now Macon-Bibb County, GA. The CBSA code remains as 31420.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25062), we proposed to implement these revisions, effective October 1, 2016, beginning with the FY 2017 wage indexes. In the FY 2017 IPPS/LTCH PPS proposed rule, we proposed to use these new definitions to calculate area IPPS wage indexes in a manner that is generally consistent with the CBSA-based methodologies finalized in the FY 2005 and the FY 2015 IPPS final rules. (We note that in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913), we finalized this proposal.) We believe that it is important for the ASC payment system 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 ASC payment system, in the CY 2017 OPSS/ASC proposed rule (81 FR 45706), we proposed to implement these revisions to the OMB statistical area delineations, effective January 1, 2017, beginning with the CY 2017 ASC wage indexes. We invited public comments on these proposals.

For CY 2017, the CY 2017 ASC wage indexes fully reflect the new 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.)

Comment: Several commenters made the same recommendation that was made in the CY 2010 (74 FR 60625), CY 2011 (75 FR 72059), CY 2012 (76 FR 74446), CY 2013 (77 FR 68463), CY 2014 (78 FR 75086), and CY 2015 (79 FR 66937) rulemakings—that is, that CMS adopt for the ASC payment system the same wage index values used for hospital payment under the OPSS.

Response: We have responded to this comment in the prior OPSS/ASC rules mentioned above, and believe our prior rationale for using unadjusted wage indexes is still sound. We continue to believe that the unadjusted hospital wage indexes, which are updated yearly and are used by almost all Medicare payment systems, appropriately account for geographic variance in labor costs for ASCs. We refer readers to our response to this comment in the CY 2011 OPSS/ASC final rule with comment period (75 FR 72059). We discuss our budget neutrality adjustment for changes to the wage indices below in section XII.G.2.b. of this final rule with comment period.

2. Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2017 and Future Years

We update the ASC relative payment weights each year using the national OPSS 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, in the CY 2017 OPSS/ASC proposed rule (81 FR 45706 through 45707), we proposed to scale the CY 2017 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 2015, we proposed to compare the total payment using the CY 2016 ASC relative payment weights with the total payment using the CY 2017 ASC relative payment weights to take into account the changes in the OPSS relative payment weights between CY 2016 and CY 2017. We proposed to use the ratio of CY 2016 to CY 2017 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2017. The proposed CY 2017 ASC scalar was 0.9030 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 OPPTS 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 OPPTS 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 OPPTS relative payment weights) would be scaled to eliminate any difference in the total payment between the current year and the update year.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. At the time of the proposed rule, we had available 98 percent of CY 2015 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 2015 ASC claims by ASC and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2015 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 OPPTS, 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 OPPTS/ASC proposed rule (81 FR 45707), we proposed 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 OPPTS wage index budget neutrality adjustment is calculated and applied to the OPPTS conversion factor. For CY 2017, we calculated this proposed adjustment for the ASC payment system by using the most recent CY 2015 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2017 ASC wage indexes. Specifically, holding CY 2015 ASC utilization and service-mix and the proposed CY 2017 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2016 ASC wage indexes (which reflect the new OMB delineations and include any applicable transition period) and the total adjusted payment using the proposed CY 2017 ASC wage indexes (which would fully reflect the new OMB delineations). 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 2016 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2017 ASC wage indexes and applied the resulting ratio of 0.9992 (the proposed CY 2017 ASC wage index budget neutrality adjustment) to the CY 2016 ASC conversion factor to calculate the proposed CY 2017 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 OPPTS/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 OPPTS/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 OPPTS/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 the proposed rule, based on IHS Global Insight's (IGI's) 2016 first quarter forecast with historical data through the fourth quarter of 2015, for the 12-month period ending with the midpoint of CY 2017, the CPI-U update was projected to be 1.7 percent. Also, based on IGI's 2016 first quarter forecast, the MFP adjustment for the period ending with the midpoint of CY 2017 was projected to be 0.5 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 OPPTS/ASC final rule with comment period (80 FR 70500 through 70501).

In the CY 2017 OPPTS/ASC proposed rule (81 FR 45708), for CY 2017, we proposed to reduce the CPI-U update of 1.7 percent by the MFP adjustment of 0.5 percentage point, resulting in an MFP-adjusted CPI-U update factor of 1.2 percent for ASCs meeting the quality reporting requirements. Therefore, we proposed to apply a 1.2 percent MFP-adjusted CPI-U update factor to the CY 2016 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 proposed to reduce the CPI-U update of 1.7 percent by 2.0 percentage points for ASCs that do not meet the quality

reporting requirements and then apply the 0.5 percentage point MFP adjustment. Therefore, we proposed to apply a -0.8 percent MFP-adjusted CPI-U update factor to the CY 2016 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also proposed that if more recent data are subsequently available (for example, a more recent estimate of the CY 2017 CPI-U update and MFP adjustment), we would use such data, if appropriate, to determine the CY 2017 ASC update for the final rule with comment period.

For CY 2017, we proposed to adjust the CY 2016 ASC conversion factor (\$44.190) by the proposed wage index budget neutrality factor of 0.9992 in addition to the MFP-adjusted CPI-U update factor of 1.2 percent discussed above, which resulted in a proposed CY 2017 ASC conversion factor of \$44.684 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we proposed to adjust the CY 2016 ASC conversion factor (\$44.190) by the proposed wage index budget neutrality factor of 0.9992 in addition to the MFP-adjusted CPI-U update factor of -0.8 percent discussed above, which resulted in a proposed CY 2017 ASC conversion factor of \$43.801.

We invited public comments on these proposals.

Comment: Several commenters suggested that CMS replace the CPI-U as the update mechanism for ASC payments with the hospital market basket. The commenters stated that the CPI-U measures inflation in a basket of consumer goods atypical of what ASCs purchase. In addition, the commenters stated that the Affordable Care Act requires CMS to reduce the update by a measure of productivity gains, which inappropriately subjects ASCs to two productivity adjustments: Improvements reflected in the price of consumer purchased goods; and the additional statutorily required reduction. The commenters believed that the hospital market basket would be the most appropriate update for ASCs; they indicated that there are various alternatives within the CPI-U that CMS could explore that more accurately reflect the economic climate in the ASC environment. MedPAC acknowledged that there may be a burden associated with requiring ASCs to submit cost reports, but recommended that CMS collect some sort of ASC cost data to determine whether an existing Medicare index is a good proxy or if there should be an ASC-specific market basket.

Response: As we have stated in response to similar comments in the past (for example, 77 FR 68465; 78 FR

75088 through 75089; 79 FR 66939; and 80 FR 70501), we continue to believe that, while commenters believed that the items included in the CPI-U index may not adequately measure inflation for the goods and services provided by ASCs, the hospital market basket does not align with the cost structures of ASCs. Hospitals provide a much wider range of services, such as room and board and emergency services, and the costs associated with providing these services are not part of the ASC cost structure. Therefore, at this time, we do not believe that it is appropriate to use the hospital market basket for the ASC annual update. We recognize that the CPI-U is an output price index that accounts for productivity. However, section 1833(i)(2)(D)(v) of the Act requires the agency to reduce the annual update factor by the MFP adjustment. For the reasons stated above, we do not believe that the hospital market basket appropriately reflects the cost structures of ASCs, and because we do not have cost data on ASCs, we are continuing to use the CPI-U which we believe provides a reasonable approximation of the price increases facing ASCs. We will continue to explore the feasibility of collecting ASC cost data. However, based on our past experience, we do not believe that collecting such data through surveys would be productive.

After consideration of the public comments we received, we are finalizing our proposal to apply our established methodology for determining the final CY 2017 ASC conversion factor. Using more complete CY 2015 data for this final rule with comment period than were available for the proposed rule, we calculated a wage index budget neutrality adjustment of 0.9996. Based on IGI's 2016 third quarter forecast, the CPI-U for the 12-month period ending with the midpoint of CY 2017 is now projected to be 2.2 percent, while the MFP adjustment (as discussed in the CY 2011 MPFS final rule with comment period (75 FR 73394 through 73396), and revised in the CY 2012 MPFS final rule with comment period (76 FR 73300 through 73301) and in the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70500 through 70501)) is 0.3 percent, resulting in an MFP-adjusted CPI-U update factor of 1.9 percent for ASCs that meet the quality reporting requirements. The final ASC conversion factor of \$45.030, for ASCs that meet the quality reporting requirements, is the product of the CY 2016 conversion factor of \$44.190 multiplied by the wage index budget neutrality adjustment of 0.9996 and the MFP-adjusted CPI-U payment update of

1.9 percent. For ASCs that do not meet the quality reporting requirements, we are reducing the CPI-U update of 2.2 percent by 2.0 percentage points and then we are applying the 0.3 percentage point MFP adjustment, resulting in a -0.1 percent MFP adjusted CPI-U update factor. The final ASC conversion factor of \$44.330 for ASCs that do not meet the quality reporting requirements is the product of the CY 2016 conversion factor of \$44.190 multiplied by the wage index budget neutrality adjustment of 0.9996 and the MFP-adjusted CPI-U payment update of -0.1 percent.

3. Display of CY 2017 ASC Payment Rates

Addenda AA and BB to this final rule with comment period (which are available via the Internet on the CMS Web site) display the updated ASC payment rates for CY 2017 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 final rates, the final payment indicators and rates set forth in this final rule with comment period are based on a comparison using the final MPFS rates that will be effective January 1, 2017. For a discussion of the MPFS rates, we refer readers to the CY 2017 MPFS final rule with comment period.

The final 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 final CY 2017 payment rates. Specifically, in Addendum AA, a "Y" in the column titled "To be Subject to Multiple Procedure Discounting" indicates that the surgical procedure would be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50-percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session.

Display of the comment indicator "CH" in the column titled "Comment Indicator" indicates a change in payment policy for the item or service, including identifying discontinued HCPCS codes, designating items or services newly payable under the ASC

payment system, and identifying items or services with changes in the ASC payment indicator for CY 2017. 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 "CY 2017 Payment Weight" are the final relative payment weights for each of the listed services for CY 2017. The final relative payment weights for all covered surgical procedures and covered ancillary services where the ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Therefore, scaling was not applied to the device portion of the device-intensive procedures, services that are paid at the MPFS nonfacility PE RVU-based amount, separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy sources that are separately paid under the OPPS, or services that are contractor-priced or paid at reasonable cost in ASCs.

To derive the final CY 2017 payment rate displayed in the "Final CY 2017 Payment Rate" column, each ASC payment weight in the "Final CY 2017 Payment Weight" column was multiplied by the CY 2017 conversion factor of \$45.030. The conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update factor as reduced by the productivity adjustment (as discussed in section XII.G.2.b. of this final rule with comment period).

In Addendum BB, there are no relative payment weights displayed in the "Final CY 2017 Payment Weight" column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The "Final CY 2017 Payment" column displays the CY 2017 national unadjusted ASC payment rates for all items and services. The CY 2017 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 October 2016 through December 2016.

Addendum EE provides the HCPCS codes and short descriptors for surgical

procedures that we are excluding from payment in ASCs for CY 2017.

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. In pursuit of 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 has generally been modeled after 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));
- 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, including the Hospital Value-Based Purchasing (VBP) Program and the End-Stage Renal Disease (ESRD)

Quality Incentive Program (QIP), that link payment to performance. 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, as well as conditions for which wide cost and treatment variations have been reported, despite established clinical 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 as part of care delivery. 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.

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.

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 the CY

2017 OPPS/ASC proposed rule (81 FR 45710), we did not propose any changes to our measure selection policy.

2. 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 OPPS/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 the CY 2017 OPPS/ASC proposed rule (81 FR 45710), we did not propose any changes to our retention policy for previously adopted measures.

3. 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 OPPS/ASC final rule with comment period (74 FR 60634 through 60635). We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473) for a discussion of our reasons for changing the term "retirement" to "removal" in the Hospital OQR Program. In the CY 2017 OPPS/ASC proposed rule (81 FR 45710), we did not propose any changes to our policy to immediately remove measures as a result of patient safety concerns.

In the CY 2013 OPPS/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 the CY 2017 OPPS/ASC proposed rule (81 FR 45710), we did not propose any changes to our measure removal policy.

b. Criteria for Removal of "Topped-Out" Measures

We refer readers to 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 the CY 2017 OPPS/ASC proposed rule (81 FR 45710), we did not propose any changes to our "topped-out" criteria policy.

4. Hospital OQR Program Quality Measures Adopted in Previous Rulemaking

We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70516) for the previously finalized measure set for the Hospital OQR Program CY 2019 payment determination and subsequent years. These measures also are listed below.

HOSPITAL OQR PROGRAM MEASURE SET PREVIOUSLY ADOPTED FOR THE CY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF #	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.
N/A	OP-9: Mammography Follow-up Rates.
N/A	OP-10: Abdomen CT—Use of Contrast Material.
0513	OP-11: Thorax CT—Use of Contrast Material.
N/A	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.
N/A	OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).

HOSPITAL OQR PROGRAM MEASURE SET PREVIOUSLY ADOPTED FOR THE CY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

NQF #	Measure name
0491	OP-17: Tracking Clinical Results between Visits.†
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.
N/A	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.
N/A	OP-25: Safe Surgery Checklist Use.
N/A	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.

† 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 OP/ASC final rule with comment period (79 FR 66946 through 66947).

5. New Hospital OQR Program Quality Measures for the CY 2020 Payment Determinations and Subsequent Years

In the CY 2017 OP/ASC proposed rule (81 FR 45711 through 45720), for the CY 2020 payment determination and subsequent years, we proposed a total of seven new measures—two of which are claims-based measures and five of which are Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures. The claims-based measures are: (1) OP-35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy; and (2) OP-36: Hospital Visits after Hospital Outpatient Surgery (NQF #2687). The OAS CAHPS Survey-based measures are: (1) OP-37a: OAS CAHPS—About Facilities and Staff; (2) OP-37b: OAS CAHPS—Communication About Procedure; (3) OP-37c: OAS CAHPS—Preparation for Discharge and Recovery; (4) OP-37d: OAS CAHPS—Overall Rating of Facility; and (5) OP-37e: OAS CAHPS—Recommendation of Facility. We discuss these measures in detail below.

We received a few comments that apply across all proposed measures and will address those first.

Comment: Several commenters expressed concern that only one of the seven measures proposed by CMS is NQF-endorsed and, therefore, questioned whether the measures were accurate and a fair representation of hospital performance.

Response: Section 1833(t)(17)(C)(i) of the Act does not require that each measure we adopt for the Hospital OQR

Program be endorsed by a national consensus building entity, or the NQF specifically. Under this provision, the Secretary has further authority to adopt non-NQF-endorsed measures. While we strive to adopt NQF-endorsed measures when possible, we believe the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, stakeholder input via a Technical Expert Panel (TEP), broad acceptance and use of the measure, and public comments. As part of that process, we sought and received extensive input on these measures from stakeholders and clinical experts.

We believe that these measures reflect consensus among the affected parties, because the MAP, which represents stakeholder groups, reviewed and conditionally supported the measures for use in the program. The MAP conditionally supported OP-35: Admissions and Emergency Department (ED) Visits for Patient Receiving Outpatient Chemotherapy.⁷ In addition, the MAP supported the OP-36: Hospital Visits after Hospital Outpatient Surgery measure for program use citing the vital importance of measures that help facilities reduce unnecessary hospital visits, and the measure received NQF endorsement on September 3, 2015.^{8,9}

⁷ Spreadsheet of MAP 2016 Final Recommendations available at: <http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369>.

⁸ MAP 2016 Considerations for Implementing Measures in Federal Programs: Hospitals. Final Report. February 15, 2016. Available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81688>.

Furthermore, the MAP encouraged continued development of OP-37a–e: Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery Survey measures, and the MAP stated that these are high impact measures that will improve both quality and efficiency of care and be meaningful to consumers.¹⁰

In evaluating and selecting these measures for inclusion in the Hospital OQR Program, we considered whether there were other available measures that have been endorsed or adopted by the NQF that assess the areas in focus for quality measurement and reporting. We were unable to identify other NQF-endorsed measures. However, we developed these measures using the same rigorous process that we have used to develop other publicly reported measures. Lastly, it is our priority to ensure we select measures that are appropriate for the Hospital OQR Program that further our goals under the National Quality Strategy and CMS Quality Strategy.

⁹ Spreadsheet of MAP 2016 Final Recommendations. February 1, 2016. Available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593>.

¹⁰ National Quality Forum. MAP 2015 Final Recommendations to HHS and CMS. Rep. National Quality Forum, Jan. 2015. Available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711>.

a. OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy Measure

(1) Background

Cancer care is a priority area for outcome measurement, because cancer is an increasingly prevalent condition associated with considerable morbidity and mortality. In 2015, there were more than 1.6 million new cases of cancer in the United States.¹¹ Each year, about 22 percent of cancer patients receive chemotherapy,¹² with Medicare payments for cancer treatment totaling \$34.4 billion in 2011, almost 10 percent of Medicare fee-for-service (FFS) dollars.¹³ With an increasing number of cancer patients receiving chemotherapy in a hospital outpatient department,¹⁴ a growing body of peer-reviewed literature identifies unmet needs in the care provided to these patients. This gap in care may be due to reasons including: (1) The large burden and delayed onset of chemotherapy side effects that patients must manage at home; (2) patients' assumption that little can be done about their symptoms, which leads to them to not seek medical assistance; and (3) limited access to providers who can tailor care to the individual.¹⁵ As a result, cancer patients who receive chemotherapy in a hospital outpatient department require more frequent acute care in the hospital setting and experience more adverse events than cancer patients who are not receiving chemotherapy.^{16 17 18}

¹¹ American Cancer Society. "Cancer Facts & Figures 2015." Available at: <http://www.cancer.org/acs/groups/content/@editorial/documents/document/acspc-044552.pdf>.

¹² Klodziej, M., J.R. Hoverman, J.S. Garey, J. Espirito, S. Sheth, A. Ginsburg, M.A. Neubauer, D. Patt, B. Brooks, C. White, M. Sitarik, R. Anderson, and R. Beveridge. "Benchmarks for Value in Cancer Care: An Analysis of a Large Commercial Population." *Journal of Oncology Practice*, Vol. 7, 2011, pp. 301–306.

¹³ Sockdale, H., K. Guillory. "Lifeline: Why Cancer Patients Depend on Medicare for Critical Coverage." Available at: <http://www.acscan.org/content/wp-content/uploads/2013/06/2013-Medicare-Chartbook-Online-Version.pdf>.

¹⁴ Vandervelde, Aaron, Henry Miller, and JoAnna Younts. "Impact on Medicare Payments of Shift in Site of Care for Chemotherapy Administration." Washington, DC: Berkeley Research Group, June 2014. Available at: http://www.communityoncology.org/UserFiles/BRG_340B_SiteofCare_ReportF_6-9-14.pdf. Accessed September 16, 2015.

¹⁵ McKenzie, H., L. Hayes, K. White, K. Cox, J. Fethney, M. Boughton, and J. Dunn. "Chemotherapy Outpatients' Unplanned Presentations to Hospital: A Retrospective Study." *Supportive Care in Cancer*, Vol. 19, No. 7, 2011, pp. 963–969.

¹⁶ Sadik, M., K. Ozlem, M. Huseyin, B. AliAyberk, S. Ahmet, and O. Ozgur. "Attributes of Cancer Patients Admitted to the Emergency Department in One Year." *World Journal of Emergency Medicine*,

Hospital admissions and ED visits among cancer patients receiving chemotherapy often are caused by predictable, and manageable, side effects from treatment. Recent studies of patients receiving chemotherapy in the outpatient setting show the most commonly cited symptoms and reasons for hospital visits are pain, anemia, fatigue, nausea and/or vomiting, fever and/or febrile neutropenia, shortness of breath, dehydration, diarrhea, and anxiety/depression.¹⁹ These hospital visits may be due to conditions related to the cancer itself or to side effects of chemotherapy. However, treatment plans and guidelines exist to support the management of these conditions. Hospitals that provide outpatient chemotherapy should proactively implement appropriate care to minimize the need for acute hospital care for these adverse events. Guidelines from the American Society of Clinical Oncology, the National Comprehensive Cancer Network, the Oncology Nursing Society, the Infectious Diseases Society of America, and other professional societies recommend evidence-based interventions to prevent and treat common side effects and complications of chemotherapy.²⁰ Appropriate outpatient care should curb potentially avoidable hospital admissions and ED

Vol. 5, No. 2, 2014, pp. 85–90. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4129880/#ref4>.

¹⁷ Hassett, M.J., J. O'Malley, J.R. Pakes, J.P. Newhouse, and C.C. Earle. "Frequency and Cost of Chemotherapy-Related Serious Adverse Effects in a Population Sample of Women with Breast Cancer." *Journal of the National Cancer Institute*, Vol. 98, No. 16, 2006, pp. 1108–1117.

¹⁸ Foltran, L., G. Aprile, F.E. Pisa, P. Ermacora, N. Pella, E. Iaiza, E. Poletto, SE. Lutrino, M. Mazzer, M. Giovannoni, G.G. Cardellino, F. Puglisi, and G. Fasola. "Risk of Unplanned Visits for Colorectal Cancer Outpatients Receiving Chemotherapy: A Case-Crossover Study." *Supportive Care in Cancer*, Vol. 22, No. 9, 2014, pp. 2527–2533.

¹⁹ Hassett, M.J., J. O'Malley, J.R. Pakes, J.P. Newhouse, and C.C. Earle. "Frequency and Cost of Chemotherapy-Related Serious Adverse Effects in a Population Sample of Women with Breast Cancer." *Journal of the National Cancer Institute*, Vol. 98, No. 16, 2006, pp. 1108–1117.

²⁰ Several evidence-based guidelines and interventions exist across professional societies. Here we provide three example citations: (1) National Comprehensive Cancer Network. "NCCN Clinical Practice Guidelines in Oncology Version 2.2016. Cancer- and Chemotherapy-Induced Anemia." Fort Washington, PA: NCCN, 2015; (2) Oncology Nursing Society. "Evidence-Based Interventions to Prevent, Manage, and Treat Chemotherapy-Induced Nausea and Vomiting." Available at: <http://www.ons.org/Research/PEP/Nausea>; (3) Freifeld, A.G., E.J. Bow, K.A. Sepkowitz, M.J. Boeckh, J.I. Ito, C.A. Mullen, I.I. Raad, K.V. Rolston, J.H. Young, and J.R. Wingard. "Clinical Practice Guideline for the Use of Antimicrobial Agents in Neutropenic Patients with Cancer: 2010 Update by the Infectious Diseases Society of America." *Clinical Infectious Diseases*, vol. 52, no. 4: 2011, pp. e56–e93.

visits for these issues and improve cancer patients' quality of life. We believe that including a measure monitoring admissions and ED visits for patients that receive outpatient chemotherapy in the Hospital OQR Program and publicly reporting results would encourage providers to improve their quality of care and lower rates of adverse events that lead to hospital admissions or ED visits after outpatient chemotherapy.

(2) Overview of Measure

We believe it is important to reduce adverse patient outcomes associated with chemotherapy treatment in the hospital outpatient setting. Therefore, in the CY 2017 OP/ASC proposed rule (81 FR 45711 through 45714), we proposed to adopt OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy in the Hospital OQR Program for the CY 2020 payment determination and subsequent years. This measure aims to assess the care provided to cancer patients and encourage quality improvement efforts to reduce the number of potentially avoidable inpatient admissions and ED visits among cancer patients receiving chemotherapy in a hospital outpatient setting. Improved hospital management of these potentially preventable symptoms—including anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—can reduce admissions and ED visits for these conditions. Measuring potentially avoidable admissions and ED visits for cancer patients receiving outpatient chemotherapy will provide hospitals with an incentive to improve the quality of care for these patients by taking steps to prevent and better manage side effects and complications from treatment.

In addition, this measure addresses the National Quality Strategy priority of "promoting the most effective prevention and treatment practices" for the leading causes of mortality. We expect the measure would promote improvement in patient care over time because measuring this area, coupled with transparency in publicly reporting scores, will make potentially preventable hospital inpatient admissions and ED visits following chemotherapy more visible to providers and patients and will encourage providers to incorporate quality improvement activities in order to reduce these visits. This risk-standardized quality measure will address an existing information gap and promote quality improvement by

providing feedback to hospitals and physicians, as well as transparency for patients on the rates and variation across hospitals in these potentially preventable admissions and ED visits following chemotherapy.

The measure is well-defined, precisely specified, and allows for valid comparisons of quality among hospitals. The measure includes only outcome conditions demonstrated in the literature as being potentially preventable in this patient population, is important to patients, is specified to attribute an outcome to other hospital(s) that provided outpatient chemotherapy in the 30 days preceding the outcome, and is risk-adjusted for patient demographics, cancer type, clinical comorbidities, and treatment exposure. Validity testing demonstrated that the measure data elements produce measure scores that correctly reflect the quality of care provided and adequately identify differences in quality. We conducted additional assessments to determine the impact of including sociodemographic status (SDS) factors in the risk-adjustment model, and NQF will review our methodology and findings under the NQF trial period described below.

Section 1890A(a)(2) of the Act outlines the prerulemaking process established under section 1890A of the Act, which requires the Secretary to make available to the public, by December 1 of each year, a list of quality and efficiency measures that the Secretary is considering. This measure (MUC ID: 15-951) was included on a publicly available document titled "List of Measures under Consideration for December 1, 2015" on the CMS Web site at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/2015-Measures-Under-Consideration-List.pdf> in compliance with section 1890A(a)(2) of the Act.

The Measure Applications Partnership (MAP), which represents stakeholder groups, conditionally supported the measure recommending that it be submitted for National Quality Forum (NQF) endorsement with a special consideration for SDS adjustments and the selection of exclusions. MAP members noted the potential for the measure to increase care coordination and spur patient activation. We refer readers to the Spreadsheet of MAP 2016 Final Recommendations available at: <http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369>.

We understand the important role that SDS plays in the care of patients. However, we continue to have concerns about holding hospitals to different

standards for the outcomes of their patients of diverse SDS because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. For all our measures, we routinely monitor the impact of SDS on hospitals' results. We will continue to investigate methods to ensure all hospitals are treated as fairly as possible within the program.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for SDS factors is appropriate. This trial entails temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of SDS factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without SDS factors in the risk-adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of SDS on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and consider how they apply to our quality programs in future rulemaking, as appropriate and feasible. We look forward to working with stakeholders in this process.

In addition, several MAP members noted the alignment of this measure concept with other national priorities, such as improving patient experience, and other national initiatives to improve cancer care, as well as the importance of this measure to raise awareness and create a feedback loop for providers (meeting transcript available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81391>). As required under section 1890A(a)(4) of the Act, we considered the input and recommendations provided by the MAP in selecting measures to propose for the Hospital OQR Program.

Section 1833(t)(17)(C)(i) of the Act requires the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings 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)(17)(C)(i) of the Act does not require that each measure we adopt for the Hospital OQR Program be endorsed by a national consensus building entity, or by the NQF specifically. As stated in the CY 2012 OPPI/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 that this proposed measure reflects consensus among the affected parties, because the MAP, which represents stakeholder groups, reviewed and conditionally supported the measure for use in the program. Further, the measure was subject to public input during the MAP and measure development processes, with some public commenters agreeing with the MAP's conclusions on the measure (MUC ID: 15-951; Spreadsheet of MAP 2016 Final Recommendations available at: <http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369>). We also note that we submitted this measure to NQF as part of the NQF Cancer Consensus Development Project in March 2016, and it is currently undergoing review.

Currently, there are no publicly available quality of care reports for providers or hospitals that provide outpatient chemotherapy treatment. Thus, adoption of this measure would provide an opportunity to enhance the information available to patients choosing among providers who offer outpatient chemotherapy. We believe this measure would reduce adverse patient outcomes after outpatient chemotherapy by capturing and making more visible to providers and patients hospital admissions and emergency department visits for symptoms that are potentially preventable through high quality outpatient care. Further, providing outcome rates to providers will make visible to clinicians, meaningful quality differences and encourage improvement.

(3) Data Sources

The proposed OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure is a claims-based measure. It uses Medicare Part A and Part B administrative claims data from Medicare FFS beneficiaries receiving chemotherapy treatment in a

hospital outpatient setting. The performance period for the measure is 1 year (that is, the measure calculation includes eligible patients receiving outpatient chemotherapy during a 1-year timeframe). For example, for the CY 2020 payment determination, the performance period would be CY 2018 (that is, January 1, 2018 through December 31, 2018).

(4) Measure Calculation

The OP-35 measure involves calculating two mutually exclusive outcomes: (1) One or more inpatient admissions; or (2) one or more ED visits for any of the following diagnoses— anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—within 30 days of chemotherapy treatment among cancer patients receiving treatment in a hospital outpatient setting. These 10 conditions are potentially preventable through appropriately managed outpatient care. Therefore, two scores will be reported for this measure. A patient can only be counted for any measured outcome once, and those who experience both an inpatient admission and an ED visit during the performance period are counted towards the inpatient admission outcome. These two distinct rates provide complementary and comprehensive performance estimates of quality of care following hospital-based outpatient chemotherapy treatment. We calculate the rates separately, because the severity and cost of an inpatient admission is different from that of an ED visit, but both adverse events are important signals of quality and represent patient-important outcomes of care.

The measure derives and reports the two separate scores, one for each mutually exclusive outcome, (also referred to as the hospital-level risk-standardized admission rate (RSAR) and risk-standardized ED visit rate (RSEDR)), each calculated as the ratio of the number of “predicted” to the number of “expected” outcomes (inpatient admissions or ED visits, respectively), multiplied by the national observed rate (of inpatient admissions or ED visits). For the RSAR and RSEDR, the numerator of the ratio is the number of patients predicted to have the measured adverse outcome (an inpatient admission for RSAR or ED visit for RSEDR with one or more of the 10 diagnoses described above within 30 days) based on the hospital’s performance with its observed case-mix. The denominator for each ratio is the number of patients expected to have the measured adverse outcome based on the average national performance and the

hospital’s observed case-mix. The national observed rate is the national unadjusted number of patients who have the adverse outcome among all qualifying patients who had at least one chemotherapy treatment in a hospital.

We define the window for identifying the outcomes of admissions and ED visits as 30 days after hospital outpatient chemotherapy treatment, as existing literature suggests the vast majority of adverse events occur within that timeframe.^{21 22 23} Limiting the window to 30 days after each outpatient chemotherapy treatment also: (1) Helps link patients’ experiences to the hospitals that provided their recent treatment, while accounting for variations in duration between outpatient treatments; (2) supports the idea that the admission is related to the management of side effects of treatment and ongoing care, as opposed to progression of the disease or other unrelated events; and (3) is a clinically reasonable timeframe to observe related side effects. For additional details on how the measure is calculated, we refer readers to: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

(5) Cohort

The cohort includes Medicare FFS patients ages 18 years and older as of the start of the performance period with a diagnosis of any cancer (except leukemia) who received at least one hospital outpatient chemotherapy treatment at a reporting hospital during the performance period. Based on discussions with clinical and technical panel experts, the measure excludes cancer patients with a diagnosis of leukemia at any time during the performance period due to the high toxicity of treatment and recurrence of disease. Therefore, admissions for leukemia patients may not reflect poorly managed outpatient care, but rather

²¹ Aprile, G., F.E. Pisa, A. Follador, L. Foltran, F. De Pauli, M. Mazzer, S. Lutrino, C.S. Sacco, M. Mansutti, and G. Fasola. “Unplanned Presentations of Cancer Outpatients: A Retrospective Cohort Study.” *Supportive Care in Cancer*, Vol. 21, No. 2, 2013, pp. 397–404.

²² Foltran, L., G. Aprile, F.E. Pisa, P. Ermacora, N. Pella, E. Iaiza, E. Poletto, SE. Lutrino, M. Mazzer, M. Giovannoni, G.G. Cardellino, F. Puglisi, and G. Fasola. “Risk of Unplanned Visits for Colorectal Cancer Outpatients Receiving Chemotherapy: A Case-Crossover Study.” *Supportive Care in Cancer*, Vol. 22, No. 9, 2014, pp. 2527–2533.

²³ McKenzie, H., L. Hayes, K. White, K. Cox, J. Fethney, M. Boughton, and J. Dunn. “Chemotherapy Outpatients’ Unplanned Presentations to Hospital: A Retrospective Study.” *Supportive Care in Cancer*, Vol. 19, No. 7, 2011, pp. 963–969.

disease progression and relapse. The measure also excludes patients who were not enrolled in Medicare FFS Parts A and B in the year before the first outpatient chemotherapy treatment during the performance period, because the risk-adjustment model (explained further below) uses claims data for the year before the first chemotherapy treatment during the performance period to identify comorbidities. Lastly, the measure excludes patients who do not have at least one outpatient chemotherapy treatment followed by continuous enrollment in Medicare FFS Parts A and B in the 30 days after the procedure, to ensure all patients have complete data available for outcome assessment.

(6) Risk Adjustment

Since the measure has two mutually exclusive outcomes (qualifying inpatient admissions and qualifying ED visits), we developed two risk-adjustment models. The only differences between the two models are the clinically relevant demographic, comorbidity, and cancer type variables used for risk adjustment. The statistical risk-adjustment model for inpatient admissions includes 20 demographic and clinically relevant risk-adjustment variables that are strongly associated with risk of one or more hospital admissions within 30 days following chemotherapy in a hospital outpatient setting. On the other hand, the statistical risk-adjustment model for ED visits include 15 demographic and clinically relevant risk-adjustment variables that are strongly associated with risk of one or more ED visits within 30 days following chemotherapy in a hospital outpatient setting. For additional methodology details, including the complete list of risk-adjustment variables, we refer readers to: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

We invited public comments on our proposal to adopt the OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure to the Hospital OQR Program for the CY 2020 payment determination and subsequent years as discussed above.

Comment: Several commenters supported the adoption of the proposed OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure in the Hospital OQR Program. Some commenters applauded CMS for recognizing cancer care as a priority area for outcome measurement, and

asserted this measure is particularly important as the number of cancer patients receiving chemotherapy in hospital outpatient settings is increasing. These commenters also agreed that it is imperative to include a measure to monitor admissions and ED visits for patients that receive outpatient chemotherapy in the Hospital OQR Program. Many commenters asserted that including an oncology measure would be an important step in holding hospitals accountable for the care they provide to chemotherapy patients—particularly because many of the reasons these patients are admitted to hospitals or visit the ED are for symptoms and side effects that can and should be anticipated and treated in nonacute care settings. These commenters asserted that reducing hospital admissions and ED visits will improve health outcomes and quality of life for chemotherapy patients, and the first step in doing so is to begin measuring the prevalence of these incidents. These commenters also asserted that publicly reporting results would encourage providers to improve their quality of care and lower rates of adverse events that lead to hospital admissions or ED visits after outpatient chemotherapy.

Response: We thank the commenters for their support.

Comment: Several commenters did not support the adoption of OP-35 because the measure is not NQF-endorsed, and asserted that CMS needs to obtain NQF approval prior to measure implementation to ensure that the measure is accurate, valid, and actionable.

Response: Section 1833(t)(17)(C)(i) of the Act does not require that each measure we adopt for the Hospital OQR Program be endorsed by a national consensus building entity, or the NQF specifically. Under this provision, the Secretary has further authority to adopt non endorsed measures. While we strive to adopt NQF-endorsed measures when possible, we believe the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad acceptance and use of the measure, and through public comments. As part of that process, we sought and received extensive input on the measure from stakeholders and clinical experts at multiple points during development, including from the MAP and the NQF.

Furthermore, in evaluating and selecting OP-35 for inclusion in the Hospital OQR Program, we considered whether there were other available measures that have been endorsed or

adopted by the NQF that assess admissions and ED visits following outpatient chemotherapy, an important area for quality measurement and reporting. We were unable to identify any other NQF-endorsed measures. We developed OP-35 using the same rigorous process that we have used to develop other publicly reported outcome measures.

Although this measure is not currently NQF-endorsed, our background research and analyses conducted during technical development demonstrate that this measure is accurate, valid, and actionable. This measure is an important signal of high quality care, measures what it intends to measure, and is specified in a way to appropriately differentiate data available between cancer hospitals providing high and low quality care for these patients. This measure assesses an aspect of care with documented unmet patient needs resulting in reduction of patient's quality of life and increase in healthcare utilization and costs. Several studies^{24 25 26} illustrate a gap in care for patients receiving chemotherapy in the hospital outpatient setting, as hospitals cannot effectively track the condition or status of patients after they return home following treatment. In addition, the performance rates and information provided to stakeholders are actionable and useful for quality improvement efforts by highlighting a specific gap in care for cancer patients treated at each hospital. The diagnoses measured include commonly cited reasons for unplanned hospitalizations and ED visits in this population that are considered potentially preventable through appropriately managed outpatient care. We have limited the outcome measure to these conditions in order to make the performance rate more meaningful and actionable to hospitals.

Thus, adoption of this measure would provide an opportunity to enhance the

²⁴ Aprile, G., F.E. Pisa, A. Follador, L. Foltran, F. De Pauli, M. Mazzer, S. Lutrino, C.S. Sacco, M. Mansutti, and G. Fasola. "Unplanned Presentations of Cancer Outpatients: A Retrospective Cohort Study." *Supportive Care in Cancer*, vol. 21, no. 2, 2013, pp. 397–404.

²⁵ Foltran, L., G. Aprile, F.E. Pisa, P. Ermacora, N. Pella, E. Iaiza, E. Poletto, SE. Lutrino, M. Mazzer, M. Giovannoni, G.G. Cardellino, F. Puglisi, and G. Fasola. "Risk of Unplanned Visits for Colorectal Cancer Outpatients Receiving Chemotherapy: A Case-Crossover Study." *Supportive Care in Cancer*, vol. 22, no. 9, 2014, pp. 2527–2533.

²⁶ McKenzie, H., L. Hayes, K. White, K. Cox, J. Fethney, M. Boughton, and J. Dunn. "Chemotherapy Outpatients' Unplanned Presentations to Hospital: A Retrospective Study." *Supportive Care in Cancer*, vol. 19, no. 7, 2011, pp. 963–969.

information available to patients choosing among providers who offer chemotherapy in the hospital outpatient setting. There currently remains a gap in care that leads to acute, potentially preventable hospitalizations among patients receiving chemotherapy. We note that, on average, cancer patients receiving chemotherapy have one hospital admission and two ED visits per year,²⁷ and therefore we believe it would be a disservice to patients to delay inclusion of the current outcome measure in quality reporting and quality improvement initiatives. As stated in the measure description above, we believe this measure would reduce adverse patient outcomes after outpatient chemotherapy by capturing and making more visible to providers and patients hospital admissions and emergency department visits for symptoms that are potentially preventable through high quality outpatient care. Further, providing outcome rates to providers will make visible to clinicians meaningful quality differences and encourage improvement.

Comment: Several commenters expressed concern that OP-35 is not risk adjusted for cancer type, SDS factors, and clinical complexity. Some commenters specifically stated that the NQF process of reviewing whether to include SDS factors in OP-35's risk-adjustment methodology is important to reflect and evaluate the effect of known disparities in access and outcomes for cancer patients in underserved areas. Some commenters asserted that OP-35 is particularly susceptible to performance variation due to SDS and factors outside the control of the hospital because chemotherapy patients may come back to an emergency department or require an inpatient admission not because of the care they received during the outpatient department visit, but because of a variety of community factors or their living conditions which may hamper the implementation of the post-discharge plan of care. One commenter further asserted that without this information, OP-35 lacks the necessary information needed to determine whether it is appropriate for public reporting.

Response: We would like to make clear that OP-35 is in fact risk-adjusted to account for the variation in patient mix and aggressiveness of treatment, and does adjust for clinical complexities

²⁷ Klodziej M, Hoverman JR, Garey JS, et al. Benchmarks for value in cancer care: An analysis of a large commercial population. *J Oncol Pract*. 2011;7:301–306.

including patient's age, sex, exposure (number of chemotherapy treatments during the performance period), cancer type, and certain clinical comorbidities. We refer readers to the measure specifications as originally made available in the CY 2017 OPPS/ASC proposed rule (81 FR 45722) at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

Regarding SDS factors, we understand the important role that SDS plays in the care of patients. However, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse SDS because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. For all our measures, we routinely monitor the impact of SDS on hospitals' results. We will continue to investigate methods to ensure all hospitals are treated as fairly as possible within the program.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. This trial entails temporarily allowing inclusion of sociodemographic factors in the risk adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are encouraged to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model. Several measures developed by CMS have been brought to NQF since the beginning of the trial, including OP-35. CMS, in compliance with NQF's guidance, has tested sociodemographic factors in the measures' risk models and made recommendations about whether or not to include these factors in the proposed measure. We intend to continue engaging in the NQF process as we consider the appropriateness of adjusting for sociodemographic factors in our outcome measures.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and consider how they

apply to our quality programs in future rulemaking, as appropriate and feasible. We look forward to working with stakeholders in this process.

During development of this measure, we assessed the relationship between the measure outcomes and SDS factors in accordance with NQF measure development guidelines as part of the 2-year NQF SDS trial period, available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=80279>. For our analysis, we used three variables that are available within or link directly to Medicare administrative claims data for evaluation of SDS factors and may capture some of the impact of community factors on patient care: Race; Medicaid dual-eligible status; and AHRQ socioeconomic status (SES) Index score. For more information on the AHRQ SES Index score, we refer readers to: <http://archive.ahrq.gov/research/findings/final-reports/medicareindicators/medicareindicators3.html>.

The results of our data analysis demonstrate no significant associations between hospital measure performance and the three tested SDS factors—patient race, patient Medicaid dual-eligible status, and patients' neighborhood AHRQ SES Index score. Based on these results, we disagree that the measure is not susceptible to performance variation due to patient and community SDS or other factors outside the control of the hospital, such as a variety of community factors or their living conditions, which may hamper the implementation of the post-discharge plan of care. At the hospital level, there was no clear relationship between median risk-standardized rates and hospitals' case mix by these three SDS factors, and the distributions of risk-standardized rates suggested that hospitals caring for a greater percentage of low SDS patients have similar rates of inpatient admission and ED visits within 30 days of hospital-based outpatient chemotherapy. Based on these findings, our final measure specifications do not risk adjust for any of these specific SDS factors. As a result, the measure does not currently adjust for SDS factors beyond those that are already accounted for as listed above (that is, age, sex, and clinical complexity).

Furthermore, based on these analyses and results, we believe this measure, as specified, effectively adjusts for patient-mix and can be publicly reported. We refer readers to [https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html)

[Methodology.html](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html) for the more information on our SDS analysis and results.

Comment: Some commenters expressed concern with the validity and reliability of the measure. Some commenters specifically stated that the NQF's Cancer Project 2015–2017 Committee failed to endorse the measure, citing reliability concerns. Commenters urged CMS to expedite additional measure testing, including sensitivity and specificity testing.

Response: As stated by the commenters, the NQF's Cancer Project 2015–2017 Committee did not endorse the proposed measure due to concerns regarding reliability. However, we disagree about the concerns with the measure's reliability. We believe that this measure is sufficiently reliable to be included in the Hospital OQR Program. We conducted several assessments of reliability during development using two different approaches given data limitations during testing. We first used the test-retest method to calculate reliability from one year of data, and then used the Intraclass Correlation Coefficient (ICC) and Spearman-Brown prophecy formula to estimate the reliability based on what would be expected if the sample size was increased. The Spearman-Brown prophecy formula^{28 29} is an accepted statistical method that estimates the ICC³⁰ based on what would be expected if the sample size was increased, to estimate the reliability score if CMS were to use a full year of data for public reporting rather than the six months of data that we used in initial testing.

Measure reliability was first calculated using a split sample of one year of data for the test-retest method.³¹ We randomly split the patient cohort at each hospital into two equal halves, calculated the measure using each half, and then calculated the agreement between these two (the "test" and the "retest"). Following this test-retest methodology, we calculated the Pearson correlation between the performance rate estimates in each half-year sample to assess reliability. We found the risk-standardized admission rate (RSAR) to have a reliability of 0.41 (95 percent

²⁸ Spearman, C. (1910). Correlation calculated from faulty data. *British Journal of Psychology*, 3, 171–195.

²⁹ Brown, W. (1910). Some experimental results in the correlation of mental abilities. *British Journal of Psychology*, 3, 296–322.

³⁰ Landis J, Koch G, The measurement of observer agreement for categorical data. *Biometrics* 1977;33:159–174.

³¹ Rousson V, Gasser T, Seifert B. Assessing intrarater, interrater and test–retest reliability of continuous measurements. *Statistics in Medicine*. 2002;21:3431–3446.

confidence interval (CI): 0.37–0.45) and the risk-standardized ED visit rate (RSEDR) to have a reliability of 0.27 (95 percent CI: 0.22–0.33) which, according to Cohen's classification, represent moderate and borderline weak-to-moderate reliability, respectively. The 95 percent CI gives us a reasonable estimate of the true reliability range.

However, our reliability estimate was arguably limited by use of only a half year of split data. We expected our reliability to be higher if we increased the amount of data we used. Therefore, after submitting the measure to NQF for endorsement review, we conducted additional calculations of the reliability testing score, this time using the ICC and the Spearman-Brown prophecy formula. The Spearman-Brown prophecy formula is an accepted statistical method that estimates the ICC based on what would be expected if the sample size was increased. It therefore provides us with an estimate of what the reliability score would be if CMS were to use a full year of data for public reporting rather than the six months of data that we used. Using the Spearman-Brown prophecy formula, we estimated that our measure will have an ICC of 0.63 (95 percent CI: 0.58–0.68) for RSAR and 0.47 percent (95 percent CI: 0.40–0.53) for RSEDR using a full year of data.

The NQF considers ICC values ranging from 0.41 to 0.60 as “moderate” reliability, and 0.61 to 0.80 as “strong” reliability.³² Our calculated ICC values of 0.63 for RSAR and 0.47 for RSEDR are interpreted as “strong” and “moderate” reliability, respectively. Therefore, we believe the measure is sufficiently reliable.

We also disagree with the concerns regarding the validity of the measure. We interpret the commenter's concern about validity to be about the degree to which the measure is measuring what it is intended to measure (that is, construct validity). Measure testing results demonstrated the measure's validity both at the conceptual level and empirically. Conceptual (or face) validity was demonstrated based on feedback from a TEP, a Cancer Workgroup that included representatives from each of the 11 PPS-exempt cancer hospitals, public comments, and NQF MAP review process. During each phase of measure development, these groups provided input to ensure that the measure specification had face validity (that is, identified outcomes both important to

the patient and related to the quality of chemotherapy administration). In addition, empirical analyses found that the most common reasons for admission (for example, pneumonia, pain, and anemia) and ED visits (for example, pain, fever, and dehydration) aligned with the diagnoses included in the measure specification. Additional details of our validity testing are provided within the materials submitted to NQF available at: <http://www.qualityforum.org/ProjectMeasures.aspx?projectID=80703>. In summary, this measure is an important signal of high quality outpatient cancer care, measures what it intends to measure by focusing on a patient-important aspect of care—avoiding potentially unnecessary ED visits and hospital admissions, and is specified in a way to appropriately differentiate between cancer hospitals providing high and low quality care for these patients.

We will consider additional measure testing, such as additional sensitivity and specificity analyses, during the annual reevaluation of the measure.

Comment: One commenter encouraged CMS to release, as part of the rulemaking process, the full measure specifications for every measure proposed, as it asserted having full specifications is critical to providers for public reporting. This commenter further expressed that hospitals not having full specifications may interpret the measures in different ways. In addition, the commenter asserted that the multiple interpretations of the measure specifications in reporting means the data reported is not comparable, and, therefore, consumers cannot make fully informed decisions based on valid and reliable data.

Response: Like this commenter, we also place great importance on transparency and clarity in measure specifications. Measure specifications for proposed measures are publicly available and provided in the proposed rules. For OP–35 in particular, measure specifications can be accessed from the CY 2017 OPPS/ASC proposed rule (81 FR 45713) and on the CMS Web site (<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>).

Comment: Some commenters questioned the appropriateness of the measure outcome, expressing concerns with the relationship between chemotherapy and the outcome. One commenter expressed concern that OP–35 is poorly calibrated for the intended outcome because the listed causes for admissions and ED visits for cancer

patients are not exclusive sequelae of outpatient chemotherapy, which may undermine the sensitivity and specificity of this measure. Some commenters expressed concern that, because the causes for admissions and ED visits are not solely the consequence of outpatient chemotherapy, they were uncertain which behavior the measure will evaluate in reality and how the results will be interpreted to infer quality. One commenter disagreed with the assumption that limiting hospital visits to those that occur within 30 days of chemotherapy ensures that the admission is due to the management of side effects and ongoing care. This commenter expressed that a variety of clinical scenarios could occur during the 30 days after chemotherapy and lead to a hospital visit for one of the 10 specified diagnoses, with some being the result of ongoing cancer care and some being the result of other issues. In addition, some commenters expressed that some causes listed in the measure numerator are not actual diagnoses because some are symptoms (nausea and pain) without a defined cause and others are based on laboratory results (anemia).

Response: Given the increase in outpatient hospital-based chemotherapy, understanding and minimizing related unplanned admissions and ED visits is a high priority. The 10 conditions that constitute the unplanned reasons for admission or ED visit are commonly cited reasons for hospital visits among patients receiving chemotherapy in the hospital outpatient setting. These 10 conditions do include symptom diagnoses, diagnoses that require lab values, and diagnoses related to infections. Hospital visits for these 10 conditions may be due to conditions related to the cancer itself or to side effects of chemotherapy, both of which affect patients' quality of care and quality of life. Admissions and ED visits for these conditions are potentially preventable through appropriately managed outpatient care and increased communication with the patient and are a potential signal of poor quality care and poor care coordination.

We recognize that by limiting the measure to these 10 potentially preventable outcome conditions, the measure will not identify admissions and ED visits from other less common potentially preventable outcome conditions, potentially limiting the sensitivity of the measure. On the other hand, we recognize that not all admissions and ED visits for these conditions over the 30-day time frame will be preventable and some may be

³² National Quality Forum. Guidance for Measure Testing and Evaluating Scientific Acceptability of Measure Properties. (2011).

due to other factors beyond the cancer and the chemotherapy treatment, such that the highest-performing hospital is unlikely to have a rate of 0, potentially limiting the specificity of the measure. Nevertheless, to strike the best possible balance between measure sensitivity and specificity, we limited the measure to these 10 conditions over a 30-day time period for identifying admissions and ED visits after hospital outpatient chemotherapy treatment. Existing literature suggests the vast majority of adverse events occur within that time frame, as were observed during testing.^{33 34 35} The measure does not evaluate compliance with certain care processes, procedures, or behaviors, but rather evaluates overall management of patients' symptoms and complications from chemotherapy, a reflection of outpatient care quality for these patients. The results can be inferred to illustrate potential gaps in the care of these patients and promote individual hospitals to reflect internally on how to improve the care they provide, especially for hospitals with outlying performance compared to their peers. While the goal is not to reach zero admissions and ED visits, the premise is that reporting this information will promote an improvement in patient care over time for two reasons. First, transparency achieved by publicly reporting this measure will raise hospital and patient awareness of unplanned hospital visits following chemotherapy. Second, this reporting will incentivize OPDs to incorporate quality improvement activities into their chemotherapy care planning in order to improve care coordination and reduce the number of these visits. We also believe that making OPDs aware of their performance, as well as the performance that might be expected given the OPD's case-mix is helpful in supporting efforts to improve outcomes. The measure is intended to improve symptom management and care coordination for

cancer patients who are undergoing chemotherapy.

Comment: Some commenters expressed concern that the measure's 30-day timeframe is misaligned with the presentation of conditions such as febrile neutropenia, a common cause of hospitalization among patients receiving chemotherapy, and further argued that the 30-day time window would not specifically address febrile neutropenia, since this condition does not correlate with any normal cycle of neutropenic nadir and recovery. One commenter believed that patients do not visit an ED for febrile neutropenia, but rather for fever and related symptoms of infection, and therefore, the cause of the visit might or might not be a complication of chemotherapy. Some commenters supported the development of a measure that addresses infection risk in cancer patients, specifically the risk of febrile neutropenia as a surrogate for infection in patients undergoing myelosuppressive chemotherapy. These commenters recommended CMS consider adopting NQF #2930 "Febrile Neutropenia Risk Assessment Prior to Chemotherapy" in the Hospital OQR Program.

Response: As stated above, we limited the time period for identifying the outcomes of admissions and ED visits, which are not limited only to complications of chemotherapy, to 30 days after hospital outpatient chemotherapy treatment, as existing literature suggests the vast majority of adverse events occur within that time frame,^{36 37 38} and we observed this during measure development testing. In addition, the TEP supported this time period because: (1) It helps link patients' experiences to the facilities that provided their recent treatment while accounting for variations in duration between outpatient treatments; (2) it supports the idea that the admission is related to the management of side effects of treatment and ongoing care, as opposed to progression of the

disease or other unrelated events; and (3) clinically, 30 days after each outpatient chemotherapy treatment is a reasonable time frame to observe related side effects.

During measure development, our TEP recommended expanding the original list of conditions that constitute the unplanned reasons for admission or ED visit, which included neutropenic fever, to include both neutropenia and fever separately to avoid missing any diagnoses of neutropenic fever since diagnosis of neutropenia requires lab results, and a single code for neutropenic fever does not exist in ICD-9 or ICD-10. We agreed that it was reasonable to expand the outcome to include fever and neutropenia to capture all potentially qualifying diagnoses. Neutropenic fever (and therefore fever and neutropenia as separate conditions) can occur at any time in the 30 days post-chemotherapy, but it is more likely to occur later on within the 30-day window, rather than directly after chemotherapy infusion.³⁹ Specifically, neutropenia often occurs between 7 and 12 days after chemotherapy, but much depends based on individual patient characteristics and the type of chemotherapy.⁴⁰ While the time course for when neutropenic fever is expected to occur after chemotherapy may not perfectly align with the current 30-day ascertainment period, we determined that a standardized approach, utilizing the same 30-day outcome timeframe for all of the 10 outcome conditions, would ease measure calculation, usability, and interpretation.

We thank the commenter for the suggestion to develop a measure that addresses infection risk in cancer patients, and specifically to include NQF #2930 "Febrile Neutropenia Risk Assessment Prior to Chemotherapy" in the Hospital OQR Program. We will consider these suggestions in the future.

Comment: One commenter recommended that CMS clearly define which chemotherapies should be included in OP-35 because there are various treatment options such as IV cytotoxic drugs, oral molecularly targeted agents, and biological therapy. The commenter recommended CMS specify whether it is exclusively examining Medicare Part A and B claims data from existing administrative reporting practices or if this measure

³³ Aprile, G., F.E. Pisa, A. Follador, L. Foltran, F. De Pauli, M. Mazzer, S. Lutrino, C.S. Sacco, M. Mansutti, and G. Fasola. "Unplanned Presentations of Cancer Outpatients: A Retrospective Cohort Study." *Supportive Care in Cancer*, vol. 21, no. 2, 2013, pp. 397-404.

³⁴ Foltran, L., G. Aprile, F.E. Pisa, P. Ermacora, N. Pella, E. Iaiza, E. Poletto, SE. Lutrino, M. Mazzer, M. Giovannoni, G.G. Cardellino, F. Puglisi, and G. Fasola. "Risk of Unplanned Visits for Colorectal Cancer Outpatients Receiving Chemotherapy: A Case-Crossover Study." *Supportive Care in Cancer*, vol. 22, no. 9, 2014, pp. 2527-2533.

³⁵ McKenzie, H., L. Hayes, K. White, K. Cox, J. Fethney, M. Boughton, and J. Dunn. "Chemotherapy Outpatients' Unplanned Presentations to Hospital: A Retrospective Study." *Supportive Care in Cancer*, vol. 19, no. 7, 2011, pp. 963-969.

³⁶ Aprile, G., F.E. Pisa, A. Follador, L. Foltran, F. De Pauli, M. Mazzer, S. Lutrino, C.S. Sacco, M. Mansutti, and G. Fasola. "Unplanned Presentations of Cancer Outpatients: A Retrospective Cohort Study." *Supportive Care in Cancer*, Vol. 21, No. 2, 2013, pp. 397-404.

³⁷ Foltran, L., G. Aprile, F.E. Pisa, P. Ermacora, N. Pella, E. Iaiza, E. Poletto, SE. Lutrino, M. Mazzer, M. Giovannoni, G.G. Cardellino, F. Puglisi, and G. Fasola. "Risk of Unplanned Visits for Colorectal Cancer Outpatients Receiving Chemotherapy: A Case-Crossover Study." *Supportive Care in Cancer*, Vol. 22, No. 9, 2014, pp. 2527-2533.

³⁸ McKenzie, H., L. Hayes, K. White, K. Cox, J. Fethney, M. Boughton, and J. Dunn. "Chemotherapy Outpatients' Unplanned Presentations to Hospital: A Retrospective Study." *Supportive Care in Cancer*, Vol. 19, No. 7, 2011, pp. 963-969.

³⁹ <http://www.cdc.gov/cancer/preventinfections/pdf/neutropenia.pdf>; <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2752227/>.

⁴⁰ <http://www.cdc.gov/cancer/preventinfections/pdf/neutropenia.pdf>.

requires any additional reporting from providers.

Response: This measure focuses on patients receiving infusion-based chemotherapy administered in a hospital outpatient department based on claims identified using Medicare Part A and B files such as ICD-9 procedure codes V58.11 (Encounter for antineoplastic chemotherapy) and 99.25 (Injection or infusion of cancer chemotherapeutic substance). We refer readers to the measure specifications, as we did in the CY 2017 OPPS/ASC proposed rule (81 FR 45722), with the code sets defining chemotherapy, available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>. Because this is a claims-based measure, it does not require any additional reporting from providers. Using claims data allows for consistent identification of chemotherapy administration in hospital OPDs and aligns with the NQF voluntary consensus standards⁴¹ and CMS standards for claims-based models for publicly reported measures.⁴²

Comment: One commenter requested that CMS exclude all planned inpatient admissions from the outcome to ensure that hospitals are held accountable only for those admissions that are unplanned. The commenter asserted that this modification would ensure alignment with readmission measures in the inpatient setting, which exclude planned readmissions. Another commenter recommended that CMS adjust OP-35 for those ED visits and hospitalizations which may be necessary, to avoid creating patient safety or value issues. This commenter asserted that a measure looking at the medical history of admitted patients to see whether they had received appropriate prophylactic measures to prevent toxicity and to assess the appropriateness of hospitalization or ED visits would be more meaningful than a simple count of ED visits and hospitalizations.

Response: We do not agree that it is necessary to exclude all planned inpatient admissions from the outcome to ensure that hospitals are held

accountable only for those admissions that are unplanned, because the outcome is defined by 10 specific reasons for the ED visit or admission, none of which are “elective” reasons for admissions and therefore, all can be considered unplanned. OP-35 is an outcome measure reporting the risk-adjusted rate of potentially preventable admissions and ED visits for cancer patients receiving outpatient chemotherapy. The measure does not assess the clinical processes that are part of the pathway to providing high-quality care for patients receiving outpatient chemotherapy (for example, whether the patient had access to primary care or whether the patient was prescribed appropriate pain medications); the measure assesses the outcomes based on the care provided. We recognize the value of process measures to support the outcome measure and reinforce certain aspects of high quality outpatient care, and we may consider process measures focused on the clinical care of cancer patients in future development. Furthermore, we use a specific set of codes to identify admissions and ED visits for 10 potentially preventable symptoms— anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—none of which are “elective” admissions and therefore, can be considered unplanned.

We do not agree that this measure needs to adjust for ED visits and admissions that may be necessary. As stated above, we do not view these outcomes as planned outcomes. We also do not think that measuring these potentially avoidable outcomes will result in hospitals making the clinical decisions that are not in the best interest of patient or put the patient care at risk. As stated previously, the goal is not to reach zero admissions and ED visits; the purpose is to identify those hospitals whose performance is worse than average, identifying areas for improvement. We will take into consideration for future rulemaking commenter’s suggestion to adopt measures that evaluate the medical history of admitted patients to see whether they had received appropriate prophylactic measures to prevent toxicity and to assess the appropriateness of hospitalization or ED visits.

Comment: Some commenters requested CMS consider additional denominator exclusions for the OP-35 measure. Two commenters expressed concerns about the measure’s inclusion of patients with hematologic malignancies other than leukemia, such as lymphoma and multiple myeloma in

the measure cohort. The commenters suggested that these patients are at an increased risk for many of these complications, compared to patients with solid tumors, and as a result, alternative measurement approaches may be more appropriate for these patients. Some commenters stated that OP-35 should exclude patients receiving chemotherapy for a condition/disease other than cancer, but who have a diagnosis of cancer as a result of having a history of cancer. These commenters urged CMS to ensure that the measure does not inappropriately include patients who are receiving chemotherapy and do not have a current cancer diagnosis, as such patients would be a clinically different population than patients with a current cancer diagnosis who are receiving chemotherapy. Commenters also expressed concerns that patients should only be included in the measure for a particular hospital if they have received at least two outpatient chemotherapy visits at that hospital to ensure that hospitals are only held accountable for patients for whom they are the primary provider of services.

Response: We specified the measure to be as inclusive as possible; we excluded, based on clinical input and rationale, only those patient groups for which hospital visits were not typically a quality signal or for which risk adjustment would not be adequate. For example, the measure excludes patients with leukemia because, given the high toxicity of treatment and recurrence of disease, admissions among this population do not reflect poorly managed outpatient care. Patients with leukemia have a high expected admission rate due to frequent relapse, which is not the type of admission the measure intends to capture. Feedback from early public input during measure development suggested that the exclusion of all patients with a hematologic malignancy would be too broad. Based on this feedback, we analyzed data which showed that patients with lymphoma and multiple myeloma experienced similar rates of ED visits and admissions for these potentially preventable hospitalizations when compared with patients with other cancer types. Therefore, we disagree that patients with hematologic malignancies other than leukemia, such as lymphoma and multiple myeloma, have an increased risk for many of these complications, compared to patients with solid tumors. For more information on our analysis we refer readers to: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment->

⁴¹ National Quality Forum. National voluntary consensus standards for patient outcomes, first report for phases 1 and 2: a consensus report. http://www.qualityforum.org/projects/Patient_Outcome_Measures_Phases1-2.aspx. Accessed August 19, 2010.

⁴² Centers for Medicare & Medicaid Services (CMS). CMS Measures Management System. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MeasuresManagementSystemBlueprint.html>. Accessed January 2016.

Instruments/HospitalQualityInits/Measure-Methodology.html. Therefore, we excluded patients with leukemia, but not other hematologic malignancies. However, as part of continued measure evaluation, we will consider reviewing rates stratified by cancer type to track the impact and inform future measure revisions.

Comment: Some commenters stated that OP-35 should exclude patients receiving chemotherapy for a condition/disease other than cancer, but who have a diagnosis of cancer as a result of having a history of cancer. These commenters urged CMS to ensure that the measure does not inappropriately include patients who are receiving chemotherapy and do not have a current cancer diagnosis, as such patients would be a clinically different population than patients with a current cancer diagnosis who are receiving chemotherapy.

Response: This measure is intended to assess the care provided to cancer patients receiving chemotherapy in the OPD. To be included in the cohort, a patient must have a diagnosis of cancer on a Medicare FFS claim during the performance period; we do not include codes for “history of cancer” in our code set to define cancer diagnosis. We refer readers to the measure specifications for more details about the cohort: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>. By limiting the cohort to those with a diagnosis of cancer on a Medicare FFS claim, the measure would only include patients currently receiving chemotherapy as part of active cancer care management, and therefore, exclude patients who are receiving chemotherapy but without a current cancer diagnosis, likely a very small number of patients. However, we will continue to monitor the cohort for any future necessary measure updates.

Comment: Commenters expressed concerns that patients should only be included in the measure for a particular hospital if they have received at least two outpatient chemotherapy visits at that hospital to ensure that hospitals are only held accountable for patients for whom they are the primary provider of services.

Response: We disagree. Excluding patients who only receive one chemotherapy treatment at a facility during the performance period may unnecessarily exclude qualifying patients. Furthermore, we believe that if an OPD provides even a single chemotherapy treatment to the cancer patient, that OPD is still expected to provide appropriate care planning,

treatment, and follow-up over the subsequent 30 days. In addition, our data show that nearly 95 percent of the patients who receive chemotherapy treatment in an OPD receive treatment at the same facility throughout the course of treatment.

After consideration of the public comments we received, we are finalizing the adoption of the OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure for the CY 2020 payment determination and subsequent years as proposed.

b. OP-36: Hospital Visits After Hospital Outpatient Surgery Measure (NQF #2687)

(1) Background

Outpatient same-day surgery is common in the United States. Nearly 70 percent of all surgeries in the United States are now performed in the outpatient setting, with most performed as same-day surgeries at hospitals.⁴³ Same-day surgery offers significant patient benefits as compared with inpatient surgery, including shorter waiting times, avoidance of hospitalizations, and rapid return home.⁴⁴ Furthermore, same-day surgery costs significantly less than an equivalent inpatient surgery, and therefore, presents a significant cost saving opportunity to the health system.⁴⁵ With the ongoing shift towards outpatient surgery, assessing the quality of surgical care provided by hospitals has become increasingly important. While most outpatient surgery is safe, there are well-described and potentially preventable adverse events that occur after outpatient surgery, such as uncontrolled pain, urinary retention, infection, bleeding, and venous thromboembolism, which can result in unanticipated hospital visits. Similarly, direct admissions after surgery that are primarily caused by nonclinical patient considerations (such as lack of transport home upon discharge) or facility logistical issues (such as delayed start of surgery) are common causes of unanticipated yet preventable hospital admissions

⁴³ Cullen KA, Hall MJ, Golosinskiy A. Ambulatory surgery in the United States, 2006. National health statistics reports. Jan 28 2009(11):1–25.

⁴⁴ International Association for Ambulatory Surgery. Day Surgery: Development and Practice. International Association for Ambulatory Surgery (IASS); 2006. Available at: <http://www.iaas-med.com/files/historical/DaySurgery.pdf>.

⁴⁵ Majholm B, Engbaek J, Bartholdy J, et al. Is day surgery safe? A Danish multicentre study of morbidity after 57,709 day surgery procedures. *Acta anaesthesiologica Scandinavica*. Mar 2012;56(3):323–331.

following same-day surgery. Hospital utilization following same-day surgery is an important and accepted patient-centered outcome reported in the literature. National estimates of hospital visit rates following surgery vary from 0.5 to 9.0 percent based on the type of surgery, outcome measured (admissions alone or admissions and ED visits), and timeframe for measurement after surgery.^{46 47 48 49 50 51 52 53} Furthermore, hospital visit rates vary among hospitals,⁵⁴ suggesting variation in surgical and discharge care quality. However, providers (hospitals and surgeons) are often unaware of their patients’ hospital visits after surgery because patients often present to the ED or to different hospitals.⁵⁵ This risk-standardized measure would provide the opportunity for providers to improve the quality of care and to lower the rate of preventable adverse events that occur after outpatient surgery.

(2) Overview of Measure

We believe it is important to reduce adverse patient outcomes associated with preparation for surgery, the procedure itself, and follow-up care. Therefore, in the CY 2017 OP/ASC proposed rule (81 FR 45714 through 45716), we proposed to include OP-36: Hospital Visits after Hospital Outpatient Surgery in the Hospital OQR Program

⁴⁶ Ibid.

⁴⁷ Linares-Gil MJ, Pelegri-Isanta MD, Pi-Siqués F, Amat-Rafols S, Esteve-Ollé MT, Gomar C. Unanticipated admissions following ambulatory surgery. *Ambulatory Surgery*. 1997;5(4):183–188.

⁴⁸ Fleisher LA, Pasternak LR, Herbert R, Anderson GF. Inpatient hospital admission and death after outpatient surgery in elderly patients: importance of patient and system characteristics and location of care. *Archives of surgery (Chicago, Ill.: 1960)*. Jan 2004;139(1):67–72.

⁴⁹ Coley KC, Williams BA, DaPos SV, Chen C, Smith RB. Retrospective evaluation of unanticipated admissions and readmissions after same day surgery and associated costs. *Journal of Clinical Anesthesia*. Aug 2002;14(5):349–353.

⁵⁰ Hollingsworth JM, Saigal CS, Lai JC, Dunn RL, Strobe SA, Hollenbeck BK. Surgical quality among Medicare beneficiaries undergoing outpatient urological surgery. *The Journal of Urology*. Oct 2012;188(4):1274–1278.

⁵¹ Bain J, Kelly H, Snadden D, Staines H. Day surgery in Scotland: patient satisfaction and outcomes. *Quality in health care: QHC*. Jun 1999;8(2):86–91.

⁵² Fortier J, Chung F, Su J. Unanticipated admission after ambulatory surgery—a prospective study. *Canadian journal of anaesthesia = Journal Canadien d'Anesthésie*. Jul 1998;45(7):612–619.

⁵³ Aldwinckle RJ, Montgomery JE. Unplanned admission rates and postdischarge complications in patients over the age of 70 following day case surgery. *Anaesthesia*. Jan 2004;59(1):57–59.

⁵⁴ Bain J, Kelly H, Snadden D, Staines H. Day surgery in Scotland: patient satisfaction and outcomes. *Quality in health care: QHC*. Jun 1999;8(2):86–91.

⁵⁵ Mezei G, Chung F. Return hospital visits and hospital readmissions after ambulatory surgery. *Annals of surgery*. Nov 1999;230(5):721–727.

for the CY 2020 payment determination and subsequent years.

We expect that the measure would promote improvement in patient care over time because measuring this area, coupled with transparency in publicly reporting scores, will make patient unplanned hospital visits (ED visits, observation stays, or unplanned inpatient admissions) after surgery more visible to providers and patients and encourage providers to engage in quality improvement activities in order to reduce these visits. This measure meets the National Quality Strategy priority of “promoting effective communication and coordination of care.” Many providers are unaware of the post-surgical hospital visits that occur because patients often present to the ED or to different hospitals. Reporting this outcome will illuminate problems that may not currently be visible. In addition, the outcome of unplanned hospital visits is a broad, patient-centered outcome that reflects the full range of reasons leading to hospitalization among patients undergoing same-day surgery. This risk-standardized quality measure would address this information gap and promote quality improvement by providing feedback to facilities and physicians, as well as transparency for patients on the rates and variation across facilities in unplanned hospital visits after outpatient same-day surgery.

Currently, there are no publicly available quality of care reports for providers or facilities that conduct same-day surgery in the hospital outpatient setting. Thus, this measure addresses an important quality measurement gap, and there is an opportunity to enhance the information available to patients choosing among hospitals that provide same-day outpatient surgery. Furthermore, providing outcome rates to hospitals will make visible to clinicians, meaningful quality differences and incentivize improvement.

This measure (MUC ID: 15–982) was included on a publicly available document titled “MAP 2016 Considerations for Implementing Measures in Federal Programs: Hospitals” on the NQF Web site at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81688> (formerly referred to as the “list of Measures Under Consideration”) in compliance with section 1890A(a)(2) of the Act.

The measure received NQF endorsement on September 3, 2015.⁵⁶ In

⁵⁶ MAP 2016 Considerations for Implementing Measures in Federal Programs: Hospitals. Final

addition, the MAP supported the measure for program use citing the vital importance of measures that help facilities reduce unnecessary hospital visits.⁵⁷ Some members cautioned that because the measure was endorsed by NQF before the start of the SDS trial period, the measure should be reexamined during maintenance to determine whether SDS adjustments are needed.⁵⁸

We believe that this proposed measure reflects consensus among the affected parties because the measure was subject to public comment during the MAP and measure development processes, with public commenters agreeing with the MAP’s conclusions on the measure.⁵⁹ As stated above, this measure also was endorsed by the NQF.

We understand the important role that SDS plays in the care of patients. However, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse SDS because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. For all our measures, we routinely monitor the impact of SDS on hospitals’ results. We will continue to investigate methods to ensure all hospitals are treated as fairly as possible within the program.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. This trial entails temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting

Report. February 15, 2016. Available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81688>.

⁵⁷ Spreadsheet of MAP 2016 Final Recommendations. February 1, 2016. Available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593>.

⁵⁸ Ibid.

⁵⁹ MAP 2016 Considerations for Implementing Measures in Federal Programs: Hospitals. Final Report. February 15, 2016. Available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81688>.

research to examine the impact of SDS on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and consider how they apply to our quality programs in future rulemaking, as appropriate and feasible. We look forward to working with stakeholders in this process.

(3) Data Sources

The proposed OP–36: Hospital Visits after Hospital Outpatient Surgery measure is a claims-based measure. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries with outpatient same-day surgery. The performance period for the measure is 1 year (that is, the measure calculation includes eligible outpatient same-day surgeries occurring within a one-year timeframe). For example, for the FY 2020 payment determination, the performance period would be CY 2018 (that is, January 1, 2018 through December 31, 2018).

(4) Measure Calculation

The measure outcome is any of the following hospital visits: (1) An inpatient admission directly after the surgery; or (2) an unplanned hospital visit (ED visits, observation stays, or unplanned inpatient admissions) occurring after discharge and within 7 days of the surgery. If more than one unplanned hospital visit occurs, only the first hospital visit within the outcome timeframe is counted in the outcome.

The facility-level measure score is a ratio of the predicted to expected number of post-surgical hospital visits among the hospital’s patients. The numerator of the ratio is the number of hospital visits predicted for the hospital’s patients accounting for its observed rate, the number of surgeries performed at the hospital, the case-mix, and the surgical procedure mix. The denominator of the ratio is the expected number of hospital visits given the hospital’s case-mix and surgical procedure mix. A ratio of less than one indicates the hospital’s patients were estimated as having fewer post-surgical visits than expected compared to hospitals with similar surgical procedures and patients; and a ratio of greater than one indicates the hospital’s patients were estimated as having more visits than expected.

In order to ensure the accuracy of the algorithm for attributing claims data and the comprehensive capture of hospital surgeries potentially affected by the CMS 3-day payment window policy, we

identified physician claims for same-day surgeries in the hospital setting from the Medicare Part B Standard Analytical Files (SAF) with an inpatient admission within 3 days and lacking a corresponding hospital facility claim. We then attribute the surgery identified as affected by this policy to the appropriate hospital facility using the facility provider identification from the inpatient claim.

For additional methodology details, we refer readers to the documents posted at: <http://www.cms.gov/Medicare/QualityInitiatives-Patient-AssessmentInstruments/HospitalQualityInits/Measure-Methodology.html> under "Hospital Outpatient Surgery."

(5) Cohort

The measure includes Medicare FFS patients aged 65 years and older undergoing same-day surgery (except eye surgeries) in hospitals.

"Same-day surgeries" are substantive surgeries and procedures listed on Medicare's list of covered ASC procedures. Medicare developed this list to identify surgeries that can be safely performed as same-day surgeries and do not typically require an overnight stay. Surgeries on the ASC list of covered procedures do not involve or require major or prolonged invasion of body cavities, extensive blood loss, major blood vessels, or care that is either emergent or life-threatening.

Although Medicare developed this list of surgeries for ASCs, we use it for this hospital outpatient measure for two reasons. First, it aligns with our target cohort of surgeries that have a low to moderate risk profile and are safe to be performed as same-day surgeries. By only including surgeries on this list in the measure, we effectively do not include surgeries performed at hospitals that typically require an overnight stay which are more complex, higher risk surgeries. Second, we use this list of surgeries because it is annually reviewed and updated by Medicare, and includes a transparent public comment submission and review process for addition and/or removal of procedures codes. The list for 2016 is posted at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1633-FC.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending> (we refer readers to Addendum AA to this final rule with comment period, which is available via the Internet on the CMS Web site).

The measure cohort excludes eye surgeries. Although eye surgery is

considered a substantive surgery, its risk profile is more representative of "minor" surgery, in that it is characterized by high volume and a low outcome ratio. The measure cohort also excludes procedures for patients who lack continuous enrollment in Medicare FFS Parts A and B in the 7 days after the procedure to ensure all patients have complete data available for outcome assessment.

(6) Risk Adjustment

The statistical risk-adjustment model includes 25 clinically relevant risk-adjustment variables that are strongly associated with risk of hospital visits within 7 days following outpatient surgery. The measure risk adjusts for surgical procedure complexity using two variables. First, it adjusts for surgical procedure complexity using the Work Relative Value Units (RVUs).⁶⁰ Work RVUs are assigned to each CPT procedure code and approximate procedure complexity by incorporating elements of physician time and effort. Second, it classifies each surgery into an anatomical body system group using the Agency for Healthcare Research and Quality (AHRQ) Clinical Classification System (CCS),⁶¹ to account for organ-specific differences in risk and complications, which are not adequately captured by the Work RVU alone.

We invited public comment on our proposal to adopt the OP-36: Hospital Visits after Hospital Outpatient Surgery measure (NQF #2687) to the Hospital OQR Program for the CY 2020 payment determination and subsequent years as discussed above.

Comment: One commenter supported the proposed adoption of the OP-36: Adoption of Hospital Visits After Hospital Outpatient Surgery measure because it provides the opportunity for providers to improve their quality of care and lower the rate of preventable adverse events that occur after outpatient surgery.

Response: We thank the commenter for its support.

Comment: Many commenters recommended that OP-36 be reviewed by the NQF's SDS trial to determine whether there is a conceptual and empirical relationship between the measure's outcomes and SDS factors before it is publicly reported.

⁶⁰ S. Coberly, The Basics; Relative Value Units (RVUs). National Health Policy Forum. January 12, 2015. Available at: http://www.nhpf.org/library/the-basics/Basics_RVUs_01-12-15.pdf.

⁶¹ HCUP Clinical Classifications Software for Services and Procedures. Healthcare Cost and Utilization Project (HCUP). 2008. Agency for Healthcare Research and Quality, Rockville, MD. Available at: https://www.hcup-us.ahrq.gov/toolsoftware/ccs_svcproc/ccsvproc.jsp.

Furthermore, commenters believed that OP-36 should be reviewed to determine if additional SDS risk adjustment are necessary. Some commenters were concerned that the measure may be heavily influenced by factors outside of the hospital's direct control. Many commenters specifically expressed concern that hospitals that serve a significant volume of patients in lower socioeconomic areas which may lack adequate infrastructure for appropriate follow-up care may be unfairly penalized as a result of this measure. Without the use of appropriate risk adjustment for this measure, many commenters asserted the clinical outcomes could be less reliable due to SDS confounding variables. In addition, many commenters expressed concern that patients with low SDS may have fewer options for managing their care and therefore may require additional hospital visits compared to patients with more resources. One commenter expressed concern that patient populations who do not have family or home care aides or ready access to pharmacies for medications may be more likely to return to the ED compared to patients with these benefits.

Response: We understand the important role that factors outside of the hospitals' direct control, for example socioeconomic and sociodemographic status, play in the care of patients. Patients with low SDS may have fewer options for managing their care and therefore, may require additional hospital visits compared to patients with more resources. In addition, patient populations that do not have family or home care aides, or ready access to pharmacies for medications, may be more likely to return to the ED compared to patients with these benefits, as commenter mentions. We routinely monitor the impact of sociodemographic status on hospitals' results. However, we do not believe that hospitals would necessarily be unfairly penalized as a result of this measure for reasons discussed below.

As stated previously, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and consider how they apply to our quality programs in future rulemaking, as appropriate and feasible. We look forward to working with stakeholders in this process.

We also note that the NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk adjusting for sociodemographic factors is appropriate. This trial entails temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of SDS factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without SDS factors in the risk-adjustment model. We intend to continue engaging in the NQF process as we consider the appropriateness of adjusting for sociodemographic factors in our outpatient quality reporting program measures.

This NQF trial period went into effect April 15, 2015,⁶² meaning that projects with measure submission deadlines beforehand fell under NQF's previous policy on SDS adjustment,⁶³ while projects with measure submission deadlines after that date are subject to the NQF trial. Because the 2015 NQF Surgery Project's measure submission deadline was January 14, 2015, both the developer and the Surgery Standing Committee conformed to the pre-trial policy regarding inclusion of SDS factors in the risk-adjustment approach.⁶⁴ Thus, OP-36 was not part of NQF's SDS trial. At this time, we do not plan to resubmit the measure to be part of the SDS trial because the measure was already reviewed and endorsed by the NQF. We will further evaluate the role of SDS when the measure is under comprehensive reevaluation.

Consistent with the pre-trial NQF SDS guidance, we evaluated the potential effects of risk adjusting for two SDS indicators—Medicaid-dual eligibility and race. These variables are available in the CMS claims data and use of Medicaid eligibility status as a proxy for SDS is consistent with prior research as well as NQF recommendations.⁶⁵ Our

results show that adjusting for these two factors at the patient level does little to change the measure scores. Unadjusted and adjusted OPD risk-standardized hospital visit (RSHV) ratios are highly correlated—Pearson correlation of 0.990 and 0.998 for adjustment for Medicaid-dual eligibility and race, respectively.⁶⁶ This suggests that including a patient-level risk adjuster for SDS will result in minimal difference in measure results after accounting for other factors already adjusted for in the model, such as age, comorbidities, and the complexity of the surgery. Thus, we are finalizing the measure as currently specified because the inclusion of SDS-related variables in the risk-adjustment model did not substantially affect measure results.

In addition, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse SDS because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations.

In addition, we examined the distribution of measure scores by quartiles of both the percentage of dual-eligible patients and the percentage of African American patients in order to explore whether there might be differences in OPD RSHV ratios by the proportion of such patients treated at the facility. A ratio of less than one indicates the OPD's patients were estimated as having fewer post-surgical visits than expected compared to OPDs with similar surgical procedures and patients, and a ratio of greater than one indicates the OPD's patients were estimated as having more visits than expected. We do not expect the rate of hospital visits to be zero. Overall, our results showed a range of measure scores across quartiles of dual-eligible patients and of African American patients. The median RSHV ratio for all quartiles was <1 (indicating better than expected performance), demonstrating that, even among facilities with the highest proportion of dual-eligible and African American patients, many OPDs can and do perform well on the measure. Furthermore, even though the distribution of measure scores was shifted slightly higher in facilities with the highest proportion of such patients, the distributions for all quartiles are

largely overlapping. Together, these two points suggest that hospitals that serve a significant volume of patients in lower socioeconomic areas that lack adequate infrastructure for appropriate follow-up care would not be unfairly penalized as a result of this measure. From these analyses, it is not clear what is causing the observed differences across hospitals with the highest and lowest proportions of dual-eligible and African American patients. One potential cause could be differences related to quality, and, as discussed above, we are particularly concerned about masking quality differences through SDS adjustments. Given these findings, we did not adjust the measure for SDS at this time. We believe that doing so will not appreciably change the measure scores and might contribute to masking disparities in care. However, as noted above, we will continue to assess the appropriateness of including SDS factors in risk adjustment to assess the reliability of the measure.

Reducing adverse outcomes is the joint responsibility of hospitals and other clinicians. Measuring hospital visits will create incentives to invest in interventions to improve outpatient care and improved transitions to post-procedure care. We recognize that the facility's performance might be affected by factors outside of the facility. However, all facilities have the opportunity to reduce the rate of hospital visits following surgeries. Because of the measure's intent to illuminate variation in quality of care across OPDs for same-day surgeries, inform patient choice, and drive quality improvement, we do not believe we should delay public reporting pending further analysis of the empirical relationship between the measure's outcomes and SDS factors.

Comment: A few commenters expressed concerns that this measure does not provide clear signals of quality or will create disincentives for seeking care in the ED when appropriate. Two commenters asserted that the measure combines admissions, observation stays and ED visits; each reflecting widely different approaches to patient-centered care and that it may not be reasonable to combine these types of hospital visits. Another commenter urged CMS to remove the ED visits and observation stays from the measure to focus only on inpatient admissions. One commenter asserted that the "expected number of post-surgical hospital visits" calculation will not provide sufficient assurance, particularly given issues related to risk-adjustment, that the current structure of the measure will avoid creating a disincentive for seeking appropriate

⁶² National Quality Forum. Socioeconomic Status (SES) Trial period. Available at: <http://www.qualityforum.org/ProjectDescription.aspx?projectID=80124>.

⁶³ Under the previous policy, only clinical factors could be included in a measure's risk adjustment model.

⁶⁴ Email from Andrew Lyzenga at NQF, June 15, 2015.

⁶⁵ National Quality Forum. Patient Outcome Measures Phases 1 and 2. Available at: http://www.qualityforum.org/projects/Patient_Outcome_Measures_Phases1-2.aspx.

⁶⁶ Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation. 2016 Measure Updates and Specifications Report: Hospital Visits after Hospital Outpatient Surgery Measure. June 2016. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Hospital-Visits-after-Hospital-Outpatient-Surgery-Measure.pdf>.

care in the emergency department. The commenter further asserted it will be methodologically difficult to come up with that expected number of visits, and further expressed that applying a measure such as this for patient-initiated services is a misstep in policy. One commenter advised CMS to monitor the use of the measure.

Response: We believe that patients with emergent medical needs will continue to seek care in an ED as needed. Providers should not have an incentive to discourage patients from seeking appropriate care for a medical problem that they feel needs to be addressed immediately since the goal of the measure is not to reach zero ED visits and the measure is risk adjusted so facilities with generally higher-risk patients will not be disadvantaged in the measure. In addition, it is not expected that patients undergoing same-day surgery would need to be placed in observation status after the procedure. We have designed the measure to capture all unplanned hospital visits that may be a signal of poor quality of care, and thereby encourage hospitals to minimize risk and the need for follow-up hospital services.

We disagree that combining admissions, observation stays and ED visits reflects widely different approaches to patient-centered care and that we should remove the ED visits and observation stays from the measure to focus only on inpatient admissions. We included ED visits and observation stays for a variety of reasons. First, hospital visits are a broad outcome that captures the full range of potentially serious adverse events related to preparing for, undergoing, and recovering from the surgery. Second, hospital visits are easily identifiable and measurable from claims data. Third, this broad outcome is consistent with a patient-centered view of care that prompts providers to fully account for and minimize to the fullest extent all acute complications, such as uncontrolled pain or urinary retention, not just those narrowly related to procedural technique. Finally, hospital visits are costly; reducing hospital visits following outpatient surgery may lead to substantial healthcare savings. As one commenter suggested, we will continue to reevaluate the measure and monitor its use.

One commenter asserted that it will be methodologically difficult to come up with the expected number of visits and will result in a misstep in policy. However, the measure's risk model is informed by the literature and expert review, and is designed to capture patient risk, not risk that might be

related to quality. Our approaches to risk adjustment and calculating both predicted and expected values using hierarchical generalized linear modeling are tailored to, and appropriate for, a publicly reported outcome measure as articulated in published scientific guidelines.^{67 68 69} In addition, these analytic methods have been widely used in other risk-adjusted outcome measures developed by CMS for quality measurement and public reporting.⁷⁰ As a result, we believe that the "expected number of post-surgical hospital visits" calculation is sound and will provide sufficient assurance and will not be a misstep in policy.

Comment: Two commenters asserted that beneficiaries will find procedure-specific outcome measures more valuable as beneficiaries choose outpatient facilities based on, in part, services and procedures offered.

Response: We disagree that a procedure-specific outcome measure would be more valuable. A broad range of surgical procedures are performed at OPDs, and the measure as specified provides consumers with a full picture of quality at a facility. This measure complements other outpatient quality measures already adopted in the Hospital OQR Program that focus on specific types of procedures or patients, for example the Facility 7-day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure. For more information on that measure, we refer readers to the CY 2015 OPPTS/ASC final rule with comment period (79 FR 66948 through 66955). In addition, as part of our standard procedures, we will provide facilities with case-level information, including the surgery performed as part of confidential preview reporting to provide facilities with actionable information for quality improvement. We believe that the

⁶⁷ Krumholz HM, Brindis RG, Brush JE, et al. Standards for Statistical Models Used for Public Reporting of Health Outcomes: An American Heart Association Scientific Statement From the Quality of Care and Outcomes Research Interdisciplinary Writing Group: Cosponsored by the Council on Epidemiology and Prevention and the Stroke Council Endorsed by the American College of Cardiology Foundation. *Circulation*. 2006; 113 (3): 456–462.

⁶⁸ Normand S-LT, Shahian DM. Statistical and Clinical Aspects of Hospital Outcomes Profiling. *Stat Sci*. 2007; 22 (2): 206–226.

⁶⁹ Centers for Medicare & Medicaid Services. Statistical Issues in Assessing Hospital Performance. January 27, 2012. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Statistical-Issues-in-Assessing-Hospital-Performance.pdf>.

⁷⁰ We refer readers to the CY 2015 OPPTS/ASC final rule with comment period (79 FR 66949) for an example of a risk-adjusted outcome measure that used the hierarchical generalized linear modeling.

measure, including the preview report, will encourage hospitals to implement systems of care that will ensure quality and reduce unplanned hospital visits in the hospital as whole.

Comment: One commenter expressed concern that the measure does not distinguish if the procedure was provided at the same hospital where the patient has the unplanned visit, making hospitals accountable for the care provided somewhere else.

Response: The measure assigns the hospital visit outcome to the facility providing the same-day outpatient surgery, not to the facility (if different) where the hospital visit took place. We refer readers to the measure specifications at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Hospital-Visits-after-Hospital-Outpatient-Surgery-Measure.pdf>.

Comment: Some commenters recommended that CMS hold providers in both hospital outpatient and ASC settings accountable by either adding outpatient surgeries performed in ASCs to OP-36 or simultaneously instituting a similar measure in the ASC setting. Commenters argued that holding providers in both settings accountable would negate the possibility of inappropriate favoring of one setting over another to avoid the negative consequence of an inpatient admission. Two commenters argued that the availability of data on complications from outpatient hospital surgeries without the corresponding data in ASC settings will negatively affect the reputation of hospitals.

Response: We thank the commenters for their suggestion to hold providers in both hospital outpatient and ASC settings accountable. We did not and do not intend to add outpatient surgeries performed in ASCs to OP-36, because ASCs are a diverse group of facilities that often specialize in very specific subspecialties and procedures, while OPDs often perform all types of surgeries across many subspecialties. Therefore, comparing ASCs to OPDs would not be fair as ASCs specializing only in orthopedic procedures, for example, may have substantially lower rates due to the nature of the procedures they perform, compared to an OPD that performs procedures across all subspecialties.

We agree that holding both hospital outpatient and ASC settings accountable would negate the possibility of inappropriate favoring of one setting over another to avoid the negative consequence of an inpatient admission. We also acknowledge that availability of

data on complications from outpatient hospital surgeries without the corresponding data in ASC settings might negatively affect the reputation of outpatient hospitals due to inappropriate favoring of one setting over another. To address these concerns, we are currently developing two new outcome measures that specifically assess hospital visits within 7 days following orthopedic and urology procedures performed at ASCs for the ASCQR Program. The measures went through the measure development public input period, and results are available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html>. To access the results scroll to the bottom of the page and select *ARCHIVED Public Comment Files between 08-18-2016 and 09-14-2016 [zip]*. Once the zip file has downloaded open *Development-of-Facility-Level-Quality-Measures-of-Unplanned-Hospital-Visits-after-Selected-Ambulatory-Surgical-Center-Procedures.zip*, and select “TEP Summary Report for Measures of Hospital Visits after Selected ASC Procedures.pdf.” The measures are anticipated to undergo MAP review in December 2016. If/when these two new measures are adopted in the ASCQR Program, we believe that they will negate the possibility of inappropriate favoring of one setting over another.

Comment: One commenter expressed concerns that OP-36 does not appropriately identify planned versus unplanned readmissions. The commenter specifically noted that if, during the episode window, a planned surgery for a chronic condition resulted in the assignment of an additional acute diagnosis, the entire admission would be deemed unplanned. The commenter recommended against classifying clinically appropriate hospital admissions following outpatient surgery as low quality care.

Response: We disagree and believe that the measure appropriately identifies planned versus unplanned admissions following index procedures. We developed the algorithm that identifies planned readmissions, and applied this algorithm to the measure. We refer readers to <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Hospital-Visits-after-Hospital-Outpatient-Surgery-Measure.pdf> for more details on this algorithm. To summarize, the algorithm uses procedure and principal discharge diagnosis codes on each hospital claim to identify admissions that are typically

planned and may occur after hospital outpatient surgery. Generally, a planned admission is defined as a non-acute admission for a scheduled procedure (for example, total hip replacement or cholecystectomy). In addition, few specific and limited types of care are always considered planned (for example, major organ transplant, rehabilitation, or maintenance chemotherapy). The measure does not count planned hospital visits, or clinically appropriate visits, as an outcome because variation in planned admissions does not reflect quality differences; therefore, these visits will not signal low quality care. On the other hand, admissions for an acute illness or for complications of care, as well as all ED and observation stay hospital visits, are considered unplanned. We refer readers to the technical report for the full planned admission algorithm at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Hospital-Visits-after-Hospital-Outpatient-Surgery-Measure.pdf>. We reassess this algorithm annually.

With regard to the commenter's concern that a planned admission might result in an acute discharge diagnosis—such as an infection from a planned procedure—and result in the hospital visit being counted as an outcome, the measure risk-adjusts for a wide variety of patient comorbidities, including chronic conditions that might increase the risk of a planned or unplanned hospital visit. We refer readers to <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Hospital-Visits-after-Hospital-Outpatient-Surgery-Measure.pdf>.

In addition, we plan to conduct a dry run of this measure in 2017, and will assess feedback from hospitals including those related to the algorithm and planned admissions. Based on the feedback, we will consider adjusting the algorithm as needed for a future iteration of the measure.

Comment: One commenter expressed concerns regarding the proposed risk adjustment variables. The commenter stated the convoluted approach of adjusting for surgical procedure complexity using RVUs and the introduction of a complicated anatomical body system classification system make the risk-adjustment methodology unclear and difficult to understand. The commenter further expressed that the documentation of comorbid conditions on same-day surgery is very limited because of the

nature of the service, and that it is problematic to depend upon extensive documentation in a same day surgery record to determine risk. This commenter asserted that surgeons who bring a patient in for a specific ambulatory-type procedure typically limit their documentation to conditions that are relevant to the specific body system related to the surgical procedure. Another commenter recommended CMS develop a more robust risk adjustment model with a higher c-statistic.

Response: We disagree that our approach of adjusting for surgical procedure complexity using RVUs and the introduction of a complicated anatomical body system classification system make the risk-adjustment methodology unclear and difficult to understand. Our approach to accounting for procedural complexity is well-documented in literature⁷¹ and aligns with the established approach used for risk adjustment in the American College of Surgeons' National Surgical Quality Improvement Program (NSQIP).⁷² To summarize, the measure risk adjusts for surgical procedural complexity using two variables. First, it adjusts for surgical procedural complexity using the Work RVUs of the procedure. Work RVUs are assigned to each CPT procedure code and approximate surgical procedural complexity by incorporating elements of physician time and effort. For patients with multiple concurrent CPT procedure codes, we risk adjust for the CPT code with the highest Work RVU value. Second, it classifies each surgery into an anatomical body system group using the AHRQ Clinical Classification System (CCS).⁷³ The measure uses the body system variable, in addition to the Work RVU of the surgery, to account for organ-specific difference in risk and complications which are not adequately captured by the Work RVU alone. We also collect all diagnoses from a patient's inpatient, outpatient, and physician claims from the year prior to identify comorbidities for adjustment (see page 14 of the technical report:

⁷¹ Raval MV, Cohen ME, Ingraham AM, et al. Improving American College of Surgeons National Surgical Quality Improvement Program risk adjustment: Incorporation of a novel procedure risk score. *Journal of the American College of Surgeons*. Dec 2010;211(6):715–723.

⁷² Raval MV, Cohen ME, Ingraham AM, et al. Improving American College of Surgeons National Surgical Quality Improvement Program risk adjustment: Incorporation of a novel procedure risk score. *Journal of the American College of Surgeons*. Dec 2010;211(6):715–723.

⁷³ Healthcare Cost and Utilization Project. Clinical Classifications Software (CCS) for Services and Procedures. Last Modified: February 3, 2016. Available at: https://www.hcup-us.ahrq.gov/toolssoftware/ccs_svcsproc/ccssvcproc.jsp.

<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Hospital-Visits-after-Hospital-Outpatient-Surgery-Measure.pdf>). Therefore, that any potential limitation of the comorbidities listed on the say-day surgery claim itself—such as limited to the specific body system related to the surgery—will not impact our ability to collect a full comorbidity history for each patient.

We disagree that we should develop a more robust risk adjustment model with a higher c-statistic. The measure's final model c-statistic is 0.71, which already indicates good model discrimination.⁷⁴ According to NQF,⁷⁵ the purpose of the c-statistic is to capture patient risk, not perfectly predict the outcome. We did not adjust for other factors because patient risk, aside from mortality, is not associated with the measure outcome.

Comment: Some commenters expressed concern that OP-36 is a duplicative measure because they believe it overlaps with OP-32: Colonoscopy Measure: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. They urged CMS to limit the duplication of OP-32 and consider only one of the two measures for inclusion in this program.

Response: OP-36 is not duplicative and does not overlap with OP-32. OP-36 does not include the colonoscopy procedures that are included in OP-32. OP-32 was adopted in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66948 through 66955) and measures facility 7-day risk-standardized hospital visit rate after outpatient colonoscopy. All endoscopy procedures (that is, low-risk colonoscopy procedures like those included in OP-32) are considered non-surgical procedures based on Medicare coding (GSI code 000)⁷⁶ and are not included in the outpatient surgery (OP-36) measure cohort.

Comment: A few commenters requested clarification regarding how the measure identifies qualifying stays, particularly inpatient admissions, immediately following surgery. Two commenters requested clarification regarding whether an inpatient

admission that is planned for a patient with multiple comorbidities who is receiving outpatient surgery would be considered “a hospital visit after an outpatient surgery.” The commenters requested further clarification on how CMS would differentiate the patient with multiple comorbidities who is receiving outpatient surgery from the patient who has an outpatient surgery and then has an immediate complication and is admitted as an inpatient. The commenters asserted that, in both cases, the patient's inpatient admission began on the same day as the surgery and the timing of the admission (prior or after surgery) would not be apparent on the claim UB-04 form because the ICD-10-PCS procedure code will be reported for the surgery.

Response: We include admissions directly after surgery in the outcome because an admission is unexpected for the procedures included in the measure, and our overall goal is to illuminate variation in unplanned hospital visits following these same-day outpatient surgeries to improve quality.

The Medicare 3-day payment window policy affects some surgeries performed at OPDs. As discussed in the CY 2012 PFS final rule with comment period (76 FR 73279 through 73286), the policy deems outpatient services (including surgical procedures) provided by a hospital or an entity wholly owned or operated by a hospital (such as an OPD) in the 3 calendar days preceding the date of a beneficiary's inpatient admission as related to the admission. For outpatient surgical procedures affected, the OPD facility claim (for the technical portion of the surgical procedure) is bundled with the inpatient claim and is not recorded in the Medicare outpatient facility claims files; the Medicare physician claim for professional services furnished is still submitted separately.⁷⁷

To capture outpatient surgeries that resulted in a same-day admission to inpatient status, we identify professional claims (formerly called carrier claims) for surgeries with an OPD place of service code that matches to an inpatient admission within 3 days, and lacks a corresponding OPD facility claim. We then attribute the surgery identified as affected by this policy to the appropriate OPD using the facility

provider identification from the inpatient claim. The measure's target cohort includes low-risk to moderate-risk surgeries that can be safely performed as same-day surgeries and do not typically require an overnight stay or an inpatient admission. In the situation of a physician who admits the patient preoperatively because the patient has multiple comorbidities and his or her anticipated length of stay is over 2 midnights, we would expect the place of service on the inpatient claim to be coded as inpatient.⁷⁸ We will further assess the approach to identifying Medicare 3-day payment window situations during the dry run of this measure in 2017.

Comment: Two commenters asserted that using physician claims data to make determinations on where the surgeries occurred leads to inaccurate determinations because it relies on the “place of service” coding. These commenters stated that the “place of service” coding is often inaccurate and will allow physicians to receive payment for the surgery whether they code it as an inpatient or an outpatient surgery.

Response: We thank the commenters for their attention to the challenges in identifying hospital outpatient-based surgeries using place of service coding. Place of service coding is used on professional claims to specify the entity where service(s) were rendered.⁷⁹ Although we expect physicians to follow coding guidance and record the correct place of service according to the guidelines, we recognize that the place of service field may contain inaccuracies due to data entry errors (unrelated to fraud/abuse). We take the approach of first identifying surgeries from Part B professional claims with an outpatient place of service code to make sure we identify surgeries billed as inpatient under the 3-day payment window policy. This policy affects some surgeries (that is, those performed at wholly owned or wholly operated entities) performed at OPDs. As discussed in the CY 2012 MPFS final rule with comment period (76 FR 73279 through 73286), the policy deems outpatient services (including surgical procedures) provided by a hospital or an entity wholly owned or operated by a hospital (such as an OPD) in the 3 calendar days preceding the date of a beneficiary's inpatient admission as related to the admission. For outpatient surgical procedures affected, the OPD facility claim (for the technical portion

⁷⁴ Hosmer, D.W. and Lemeshow, S. (2000) Multiple Logistic Regression, in Applied Logistic Regression, Second Edition, John Wiley & Sons, Inc., Hoboken, NJ, USA. doi: 10.1002/0471722146.ch2.

⁷⁵ National Quality Forum. What Good Looks Like—Measure Submission Examples. Available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdIdentifier=id&ItemID=73367>.

⁷⁶ <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/GlobalSurgery-ICN907166.pdf>.

⁷⁷ Centers for Medicare & Medicaid Services. Frequently Asked Questions (FAQs) on the 3-day Payment Window for Services Provided to Outpatients Who Later Are Admitted as Inpatients. December 2012. Available at: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1232.pdf>.

⁷⁸ CY 2016 OPPS/ASC final rule with comment period (80 FR 70538 through 70545).

⁷⁹ CY 2007 PFS proposed rule (71 FR 49062).

of the surgical procedure) is bundled with the inpatient claim and is not recorded in the Medicare hospital outpatient claims; however, the Medicare physician claim for professional services furnished is still submitted separately.⁸⁰

The measure first attributes surgeries to an OPD if a claim is present in the Medicare Part B claims indicating an outpatient surgical procedure. We identify physician claims with outpatient hospital department or physician office place of service code in the Part B claims file. We then link Part B claims to outpatient facility claims to identify the OPD where the surgery took place. Based on prior findings by the OIG,⁸¹ we allow the match of those with an office place of service to hospital outpatient claims for situations where a physician in a hospital-based practice assigns an office place of service. If we find no match for physician claims that indicate an outpatient place of service with outpatient facility claims, we then look for a match with inpatient claims to identify hospital admissions subject to the CMS 3-day payment policy. We identify in the professional claims surgeries in the OPD setting with an inpatient admission within 3 days and lacking a corresponding OPD facility claim. We then attribute the surgery identified as affected by this policy to the appropriate OPD using the facility provider identification from the inpatient claim.

We intend to further assess the approach to attributing outpatient surgeries during the dry run of this measure in 2017 and prior to measure implementation.

After consideration of the public comments we received, we are finalizing the adoption of the OP–36: Hospital Visits after Hospital Outpatient Surgery measure (NQF #2687) for the CY 2020 payment determination and subsequent years as proposed.

⁸⁰ Centers for Medicare & Medicaid Services. Implementation of New Statutory Provision Pertaining to Medicare 3-Day Payment Window—Outpatient Services Treated as Inpatient. August 9, 2010. Available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/JSMTDL-10382-ATTACHMENT.pdf>.

⁸¹ OIG, Incorrect Place-Of-Service Claims Resulted in Potential Medicare Overpayments Costing Millions (A–01–13–00506), issued May 2015 and available at: <https://oig.hhs.gov/oas/reports/region1/11300506.pdf>.

c. OP–37a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey Measures

(1) Background

Currently, there is no standardized survey available to collect information on the patient's overall experience for surgeries or procedures performed within a hospital outpatient department. Some HOPDs are conducting their own surveys and reporting these results on their Web sites, but there is not one standardized survey in use to assess patient experiences with care in HOPDs that would allow valid comparisons across HOPDs. Patient-centered experience measures are a component of the 2016 CMS Quality Strategy, which emphasizes patient-centered care by rating patient experience as a means for empowering patients and improving the quality of their care.⁸² In addition, information on patient experience with care at a provider/facility is an important quality indicator to help providers and facilities improve services furnished to their patients and to assist patients in choosing a provider/facility at which to seek care.

(2) Overview of Measures

The Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey was developed as part of the U.S. Department of Health and Human Services' (HHS) Transparency Initiative to measure patient experiences with hospital outpatient care.⁸³ In 2006, CMS implemented the Hospital CAHPS (HCAHPS) Survey, which collects data from hospital inpatients about their experience with hospital inpatient care (71 FR 48037 through 48039). The HCAHPS Survey, however, is limited to data from patients who receive inpatient care for specific diagnosis-related groups for medical, surgical, and obstetric services; it does not include patients who received outpatient surgical care or procedures from ASCs or hospitals. We note that the OAS CAHPS Survey was developed to assess patients' experience of care following a procedure or surgery in a hospital outpatient department; therefore, the

⁸² CMS National Quality Strategy 2016. Available at: <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/qualityinitiativesgeninfo/downloads/cms-quality-strategy.pdf>.

⁸³ U.S. Department of Health and Human Services. *HHS Strategic Plan, Strategic Goal 4: Ensure Efficiency, Transparency, Accountability, and Effectiveness of HHS Programs*. Feb. 2016. Available at: <http://www.hhs.gov/about/strategic-plan/strategic-goal-4/index.html>.

survey does not apply to emergency departments. Throughout the development of the OAS CAHPS Survey, CMS considered the type of data collected for HCAHPS and other existing CAHPS surveys as well as the terminology and question wording to maximize consistency across CAHPS surveys. CMS has developed similar surveys for other settings of care that are currently used in other quality reporting and value-based purchasing programs, such as the Hospital IQR Program (71 FR 68203 through 68204), the Hospital VBP Program (76 FR 26497, 26502 through 26503, and 26510), the ESRD QIP (76 FR 70269 through 70270), the HH QRP (80 FR 68709 through 68710), and the HQR (80 FR 47141 through 47207).

The OAS CAHPS Survey contains 37 questions that cover topics such as access to care, communications, experience at the facility, and interactions with facility staff. The survey also contains two global rating questions and asks for self-reported health status and basic demographic information (race/ethnicity, educational attainment level, languages spoken at home, among others). The basic demographic information is captured in the OAS CAHPS Survey through standard AHRQ questions used to develop case-mix adjustment models for the survey. Furthermore, the survey development process followed the principles and guidelines outlined by AHRQ and its CAHPS Consortium®. The OAS CAHPS Survey received the registered CAHPS trademark in April 2015. OAS CAHPS Survey questions can be found at: <https://oascahps.org/Survey-Materials> under "Questionnaire."

In the CY 2017 OPDS/ASC proposed rule (81 FR 45716 through 45720), we proposed to adopt five survey-based measures derived from the OAS CAHPS Survey for the CY 2020 payment determination and subsequent years—three OAS CAHPS composite survey-based measures and two global survey-based measures (discussed below). We believe that these survey-based measures will be useful to assess aspects of care where the patient is the best or only source of information, and to enable objective and meaningful comparisons between HOPDs. We note that we made similar proposals in the ASCQR Program in section XIV.B.4.c. of the proposed rule. The three OAS CAHPS composite survey-based measures are:

- OP–37a: OAS CAHPS—About Facilities and Staff;
- OP–37b: OAS CAHPS—Communication About Procedure; and

• OP-37c: OAS CAHPS—Preparation for Discharge and Recovery.

Each of the three OAS CAHPS composite survey-based measures consists of six or more questions.

Furthermore, the two global survey-based measures are:

• OP-37d: OAS CAHPS—Overall Rating of Facility; and

• OP-37e: OAS CAHPS—Recommendation of Facility.

The two global survey-based measures are comprised of a single question each and ask the patient to rate the care provided by the hospital and their willingness to recommend the hospital to family and friends. More information about these measures can be found at the OAS CAHPS Survey Web site (<https://oascahps.org>).

The five survey-based measures (MUC IDs: X3697; X3698; X3699; X3702; and X3703) we proposed were included on the CY 2014 MUC list,⁸⁴ and reviewed by the MAP.⁸⁵ The MAP encouraged continued development of these survey-based measures; however, we note that these measures had not been fully specified by the time of submission to the MUC List.⁸⁶ The MAP stated that these are high impact measures that will improve both quality and efficiency of care and be meaningful to consumers.⁸⁷ Further, the MAP stated that given that these measures are also under consideration for the ASCQR Program, they help to promote alignment across care settings.⁸⁸ It also stated that these measures would begin to fill a gap MAP has previously identified for this program including patient reported outcomes and patient and family engagement.⁸⁹ Several MAP workgroup members noted that CMS should consider how these measures are related to other existing ambulatory surveys to ensure that patients and facilities are not overburdened.⁹⁰

These measures have been fully developed since being submitted to the MUC List. The survey development process followed the principles and guidelines outlined by the AHRQ⁹¹ and

its CAHPS Consortium⁹² in developing a patient experience of care survey, such as: Reporting on actual patient experiences; standardization across the survey instrument; administration protocol; data analysis and reporting; and extensive testing with consumers. Development also included: Reviewing surveys submitted under a public call for measures; reviewing existing literature; conducting focus groups with patients who had recent outpatient surgery; conducting cognitive interviews with patients to assess their understanding and ability to answer survey questions; obtaining stakeholder input on the draft survey and other issues that may affect implementation; and conducting a field test.

In addition, we received public input from several modes. We published a request for information in the **Federal Register** on January 25, 2013 (78 FR 5460) requesting information regarding publicly available surveys, survey questions, and measures indicating patient experience of care and patient-reported outcomes from surgeries or other procedures for consideration in developing a standardized survey to evaluate the care received in these facilities from the patient's perspective. Stakeholder input was also obtained through communications with a TEP comprised of experts on outpatient surgery, including clinicians, providers, patient advocates, and accreditation organizations. The TEP provided input and guidance on issues related to survey development, and reviewed drafts of the survey throughout development.

After we determined that the survey instrument was near a final form, we tested the effect of various data collection modes (that is, mail-only, telephone-only, or mail with telephone follow-up of non-respondents) on survey responses. In addition, we began voluntary national implementation of the OAS CAHPS Survey in January 2016.⁹³ In addition, while the proposed OAS CAHPS Survey-based measures are not currently NQF-endorsed, they will be submitted to the NQF for endorsement under an applicable call for measures in the near future.

In section XIX. of this final rule with comment period, for the Hospital VBP Program, we are removing the HCAHPS

at: <https://cahps.ahrq.gov/about-cahps/principles/index.html>.

⁹² Agency for Healthcare Research and Quality. "The CAHPS Program." Available at: <https://cahps.ahrq.gov/about-cahps/cahps-program/index.html>.

⁹³ Outpatient and Ambulatory Surgery CAHPS Survey: "National Implementation." Available at: <https://oascahps.org/General-Information/National-Implementation>.

Pain Management dimension (which consists of three questions) in the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain. For more information about the pain management questions captured in the HCAHPS Survey and their use in the Hospital VBP Program, we refer readers to section XIX.B.3. of this final rule with comment period.

The OAS CAHPS Survey also contains two questions regarding pain management. We believe pain management is an important dimension of quality, but realize that there are concerns about these types of questions. We refer readers to section XIX. of this final rule with comment period for more information on stakeholders' concerns. However, the pain management questions in the OAS CAHPS Survey are very different from those contained in the HCAHPS Survey because they focus on communication regarding pain management rather than pain control and are part of a composite measure focusing on the preparation for discharge and recovery. Specifically, the OAS CAHPS Survey pain management communication questions read:

Q: Some ways to control pain include prescription medicine, over-the-counter pain relievers or ice packs. Did your doctor or anyone from the facility give you information about what to do if you had pain as a result of your procedure?

- A1: Yes, definitely.
 A2: Yes, somewhat.
 A3: No.

Q: At any time after leaving the facility, did you have pain as a result of your procedure?⁹⁴

- A1: Yes.
 A2: No.

Unlike the HCAHPS pain management questions, which directly address the adequacy of the hospital's pain management efforts, the OAS CAHPS pain management communication questions focus on the information provided to patients regarding pain management following discharge from a hospital. We continue to believe that pain control is an appropriate part of routine patient care that hospitals should manage and is an important concern for patients, their families, and their caregivers. We also note that appropriate pain management includes communication with patients about pain-related issues, setting expectations about pain, shared decision-making, and proper prescription practices. However, we also

⁹⁴ We note that this question is a control question only used to determine if the facility should have given a patient additional guidance on how to handle pain after leaving the facility. The facility is not scored based on this question.

⁸⁴ National Quality Forum. *List of Measures under Consideration for December 1, 2014*. National Quality Forum, Dec. 2014. Available at: https://www.qualityforum.org/Setting_Priorities/Partnership/Measures_Under_Consideration_List_2014.aspx.

⁸⁵ National Quality Forum. *MAP 2015 Final Recommendations to HHS and CMS*. Rep. National Quality Forum, Jan. 2015. Available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdIdentifier=id&ItemID=78711>.

⁸⁶ *Ibid.*

⁸⁷ *Ibid.*

⁸⁸ *Ibid.*

⁸⁹ *Ibid.*

⁹⁰ *Ibid.*

⁹¹ Agency for Healthcare Research and Quality. "Principles Underlying CAHPS Surveys". Available

recognize that questions remain about the ongoing prescription opioid epidemic. For these reasons, we proposed to adopt the OAS CAHPS Survey measures as described in this section, including the pain management communication questions, but will continue to evaluate the appropriateness and responsiveness of these questions to patient experience of care and public health concerns. We also welcomed feedback on these pain management communication questions for use in future revisions of the OAS CAHPS Survey.

(3) Data Sources

As discussed in the Protocols and Guidelines Manual for the OAS CAHPS Survey (<https://oascahps.org/Survey-Materials>), the survey has three administration methods: Mail-only; telephone-only; and mixed mode (mail with telephone follow-up of non-respondents). We refer readers to section XIII.D.4. of this final rule with comment period for an in-depth discussion of the data submission requirements associated with the proposed OAS CAHPS Survey measures. To summarize, to meet the OAS CAHPS Survey requirements for the Hospital OQR Program, we proposed that hospitals contract with a CMS-approved vendor to collect survey data for eligible patients at the hospitals on a monthly basis and report that data to CMS on the hospital's behalf by the quarterly deadlines established for each data collection period. Hospitals may elect to add up to 15 supplemental questions to the OAS CAHPS Survey. These could be questions hospitals develop or use from an existing survey. All supplemental questions must be placed after the core OAS CAHPS Survey questions (Questions 1 through 24). The list of approved vendors is available at: <https://oascahps.org>. We also proposed to codify the OAS CAHPS Survey administration requirements for hospitals and vendors under the Hospital OQR Program at 42 CFR 419.46(g), and refer readers to section XIII.D.4. of this final rule with comment period for more details. It should be noted that nondiscrimination requirements for effective communication with persons with disabilities and language access for persons with limited English proficiency should be considered in administration of the surveys. For more information, we refer readers to: <http://www.hhs.gov/civil-rights>.

We proposed that the data collection period for the OAS CAHPS Survey measures would be the calendar year 2 years prior to the applicable payment

determination year. For example, for the CY 2020 payment determination, hospitals would be required to collect data on a monthly basis, and submit this collected data on a quarterly basis, for January 1, 2018–December 31, 2018 (CY 2018).

We further proposed that, as discussed in more detail below, hospitals will be required to survey a random sample of eligible patients on a monthly basis. A list of acceptable sampling methods can be found in the OAS CAHPS Protocols and Guidelines Manual (<https://oascahps.org/Survey-Materials>). We also proposed that hospitals would be required to collect at least 300 completed surveys over each 12-month reporting period (an average of 25 completed surveys per month). We acknowledge that some smaller hospitals may not be able to collect 300 completed surveys during a 12-month period; therefore, we proposed an exemption for facilities with lower patient censuses. Hospitals would have the option to submit a request to be exempted from performing the OAS CAHPS Survey-based measures if they treat fewer than 60 survey-eligible patients during the year preceding the data collection period. We refer readers to section XIII.B.5.c.(6) of this final rule with comment period for details on this proposal. However, we believe it is important to capture patients' experience of care at hospitals. Therefore, except as discussed in section XIII.B.5.c.(6) of this final rule with comment period below, we also proposed that smaller hospitals that cannot collect 300 completed surveys over a 12-month reporting period will only be required to collect as many completed surveys as possible, during that same time period, with surveying all eligible patients (that is, no sampling). For more information regarding these survey administration requirements, we refer readers to the OAS CAHPS Survey Protocols and Guidelines Manual at: <https://oascahps.org/Survey-Materials>.

Furthermore, we proposed that hospital eligibility to perform the OAS CAHPS Survey would be determined at the individual Medicare participating hospital level. In other words, all data collection and submission, and ultimately, also public reporting, for the OAS CAHPS Survey measures would be at the Medicare participating hospital level as identified by the hospital's CCN. Therefore, the reporting for a CCN would include all eligible patients from all eligible hospital locations of the Medicare participating hospital that is identified by the CCN.

(4) Measure Calculations

As noted above, we proposed to adopt three composite OAS CAHPS Survey-based measures (OP-37a, OP-37b, and OP-37c) and two global OAS CAHPS Survey-based measures (OP-37d and OP-37e). As with the other measures adopted for the Hospital OQR Program, a hospital's performance for a given payment determination year will be based upon the successful submission of all required data in accordance with the administrative, form, manner and timing requirements established for the Hospital OQR Program. Our proposals for OAS CAHPS data submission requirements are discussed in section XIII.D.4. of this final rule with comment period. Therefore, hospitals' scores on the OAS CAHPS Survey-based measures, discussed below, will not affect whether they are subject to the 2.0 percentage point payment reduction for hospitals that fail to report data required to be submitted on the measures selected by the Secretary, in the form and manner, and at a time, specified by the Secretary. These measure calculations will be used for public reporting purposes only.

(A) Composite Survey-Based Measures

Hospital rates on each composite OAS CAHPS Survey-based measure would be calculated by determining the proportion of "top-box" responses (that is "Yes" or "Yes Definitely") for each question within the composite and averaging these proportions over all questions in the composite measure. For example, to assess hospital performance on the composite measure OP-37a: OAS CAHPS—About Facilities and Staff, we would calculate the proportion of top-box responses for each of the measure's six questions, add those proportions together, and divide by the number of questions in the composite measure (that is, six).

As a specific example, we take a hospital that had 50 surveys completed and received the following proportions of "top-box" responses through sample calculations:

- 25 "top-box" responses out of 50 total responses on Question One
- 40 "top-box" responses out of 50 total responses on Question Two
- 50 "top-box" responses out of 50 total responses on Question Three
- 35 "top-box" responses out of 50 total responses on Question Four
- 45 "top-box" responses out of 50 total responses on Question Five
- 40 "top-box" responses out of 50 total responses on Question Six

Based on the above responses, we would calculate that hospital's measure score for public reporting as follows:

$$\text{Hospital Publicly Reported Score} = \frac{(0.5 + 0.8 + 1 + 0.7 + 0.9 + 0.8)}{6}$$

This calculation would give this example hospital a raw score of 0.78 or 78 percent for the OP-37a measure for purposes of public reporting. We note that each percentage would then be adjusted for differences in the characteristics of patients across hospitals as described in XIII.B.5.c.(7) of this final rule with comment period, below. As a result, the final percentages may vary from the raw percentage as calculated in the example above.

(B) Global Survey-Based Measures

We proposed to adopt two global OAS CAHPS Survey measures. OP-37d asks the patient to rate the care provided by the hospital on a scale of 0 to 10, and OP-37e asks about the patient's willingness to recommend the hospital to family and friends on a scale of "Definitely No" to "Definitely Yes." Hospital performance on each of the two global OAS CAHPS Survey-based measures would be calculated by proportion of respondents providing high-value responses (that is, a 9-10 rating or "Definitely Yes") to the survey questions over the total number of respondents. For example, if a hospital received 45 9- and 10-point ratings out of 50 responses, this hospital would receive a 0.9 or 90 percent raw score, which would then be adjusted for differences in the characteristics of patients across hospitals as described in section XIII.B.5.c.(7) of this final rule with comment period below, for purposes of public reporting.

(5) Cohort

The OAS CAHPS Survey is administered to all eligible patients—or a random sample thereof—who had at least one outpatient surgery/procedure during the applicable month. Eligible patients, regardless of insurance or method of payment, can participate.

For purposes of each survey-based measure captured in the OAS CAHPS Survey, an "eligible patient" is a patient 18 years or older:

- Who had an outpatient surgery or procedure in a hospital, as defined in the OAS CAHPS Survey Protocols and Guidelines Manual (<https://oascahps.org/Survey-Materials>);
- Who does not reside in a nursing home;

- Who was not discharged to hospice care following their surgery;
- Who is not identified as a prisoner; and
- Who did not request that hospitals not release their name and contact information to anyone other than hospital personnel.

There are a few categories of otherwise eligible patients who are excluded from the measure as follows:

- Patients whose address is not a U.S. domestic address;
- Patients who cannot be surveyed because of State regulations;
- Patient's surgery or procedure does not meet the eligibility CPT or G-codes as defined in the OAS CAHPS Protocols and Guidelines Manual (<https://oascahps.org/Survey-Materials>); and
- Patients who are deceased.

(6) Exemption

We understand that hospitals with lower patient censuses may be disproportionately impacted by the burden associated with administering the survey and the resulting public reporting of OAS CAHPS Survey results. Therefore, we proposed that hospitals may submit a request to be exempted from participating in the OAS CAHPS Survey-based measures if they treat fewer than 60 survey-eligible patients during the "eligibility period," which is the calendar year before the data collection period. All exemption requests will be reviewed and evaluated by CMS. For example, for the CY 2020 payment determination, this exemption request would be based on treating fewer than 60 survey-eligible patients in CY 2017, which is the calendar year before the data collection period (CY 2018) for the CY 2020 payment determination.

To qualify for the exemption, hospitals must submit a participation exemption request form, which will be made available on the OAS CAHPS Survey Web site (<https://oascahps.org>) on or before May 15 of the data collection calendar year. For example, the deadline for submitting an exemption request form for the CY 2020 payment determination would be May 15, 2018. We determined the May 15 deadline in order to align with the deadline for submitting Web-based measures, and because we believe this

deadline allows hospitals sufficient time to review the previous years' patient lists and determine whether they are eligible for an exemption based on patient population size.

In addition, as discussed above, hospital eligibility to perform the OAS CAHPS Survey would be determined at the individual Medicare participating hospital level; therefore, an individual hospital that meets the exemption criteria outlined above may submit a participation exemption request form. CMS will then assess that hospital's eligibility for a participation exemption due to facility size. However, no matter the number of hospital locations of the Medicare participating hospital, all data collection and submission, and ultimately, also public reporting, for the OAS CAHPS Survey measures would be at the Medicare participating hospital level, as identified by its CCN.

Therefore, the reporting for a CCN would include all eligible patients from all locations of the eligible Medicare participating hospital as identified by its CCN.

(7) Risk Adjustment

In order to achieve the goal of fair comparisons across all hospitals, we believe it is necessary and appropriate to adjust for factors that are not directly related to hospital performance, such as patient case-mix, for these OAS CAHPS Survey measures. The survey-based measures are adjusted for patient characteristics such as age, education, overall health status, overall mental health status, type of surgical procedure, and how well the patient speaks English. These factors influence how patients respond to the survey but are beyond the control of the hospital and are not directly related to hospital performance. For more information about patient-mix adjustment for these measures, we refer readers to: <https://oascahps.org/General-Information/Mode-Experiment>.

(8) Public Reporting

We will propose a format and timing for public reporting of OAS CAHPS Survey data in future rulemaking prior to implementation of the measures. Because CY 2016 is the first year of voluntary national implementation for the OAS CAHPS Survey, and we believe

using data from this voluntary national implementation will help inform the displays for public reporting of OAS CAHPS Survey data for the Hospital OQR Program, we did not propose a format or timing for public reporting of OAS CAHPS Survey data in the proposed rule.

As currently proposed, hospital locations that are part of the same Medicare participating hospital (operates under one Medicare provider agreement and one CCN) must combine data for collection and submission for the OAS CAHPS Survey across their multiple facilities. These results from multiple locations of the Medicare participating hospital would then be combined and publicly reported on the *Hospital Compare* Web site for the single Medicare participating hospital. To increase transparency in public reporting and improve the usefulness of the *Hospital Compare* Web site, we intend to note on the Web site instances where publicly reported measures combine results from two or more locations of a single multi-location Medicare participating hospital.

We invited public comments on our proposals as discussed above to adopt, for the CY 2020 payment determination and subsequent years, the five survey-based measures: (1) OP-37a: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS)—About Facilities and Staff; (2) OP-37b: OAS CAHPS—Communication About Procedure; (3) OP-37c: OAS CAHPS—Preparation for Discharge and Recovery; (4) OP-37d: OAS CAHPS—Overall Rating of Facility; and (5) OP-37e: OAS CAHPS—Recommendation of Facility.

Comment: Several commenters supported inclusion of the OP-37a-e OAS CAHPS Survey-based measures in the Hospital OQR Program. One commenter agreed with the MAP that these survey measures are “high impact measures that will improve care quality and efficiency of care and be meaningful to consumers.” This commenter also supported CMS’ proposal to include the same measures for the ASCQR program to facilitate alignment between the programs. Another commenter supported the OAS CAHPS Survey-based measures because patient-reported outcomes are an integral part in understanding how the delivery system is performing and also helps to bridge a partnership with patients. One commenter agreed with CMS’ reasons for proposing to adopt the OAS CAHPS Survey-based measures in the Hospital OQR Program, and asserted the importance of pain management communication, including

communication with patients about pain-related issues, setting expectations about pain, shared decision-making and proper prescription practices. One commenter appreciated CMS’ attempt to fill an important gap because there are currently no standardized surveys available to collect information on the patient’s overall experience for surgeries or procedures performed within a hospital outpatient department. One commenter agreed that the OAS CAHPS Survey-based measures are an important quality indicator that can ultimately be used in combination with other measures to assist patients as they decide where to seek care, and has seen significant interest among HOPDs that want to begin collecting data voluntarily.

Response: We thank the commenters for their support.

Comment: A few commenters expressed concerns that there is very little publicly available information detailing the survey development. The commenters requested additional information regarding the OAS CAHPS Survey development process, and also requested clarification on whether the measures were developed with multi-stakeholder input.

Response: As discussed in the CY 2017 OP/ASC proposed rule (81 FR 45716 through 45718), background on the survey development process is publicly available on the OAS CAHPS Web site: <http://oascahps.org/>. The OAS CAHPS Survey development process followed the principles and guidelines outlined by the AHRQ⁹⁵ and its CAHPS Consortium⁹⁶ in developing a patient experience of care survey, such as: Reporting on actual patient experiences; standardization across the survey instrument; administration protocol; data analysis and reporting; and extensive testing with consumers. This process included: Reviewing surveys submitted under a public call for measures; reviewing existing literature; conducting focus groups with patients who had recent outpatient surgery; conducting cognitive interviews with patients to assess their understanding and ability to answer survey questions; obtaining stakeholder input on the draft survey and other issues that may affect implementation; conducting a field test; and conducting a test of the various data

collection mode effects on survey responses.

We published a request for information on January 25, 2013 (78 FR 5459) requesting information regarding publicly available surveys, survey questions, and measures indicating patient experience of care and patient-reported outcomes from surgeries or other procedures for consideration in developing a standardized survey to evaluate the care received in these facilities from the patient’s perspective. In 2013 and 2014, we conducted six focus groups with patients who had recent outpatient surgeries or procedures in an HOPD or ASC. Analysis of the focus group feedback⁹⁷ led to development of the final domain structure for the survey, and identified the following topic areas for assessment under a patient experience of care survey for these procedures: (1) Preparations for surgery; (2) check-in process; (3) facility environment; (4) staff communication; (5) discharge; (6) recovery and outcomes; and (7) overall experience.

We convened and consulted with two TEPs throughout the development and testing of the OAS CAHPS Survey.⁹⁸ In 2013, we established a 10-member TEP consisting of experts on outpatient surgery, including clinicians, providers, patient advocates, and representatives from other stakeholder organizations to provide preliminary guidance in the establishment of relevant topics and to comment on the draft versions for cognitive testing and the field test. Information about the TEP was documented in materials supporting an information collection request for the voluntary national implementation of the OAS CAHPS Survey published in the **Federal Register** (80 FR 2430 through 2431).⁹⁹ We established a second TEP in 2015 to solicit input and guidance related to national implementation protocols and the survey mode experiment.

We conducted three rounds of cognitive testing among patients who received outpatient surgery at an ASC or hospital outpatient department before finalizing the field test version of the OAS CAHPS Survey. With each round of testing, we modified the survey to

⁹⁷ Hospital Outpatient Surgery Department/ Ambulatory Surgery Center Experience of Care Survey Focus Group Report (Submitted to CMS June 2013).

⁹⁸ Information about feedback from the first TEP was documented in the **Federal Register** at 80 FR 2430.

⁹⁹ Available at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10500.html>.

⁹⁵ Agency for Healthcare Research and Quality. “Principles Underlying CAHPS Surveys.” Available at: <https://cahps.ahrq.gov/about-cahps/principles/index.html>.

⁹⁶ Agency for Healthcare Research and Quality. “The CAHPS Program.” Available at: <https://cahps.ahrq.gov/about-cahps/cahps-program/index.html>.

reflect the comments from the previous round.

The survey was tested in both the outpatient and ASC setting in 2014 (field testing) and 2015 (mode testing) and found to be reliable. We refer readers to 80 FR 2430 and the OAS CAHPS Information Collection Request Paperwork Reduction Act Package¹⁰⁰ for more information about field and mode testing for these measures. The field test collected data through a mixed-mode design, which consisted of a mail survey with telephone follow-up of non-respondents. We recruited a total of 36 facilities for the field test: 18 hospital outpatient departments and 18 ASCs. Approximately 116 patient records were selected from each of the 36 facilities, for a total sample of 4,179 patients. The field test data collection yielded a 46-percent adjusted response rate, or 1,863 completed surveys (31 percent computer-assisted telephone interviewing, 68 percent mail, and 0.8 percent break-offs). Once partial surveys were removed from the analysis set, 1,849 total surveys were used in the evaluation. The field test data were evaluated and analyzed to identify item-level refinements necessary for the survey instrument. The field test psychometric analysis included evaluations of individual items and composite item sets. Individual items were analyzed to report item-level missing data and item response distributions (including ceiling and floor effects), which included response variance. Composite item sets were analyzed using factor analysis and item response theory (IRT) analysis to assess dimensionality, discriminability, dimensional coverage, and subgroup response differences. Internal consistency statistics (reliability) and correlational checks for composite validity were performed to evaluate the final composite item sets. The item-level recommendations for the field test were based on the findings from the factor analyses, the internal consistency checks, and the IRT analysis. As a result, 10 questions were recommended for deletion. Reliability of the remaining measures was assessed using the Cronbach's alpha coefficient, with an estimate range from zero to one. An estimate of zero indicated no measurement consistency and one indicates perfect consistency. The cutoff criterion for the examination was 0.70, which indicated adequate

consistency.¹⁰¹ The composites analytically derived maintained adequate internal consistency even when reduced to Top-Box scoring and across the facility types and modes of administration.

In 2015, we conducted a mode experiment for the OAS CAHPS Survey. We refer readers to <https://oascahps.org/General-Information/Mode-Experiment> for more details. The facility sample included hospital outpatient departments and ASCs that reflect industry characteristics and was sorted to achieve implicit stratification by four facility characteristics: Single specialty or multispecialty; facility size (large, medium, or small); facility location (urban or rural), and facility ownership (public, private, or other). A total of 70 facilities (38 hospital outpatient departments and 32 ASCs) participated in the mode experiment by providing a monthly patient information file for patients served during one or more of the three sample months (July, August, and September 2015). The patient sample consisted of 13,576 patients who had an eligible surgery or procedure during a sample month and who met other survey eligibility criteria. Data collection for each sample month began approximately 21 days after the sample month closed and ended within a 6-week period after the survey was initiated. The overall response rate (for all three modes) was 39 percent. The response rate for the mail-only mode was 37 percent, the telephone-only response rate was 34 percent, and the mixed-mode response rate was 50 percent.

We began voluntary national implementation of the OAS CAHPS Survey in January 2016 and refer readers to <https://oascahps.org/General-Information/National-Implementation> for more details. Preliminary data from the voluntary reporting period (Quarter 1 data), which included 24,201 sampled patients from 74 facilities, indicate a response rate of 33 percent for both telephone and mail modes. Voluntary national implementation is ongoing.

Comment: Several commenters recommended that CMS delay implementation of OAS CAHPS measures because the measures are not NQF-endorsed, and asserted that this will significantly limit hospitals' insight into whether the measures portray hospital performance in a fair and accurate manner until they are endorsed by the NQF.

Response: We disagree with commenters' recommendation that we should delay implementation of the OAS CAHPS measures in the Hospital OQR Program. We refer readers to our discussion above regarding measures that are not NQF endorsed. The OAS CAHPS Survey has undergone rigorous testing. As discussed in the measure description, the five survey-based measures (MUC IDs: X3697; X3698; X3699; X3702; and X3703) were included on the CY 2014 MUC list,¹⁰² and reviewed by the MAP.¹⁰³ The MAP encouraged continued development of these survey-based measures; however, we note that these measures had not been fully specified by the time of submission to the MUC List.¹⁰⁴ The MAP stated that these are high impact measures that will improve both quality and efficiency of care and be meaningful to consumers.¹⁰⁵ Further, the MAP stated that given that these measures are also under consideration for the ASCQR Program, they help to promote alignment across care settings.¹⁰⁶ It also stated that these measures would begin to fill a gap MAP has previously identified for this program including patient reported outcomes and patient and family engagement.¹⁰⁷ Several MAP workgroup members noted that CMS should consider how these measures are related to other existing ambulatory surveys to ensure that patients and facilities are not overburdened.¹⁰⁸

These measures have been fully developed since being submitted to the MUC List. The survey development process followed the principles and guidelines outlined by the AHRQ¹⁰⁹ and its CAHPS Consortium¹¹⁰ in developing a patient experience of care survey, such as: Reporting on actual patient experiences; standardization across the survey instrument; administration protocol; data analysis

¹⁰² National Quality Forum. *List of Measures under Consideration for December 1, 2014*. National Quality Forum, Dec. 2014. Available at: https://www.qualityforum.org/Setting_Priorities/Partnership/Measures_Under_Consideration_List_2014.aspx.

¹⁰³ National Quality Forum. *MAP 2015 Final Recommendations to HHS and CMS*. Rep. National Quality Forum, Jan. 2015. Available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdIdentifier=id&ItemID=78711>.

¹⁰⁴ Ibid.

¹⁰⁵ Ibid.

¹⁰⁶ Ibid.

¹⁰⁷ Ibid.

¹⁰⁸ Ibid.

¹⁰⁹ Agency for Healthcare Research and Quality. "Principles Underlying CAHPS Surveys". Available at: <https://cahps.ahrq.gov/about-cahps/principles/index.html>.

¹¹⁰ Agency for Healthcare Research and Quality. "The CAHPS Program." Available at: <https://cahps.ahrq.gov/about-cahps/cahps-program/index.html>.

¹⁰⁰ OMB Control Number 0938-1240, "Consumer Assessment of Healthcare providers and Systems Outpatient and Ambulatory Surgery (OAS CAHPS) Survey (CMS-10500)." Available at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201510-0938-003.

¹⁰¹ Aron, A. and Aron, E.N. *Statistics for Psychology*. (1999) 2nd ed. New Jersey: Prentice Hall.

and reporting; and extensive testing with consumers. Development also included: Reviewing surveys submitted under a public call for measures; reviewing existing literature; conducting focus groups with patients who had recent outpatient surgery; conducting cognitive interviews with patients to assess their understanding and ability to answer survey questions; obtaining stakeholder input on the draft survey and other issues that may affect implementation; and conducting a field test.

In addition, as discussed above, we received public input from several modes. We published a request for information in the **Federal Register** on January 25, 2013 (78 FR 5460) requesting information regarding publicly available surveys, survey questions, and measures indicating patient experience of care and patient-reported outcomes from surgeries or other procedures for consideration in developing a standardized survey to evaluate the care received in these facilities from the patient's perspective. As stated in more detail above, stakeholder input was also obtained through communications with a Technical Expert Panel (TEP) comprised of experts on outpatient surgery, including clinicians, providers, patient advocates, and accreditation organizations. The TEP provided input and guidance on issues related to survey development, and reviewed drafts of the survey throughout development.

After we determined that the survey instrument was near a final form, we tested the effect of various data collection modes (that is, mail-only, telephone-only, or mail with telephone follow-up of non-respondents) on survey responses. In addition, we began voluntary national implementation of the OAS CAHPS Survey in January 2016.¹¹¹

Given these consensus-building efforts, we believe the measure reflects consensus among affected parties for a standardized instrument assessing patients' experience of care in the hospital setting. As such, we do not think it is necessary to delay implementation of the OAS CAHPS Survey until it achieves NQF endorsement. We believe the benefits of measure data for patients and hospitals outweigh waiting for NQF endorsement. We also note, however, that we intend to submit the OAS CAHPS Survey-based measures to NQF for endorsement under

an applicable call for measures in the near future.

We also disagree with commenters' assertion that lack of NQF endorsement will limit hospitals' insight into whether the measures portray hospital performance in a fair and accurate manner. The survey was tested in both the outpatient and ASC setting in 2014 (field testing) and 2015 (mode testing) and found to be reliable. We refer readers to <https://oascahps.org/> for more information about field and mode testing for these measures. The OAS CAHPS Survey development process followed the principles and guidelines outlined by AHRQ and its CAHPS Consortium.¹¹² This process included reviewing existing literature; reviewing surveys submitted under a public call for measures; conducting focus groups with patients who had recent outpatient surgery; conducting cognitive interviews with patients to assess their understanding and ability to answer survey questions; obtaining stakeholder input on the draft survey and other issues that may affect implementation; conducting a field test; and conducting a test of the various data collection mode effects on survey responses.

In 2014, the field test data were evaluated and analyzed to identify item-level refinements necessary for the survey instrument. The field test psychometric analysis included evaluations of individual items and composite item sets. Individual items were analyzed to report item-level missing data and item response distributions (including ceiling and floor effects), which included response variance. Composite item sets were analyzed using factor analysis and item response theory (IRT) analysis to assess dimensionality, discriminability, dimensional coverage, and subgroup response differences. Internal consistency statistics (reliability) and correlational checks for composite validity were performed to evaluate the final composite item sets. The item-level recommendations for the field test were based on the findings from the factor analyses, the internal consistency checks, and the IRT analysis. As a result, 10 questions were recommended for deletion. Reliability of the remaining measures was assessed using the Cronbach's alpha coefficient, with an estimate range from zero to one. An estimate of zero indicated no measurement consistency and one indicates perfect consistency. The cutoff criterion for the examination was 0.70,

which indicated adequate consistency.¹¹³ The composites analytically derived maintained adequate internal consistency even when reduced to Top-Box scoring and across the facility types and modes of administration.

Based on the rigorous testing that was undertaken during the development process, we believe the OAS CAHPS Survey, and measure scores derived therefrom, are both reliable and valid. Therefore, we believe it is unnecessary to delay implementation of the OAS CAHPS Survey in the hospital outpatient setting.

Comment: Some commenters recommended CMS to convene stakeholder group of providers, consumers, vendors, and other relevant parties to discuss the CAHPS survey questions holistically to address how these surveys should be distributed in the future, prioritize the development of these survey tools to a limited subset of provider settings, and determine how to manage the issue of overlapping care.

Response: We refer readers to our response above discussing measure development and stakeholder input. To reiterate, we received public input for the OAS CAHPS Survey from several modes. As stated above, we published a request for information in the **Federal Register** on January 25, 2013 (78 FR 5460). Stakeholder input was also obtained through communications with two TEPs and the MAP. However, moving forward, we will continue to seek stakeholder input on the appropriateness of procedures that are appropriate for the hospital setting as well as improving the quality of care provided in the hospital outpatient setting.

Comment: Commenters expressed concerns about the significant resources needed to collect the survey, and also expressed concerns that the CAHPS® program already includes multiple overlapping survey tools. The commenters asserted that the inclusion of another survey may lead to confusion among patients about which provider is being assessed and create excessive survey administration burden for hospitals.

Response: While we understand commenters' concerns regarding resources needed to collect the survey, and survey administration burden for hospitals, the OAS CAHPS Survey was developed for use in assessing patient experience of care for select outpatient surgical procedures. We are dedicated to

¹¹¹ Outpatient and Ambulatory Surgery CAHPS Survey: "National Implementation." Available at: <https://oascahps.org/General-Information/National-Implementation>.

¹¹² Agency for Healthcare Research and Quality. "The CAHPS Program." Available at: <https://ahrq.gov/cahps/index.html>.

¹¹³ Aron, A. and Aron, E.N. *Statistics for Psychology*. (1999) 2nd ed. New Jersey: Prentice Hall.

improving the quality of care provided to patients, and believe patients are a vital source of information in assessing the quality of care provided at a hospital outpatient department. We believe that the benefits of this measure, such as giving patients the opportunity to compare and assess quality of care in the outpatient setting in a standardized and comparable manner, outweigh the burdens. Regarding confusion among patients and multiple overlapping survey tools, other CAHPS surveys, such as the HCAHPS Survey, are tailored to different aspects of care provided by hospitals, such as inpatient care. In addition, the survey introduction letter provided to patients includes the date and location of the surgery or procedure that the patient received at the facility. Furthermore, patients will also be reminded of the date and location of the surgery or procedure they received during the telephone interviews. For these reasons, we do not believe there will be issues associated with overlap or confusion for these surveys.

Comment: One commenter asserted that requiring hospitals to meet the proposed target minimum number of surveys (that is, 300 completed surveys) would be difficult for smaller facilities and recommended that the target minimum number of surveys instead be set at 100 completed surveys, in alignment with the requirements from the first year of the HCAHPS Survey's use in the inpatient setting. Another commenter expressed concerns that comparing an HOPD with a small patient population to a sample of a much larger HOPD's population may weaken the statistical reliability of the survey results and comparability of facilities' scores. This commenter recommended that facilities should be measured against comparable facility size and clinical make-up, and urged CMS to increase the number of survey-eligible patients a facility can have to qualify for the exception.

Response: We are committed to ensuring high reliability in publicly reported OAS CAHPS Survey results. To make abundantly clear our policies discussed in the proposed rule, hospital outpatient departments will fall into one of three categories based on their past and projected total patient volume, will fall into one of three scenarios. In order to determine its projected total patient volume, we recommend hospitals review their accounts receivable and payable records. From these accounting documents, a facility can determine its past patient volume and project future patient volume. Acceptable methods of sampling survey-eligible patients can be

found in Chapter IV-Sampling Procedures of the Protocols and Guidelines Manual at <https://oascahps.org/Survey-Materials>.

The first category includes hospitals that estimate receiving more than 300 completed surveys during the 12-month reporting period based on its past and projected total patient volume. We note that in the CY 2017 OPPS/ASC proposed rule (81 FR 45718), we stated that "hospitals will be required to survey a random sample of eligible patients on a monthly basis." We also note that elsewhere in the proposed rule (81 FR 45719), we also stated that, "the OAS CAHPS Survey is administered to all eligible patients—or a random sample thereof—who had at least one outpatient surgery/procedure during the applicable month." We recognize that the language is confusing and are clarifying here that hospitals that anticipate receiving more than 300 surveys have a choice. They are required to either: (1) Randomly sample their eligible patient population, or (2) survey their entire OAS CAHPS eligible patient population. In other words, random sampling is optional.

We calculated the number 300 by using the reliability criterion for the OAS CAHPS Survey measures, which is 0.8 or higher.¹¹⁴ This requires facilities with large patient populations to randomly sample a sufficient number of patients to yield at least 300 completed surveys over each 12-month reporting period. This criterion allows at least 80 percent power to detect a 10 percent difference for binary survey outcome at the 0.05 significance level.¹¹⁵ A reliability criterion of 0.8 is the normal standard for random sample surveys.¹¹⁶ The 300 completed surveys translates into approximately 25 completed surveys per month (25 completes x 12 months = 300 completes per year). At this time, there are no plans to adjust the threshold of the target minimum of 300 completed surveys for the OAS CAHPS Survey for larger facilities that have the option to undertake random sampling. To do so could decrease the reliability of the OAS CAHPS survey results. Survey data will be collected on a monthly basis and uploaded on a quarterly basis. As stated in the Protocols and Guideline Manual, survey vendors will report the "total patient volume," "total eligible patients," "number of patients sampled," and the "number of completed surveys" for each

reporting period.¹¹⁷ These reported patient data will be used to ensure sampling requirements are followed.

Second, if a hospital does not anticipate receiving 300 completed surveys during the 12-month reporting period based on its past and projected total patient volume, it must survey all eligible patients served during the reporting period. In other words, these smaller facilities must undertake a census of all eligible patients served; there is no option to randomly sample. Smaller facilities' OAS CAHPS survey results are not affected by the reliability issues underlying the target minimum policy because conducting a census—surveying all eligible patients in a population, as opposed to sampling and administering the survey to a portion of that eligible patient population—measures the true value of the patient population by including all eligible patients at the facility in the survey population. However, we will continue to review the data from the voluntary implementation to identify and address any issues related to the reliability and comparability of OAS CAHPS Survey-based measure rates across facilities. Thus the OAS CAHPS results for the larger facilities and the smaller facilities both achieve the statistical precision of the reliability criterion. For example, if two different facilities with large patient volumes in a particular year, both randomly sample their eligible patients and receive 300 completed surveys, they would both have met the reliability criterion during that year. As a second example, if in a particular year, one facility estimates it will receive more than 300 completed surveys in that year and samples and obtains 300 completed surveys while, during that same year, a different facility does not anticipate receiving 300 completed surveys and undertakes a census of its entire survey-eligible patients, both facilities would achieve the statistical precision of the reliability criterion for that year. As a third example, for a facility that obtained 300 completed surveys from their 1500 total eligible patients served in one year, but experienced a change in patient volume during the next year, and surveyed their entire 200 eligible patients served the next year, the facility would have met the reliability criterion during both years.

Third, if in the prior year a hospital serves less than 60 survey eligible patients, the facility can request an exemption from the OAS CAHPS

¹¹⁴ Cohen, Jacob. 1977. *Statistical Power Analysis for the Behavioral Sciences*. New York: Academic Press.

¹¹⁵ *Ibid.*

¹¹⁶ *Ibid.*

¹¹⁷ Outpatient and Ambulatory Surgery CAHPS Survey: "Protocol and Guidelines Manual." Available for download at: <https://oascahps.org/Survey-Materials>.

Survey administration requirement because these few surveys would not provide reliable data and the burden associated with administering the survey as well as the resulting public reporting of OAS CAHPS Survey results would be disproportionately burdensome. At this time, there are no plans to adjust the threshold for the exemption. This request and related deadlines will be available on the OAS CAHPS Survey Web site (<https://oascahps.org>) on or before May 15 of the data collection calendar year as discussed in the proposed rule (81 FR 45719).

The facility-level data for both large and small facilities will be adjusted to account for patient characteristics that impact response tendencies (that is, patient-mix) and ensure fair comparisons across all facilities. As discussed in the CY 2017 OPPS/ASC proposed rule (81 FR 45720), the survey-based measures are adjusted for patient characteristics such as age, education, overall health status, overall mental health status, type of surgical procedure, and how well the patient speaks English. We refer readers to the Protocols and Guidelines Manual, available at: <https://oascahps.org/Survey-Materials>, for more information regarding the patient-mix adjustment methodology. However, we do not adjust for facility-level characteristics that are under control of the facility, for example, specialty or geographic location. During the voluntary implementation of the survey, we will continue to review the data collected to identify and address any issues related to the reliability and comparability of measure rates across facilities as appropriate. In addition, we believe the 60 survey-eligible patient exemption policy appropriately balances the benefit of ensuring that patient experience of care data is collected and publicly reported for use by patients in making decisions about their health care against the burden of requiring facilities to administer the OAS CAHPS Survey. For this reason, we do not believe it would be appropriate to increase the exemption threshold at this time.

Comment: Many commenters expressed concerns regarding the length of the OAS CAHPS Survey. A number of commenters recommended that CMS shorten the OAS CAHPS Survey in order to increase the survey completion rates, and further recommended CMS allow each facility to have more choice in the questions they include in its survey. One commenter expressed concern that the OAS CAHPS Survey's length will limit the number of completed surveys a hospital receives

because patients will be overwhelmed by the number of questions in the survey or otherwise unable to complete the survey, and in turn, impact the ability of the hospital to use the survey data in quality improvement activities.

Response: The OAS CAHPS Survey is comparable in length and survey response rate to other patient experience of care surveys. For example, the HCAHPS Survey is 32 questions long, (<http://www.hcahpsonline.org/surveyinstrument.aspx>), and the response rate for the HCAHPS Survey has generally been 32 to 33 percent, (for example see: <https://www.medicare.gov/hospitalcompare/details.html?msrCd=prnt1grp1&ID=220066&stCd=MA&stName=Massachusetts>). By comparison, the OAS CAHPS Survey is 37 questions long, and the survey's 2015 mode experiment showed an overall response rate of 39 percent.¹¹⁸ The mode experiment, a final step in the measurement development process, was conducted in 2015 to test the OAS CAHPS Survey questions when administered by mail-only, telephone-only, and mixed-mode (mail with telephone follow-up).

In addition, the 24 core questions of the OAS CAHPS Survey are either directly actionable (that is, give feedback to hospitals) or inform the need for patients to answer subsequent questions that are actionable. For example, Question 10, which asks whether a patient received anesthesia, establishes whether a patient should respond to Question 11 and Question 12, which provide actionable feedback to hospitals with the patient about the anesthesia process and possible side effects. We also encourage hospitals to consider adding specific questions of interest to the OAS CAHPS Survey. As noted in the CY 2017 OPPS/ASC proposed rule (81 FR 45718), HOPDs may elect to add up to 15 supplemental questions to the OAS CAHPS Survey. These could be questions HOPDs develop specifically for use alongside the OAS CAHPS Survey, or questions from an existing survey.

However, we continue to evaluate the utility of individual questions as we collect new data from the survey's national implementation and will consider different options for shortening the OAS CAHPS Survey without the loss of important data in the future. Specifically, we are contemplating removing two demographic questions—the “gender” and “age” questions—from

¹¹⁸ Outpatient and Ambulatory Surgery CAHPS Survey: “Mode Experiment.” Available at: <https://oascahps.org/General-Information/Mode-Experiment>.

the OAS CAHPS Survey in its next update if we determine that it is feasible, when collecting information on survey-eligible patients from facility records, that gender and age information could also be collected via these records.

Comment: One commenter requested that CMS remove or revise two questions on the OAS CAHPS Survey asking whether a doctor or anyone from the facility: (1) Gave the patient all the information needed about their procedure; and/or (2) gave the patient easy to understand instructions about preparing for their procedure. This commenter asserted that patient education is solely within the purview of the doctor's office, not the facility, and should therefore be removed from a survey assessing patients' experience of care at the facility.

Response: We disagree with the commenter's assertion that patient education is solely within the purview of the doctor's office. We believe it is the facility's responsibility to ensure that a doctor, nurse, or other facility staff member provides the patient with information about preparing for their procedure, the procedure itself, and what to expect following discharge from the hospital. Furthermore, the OAS CAHPS Survey-based measures were reviewed by two 10-member TEPs comprised of experts on outpatient surgery, including clinicians, providers, patient advocates, and representatives from other stakeholder organizations. These TEPs provided guidance in the establishment of relevant topics for assessing patient experience of care at an outpatient facility, and commented on draft versions of the survey for cognitive and field testing. These TEPs agreed with the questions as drafted, including those regarding the facility's communication with patients. Therefore, we believe it is appropriate to include these important communications between the patient and the facility about their care in the OAS CAHPS Survey.

The OAS CAHPS Survey is focused on patients' experience of care received for their ambulatory surgery or procedure. A physician/surgeon who performs surgeries/procedures at a facility is a member of that facility with both rights and responsibilities. We believe it is the facility's responsibility to ensure that someone—whether the doctor, nurse, or other facility staff member—provide patients with information about preparing for their procedure, about the procedure itself, as well as what to expect following the procedure/surgery. Therefore, we believe it is appropriate to include these

important communications with patients in the OAS CAHPS Survey.

Comment: One commenter requested that CMS reconsider its position on respondent confidentiality for the OAS CAHPS Survey administration to align with the HCAHPS survey, which allows for the release of patient-level data for quality improvement purposes, with the stipulation that a patient's identity should not be shared with direct care staff.

Response: The administration protocols for OAS CAHPS follow protocols for other more recent CAHPS® Surveys, restricting the release of patient-level data if the patient has not consented. For example, the Home Health Care CAHPS (HHCAPHS) Survey protocol states: "HHCAPHS Survey approved vendors can provide responses linked to a sample patient's name and other identifying information only if the sample patient gives his or her consent on the 'Consent to Share Identifying Information' question."¹¹⁹ For the Hospital IQR Program, because hospitals can self-administer the HCAHPS Survey, we do not state that patients' responses and identifying information will not be shared with the hospital. However, HCAHPS Surveys administered via a third-party vendor are not linked to a sample patient's name unless the patient gives his or her consent, and we encourage hospitals to undertake measures to protect patient confidentiality when self-administering the survey. We note that facilities may choose to add the "Consent to Share" question¹²⁰ to the OAS CAHPS Survey. This question asks whether a patient gives permission for their name to be linked to their survey responses. However, we note that each facility should consult with its own counsel to ensure compliance with applicable privacy and security laws.

Comment: One commenter recommended that CMS align the OAS CAHPS Survey with the HCAHPS Survey by: (1) Adopting the same four-point scale used in the HCAHPS Survey for ratings questions (that is, "Always; Usually; Sometimes; or Never" responses); (2) separating questions about nurses and doctors treating a patient into two separate sets of questions; (3) adopting the same series of questions used in the HCAHPS Survey regarding interactions with doctors and nurses; and (4) adding the same new medication questions used in

the HCAHPS Survey to the OAS CAHPS Survey (Question 15: "During this hospital stay, were you given any medicine that you had not taken before?"; Question 16: "Before giving you any new medicine, how often did hospital staff tell you what the medicine was for?"; Question 17: "Before giving you any new medicine, how often did hospital staff describe possible side effects in a way you could understand?").

Response: As part of the survey development process, the OAS CAHPS Survey was aligned as appropriate with other CAHPS Surveys, including the HCAHPS Survey. However, unlike HCAHPS, which assesses patients experience in the inpatient setting; the OAS CAHPS Survey assesses patient experience of care for outpatient surgical procedures, and therefore, takes the outpatient/ambulatory setting into account and captures information about the appropriate experiences of care for this particular setting.

We note that the four-point scale response set used for some HCAHPS Survey questions, "Always; Usually; Sometimes; or Never," is appropriate to use when a question includes the phrase "how often." This is appropriate in the inpatient setting, where patients stay in the hospital for a longer period of time. The OAS CAHPS Survey questions use a single point in time reference for an outpatient surgery or procedure because patients spend a significantly shorter period of time in the facility. Therefore, we believe the OAS CAHPS Survey questions and response options are worded appropriately (that is, for the majority of the OAS CAHPS Survey questions, the response categories are: "Yes, definitely;" "Yes, somewhat;" or "No." Response categories for other questions are: "Yes" or "No" for this setting of care and treatment situation. The OAS CAHPS Survey instrument can be found at: <https://oascahps.org/Survey-Materials>.

In the OAS CAHPS Survey, references to the doctors, nurses, and other staff at the facility are grouped together for two reasons. First, grouping assessment of the health care personnel at a facility helps reduce the overall length of the survey so that similar questions are not repeated separately for doctors and nurses. Second, the questions under section I, II, III and IV (Before Your Procedure, Facility and Staff, Communications, and Recovery) include aspects of the patient's care that could be addressed by either the doctor or someone else at the facility. Combining these professionals under a single series of questions allows the patient to report that someone provided

information and explained the process without having to recall the specific individual who gave the information. This is important because the OAS CAHPS Survey is intended to assess the patient's experience of care at the facility, including, but not separating out, all the staff that work at the facility.

For these reasons, we believe it is appropriate to ask these questions in a way that reflects the care provided by doctors, nurses, and other facility staff combined. We note that during the OAS CAHPS Survey field test conducted in 2014 and the mode experiment conducted in 2015, we did not receive any indications that the respondents had any difficulty answering these questions as they are currently written. The nonresponse, which is an indication of difficulty answering a question, was very low for the two questions that combine doctors and nurses (Question 7, which is about treating the patient with courtesy and respect and Question 8, which is about making sure the patient was a comfortable as possible). For the field test, less than 0.5 percent of the respondents did not respond to these questions while 99.5 percent were able to answer these questions. For the mode experiment just over 1 percent of the respondents did not respond to the questions while nearly 99 percent were able to answer them. These nonresponse rates were very similar to the questions that were about clerks and receptionists.

While there are no plans to add questions about new medications to the OAS CAHPS Survey at this time, we will take this recommendation into consideration during future updates to the survey.

Comment: One commenter requested clarification from CMS about why the OAS CAHPS Survey does not use same administration method as the HCAHPS Survey. One commenter recommended that CMS to align the outpatient version of patient's experience of care survey with the current inpatient version from a content, timeline and administration method standpoint, and requested CMS to review these requirements to prevent duplication of effort and provide a uniform process for patients. One commenter requested that CMS compare the OAS CAHPS Survey questions to the HCAHPS survey questions.

Response: Regarding survey content and questions, the OAS CAHPS survey was designed for the outpatient/ASC setting in order to more appropriately evaluate patient experience of care there. Therefore, the content should not be and is not the same as the HCAHPS survey. We refer readers to our discussion above regarding OAS CAHPS

¹¹⁹ Home Health Care CAHPS Survey: "Protocols and Guidelines Manual." Available at: <https://homehealthcahps.org/Portals/0/PandGManual.pdf>.

¹²⁰ Outpatient and Ambulatory Surgery CAHPS Survey: "Survey Materials." Available at: <https://oascahps.org/Survey-Materials>.

survey development. Regarding administration method, the only difference between the HCAHPS and OAS CAHPS survey administration is that for the HCAHPS survey, hospitals are allowed to either self-administer or contract with a vendor. For the OAS CAHPS survey, on the other hand, hospitals must contract with a vendor. There is no option to self-administer. However, procedures related to vendors are aligned between both surveys. Therefore, we believe that processes streamline any duplication of efforts and processes for patients.

Comment: A few commenters expressed concerns that two existing CAHPS surveys, Clinician/Group CAHPS (CG-CAHPS) and the Surgical CAHPS (S-CAHPS), already capture the information that is being assessed in the OAS CAHPS Survey. One commenter recommended that the Hospital OQR Program to use the S-CAHPS survey for measurement of patient experience before, during, and after surgery.

Response: The CG-CAHPS survey¹²¹ assesses patients' experiences with health care providers and staff in doctors' offices, and the focus of the S-CAHPS survey¹²² is to obtain a patient's experience of care received specifically from a surgeon. Neither of those surveys focus on a patient's experience of care received from an HOPD or an ASC specifically, like the OAS CAHPS survey was designed to do. We do not believe the units of analyses are the same. However, we will take these suggestions into consideration for the future.

Comment: Some commenters urged CMS to make testing and revision of the Emergency Department Patient Experiences with Care (EDPEC) Survey a priority, and asserted that patient experiences in the ED setting require unique questions that are not necessarily reflected in the OAS CAHPS Survey. Another commenter recommended that CMS finalize the EDPEC Survey, and establish expectations for compliance across all hospitals first, including publishing results from the pilot, before requiring mandatory compliance with the OAS CAHPS. One commenter urged CMS to ensure the data collected from the EDPEC and OAS CAHPS Surveys accurately reflects the quality of care provided by physicians and facilities and accounts for the nuances and

differences required when providing care in the emergency department.

Response: The Emergency Department Patient Experiences with Care (EDPEC) Survey is a survey tool that is currently under development at CMS that assesses patient experiences of care in the emergency department. We have made considerable investments in developing and testing the EDPEC Survey to measure experiences of patients (18 and older) with emergency department care specifically. The survey respondents include patients admitted to the hospital following their emergency department visit and those visiting the emergency department who are discharged to the community. For additional details regarding the EDPEC Survey, we refer readers to: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/CAHPS/ed.html>. However, the EDPEC Survey cannot be finalized at this time, because it is still under development and would need to be reviewed by the MAP prior to CMS proposing the survey. We will take commenter's suggestion into consideration that the EDPAC accurately reflects the quality of care provided by physicians and facilities and accounts for the nuances and differences required when providing care in the emergency department.

In addition, to be abundantly clear, the OAS CAHPS Survey was developed to assess the quality of care provided to patients during select surgical outpatient procedures only. Therefore, the OAS CAHPS Survey should not be administered to ED patients. The EDPEC Survey can only be administered in the emergency department setting, and not in the hospital outpatient setting or ASC setting. Regarding the commenter's concern about the OAS CAHPS Survey accurately reflecting the quality of care provided by physicians and facilities, we believe the survey accurately does this and we point readers to our discussion above detailing the survey development process and TEP input. Regarding the comment about establishing expectations for compliance, we refer readers to our previous response above regarding the different categories of compliance for the OAS CAHPS Survey as well as the measure description in the proposed rule. We interpret commenter's request for CMS to publish results from the pilot to refer to the voluntary national implementation of the OAS CAHPS Survey, and we will publish results when available. However, we do not agree that we should delay implementation of this measure pending this publication, because the valuable information that this measure will

provide to patients and hospitals outweighs waiting for these results.

Comment: One commenter requested clarification from CMS regarding the inclusion of pain management-related questions in the OAS CAHPS Survey. The commenter expressed concern that the pain management communication question may negatively influence patient perceptions about their overall care and, in turn, result in negative responses throughout the survey. Another commenter expressed concern that the OAS CAHPS Survey's questions regarding communication about pain management may not reflect the true perception patients have of their experience relative pain management, and recommended CMS continue to explore ways to ensure better measurement of patients' experience with pain management.

Response: The OAS CAHPS Survey pain management communication questions focus on the information provided to patients regarding pain management following discharge from a hospital outpatient department, not the hospital outpatient department's direct control or management of patients' pain. The hospital outpatient department is responsible for providing the patient with this information if there is a possibility that the patient might have pain as a result of the procedure. Communication about possible effects during recovery is important for patients. As discussed previously, the OAS CAHPS Survey underwent a rigorous survey development process, the results of which did not indicate any negative impact to overall survey responses resulting from the inclusion of these questions regarding pain management communication. In addition, we have no reason to believe that patients' responses to the pain management communication questions would not accurately reflect their experience with the facility. Therefore, we do not believe that the pain management communication question would negatively influence patient perceptions about their overall care, resulting in negative responses throughout the survey. However, as noted in the CY 2017 OPPS/ASC proposed rule (81 FR 45718), we will continue to evaluate the appropriateness and responsiveness of these questions to patient experience of care and public health concerns.

Comment: A number of commenters expressed concern regarding the OAS CAHPS Survey pain management communication question, "Some ways to control pain include prescription medicine, over-the-counter pain relievers or ice packs. Did your doctor

¹²¹ Clinician and Group Survey CAHPS. Available at: <http://www.pqrscahps.org/>.

¹²² American College of Surgeons. "S-CAHPS (Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey)." Available at: <https://www.facs.org/advocacy/quality/cahps>.

or anyone from the facility give you information about what to do if you had pain as a result of your procedure?" One commenter recommended that CMS refine this question to be clear the survey is asking whether patients received pain management information that could be applied once they left the facility, and that the information could include, but is not limited to, information about pain management using appropriate medications. Another commenter recommended reorganizing the pain management methods listed in the first question to run from non-medication pain management to prescription pain medication treatment. Another commenter recommended that CMS expand this question to include other methods of pain management, such as physical therapy because the commenter believed using a more inclusive list of pain control methods would help to further combat the over prescription of opioids for pain management.

Some commenters also expressed concerns regarding the pain management communication control question, "At any time after leaving the facility, did you have pain as a result of your procedure?" Specifically, a few commenters requested that CMS revise the pain management communication control question to ask whether, at any time after leaving the facility, the patient experienced pain as a result of their procedure that they felt they could not manage based on the information they received from the facility or treating physician.

Response: We thank the commenters for their recommendations. As discussed previously, the OAS CAHPS Survey underwent a rigorous survey development process, the results of which indicated that patients understand these questions as presented, and that the questions were sufficiently developed for use in the survey.¹²³ As discussed previously, the OAS CAHPS Survey-based measures were reviewed by two 10-member TEPs comprised of experts on outpatient surgery, including clinicians, providers, patient advocates, and representatives from other stakeholder organizations. These TEPs provided guidance in the establishment of relevant topics for assessing patient experience of care at an outpatient facility, and commented

on draft versions of the survey for cognitive and field testing.

The possible treatments for pain included in the survey reflect what is tested and reflected to work, and their order is not intended to reflect a preference for any single pain treatment method, only to provide examples of types of pain management a facility may discuss with a patient prior to discharge. The examples provided in this question are also not intended to be an exhaustive list, and we acknowledge that there are many methods for addressing pain following a procedure performed at a hospital outpatient department, including physical therapy. Because this is not an exhaustive list, we do not believe it is necessary to exclude, expand, or reorganize these questions at this time. However, we will take these suggestions, including reorganizing the pain management methods, into consideration for future iterations of the survey.

Comment: Two commenters expressed concerns that the pain management communication control question raises an unrealistic expectation regarding pain control, and may potentially encourage over prescription of opioids. These commenters therefore recommended removing the pain management communication control question from the OAS CAHPS Survey.

Response: We also note that Question 16 "At any time after leaving the facility, did you have pain as a result of your procedure?" is a control question; in other words, an answer of "yes" or of "no" would not affect provider scores on the OAS CAHPS survey questions. The scores are based on the previous Question 15, which asked if the doctor or anyone from the facility gave the patient information about what to do if the patient had pain as a result of the procedure. We will not publicly report the data from the control question that asks if the patient had pain as a result of the procedure, rather, that question is only used to determine if the previous question should be included in the score or not. For example, if the patient reported having had pain in Question 16, then the response to Question 15 would be included in the score that is reported for the hospital.

For example, the focus of Questions 15 and 16 is to determine whether a patient who is expected to experience pain as a result of a procedure was given information from the doctor or anyone from the facility about what to do about pain. If a patient experiences pain as a result of a procedure (Question 16), it is important that the patient was provided information as to what to do about the

pain (Question 15). In these instances the response to Question 15 would be included in the score. However, for some procedures conducted in a hospital outpatient department (for example colonoscopies), there is little expectation that the patient will experience pain. In these instances, a doctor or anyone from the facility may not have given a patient information about what to do about pain because such information would not be relevant. In these latter instances, the response to Question 15 would not be included in the score unless the patient response is a top-box (that is, "Yes, definitely") response.

We do not believe a question asking whether patients experienced pain would have an undue influence on patients' responses to the OAS CAHPS Survey or warrant its removal from the OAS CAHPS Survey. As stated above, the OAS CAHPS Survey underwent a rigorous survey development process, the results of which did not indicate any negative impact to overall survey responses resulting from the inclusion of these questions regarding pain management communication. In addition, we have no reason to believe that patients' responses to the pain management communication questions would not accurately reflect their experience with the facility. Therefore, we do not believe that the pain management communication question would negatively influence patient perceptions about their overall care, resulting in negative responses throughout the survey.

Furthermore, as stated in the CY 2017 OPPI/ASC proposed rule at 81 FR 45717 through 45718, this control question will not affect scores on the OAS CAHPS survey. Rather, scores are based on the previous Question 15, which asks if the doctor or anyone from the facility gave the patient information about what to do if the patient had pain as a result of the procedure. However, we will review the data from the voluntary national implementation and continue to evaluate the appropriateness and responsiveness of these questions, particularly for any unintended consequences.

Comment: One commenter requested clarification about whether CMS intends to publicly report HOPD scores on the pain management communication control question.

Response: We interpret the comment to refer to Question 16. Question 16, "At any time after leaving the facility, did you have pain as a result of your procedure?" is a control question; in other words, an answer of "yes" or of "no" would not affect provider scores

¹²³ A description of the field test analysis of the survey questions was documented in the **Federal Register** notice (January 16, 2015; 80 FR 2430). <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10500.html>.

on the OAS CAHPS Survey questions. The scores are based on the previous Question 15, which asked if the doctor or anyone from the facility gave the patient information about what to do if the patient had pain as a result of the procedure.

Comment: One commenter recommended that CMS remove the questions on the OAS CAHPS Survey asking patients whether they experienced pain, nausea, or bleeding following a procedure because the commenter believes this information is not useful to facilities in quality improvement activities, as these are all risks associated with surgery.

Response: Question 17 (“Before you left the facility, did your doctor or anyone from the facility give you information about what to do if you had nausea or vomiting?”) and Question 18 (“At any time after leaving the facility, did you have nausea or vomiting as a result of either your procedure or the anesthesia?”) are intended to assess the information provided to patients regarding what to expect following a surgery/procedure. We believe it is the facility’s responsibility to ensure that the patient is aware of the potential side effect of their treatment, and, therefore, believe these questions are indicative of quality of care. As above, we note that Question 18 is a control question, so an affirmative or negative response would not be included in the provider scores on the OAS CAHPS Survey, but rather is used to determine if the provider should have given guidance on how to handle nausea or vomiting (Question 17). The information will be useful to facilities because they will be able to ensure that the information that patients need during recovery is adequately addressed by the facility staff. These questions are not reporting whether the patients experienced pain, nausea, vomiting, bleeding or signs of infection; the questions are reporting if the patients were informed what to do if they had these outcomes.

For example, the focus of Questions 17 and 18 is to determine whether a patient who might likely experience nausea or vomiting as a result of a procedure was given information from the doctor or anyone from the facility about what to do to manage these outcomes. If a patient experiences these outcomes as a result of a procedure, it is important that the patient was provided information on how to manage these outcomes. In these instances, the response to Question 17 would be included in the score. However, for some procedures conducted in a hospital (for example laser surgeries), there is little expectation of the patient

experiencing nausea or vomiting and in these instances a doctor or anyone from the facility may not have given a patient information on how to manage these outcomes as such information would not be relevant. In these latter instances, the responses to Question 17 would not be included in the score unless the patient response is a top-box (that is, “Yes, definitely”) response.

Furthermore, as stated in the CY 2017 OPPTS/ASC proposed rule (81 FR 45717 through 45718), this control question will not affect scores on the OAS CAHPS survey. Rather, scores are based on the previous Question 17, which asks if the doctor or anyone from the facility gave information about what to do if the patient had nausea or vomiting. However, we will review the data from the voluntary national implementation and continue to evaluate the appropriateness and responsiveness of these questions, particularly for any unintended consequences.

Comment: One commenter urged CMS to examine the necessity and utility of the OAS CAHPS measures and adjust for all factors (for example, limited English proficiency, low health literacy) that could influence how patients respond to the survey but are beyond the control of the hospital and not directly related to hospital performance.

Response: In order to achieve the goal of fair comparisons across all hospitals, the OAS CAHPS Survey-based measures risk-adjust for factors that are not directly related to facility performance. The measures are risk-adjusted for patient case-mix, which proved to be significant predictors: age; education; overall health status; overall mental health status; type of surgical procedure; and English proficiency. Health literacy is not one of the patient characteristics used because assessing a patient’s health literacy would add significant burden to the survey. The self-reported education is used as a surrogate and only requires one additional question. We refer readers to <http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/perfmeasguide/perfmeaspt2a.html> for more details about the risk-adjustment.

Comment: One commenter recommended the OAS CAHPS Survey be administered only to patients receiving surgeries and certain other procedures in the HOPD setting.

Response: We agree with the commenter and refer readers to section XIII.B.5.c.(5) of this final rule with comment period (Cohort) in the measure description above as well as in the CY 2017 OPPTS/ASC proposed rule (81 FR 45719). As we stated there, a criterion

to be an eligible patient is one “who had an outpatient surgery or procedure in a hospital, as defined in the OAS CAHPS Survey Protocols and Guidelines Manual (<https://oascahps.org/Survey-Materials>).” The OAS CAHPS Survey was specifically developed to assess patients’ experience of care for selected outpatient surgical procedures. The surgeries and procedures eligible for the OAS CAHPS Survey measures fall within the Category I CPT–4 range Codes for Surgery (for example, CPT codes between 10021–69990) or one of the following Category II G-codes: G0104; G0105; G0121; or G0260. All other CPT codes are considered ineligible for the OAS CAHPS Survey-based measures. We refer readers to the OAS CAHPS Protocols and Guidelines Manual for more information, which is available at: <https://oascahps.org/Survey-Materials>.

Comment: One commenter expressed concerns that additional review and consideration is needed regarding the CPT codes involving the insertion/use of Foley catheters, 51701 and 51702.

Response: For the OAS CAHPS Survey, the primary criterion for determining eligible surgeries and procedures is the CPT code.¹²⁴ OAS CAHPS-eligible surgeries and procedures fall within the range Category I Codes for Surgery (that is, CPT codes between 10021 and 69990) or one of the following Category II G-codes: G0104; G0105; G0121; or G0260. Among the 60,000 surgeries and procedures documented in the Codes for Surgery range, there are some relatively minor procedures that fall within the range that are considered ineligible for OAS CAHPS. The OAS CAHPS protocol¹²⁵ documents the ineligible CPT codes that have been excluded, but because the codes are maintained by the American Medical Association and are subject to periodic updates, the list of exclusions must be open for expansion. CMS protocols for the OAS CAHPS Survey¹²⁶ allow survey vendors to work with hospital outpatient departments to submit for consideration other specific CPT codes to be considered for exclusion. As additional exclusions are approved, the survey protocols are updated and announced. The two CPT codes in question (51701 and 51702) are currently under consideration by CMS for exclusion.

Comment: One commenter recommended that CMS delay public

¹²⁴ CPT only copyright 2015 American Medical Association. All rights reserved.

¹²⁵ Outpatient and Ambulatory Surgery CAHPS Survey: “Protocols and Guidelines Manual.” Available at: <https://oascahps.org/Survey-Materials>.

¹²⁶ <https://oascahps.org/Survey-Materials>.

reporting of hospital outpatient department measure rates on the OAS CAHPS Survey-based measures for at least one year to allow hospitals to become familiar with the measures and survey administration.

Response: As stated in the CY 2017 OPPS/ASC proposed rule (81 FR 45720), this measure was proposed for the CY 2020 payment determination and subsequent years. Therefore, hospitals would not be required to submit OAS CAHPS Survey data until CY 2018. We refer readers to section XII.D.4. of this final rule with comment period for data submission requirements. This gives hospitals an additional year to become familiar with both the OAS CAHPS Survey and its administration requirements, as well as to contract with a third-party vendor to administer the survey. We refer hospitals to the list of CMS-approved survey vendors available on the OAS CAHPS Web site (<https://oascahps.org/General-Information/Approved-Survey-Vendors>) and encourage hospitals to compare prices across vendors, as they may vary. We believe this additional year is sufficient

time for hospitals to become familiar with the measures and survey administration before it is a requirement of the Hospital OQR Program and before measures data is publicly reported. Furthermore, we encourage hospitals to participate in the voluntary national implementation of the OAS CAHPS Survey to gain experience. More information can be found at: <https://oascahps.org/>.

Moreover, as stated in the CY 2017 OPPS/ASC proposed rule (81 FR 45720), we will propose a format and timing for public reporting of OAS CAHPS Survey data in future rulemaking prior to implementation of the measures. Because CY 2016 is the first year of voluntary national implementation for the OAS CAHPS Survey, and we believe using data from this voluntary national implementation will help inform the displays for public reporting of OAS CAHPS Survey data for the Hospital OQR Program, we did not propose a format or timing for public reporting of OAS CAHPS Survey data in the proposed rule.

After consideration of the public comments we received, we are

finalizing the adoption of the OP-37a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey Measures for the CY 2020 payment determination and subsequent years as proposed with a clarification that hospitals that anticipate receiving more than 300 surveys are required to either: (1) Randomly sample their eligible patient population, or (2) survey their entire OAS CAHPS eligible patient population. We note that these measures are also being finalized in the ASCQR Program and refer readers to section XIV.B.4.c of this final rule with comment period for more details.

d. Summary of Previously Adopted and Newly Adopted Hospital OQR Program Measures for the CY 2020 Payment Determinations and Subsequent Years

The table below outlines the finalized Hospital OQR Program measure set for the CY 2020 payment determination and subsequent years, and includes both previously adopted measures and measures newly adopted in this final rule with comment period.

PREVIOUSLY FINALIZED AND NEWLY 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.
N/A	OP-9: Mammography Follow-up Rates.
N/A	OP-10: Abdomen CT—Use of Contrast Material.
0513	OP-11: Thorax CT—Use of Contrast Material.
N/A	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.
N/A	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.
N/A	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.
N/A	OP-25: Safe Surgery Checklist Use.
N/A	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.
N/A	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy.****
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery.****
N/A	OP-37a: OAS CAHPS—About Facilities and Staff.****
N/A	OP-37b: OAS CAHPS—Communication About Procedure.****
N/A	OP-37c: OAS CAHPS—Preparation for Discharge and Recovery.****
N/A	OP-37d: OAS CAHPS—Overall Rating of Facility.****
N/A	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 OP/ASC final rule with comment period (79 FR 66946 through 66947).

**** New measure finalized for the CY 2020 payment determination and subsequent years.

6. Hospital OQR Program Measures and Topics for Future Consideration

In the CY 2017 OP/ASC proposed rule (81 FR 45721 through 45722), we sought public comment on future measure topics generally, electronic clinical quality (eCQM) measures implementation, and specifically the future measure concept, Safe Use of Opioids-Concurrent Prescribing eCQM, for future consideration in the Hospital OQR Program. 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, the use of Health Information Technology (health IT), care coordination, patient safety, and volume. 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 the Medicare program. We invited public comments on possible measure topics for future consideration in the Hospital OQR Program. We specifically requested 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.

Comment: One commenter requested that, in selecting future measures and topics, CMS streamline, align, focus, and collaborate on measures that matter most for improving patient care. The commenter also expressed its support for CMS' focus on outcome measures.

Response: We thank the commenter for its suggestion. As discussed in the CY 2012 OP/ASC final rule with comment period (76 FR 74458 through 74460), in general, when selecting measures for the Hospital OQR Program,

we take into account several considerations and goals. These include:

(a) Expanding the types of measures beyond process of care measures to include an increased number of outcome measures, efficiency measures, and patients' experience-of-care measures; (b) expanding the scope of hospital services to which the measures apply; (c) considering the burden on hospitals in collecting chart-abstracted data; (d) harmonizing the measures used in the Hospital OQR Program with other CMS quality programs to align incentives and promote coordinated efforts to improve quality; (e) seeking to use measures based on alternative sources of data that do not require chart abstraction or that utilize data already being reported by many hospitals, such as data that hospitals report to clinical data registries, or all-payer claims data bases; and (f) weighing the relevance and utility of the measures compared to the burden on hospitals in submitting data under the Hospital OQR Program. We also stated that we assign priority to quality measures that assess performance on: (a) Conditions that result in the greatest mortality and morbidity in the Medicare population; (b) conditions that are high volume and high cost for the Medicare program; and (c) conditions for which wide cost and treatment variations have been reported, despite established clinical guidelines (76 FR 74458 through 74459). To the extent possible, we seek to streamline reporting, align with other hospital quality reporting and performance programs, and focus on measures that have high impact and support national priorities as reflected in the NQS and the CMS Quality Strategy. We thank the commenter for its support of our move toward adopting more outcome-based measures in the future.

Comment: Several commenters recommended increasing the number of immunization measures, specifically, adult immunization measures, in the program, including: (1) A pneumococcal immunization measure, such as NQF #0043; (2) an influenza immunization measure, such as NQF #0041; (3) an HPV vaccination catch-up measure for females ages 19–26 years and for males 19–21 years; (4) a measure for Tdap/pertussis-containing vaccine for ages 19+ years; (5) a measure for Zoster vaccination for ages 60–64 years; and (6) a measure for Zoster vaccination for

ages 65+ years. Commenters noted that several of these measures are already required by the PQRS Program. One commenter recommended that CMS address all Advisory Committee on Immunization Practices (ACIP)-recommended vaccines for adults. Other commenters also strongly supported maintaining the Influenza Vaccination Coverage among Healthcare Personnel measure in the Hospital OQR Program.

Response: We acknowledge commenters' suggestions that we should include additional immunization performance measures in the Hospital OQR Program to help ensure vaccines are routinely offered and administered to patients in the hospital outpatient setting. We also refer readers to the CY 2016 PFS final rule with comment period (80 FR 71216 through 71259) for measures currently included in the PQRS Program. We will take these suggestions into consideration for future rulemaking. We thank commenters for supporting the continued inclusion of OP–27: Influenza Vaccination Coverage among Healthcare Personnel.

b. Electronic Clinical Quality Measures

We are working toward incorporating electronic clinical quality measures (eCQMs) in the Hospital OQR Program in the future. We believe automated electronic extraction and reporting of clinical quality data, potentially including measure results calculated automatically by appropriately certified health IT, would significantly reduce the administrative burden on hospitals under the Hospital OQR Program. We recognize that considerable work needs to be done by measure stewards and developers to make this possible with respect to the clinical quality measures targeted for electronic specifications (e-specifications) for the outpatient setting. This includes completing e-specifications for measures, pilot testing, reliability and validity testing, submitting for endorsement of e-specified version (if applicable) and implementing such specifications into certified EHR technology to capture and calculate the results, and implementing the systems. We continue to work to ensure that eCQMs will be smoothly incorporated into the Hospital OQR Program.

We invited public comments on future implementation of eCQMs as well

as specific future eCQMs for the Hospital OQR Program.

Comment: Some commenters supported CMS' goal to incorporate electronic clinical quality measures (eCQMs) in the Hospital OQR Program in the future. One commenter asserted that eCQMs will help quantify healthcare processes and outcomes that are associated with the ability to provide high quality health care, and the development of eCQMs increases clinical data availability and improves measure quality and outcomes. One commenter agreed with the development of outpatient eCQMs because it would better align the outpatient and inpatient hospital quality reporting programs; this commenter asserted that the outpatient areas lag behind inpatient areas in the implementation of electronic health records. Another commenter encouraged CMS to make the transition to eCQM reporting a high priority to align with the Hospital IQR Program and The Joint Commission's ORYX® Reporting Program.

Response: We thank the commenters for their support of incorporating eCQMs in the Hospital OQR Program in the future. We are evaluating eCQM implementation in the Hospital IQR Program, as well as other Medicare payment programs, and will take lessons learned in that program into consideration when crafting policy for the Hospital OQR Program. Furthermore, we consider the alignment with the Hospital IQR Program and the Joint Commission's ORYX® Reporting Program a high priority for our transition to eCQM reporting in the Hospital OQR Program, and we will take this recommendation into consideration. For additional information regarding the Joint Commission's ORYX® Reporting Program, we refer readers to: https://www.jointcommission.org/facts_about_oryx_for_hospitals/. We also acknowledge the commenter's concerns that outpatient areas lag behind inpatient areas in the implementation of electronic health records, and we will consider this issue as we develop eCQMs for the Hospital OQR Program.

Comment: One commenter recommended a gradual start with one measure, and recommended the Hospital OQR Program start with the ED-3 measure (Median Time from ED Arrival to ED Departure for Discharge ED Patients). The commenter expressed concerns that CMS did not take advantage of eCQM ED-3 measure to begin accepting Quality Reporting Document Architecture (QRDA-1) files for CY 2017. The commenter strongly

recommended CMS show continued support for ED-3 and add it to the list of future eCQM requirements.

Response: We acknowledge the commenter's concern regarding gradually including eCQMs in the Hospital OQR Program, beginning with the inclusion of the ED-3: Median Time from ED Arrival to ED Departure for Discharge ED Patients measure. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72074), we finalized OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496), the only measure in our current measure set which is currently specified as an eCQM; it is e-specified as ED-3. The e-specification for this measure is available at: http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/2014_eCQM_Specs_for_EH.zip in the folder entitled: EH_CMS32v2_NQF0496_ED3_MedianTime. The ED-e measure could not be proposed or adopted previously due to the statutory limitations of the Hospital OQR Program. This e-measure would be required to undergo the prerulemaking process in accordance with section 1890A of the Act. This e-measure is currently on the 2016 MUC List, and we are considering it for future use in the program, because we believe it is important to encourage providers to submit this measure electronically.

Comment: A few commenters did not support CMS' goal to incorporate eCQMs in the Hospital OQR Program. One commenter asserted that requiring eCQM reporting in the quality programs would create a duplicative penalty for hospitals unable to meet Meaningful Use requirements. This commenter further argued there has not been sufficient development of eCQMs for the Hospital OQR Program. Another commenter expressed concerns that providers will not have sufficient time and information systems and technology resources to be fully prepared for reporting eCQMs. This commenter requested more flexibility from CMS, and requested decreasing required measures until the specifications have been tested and validated. This commenter also requested that data from eCQMs not be published in *Hospital Compare* until benchmarks for each measure are available.

Response: We disagree that any future requirements for electronic reporting in the Hospital OQR Program would duplicate penalties. Incorporating eCQMs is part of an effort to align various programs, including the Hospital IQR Program and Medicare and Medicaid EHR Incentive Programs, in

order to reduce overall burden. Furthermore, we believe that it is appropriate to consider incorporating eCQMs because measures available now and those being developed for the future are increasingly based on electronic standards (80 FR 49696). In addition, as described in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57156), we have observed the successes of hospitals meeting the meaningful use requirements and our data show that 95 percent of hospitals already attest to successful eCQM reporting under the EHR Incentive Program.

We acknowledge the commenter's concerns that providers will not have sufficient time and information systems and technology resources to be fully prepared for reporting eCQMs. We anticipate that as EHR technology evolves and more health IT infrastructure is operational, in cooperation with the efforts of the ONC Health IT Certification Program, data elements and information systems requirements will become more standardized. Reliable, accurate data and electronic reporting are all important priorities to us. We believe that, with the advancement of technology and the use of electronic measures, even more precise, accurate, and reliable data will be captured for analysis. We also acknowledge commenters' concerns and recommendations regarding the use of eCQMs in the Hospital OQR Program, such as decreasing required measures until the specifications have been tested and validated and delaying public reporting on Hospital Compare until benchmarks for each measure are available. In addition, we understand the commenter's concerns that there has not been sufficient development of eCQMs for the Hospital OQR Program. We aim to ease the transition to reporting of electronic clinical quality measures, but any policies regarding the specific timelines and requirements related to data submission would be proposed in future rulemaking. We will consider these comments and work with stakeholders to address their concerns evaluating any eCQMs we propose to adopt in future rulemaking.

Comment: One commenter recommended that, for anesthesia measures, eCQMs should communicate across the continuum of patient care, and disparate information systems should interface between offices, clinics, hospitals, and pharmacy platforms to communicate across the patient's experience to increase patient safety, improve outcomes and decrease cost of care. This commenter recommended that these anesthesia

measures should include standardized taxonomy and fields and require providers to use these measures across various platforms to optimize communication of care and interoperability. This commenter also asserted that free text fields are more complex and require dedicated staff to abstract charts for quality reporting instead of electronic capture from the EHR of specific data fields. This commenter therefore recommended CMS make data available to all interested parties to identify trends and opportunities for improvement as data is reported.

Response: We appreciate the commenter's recommendations regarding the inclusion of e-specified anesthesia-related measures in the Hospital OQR Program. Furthermore, we acknowledge concerns about disparate information systems and conflicting data elements resulting in issues of comparability, completeness, and accuracy of eCQM data as well as concerns that e-specified anesthesia measures should include standardized taxonomy and fields, and require providers to use these measures across various platforms to optimize communication of care and interoperability. In the future, if we consider adopting e-specified measures related to patients undergoing anesthesia, we will be mindful of these concerns. Furthermore, regarding making data available to all interested parties to identify trends and opportunities for improvement as data is reported, we will consider the feasibility of this within the constraints of the HIPAA Privacy and Security Rules and other data privacy laws.

Comment: One commenter recommended the following existing Hospital OQR Program measures be slated for future eCQM development: OP-1: Median Time to Fibrinolysis; OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival; OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention; OP-5: Median Time to ECG; OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional; and OP-21: Median Time to Pain Management for Long Bone Fracture.

Response: We will share these suggested existing Hospital OQR Program measures with the measure developers for consideration as future eCQMs and will take these comments under consideration as we develop future eCQM policy for the Hospital OQR Program.

Comment: One commenter requested that, when referencing providers within eCQMs, CMS use provider-neutral

language consistent with the language used by CMS that supports inter-professional team care delivery and outcomes.

Response: We interpret provider-neutral language as language that includes eligible professionals. As defined under section 1861(r) of the Act and finalized in the EHR Incentive Programs Stage 1 final rule (75 FR 44442), an eligible professional is a doctor of medicine or osteopathy; a doctor of dental surgery or dental medicine; a doctor of podiatric medicine; a doctor of optometry; or a chiropractor, nurse practitioners, physician assistants, and other health care practitioners as health care providers. We strive to use language that eliminates bias and minimizes assumptions in their writing. In addition, hospital measures are not generally reported on the individual-level (for example, by each physician); instead they are reported by CCN (for example, hospital-wide) in order to encourage coordinated care delivery.

Comment: One commenter expressed concerns that the size and scope of CMS testing and validation for eCQMs may be too narrow for an accurate review.

Response: We thank the commenter for sharing its suggestions and concerns regarding the testing and validation for eCQMs for the future measure concept. As we have not yet developed policy for Hospital OQR Program eCQM validation, we believe the commenter is referring to the Hospital IQR Program Validation Pilot for eCQMs that was finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50269 through 50273). We refer readers to FY 2015 IPPS/LTCH PPS final rule (79 FR 50269 through 50273) for our discussions of size and scope of Hospital IQR Program eCQM Validation Pilot. Additional details about the Hospital IQR Program 2015 eCQM Validation Pilot are available at: <https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPPage%2FQnetTier3&cid=1140537256076>. We also refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57173 through 57181), for a summary of results from the pilot test and our most recent eCQM validation policies in the Hospital IQR Program. We will consider these comments as we develop eCQM policy for the Hospital OQR Program.

c. Possible Future eCQM: Safe Use of Opioids-Concurrent Prescribing

Unintentional opioid overdose fatalities have become an epidemic in the last 20 years and a major public

health concern in the United States.¹²⁷ HHS has made addressing opioid misuse, dependence, and overdose a priority. HHS is implementing evidence-based initiatives focused on informing prescribing practices to combat misuse and overdose deaths.¹²⁸ Several other organizations, including the Centers for Disease Control and Prevention (CDC), the Federal Interagency Workgroup for Opioid Adverse Drug Events, the National Action Plan for Adverse Drug Event Prevention, and the Substance Abuse and Mental Health Services Administration, have joined the effort. Prescribing opioids to patients already using an opioid or patients using benzodiazepines (sedation-inducing central nervous system depressant) increases their risk of respiratory depression and death.¹²⁹ These prescribing scenarios can occur in any setting including: Inpatient hospital; outpatient hospital practices; outpatient emergency departments; and other urgent care settings. With a limited evaluation focused on the patient's acute condition, the clinician in these settings may not know the patient's full medical history.¹³⁰ An analysis of national prescribing patterns shows that more than half of patients who received an opioid prescription in 2009 had filled another opioid prescription within the previous 30 days.¹³¹ Studies of multiple claims and prescription databases have shown that between 5 and 15 percent of patients receive overlapping opioid prescriptions and 5 to 20 percent of patients receive

¹²⁷ Rudd, R., Aleshire, N., Zibbell, J., et al. "Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014". *MMWR*, Jan 2016. 64(50);1378–82. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm>.

¹²⁸ United States Department of Health and Human Services "ASPE Issue Brief: Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths". March 2015. Available at: https://aspe.hhs.gov/sites/default/files/pdf/107956/ib_OpioidInitiative.pdf.

¹²⁹ Dowell, D., Haegerich, T., Chou, R. "CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016". *MMWR Recomm Rep* 2016;65. Available at: <http://www.cdc.gov/media/dpk/2016/dpk-opioid-prescription-guidelines.html>.

¹³⁰ Governale, Laura. "Outpatient Prescription Opioid Utilization in the U.S., Years 2000–2009." 2010. Drug Utilization Data Analysis Team Leader, Division of Epidemiology, Office of Surveillance and Epidemiology. Presentation for U.S. Food and Drug Administration. Available at: <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndLifeSupportDrugsAdvisoryCommittee/UCM220950.pdf>.

¹³¹ National Institute on Drug Abuse. "Analysis of opioid prescription practices finds areas of concern". April 2011. Available at: <https://www.drugabuse.gov/news-events/news-releases/2011/04/analysis-opioid-prescription-practices-finds-areas-concern>.

overlapping opioid and benzodiazepine prescriptions across all settings.^{132 133 134}

The 2016 *CDC Guideline for Prescribing Opioids for Chronic Pain*¹³⁵ recommends that providers avoid concurrently prescribing opioids and benzodiazepines because rates of fatal overdose are 10 times higher in patients who are co-dispensed opioid analgesics and benzodiazepines than opioids alone¹³⁶ and concurrent use of benzodiazepines with opioids was prevalent in 31 percent to 51 percent of fatal overdoses.¹³⁷ ED visit rates involving both opioid analgesics and benzodiazepines increased from 11.0 in 2004 to 34.2 per 100,000 population in 2011.¹³⁸ Opioid overdose events resulting in ED use can cost the United States approximately \$800 million per year.¹³⁹

To address concerns associated with overlapping or concurrent prescribing of opioids or opioids and benzodiazepines, we are in early development of a new electronic clinical quality measure for the Hospital IQR and OQR Programs that would capture the proportion of patients 18 years of age and older who have an active prescription for an opioid and have an additional opioid or benzodiazepine prescribed to them during the qualifying care encounter. This measure is being designed to reduce preventable deaths as well as

reduce costs associated with the treatment of opioid-related ED use by encouraging providers to identify patients at high risk for overdose due to respiratory depression or other adverse drug events.

We requested public comments on this future measure concept specifically for the Hospital OQR Program setting.

In addition, in order to solicit further public comment from a wide variety of stakeholders, we will also post this measure concept to the CMS Measures Management System (MMS) Call for Public Comment Web page, available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html>. Readers can subscribe to receive updates through the MMS Listserv at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Listserv.html>.

Comment: Several commenters supported the future eCQM “Safe Use of Opioids-Concurrent Prescribing” measure concept currently under development for the Hospital OQR Program. One commenter specifically supported the development of measures to help address the opioid epidemic. Another commenter supported the future measure concept because the large number of people receiving health care who take multiple medications, and the resulting complexity of managing those medications, makes medication reconciliation an important safety process. This commenter further asserted that effective medication reconciliation programs require a complete understanding of what the patient was prescribed and what medications the patient is actually taking, and is particularly important when prescribing opioids.

Response: We thank commenters for their support of the development of a future measure addressing safe use of opioids and concurrent prescribing. We note that the measure is still under development. However, we will consider these recommendations in our ongoing measure development activities.

Comment: Several commenters disagreed with the scope and intention of the future opioid measure concept and asserted that measures that simply assess the proportion of adults with a prescription are inadequate because they do not consider if opioid prescriptions are appropriate. One commenter asserted that clinicians should be able to use their clinical judgment and should not be punished if the clinicians sincerely believed that prescribing both classes of medication

together is more beneficial than prescribing only one class of medication alone.

Response: We thank the commenters for sharing their suggestions and concerns about the scope and intention of the future opioid measure. We understand commenters’ concerns about measures that assess the proportion of adults with a prescription are inadequate, and will consider this issue while we develop this future measure. During initial development of this measure, experts were interviewed and recognized that there will be clinically necessary instances where a patient with an active opioid or benzodiazepine may require a short-term prescription for a second medication. However, the 2016 *CDC Guideline for Prescribing Opioids for Chronic Pain*¹⁴⁰ recommends that providers avoid concurrently prescribing opioids and benzodiazepines because rates of fatal overdose are 10 times higher in patients who are co-dispensed opioid analgesics and benzodiazepines than opioids alone¹⁴¹ and concurrent use of benzodiazepines with opioids was prevalent in 31 percent to 51 percent of fatal overdoses.¹⁴² We do not expect sites to have numerators of zero, but we do intend the measure to alert providers to the risks of concurrent opioid or opioid and benzodiazepine therapy. We will continue to engage with stakeholders, including clinicians, as we develop this future measure. We note that the measure is still under development, and we will consider these recommendations in our ongoing measure development and testing activities.

Comment: Some commenters expressed concerns that the measure concept may introduce unintended consequences such as under-treatment and placing undue accountability on acute settings for long-term pain management; patients on small doses of a benzodiazepine for a chronic problem (anxiety, insomnia) might not be able to be given opioids if they have an acute injury or fracture; and creating withdrawal in a patient who has been on long standing opioids with

¹³² Liu, Y., Logan, J., Paulozzi, L., et al. “Potential Misuse and Inappropriate Prescription Practices Involving Opioid Analgesics”. *Am J Manag Care*. 2013 Aug;19(8):648–65.

¹³³ Mack, K., Zhang, K., et al. “Prescription Practices Involving Opioid Analgesics among Americans with Medicaid, 2010.” *J Health Care Poor Underserved*. 2015 Feb; 26(1): 182–198. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4365785/>.

¹³⁴ Jena, A., et al. “Opioid prescribing by multiple providers in Medicare: retrospective observational study of insurance claims.” *BMJ* 2014; 348:g1393 doi: 10.1136/bmj.g1393. Available at: <http://www.bmj.com/content/348/bmj.g1393>.

¹³⁵ Dowell D, Haegerich TM, Chou R. *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*. *MMWR Recomm Rep* 2016;65:1–49. DOI: <http://dx.doi.org/10.15585/mmwr.rr6501e1>.

¹³⁶ Dasgupta, N., et al. “Cohort Study of the Impact of High-dose Opioid Analgesics on Overdose Mortality.” *Pain Medicine*, Wiley Periodicals, Inc., 2015.

¹³⁷ Dowell, D., Haegerich, T., Chou, R. “CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016.” *MMWR Recomm Rep* 2016;65. Available at: <http://www.cdc.gov/media/dpk/2016/dpk-opioid-prescription-guidelines.html>.

¹³⁸ Jones, CM., McAninch, JK. “Emergency Department Visits and Overdose Deaths From Combined Use of Opioids and Benzodiazepines”. *Am J Prev Med*. 2015 Oct;49(4):493–501. doi: 10.1016/j.amepre.2015.03.040. Epub 2015 Jul 3. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/26143953>.

¹³⁹ Inocencio, TJ., et al. “The economic burden of opioid-related poisoning in the United States,” *October 2013*. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/23841538>.

¹⁴⁰ Dowell D, Haegerich TM, Chou R. *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*. *MMWR Recomm Rep* 2016;65:1–49. DOI: <http://dx.doi.org/10.15585/mmwr.rr6501e1>.

¹⁴¹ Dasgupta, N., et al. “Cohort Study of the Impact of High-dose Opioid Analgesics on Overdose Mortality.” *Pain Medicine*, Wiley Periodicals, Inc., 2015.

¹⁴² Dowell, D., Haegerich, T., Chou, R. “CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016.” *MMWR Recomm Rep* 2016;65. Available at: <http://www.cdc.gov/media/dpk/2016/dpk-opioid-prescription-guidelines.html>.

concurrent benzodiazepines. One commenter urged CMS to exercise caution when implementing measures that have the potential to inadvertently discourage providers from prescribing opioids to those patients who need them.

Response: We thank the commenters for sharing their suggestions and concerns about the potential of the future measure concept to introduce unintended consequences for patients using benzodiazepines. We also acknowledge commenters' concerns that the future measure concept may place undue accountability on facilities providing acute care for patients receiving long-term treatment for chronic pain, and we will take this issue into consideration as we develop the measure. We also believe it is important to understand and monitor the potential for unintended consequences, and we will take these issues into consideration to inform our ongoing measure development efforts.

Comment: One commenter recommended that CMS consider physician burden and time in developing this measure. This commenter further expressed concerns that emergency physicians do not always have access to the list of a patient's medications. Another commenter expressed concern that ED providers deliver episodic care and do not have control over the medications that their patients have been prescribed prior to arrival to the ED, and therefore performance on this measure is largely outside of the control of ED providers.

Response: We thank the commenters for sharing their concerns regarding ED physician burden and time, and concerns that performance on the measure may be largely outside the control of providers. The measure is not intended to hold facilities accountable for undocumented opioid or benzodiazepine prescriptions; if a patient's opioid or benzodiazepine medications are not recorded in the EHR because they could not be reconciled by the provider during the healthcare encounter, that patient will not be captured by the measure. While it may be difficult to gather a complete record of all medications from each patient during a healthcare encounter, we believe it is best practice to make reasonable efforts to determine what medications a patient is taking at the beginning of an encounter and document that in the clinical record. This approach aligns with The Joint Commission's National Patient Safety Goals which includes medication reconciliation as an important component of improving the safe use of

medications.¹⁴³ We understand the importance of not developing and implementing measures that are overly burdensome regarding providers' time and burden, and we are committed to working with stakeholders, including providers, in developing this future measure. Although ED providers may face challenges that are unique to acute pain management, it is not reasonable to exclude them from this measure, due to the high rates of opioid prescriptions from ED settings. A study that analyzed data on ED discharges from the 2006 through 2010 National Hospital Ambulatory Medical Care Survey found that opioids were prescribed for 18.7 percent of all ED discharges, representing 21.7 million prescriptions per year.¹⁴⁴ Rates of opioids prescriptions in the outpatient settings may be high, but opioid prescription rates from the ED setting are also significant. Furthermore, discharge planning with the patient's primary care provider is a routine expectation for care coordination. We will consider these recommendations to inform our ongoing measure development and testing efforts.

Comment: Some commenters recommended that CMS explore the development and use of appropriate use criteria for opioid prescribing, and also recommended CMS explore measures of overuse; for example, the percentage of patients with more than a certain number of prescription fills over a time period.

Response: We appreciate the commenters' recommendations to explore appropriate use criteria for opioid prescribing, and we also will take into consideration the recommendation to explore measures of overuse in the Hospital OQR Program. We will consider these recommendations when developing a future measure addressing safe use of opioids and concurrent prescribing.

Comment: One commenter recommended that hospitals be held accountable for instances in which they initiate new combination opioid therapy or opioid-benzodiazepine therapy, and recommended that the measure not penalize hospitals for continuing home combination therapy. The commenter recommended that CMS establish a

¹⁴³ Joint Commission's National Patient Safety Goals. https://www.jointcommission.org/assets/1/6/2016_NPSG_HAP.pdf.

¹⁴⁴ Kea, B., Fu, R., Lowe, R., et al. (2016). Interpreting the National Hospital Ambulatory Medical Care Survey: United States Emergency Department Opioid Prescribing, 2006–2010. *American Emergency Medicine*. Wiley Periodicals, Inc. Retrieved [March 2016] from <http://onlinelibrary.wiley.com/doi/10.1111/acem.12862/abstract>.

medication management plan, with pain management or primary care signing on, before sending a patient on combination therapy home.

Response: As we move through the development of this measure concept, we will consider the commenter's recommendations on holding hospitals accountable when they initiate new combination therapy, and not penalizing hospitals for continuing home combination therapy, which means treatment in which a patient is given two or more drugs (or other therapeutic agents) for a single disease. In addition, the recommendation to institute a medication management plan may help to inform our ongoing measure development.

Comment: One commenter requested clarification on how hypnotics will be viewed for purposes of this measure.

Response: We thank the commenter for requesting this clarification. Hypnotic drug products are a class of drugs used to induce and/or maintain sleep.¹⁴⁵ At this time, we are not including any non-benzodiazepine hypnotics in the scope of the measure. We are still developing this measure, and we will consider this comment to inform our ongoing measure development efforts.

Comment: Some commenters recommended that CMS exclude several groups from the measure, including hospice patients, cancer patients, and patients with sickle cell disease. One commenter recommended that the measure concept be limited to large quantities of medications because this would provide the option for emergency physicians to continue a patient's opioid, or opioid/benzodiazepine regimen, for a 5-day period. This commenter also encouraged CMS to consider alternative strategies that are more practical for the ED, such as better counseling on the risks and benefits of these medications, as well as investment in the development and promotion of clinical practice guidelines that focus on pain management and prescribing.

Response: We appreciate the commenters' recommendations on excluding certain populations from the measure, limiting the measure to cases involving large quantities of medications, and considering alternative strategies that are more practical for the ED. We will take the commenters' recommendations into

¹⁴⁵ U.S. Food and Drug Administration. (2015). Sleep Disorder (Sedative-Hypnotic) Drug Information. Retrieved October 6, 2016, from <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm101557.htm>.

consideration in our measure development and testing efforts.

Comment: One commenter recommended removal of the following medication value sets: Benzodiazepines RXNORM Value Set and Schedule II and Schedule III Opioids RXNORM Value Set. This commenter expressed concerns regarding the feasibility of capturing the concept of “medications that are active and do not end.” The commenter also recommended that the measure solely address concurrent discharge medications.

Response: We interpret the concept of “medications that are active and do not end” as to refer to medications active on arrival or active home medications, which continue to remain on the patient’s medications list at discharge if they were not discontinued by the provider, and that the commenter is concerned about how they would be captured in an eCQM value set. We interpret eCQM value sets as lists of specific values (terms and their codes) used to describe clinical and administrative concepts in the quality measures. They provide groupings of unique values along with a standard description or definition from one or more standard vocabularies used to describe the same clinical concept (for example, diabetes, clinical visit, demographics) within the quality measures. For more information about eCQM value sets, we refer readers to: <https://ecqi.healthit.gov/ecqm-tools/tool-library/value-set-authority-center-vsac>.

We will consider the most appropriate eCQM value sets for the measure specifications during feasibility testing. The measure concept is currently specified to address concurrent medication prescribing at discharge. We will consider these recommendations in our ongoing measure development efforts, and we thank the commenter for its suggestions.

Comment: One commenter recommended that a denominator exclusion is needed for “Medical Reason” for concurrent discharge medications; and to ensure accurate timeframes of data, the measurement period must be defined in the logic or within the Quality Data Model (QDM) variables.

Response: We thank the commenter for sharing its recommendation regarding excluding “Medical Reason” for concurrent discharge medications from the denominator and defining a measurement period in logic or QDM variables. As currently developed, the measurement period is defined as one year. We will take the commenter’s recommendations into consideration in

our measure development and testing efforts.

Comment: Some commenters expressed concern that the future measure concept is reliant on Prescription Drug Monitoring Programs (PDMP), and until coordinated PDMPs are in place, the measure should not be a part of a quality and patient safety initiative for emergency physician scoring. One commenter expressed concerns that the future measure concept is a poor measure for the ED given the ongoing lack of universal access to reliable PDMP data, the time it would take for ED physicians to gather this data, the potential for unintended consequences, and the relatively low number of opioid prescriptions linked to the ED setting. One commenter requested clarification on whether providers will be required to confirm opioid or benzodiazepine therapy through prescription monitoring programs, and how would this work for hospitals servicing patients from other States. Another commenter asserted that there needs to be a drug monitoring infrastructure that exchanges data with EHRs, dispensing pharmacies, and other relevant sources and compiles the data into one mechanism before CMS develops the concurrent prescribing of opioids measure. This commenter further asserted that implementing the future measure concept without taking in consideration the drug monitoring infrastructure would be premature, potentially confusing, and burdensome for facilities, and result in an inappropriate application of accountability.

Response: We interpret the commenters’ use of the term PDMP to refer to a statewide electronic database, which collects designated data on substances dispensed in the State. We refer readers to <http://www.pdmpassist.org/> for information about PDMPs. We thank the commenters for sharing their concerns about the availability of PDMP data and that a drug monitoring infrastructure should be in place before we implement the proposed measure concept. The measure, as currently specified, uses data from the hospital EHR. We recognize that data on active prescriptions may not always be available, but the measure does not include undocumented prescriptions. This measure is intended to influence current prescribing practices to avoid concurrent prescriptions, but is not prescriptive of how hospitals approach this goal. The commenters’ suggested practices of using PDMPs and interdisciplinary care teams are means to reach that goal. In addition, studies

have shown that there are high rates of opioid prescriptions from ED settings. A study that analyzed data on ED discharges from the 2006 through 2010 National Hospital Ambulatory Medical Care Survey found that opioids were prescribed for 18.7 percent of all ED discharges, representing 21.7 million prescriptions per year.¹⁴⁶ Rates of opioid prescriptions in the outpatient settings may be high, but opioid prescription rates from the ED setting are also significant. We will consider these concerns to inform our ongoing measure development efforts.

Comment: One commenter urged CMS to leave the measure posted for stakeholder input for a substantial length of time (for example, more than 90 days) to allow stakeholders to conduct the necessary information-gathering. This commenter also recommended CMS engage with pharmacists in the future measure concept’s development and implementation.

Response: We thank the commenter for its view and suggestion. We will continue to engage with stakeholders, including pharmacists, as we develop the future measure. We note that because this measure is still in development, additional public input opportunities exist prior to measure proposal in rulemaking, such as during MAP review and the NQF process. We also will consider allowing stakeholders more time to provide input into the development of the future measure concept.

Lastly, we invite all commenters to continue to actively engage in the measures development process for the Hospital OQR Program and other CMS quality reporting programs and encourage them to monitor the CMS Web site for future public input opportunities.

7. Maintenance of Technical Specifications for Quality Measures

CMS maintains technical specifications for previously adopted Hospital OQR Program measures. These specifications are updated as we continue to develop 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=>

¹⁴⁶ Kea, B., Fu, R., Lowe, R., et al. (2016). Interpreting the National Hospital Ambulatory Medical Care Survey: United States Emergency Department Opioid Prescribing, 2006–2010. *American Emergency Medicine*. Wiley Periodicals, Inc. Retrieved [October 2016] from <http://online.library.wiley.com/doi/10.1111/acem.12862/abstract>.

Page&pagename=QnetPublic%2FPPage%2FQnetTier2&cid=1196289981244.

We refer readers to the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68469 through 68470), for a discussion of our policy for updating Hospital OQR Program measures, the same policy we adopted for updating Hospital IQR Program measures, which includes the subregulatory process for making updates to the adopted measures (77 FR 53504 through 53505). This policy expanded upon the subregulatory process for updating measures that we finalized in the CY 2009 OPPTS/ASC final rule with comment period (73 FR 68766 through 68767). In the CY 2017 OPPTS/ASC proposed rule (81 FR 45722), we did not propose any changes to our technical specifications policies.

8. Public Display of Quality Measures

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. It also states 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. In the CY 2017 OPPTS/ASC proposed rule (81 FR 45722), we formalized our current public display practices regarding timing of public display and the preview period, as discussed in more detail below. We also proposed how we will announce the preview period timeframes.

In the CY 2014 OPPTS/ASC proposed rule and final rule with comment period (78 FR 43645 and 78 FR 75092), we stated that we generally strive to display hospital quality measures data on the *Hospital Compare* Web site as soon as possible after measure data have been submitted to CMS. However, if there are unresolved display issues or pending design considerations, we may make the data available on other, non-interactive, CMS Web sites (78 FR 43645). Patient-level data that is chart-abstracted are updated on *Hospital Compare* quarterly, while data from claims-based measures and measures that are submitted using a Web-based tool are updated annually. Historically, preview for the April *Hospital Compare* data release typically occurs in January, preview for the July *Hospital Compare* data release typically occurs in April, preview for the October *Hospital Compare* data release typically occurs in July, and the preview for the December *Hospital Compare* data release typically occurs in October. During the preview period, hospitals have generally had approximately 30 days to preview their data.

In the proposed rule, therefore, we proposed to publicly display data on the *Hospital Compare* Web site, or other CMS Web site, as soon as possible after measure data have been submitted to CMS, consistent with current practice. In addition, we proposed that hospitals will generally have approximately 30 days to preview their data, also consistent with current practice. Lastly, moving forward, we proposed to announce the timeframes for the preview period starting with the CY 2018 payment determination on a CMS Web site and/or on our applicable listservs.

We invited public comments on our public display proposals as discussed above.

Comment: Some commenters supported CMS' proposal to formalize the current public display and reporting practices. One commenter expressed support of CMS' efforts to ensure consumers have adequate information with which to make informed health care decisions. This commenter further expressed that formalizing the current public display and reporting practices will not only help consumers make decisions about where to get their care, but will also encourage hospitals to ensure high quality of care. Another commenter applauded CMS' move toward a more transparent process for quality reporting. This commenter further asserted that making the publication of healthcare data more transparent will better educate both patients and providers, and lead to significant changes and improvement in the delivery system.

Response: We thank the commenters for their support.

Comment: One commenter did not support CMS' proposal to formalize current public display and reporting practices, and recommended CMS revise the preview timeframe from 30 to a minimum of 60 days to allow providers sufficient time to ensure information submitted is accurate.

Response: We believe 30 days is sufficient time for hospitals to preview their data in advance of the information being made public. We also note that the 30-day preview period practice is consistent with the preview period timeframe for publicly reporting program data with the Hospital IQR Program (77 FR 53505), the Hospital Readmissions Reduction Program (76 FR 51672 through 51673), the Hospital-Acquired Condition Reduction Program (78 FR 50727 through 50728), the PPS-Exempt Cancer Hospital Quality Reporting Program (77 FR 53562 through 53563), and the Inpatient Psychiatric Facility Quality Reporting

Program (77 FR 53653 through 77 FR 53654). We also note that the ASCQR Program is finalizing a similar proposal in section XIV.B.7. of this final rule with comment period. We believe that this alignment across CMS quality programs will reduce burden on facilities (78 FR 50898). Furthermore, the complexity of measures and required calculations involve a significant amount of programming resources. Implementing a longer preview period would affect our ability to publish Hospital OQR Program data in a timely manner and result in substantial delays between hospital performance and the public reporting of measure data.

While we understand that a 60-day preview period would allow hospitals more time to review their Hospital OQR Program data prior to its publication, we believe 30 days provides an appropriate balance between sufficient time to review data and timely publication, providing patients with the most up to date information for use in making decisions about their care.

Implementing a longer preview period would affect our ability to publish Hospital OQR Program data in a timely manner and likely result in longer delays between hospital performance and the public reporting of measure data because the complexity of these measures and the required calculations will involve a significant amount of programming resources.

After consideration of the public comments we received, we are finalizing, as proposed starting with the CY 2018 payment determination, our proposals to: (1) Publicly display data on the *Hospital Compare* Web site, or other CMS Web site, as soon as possible after measure data have been submitted to CMS; (2) provide hospitals with approximately 30 days to preview their data; and (3) announce the timeframes for the preview period on a CMS Web site and/or on our applicable listservs.

C. Administrative Requirements

1. QualityNet Account and Security Administrator

The QualityNet security administrator requirements, including setting up a QualityNet account and the associated timelines, are unchanged from those adopted 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). In the CY 2017 OPPTS/ASC proposed rule (81 FR 45722), we did not propose any changes to these requirements.

2. Requirements Regarding Participation Status

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 procedural requirements at 42 CFR 419.46(b). In the CY 2017 OPPTS/ASC proposed rule (81 FR 45722), we did not propose any changes to our requirements regarding participation status.

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 also 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. Those finalized deadlines for the CY 2017 payment determination and CY 2018 payment determination and subsequent years are illustrated in the tables below.

CY 2017 PAYMENT DETERMINATION (TRANSITION PERIOD)

Patient encounter quarter	Clinical data submission deadline
Q3 2015 (July 1–September 30)	2/1/2016
Q4 2015 (October 1–December 31)	5/1/2016
Q1 2016 (January 1–March 31)	8/1/2016

CY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Patient encounter quarter	Clinical data submission deadline
Q2 2016 (April 1–June 30) ...	11/1/2016
Q3 2016 (July 1–September 30)	2/1/2017
Q4 2016 (October 1–December 31)	5/1/2017
Q1 2017 (January 1–March 31)	8/1/2017

In the CY 2017 OPPTS/ASC proposed rule (81 FR 45722 through 45723), we did not propose any changes to these policies.

2. Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS for the CY 2019 Payment Determination and Subsequent Years

The following previously finalized Hospital OQR Program chart-abstracted measures require patient-level data to be submitted for the CY 2019 payment determination and subsequent years:

- OP–1: Median Time to Fibrinolysis (NQF #0287);
- 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–4: Aspirin at Arrival (NQF #0286);
- 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–20: Door to Diagnostic Evaluation by a Qualified Medical Professional;
- OP–21: Median Time to Pain Management for Long Bone Fracture (NQF #0662); and
- OP–23: Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT Scan Interpretation Within 45 Minutes of ED Arrival (NQF #0661).

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 these measures for the CY 2014 payment determination and subsequent years.

In the CY 2017 OPPTS/ASC proposed rule (81 FR 45723), we did not propose any changes to our policies regarding the submission of chart abstracted measure data where patient-level data are submitted directly to CMS.

3. Claims-Based Measure Data Requirements for the CY 2019 Payment Determination and Subsequent Years and CY 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2014 OPPTS/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 the CY 2017 OPPTS/ASC proposed rule (81 FR 45723),

we did not propose any changes to these policies for the CY 2019 payment determination.

However, in sections XIII.B.5.a. and b. of this final rule with comment period, we are adopting two claims-based measures beginning with the CY 2020 payment determination: OP–35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy; and OP–36: Hospital Visits after Hospital Outpatient Surgery. The previously adopted submission requirements also apply to these measures.

There will be 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).

In the CY 2017 OPPTS/ASC proposed rule (81 FR 45723), we did not propose any changes to our claims-based measures submission policies for the CY 2020 payment determination and subsequent years.

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

As discussed in section XIII.B.5.c. of this final rule with comment period, we are adopting five survey-based measures derived from the OAS CAHPS Survey for the CY 2020 payment determination and subsequent years—three OAS CAHPS composite survey-based measures and two global survey-based measures. In this section, we proposed requirements related to survey administration and vendors. We note that we are adopting similar policies in

the ASCQR Program in section XIV.D.5. of this final rule with comment period.

a. Survey Requirements

The survey has three administration methods: Mail-only; telephone-only; and mixed mode (mail with telephone follow-up of nonrespondents). We refer readers to the Protocols and Guidelines Manual for the OAS CAHPS Survey (<https://oascahps.org/Survey-Materials>) for materials for each mode of survey administration.

For all three modes of administration, we proposed that data collection must be initiated no later than 21 days after the month in which a patient has a surgery or procedure at a hospital, and completed within 6 weeks (42 days) after initial contact of eligible patients begins. We proposed that hospitals, via their CMS-approved vendors (discussed below), must make multiple attempts to contact eligible patients unless the patient refuses or the hospital/vendor learns that the patient is ineligible to participate in the survey. In addition, we proposed that hospitals, via their CMS-approved survey vendor, collect survey data for all eligible patients using the timeline established above and report that data to CMS by the quarterly deadlines established for each data collection period unless the hospital has been exempted from the OAS CAHPS Survey requirements under the low volume exemption discussed in section XIII.B.5.c.(6) of this final rule with comment period, above. These submission deadlines would be posted on the OAS CAHPS Survey Web site (<https://oascahps.org>). Late submissions would not be accepted.

As discussed in more detail below, compliance with the OAS CAHPS Survey protocols and guidelines, including this monthly reporting requirement, will be overseen by CMS or its contractor that will receive approved vendors' monthly submissions, review the data, and analyze the results. As stated previously, all data collection and submission for the OAS CAHPS Survey measures is done at the Medicare participating hospital level, as identified by its CCN. All locations, that offer outpatient services, of each eligible Medicare participating hospital would be required to participate in the OAS CAHPS Survey. Therefore, the survey data reported using a Medicare participating hospital's CCN must include all eligible patients from all outpatient locations (whether the hospital outpatient department is on campus or off campus) of eligible Medicare participating hospital. Survey vendors acting on behalf of hospitals

must submit data by the specified data submission deadlines. If a hospital's data are submitted after the data submission deadline, it will not fulfill the OAS CAHPS quality reporting requirements. We therefore strongly encourage hospitals to be fully appraised of the methods and actions of their survey vendors—especially the vendors' full compliance with OAS CAHPS Survey administration protocols—and to carefully inspect all data warehouse reports in a timely manner.

We note that the use of predictive or auto dialers in telephonic survey administration is governed by the Telephone Consumer Protection Act (TCPA) (47 U.S.C. 227) and subsequent regulations promulgated by the Federal Communications Commission (FCC) (47 CFR 64.1200) and Federal Trade Commission. We refer readers to the FCC's declaratory ruling released on July 10, 2015 further clarifying the definition of an auto dialer, available at: https://apps.fcc.gov/edocs_public/attachmatch/FCC-15-72A1.pdf. In the telephone-only and mixed mode survey administration methods, HOPDs and vendors must comply with the regulations discussed above, and any other applicable regulations. To the extent that any existing CMS technical guidance conflicts with the TCPA or its implementing regulations regarding the use of predictive or auto dialers, or any other applicable law, CMS expects vendors to comply with applicable law.

b. Vendor Requirements

To ensure that patients respond to the survey in a way that reflects their actual experiences with outpatient surgical care, and is not influenced by the hospital, we proposed that hospitals must contract with a CMS-approved OAS CAHPS Survey vendor to conduct or administer the survey. We believe that a neutral third-party should administer the survey for hospitals, and it is our belief that an experienced survey vendor will be best able to ensure reliable results. CAHPS survey approved vendors are also already used or required in the following CMS quality programs: the Hospital IQR Program (71 FR 68203 through 68204); the Hospital VBP Program (76 FR 26497, 26502 through 26503, and 26510); the ESRD QIP (76 FR 70269 through 70270); the HH QRP (80 FR 68709 through 68710); and the HQRPs (80 FR 47141 through 47207).

Information about the list of approved survey vendors and how to authorize a vendor to collect data on a hospital's behalf is available through the OAS CAHPS Survey Web site at: <https://>

oascahps.org. The Web portal has both public and secure (restricted access) sections to ensure the security and privacy of selected interactions. Hospitals will need to register on the OAS CAHPS Survey Web site (<https://oascahps.org>) in order to authorize the CMS-approved vendor to administer the survey and submit data on their behalf. Each hospital must then administer (via its vendor) the survey to all eligible patients treated during the data collection period on a monthly basis according to the guidelines in the Protocols and Guidelines Manual (<https://oascahps.org>) and report the survey data to CMS on a quarterly basis by the deadlines posted on the OAS CAHPS Survey Web site as stated above. Moreover, we proposed to codify these OAS CAHPS Survey administration requirements for hospitals and survey vendors under the Hospital OQR Program at 42 CFR 419.46(g).

As stated previously, we encourage hospitals to participate in voluntary national implementation of the OAS CAHPS Survey that began in January 2016. This will provide hospitals the opportunity to gain first-hand experience collecting and transmitting OAS CAHPS data without the public reporting of results or Hospital OQR Program payment implications. For additional information, we refer readers to: <https://oascahps.org/General-Information/National-Implementation>.

We invited public comments on our proposals for the data submission requirements for the five proposed OAS CAHPS Survey measures for the CY 2020 payment determination and subsequent years as discussed above.

Comment: Many commenters recommended that CMS include an electronic method of administration, such as portal messages and/or email, for the OAS CAHPS Survey because electronic methods of survey administration would be more cost-effective for hospitals and more convenient for patients than administration via phone or standard mail. One commenter noted that electronic survey administration has allowed many hospitals to achieve significant cost savings in the administration of patient surveys, and asserted electronic administration may increase patient response rates. Some commenters expressed concerns that CMS has not explored and tested alternative data collection methods that may significantly decrease providers' cost in administering the survey and enhance patient participation. The commenters expressed concerns that CMS has not tested the OAS CAHPS

Survey in an online format as an alternative mode of administration of the survey.

Response: While email and Web-based survey administration modes are not available at this time, we are actively investigating these modes as possible new options for the future. This ongoing investigation includes, among other things, determining whether hospitals receive reliable email addresses from patients, whether there is adequate access to the Internet across all types of patients, and whether implementing a Web-based survey administration method would introduce bias into the survey administration process. However, we note that a previous study¹⁴⁷ investigating the suitability of speech-enabled interactive voice response (SE-IVR) and Web modes for publicly reported surveys of patients' experience of hospital care found lower response rates for mixed-mode administrations including a Web-based option than for mail-only and SE-IVR administrations. Portal messaging, like systems that are sometimes used to address patient questions, would require a Web portal that patients can access. If this were housed at the facility, patient confidentiality could potentially be an issue. Furthermore, as currently specified, the OAS CAHPS Survey requires that the survey be administered by an approved survey vendor. This is to ensure that patients respond to the survey in a way that reflects their actual experiences with outpatient surgical care, and is not influenced by the hospital. Removing vendors, neutral third parties, could raise issues of objectivity and bias. However, as stated above, we are actively investigating new modes of conducting this survey as possible options for the future. We believe that the data collected by this measure is so significant and important that collecting data and publicly reporting it sooner rather than later outweighs waiting for a Web-based survey administration method to be developed, tested, and implemented nationwide.

After consideration of the public comments we received, we are finalizing our proposals for the data submission requirements for the five OAS CAHPS Survey measures we are finalizing for the CY 2020 payment determination and subsequent years as proposed.

¹⁴⁷ Elliot, MN, Brown JA, Lehrman WG, Beckett MK, Hambarsoomian K, Giordano LA, Goldstein EH. A randomized experiment investigating the suitability of speech-enabled IVR and Web modes for publicly reported surveys of patients' experience of hospital care. *Med Care Res Rev*. 2013 April;70(2): 165-84.

5. Data Submission Requirements for Previously Finalized Measures for Data Submitted via a Web-Based Tool for the CY 2019 Payment Determination and Subsequent Years

The following Web-based quality measures previously finalized and retained in the Hospital OQR Program require data to be submitted via a Web-based tool (CMS' QualityNet Web site or CDC's NHSN Web site) for the CY 2018 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-25: Safe Surgery Checklist Use (via CMS' QualityNet Web site);
- OP-26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (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).

We refer readers to the CY 2014 OPPTS/ASC final rule with comment period (78 FR 75112 through 75115) and the CY 2016 OPPTS/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%2FPPage%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 OPPTS/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 CDC NHSN Web site.

In the CY 2017 OPPTS/ASC proposed rule (81 FR 45724 through 45725), we did not propose any changes to our policies regarding the submission of measure data submitted via a Web-based tool.

6. Population and Sampling Data Requirements for the CY 2019 Payment Determination and Subsequent Years

We refer readers to the CY 2011 OPPTS/ASC final rule with comment period (75 FR 72100 through 72103) and the CY 2012 OPPTS/ASC final rule with comment period (76 FR 74482 through 74483) for discussions of our policy that hospitals may voluntarily submit aggregate population and sample size counts for Medicare and non-Medicare encounters for the measure populations for which chart-abstracted data must be submitted.

In the CY 2017 OPPTS/ASC proposed rule (81 FR 45725), we did not propose 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 2019 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68484 through 68487) and the CY 2015 OPPTS/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 OPPTS/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 the CY 2017 OPPTS/ASC proposed rule (81 FR 45725), we did not propose any changes to our validation requirements.

8. Extension or Exemption Process for the CY 2019 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 proposed rule (81 FR 45725), we proposed to update 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. This proposal would become effective with ECEs requested on or after January 1, 2017. In the past, we have allowed hospitals to submit an ECE request form for measures within 45 days following an event that causes hardship and prevents them from providing data for measures (76 FR 74478 through 74479). In certain circumstances, however, it may be difficult for hospitals to timely evaluate the impact of certain extraordinary events within 45 days. We believe that extending the deadline to 90 days would allow hospitals more time to determine whether it is necessary and appropriate to submit an ECE request and to provide a more comprehensive account of the extraordinary circumstance in their ECE request form to CMS. For example, if a hospital has suffered damage due to a hurricane on January 1, it would have until March 31 to submit an ECE form via the QualityNet Secure Portal, mail, email, or secure fax as instructed on the ECE form.

This timeframe (90 calendar days) also aligns with the ECE request deadlines for the Hospital VBP Program (78 FR 50706), the Hospital-Acquired Condition Reduction Program (80 FR 49580), and the Hospital Readmissions Reduction Program (80 FR 49542 through 49543). We note that in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57181 through 81 FR 57182; 81 FR 57230 through 57231), we finalized a deadline of 90 days following an event causing hardship for the Hospital IQR Program (in non-eCQM circumstances) and for the LTCH QRP Program. In section XIV.D.6. of this final rule with comment period, we also are also

finalizing a deadline of 90 days following an event causing hardship for the ASCQR Program.

We invited public comments on our proposal to extend the submission deadline for an extraordinary circumstances extension or exemption to within 90 days of the date that the extraordinary circumstance occurred, effective January 1, 2017, for the CY 2019 payment determination and subsequent years, as discussed above.

Comment: Commenters supported CMS' proposal to change the extraordinary circumstances extension request deadline from 45 days to 90 days following an event causing hardship. The commenters asserted that extending the deadline for filing from 45 to 90 days will allow facilities to respond to the event and ensure patient safety before submitting the request for an extension or exemption.

Response: We thank the commenters for their support.

After consideration of the public comments received, we are finalizing our proposal to extend the submission deadline for requests for an extraordinary circumstances extension or exemption to within 90 days of the date that the extraordinary circumstance occurred, effective January 1, 2017, for the CY 2019 payment determination and subsequent years, as proposed.

9. Hospital OQR Program Reconsideration and Appeals Procedures for the CY 2019 Payment Determination and Subsequent Years—Clarification

We are making one clarification to our reconsideration and appeals 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), and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524) for a discussion of our reconsideration and appeals procedures. Currently, a hospital must submit a reconsideration request to CMS via the QualityNet Web site no later than the first business day of the month of February of the affected payment year (78 FR 75118 through 75119). A hospital that is dissatisfied with a decision made by CMS on its reconsideration request may file an appeal with the Provider Reimbursement Review Board (78 FR 75118 through 75119). Beginning with the CY 2018 payment determination, however, hospitals must submit a reconsideration request to CMS via the QualityNet Web site by no later than the first business day on or after March 17 of the affected payment year (80 FR

70524). 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.

In the CY 2017 OPPS/ASC proposed rule (81 FR 45725), we clarified our policy regarding appeals procedures. Specifically, if a hospital fails to submit a timely reconsideration request to CMS via the QualityNet Web site by the applicable deadline, then the hospital will not subsequently be eligible to file an appeal with the Provider Reimbursement Review Board. This clarification will be effective January 1, 2017 for the CY 2017 payment determination and subsequent years.

We did not receive any public comments on our clarification to our reconsideration and appeals procedures. In summary, for the CY 2017 payment determination and subsequent years, we clarify that if a hospital fails to submit a timely reconsideration request to CMS via the QualityNet Web site by the applicable deadline, then the hospital will not subsequently be eligible to file an appeal with the Provider Reimbursement Review Board.

E. Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2017 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 the 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 payment year.

The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data in order to receive the full payment update factor and that fail to meet the Hospital OQR Program requirements. Hospitals that meet the reporting requirements receive the full OPPS payment update without

the reduction. For a more detailed discussion of how this payment reduction was initially implemented, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative payment weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to the proposed rule, which is available via the Internet on the CMS Web site): “J1,” “J2,” “P,” “Q1,” “Q2,” “Q3,” “R,” “S,” “T,” “V,” or “U.” 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 final rule with comment period.

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2017

In the CY 2017 OPPS/ASC proposed rule (81 FR 45726 through 45727), we proposed to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2017 annual payment update factor. For the CY 2017 OPPS, the proposed reporting ratio is 0.980, calculated by dividing the proposed reduced conversion factor of 73.411 by the proposed full conversion factor of 74.909. We proposed to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2017 OPPS, we proposed 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,” “Q4,” “R,” “S,” “T,” “V,” and “U” (other than new technology APCs to which we have proposed status indicator assignment of “S” and “T”). We proposed to continue to exclude services paid under New Technology APCs. We proposed to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements. We also proposed to continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we proposed to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements.

We invited public comments on these proposals. We did not receive any public comments on these proposals. In this final rule with comment period, we are clarifying 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 through the OPPS. Otherwise, we are finalizing application of the reporting ratio as proposed. For the CY 2017 OPPS, the final reporting ratio is 0.980, calculated by dividing the final reduced conversion factor of \$75.001 by the final full conversion factor of \$73.501.

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 final rule with comment period 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 refer readers to section XV.A.3. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 75122), section XIV.4. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66966 through 66987), and section XIV. of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70526 through 70537) 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 OPPS/ASC final rule with comment period (77 FR 68493 through 68494) for a detailed discussion of the priorities we consider for ASCQR Program quality measure selection. In the CY 2017 OPPS/ASC proposed rule (81 FR 45727),

we did not propose any changes to this policy.

2. Policies for Retention and Removal of Quality Measures From the ASCQR Program

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; 79 FR 66967 through 66969). In the CY 2017 OPPS/ASC proposed rule (81 FR 45727), we did not propose any changes to this policy.

We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66967 through 66969) and 42 CFR 416.320 for a detailed discussion of the process for removing adopted measures from the ASCQR Program. In the CY 2017 OPPS/ASC proposed rule (81 FR 45727), we did not propose any changes to this process.

3. ASCQR Program Quality Measures Adopted in Previous Rulemaking

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517), we implemented the ASCQR Program effective with the CY 2014 payment determination. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74496 through 74511), we adopted five claims-based measures for the CY 2014 payment determination and subsequent years, two measures with data submission

directly to CMS via an online data submission tool for the CY 2015 payment determination and subsequent years, and one process of care, preventive service measure submitted via an online data submission tool to CDC's National Health Safety Network (NHSN) for the CY 2017 payment determination and subsequent years. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75124 through 75130), we adopted three chart-abstracted measures with data submission to CMS via an online data submission tool for the CY 2017 payment determination and subsequent years. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985), we excluded one of these measures, ASC-11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536), from the CY 2017 payment determination measure set and allowed for voluntary data collection and reporting for the CY 2017 payment determination and subsequent years. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66970 through 66979), we adopted one additional claims-based measure for the CY 2018 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70526 through 70537), we did not adopt any additional measures for the CY 2019 payment determination and subsequent years.

The previously finalized measure set for the ASCQR Program for the CY 2019 payment determination and subsequent years is listed below.

ASCQR PROGRAM MEASURE SET PREVIOUSLY FINALIZED FOR THE CY 2019 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	N/A	Safe Surgery Checklist Use.
ASC-7	N/A	ASC Facility Volume Data on Selected ASC Surgical 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.

† We note that NQF endorsement for this measure was removed.

* Procedure categories and corresponding HCPCS codes are located at: <http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPages%2FQnetTier2&cid=1228772475754>.

** Measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in section XIV.E.3.c. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).

4. ASCQR Program Quality Measures 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 75124) for a detailed discussion of our approach to measure selection for the ASCQR Program. In the CY 2017 OPPS/ASC proposed rule (81 FR 45728 through 45734), we proposed to adopt a total of seven measures for the CY 2020 payment determination and subsequent years: Two measures collected via a CMS online data submission tool and five Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures. The two measures that require data to be submitted directly to CMS via an online data submission tool are: (1) ASC-13: Normothermia Outcome; and (2) ASC-14: Unplanned Anterior Vitrectomy. The five proposed survey-based measures (ASC-15a-e) are collected via the OAS CAHPS Survey. These measures are discussed in detail below.

a. ASC-13: Normothermia Outcome

(1) Background

Impairment of thermoregulatory control due to anesthesia may result in perioperative hypothermia. Perioperative hypothermia is associated with numerous adverse outcomes, including: Cardiac complications;¹⁴⁸ surgical site infections;¹⁴⁹ impaired coagulation;¹⁵⁰ and colligation of drug effects;¹⁵¹ as well as post-anesthetic shivering and thermal discomfort. When intraoperative normothermia is maintained, patients experience fewer adverse outcomes and their overall care costs are lower.¹⁵² Several methods to maintain normothermia are available. While there is no literature currently available on variation in rates of normothermia among ASC facilities, variability in maintaining normothermia

¹⁴⁸ Frank SM, Fleisher LA, Breslow MJ, et al. Perioperative maintenance of normothermia reduces the incidence of morbid cardiac events: A randomized clinical trial. *JAMA*. 1997;277(14):1127-1134.

¹⁴⁹ Kurz A, Sessler DI, Lenhardt R. Perioperative normothermia to reduce the incidence of surgical-wound infection and shorten hospitalization: Study of wound infection and temperature group. *N Engl J Med*. 1996;334(19):1209-1215.

¹⁵⁰ Rajagopalan S, Mascha E, Na J, Sessler DI. The effects of mild hypothermia on blood loss and transfusion requirements during total hip arthroplasty. *Lancet*. 1996;347(8997):289-292.

¹⁵¹ Kurz A. Physiology of thermoregulation. *Best Pract Res Clin Anaesthesiol*. 2008;22(4):627-644.

¹⁵² Mahoney CB, Odom J. Maintaining intraoperative normothermia: A meta-analysis of outcomes with costs. *AANA Journal*. 1999;67(2):155-164.

has been demonstrated in other clinical care settings.¹⁵³ This measure provides the opportunity for ASCs to improve quality of care and lower the rates of anesthesia-related complications in the ASC setting.

(2) Overview of Measure

We believe it is important to monitor the rate of anesthesia-related complications in the ASC setting because many surgical procedures performed at ASCs involve anesthesia. Therefore, we proposed to adopt the ASC-13: Normothermia Outcome 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 2020 payment determination and subsequent years. We expect the measure will promote improvement in patient care over time, because measurement coupled with transparency in publicly reporting of measure information would make patient outcomes following procedures performed under general or neuraxial anesthesia more visible to ASCs and patients and incentivize ASCs to incorporate quality improvement activities to reduce perioperative hypothermia and associated complications 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-13 measure was included on a publicly available document entitled "List of Measures under Consideration for December 1, 2014."¹⁵⁴ The MAP reviewed the measure (MUC ID: X3719) and conditionally supported it for the ASCQR Program, pending completion of reliability testing and NQF review and endorsement.¹⁵⁵ The MAP agreed that

¹⁵³ Frank SM, Beattie C, Christopherson R, et al. Unintentional Hypothermia is associated with Postoperative Myocardial Ischemia: The Perioperative Ischemia Randomized Anesthesia Trial Study Group. *Anesthesiology* 1993;78(3):468-476.

¹⁵⁴ National Quality Forum. *List of Measures under Consideration for December 1, 2014*. National Quality Forum, Dec. 2014. Available at: https://www.qualityforum.org/Setting_Priorities/Partnership/Measures_Under_Consideration_List_2014.aspx.

¹⁵⁵ National Quality Forum. *MAP 2015 Final Recommendations to HHS and CMS*. Rep. National Quality Forum, Jan. 2015. Available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711>.

this measure is highly impactful and meaningful to patients. It stated that anesthetic-induced thermoregulatory impairment may cause perioperative hypothermia, which is associated with adverse outcomes including significant morbidity (decrease in tissue metabolic rate, myocardial ischemia, surgical site infections, bleeding diatheses, prolongation of drug effects) and mortality. As an intermediate outcome measure, the workgroup agreed that this measure moves towards an outcome measure that fills the workgroup identified gap of anesthesia-related complications.¹⁵⁶

Furthermore, 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-13 measure is not NQF-endorsed. However, this measure is maintained by the ASC Quality Collaboration,¹⁵⁷ 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 procedures using anesthesia are commonly performed in ASCs and, as discussed above, maintenance of

¹⁵⁶ Ibid.

¹⁵⁷ ASC Quality Collaboration. "ASC Quality Collaboration." Available at: <http://www.ascquality.org/>.

perioperative normothermia can signify important issues in the care being provided by ASCs. While the Normothermia Outcome 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 measure for use in the ASCQR Program. The MAP agreed that this measure “is highly impactful and meaningful to patients” and that, as an intermediate outcome measure, the Normothermia Outcome measure moves towards an outcome measure that fills the workgroup-identified gap of anesthesia-related complications. Moreover, we believe this measure is reliable because reliability testing completed by the measure steward comparing ASC-reported normothermia rates and re-abstracted normothermia rates found the difference from originally submitted and re-abstracted normothermia rates ranged from -1.6 percent to 0.9 percent, with a 95 percent confidence interval of -0.9 percent, 0.5 percent. Because this confidence interval includes zero, there is no evidence that the submitted and abstracted rates are statistically different at the $p = 0.05$ level. Therefore, we believe there is strong evidence that the Normothermia Outcome measure is reliable.

(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 proposed that the data collection period for the proposed ASC-13 measure would be the calendar year 2 years prior to the applicable payment determination year. For example, for the CY 2020 payment determination, the data collection period would be CY 2018. We also proposed 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 2020 payment determination, the submission period would be January 1, 2019 to May 15, 2019. We refer readers to section XIV.D.3.b. of this final rule with comment period 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-13 measure is the percentage of patients having surgical procedures under general or neuraxial anesthesia of 60 minutes or more in

duration who are normothermic within 15 minutes of arrival in the post-anesthesia care unit (PACU). The numerator is the number of surgery patients with a body temperature equal to or greater than 96.8 degrees Fahrenheit/ 36 degrees Celsius recorded within 15 minutes of arrival in the PACU. The denominator is all patients, regardless of age, undergoing surgical procedures under general or neuraxial anesthesia of greater than or equal to 60 minutes in duration.

(5) Cohort

The measure includes all patients, regardless of age, undergoing surgical procedures under general or neuraxial anesthesia of greater than or equal to 60 minutes' duration.

The measure excludes: Patients who did not have general or neuraxial anesthesia; patients whose length of anesthesia was less than 60 minutes; and patients with physician/advanced practice nurse/physician assistant documentation of intentional hypothermia for the procedure performed. 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 measure is not risk-adjusted.

We invited public comments on our proposal to adopt the ASC-13: Normothermia Outcome measure for the CY 2020 payment determination and subsequent years as discussed above.

Comment: Many commenters supported adoption of the proposed ASC-13 measure because impairment of thermoregulatory control due to anesthesia may result in perioperative hypothermia, which has been associated with numerous adverse outcomes, and commenters believe this measure would promote improvement in patient care outcomes. Some commenters supported adoption of the proposed ASC-13 measure because the commenters believe this measure will promote improvement in patient care over time, and incentivize ASCs to engage in more quality improvement activities through public reporting of measure performance data.

Response: We thank commenters for their support.

Comment: A number of commenters did not support adoption of the proposed ASC-13 measure because they believe there is a lack of evidence of a performance gap in this area for ASCs.

Response: While we acknowledge there is currently a lack of evidence

regarding a performance gap in normothermia outcomes, we believe the serious adverse outcomes associated with perioperative hypothermia, coupled with the frequency of procedures using anesthesia being performed in ASCs, warrant proactive monitoring of normothermia outcomes in the ASC setting. In addition, we note that some evidence suggests variability in normothermia maintenance in other clinical settings.¹⁵⁸ We also believe the resulting publicly reported data on normothermia outcomes will help inform patient decision-making, and incentivize ASCs to engage in quality improvement efforts.

Comment: A few commenters did not support adoption of the proposed ASC-13 measure because the measure is chart-abstracted and because the measure is not NQF-endorsed.

Response: In selecting measures for the ASCQR Program, we weigh the relevance and utility of measures against the potential burden to ASCs resulting from the measure's adoption. While we understand the commenters' concerns regarding the burden of chart-abstraction measures, we believe the benefits of including it in the ASCQR Program and publicly reporting normothermia outcome data for use in patient decision-making and incentivizing ASCs to engage in quality improvement efforts to reduce rates of perioperative hypothermia outweigh the burden associated with collecting aggregate data on patients treated at an ASC.

In addition, as we discuss above, section 1833(t)(17)(C)(i) of the Act does not require that each measure we adopt for the ASCQR Program be endorsed by a national consensus building entity, or 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. While we strive to adopt NQF-endorsed measures when possible, we believe the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad acceptance and use of the measure, and through public comments. As noted in the CY 2017 OPPS/ASC proposed rule (81 FR 45728), ASC-13 is maintained by

¹⁵⁸ Frank SM, Beattie C, Christopherson R, et al. Unintentional Hypothermia is associated with Postoperative Myocardial Ischemia: The Perioperative Ischemia Randomized Anesthesia Trial Study Group. *Anesthesiology* 1993;78(3):468-476.

the ASC Quality Collaboration, an entity recognized within the community as an expert in measure development for the ASC setting. In addition, this measure is already publicly reported as part of the ASC Quality Collaboration's quarterly Quality Report. Furthermore, the MAP, which represents stakeholder groups, reviewed and conditionally supported the measure for use in the ASCQR Program. Therefore, we believe the measure reflects consensus among affected parties.

Comment: One commenter asserted that, because the proposed ASC-13 measure only tracks post-operative temperature and not perioperative temperature, it is an inappropriate or imprecise quality measure, and therefore, should not be included in the ASCQR Program measure set.

Response: We disagree with the commenter's assertion that only tracking patient temperature immediately following anesthesia end time results in an imprecise or inappropriate quality measure. The field testing conducted for the ASC-13 measure found that, under its current specifications, the measure is able to distinguish levels of performance across facilities, thereby demonstrating its precision as a quality measure. We therefore believe the measure as currently specified is appropriate for use in the ASCQR Program, because we believe it will incentivize ASCs to engage in quality improvement efforts around patients' return to normothermia. One of the central goals of the ASCQR Program is to drive improvement in the quality of care provide in the ASC setting, and we, therefore, believe the measure's focus on return to normothermia within 15 minutes of arrival in the PACU is appropriate for assessing ASC performance on this measure. However, we will continue to assess the appropriateness and precision of this measure as currently specified as a driver of quality improvement.

Comment: One commenter noted that a similar measure was previously used for inpatient surgical procedures and subsequently retired based on sustained improvement in normothermia following general anesthesia. The commenter recommended that the ASCQR Program take a similar approach by adopting the proposed ASC-13 measure and then retiring the measure once there is validation of sustained normothermia compliance.

Response: We thank the commenter for its recommendation and note that the ASCQR Program has previously adopted policies regarding the retention and removal of quality measures (76 FR 74494 and 74504; 77 FR 68494 through

68495; 78 FR 75122; 79 FR 66967 through 66969). One of these criteria is an assessment of whether a measure is "topped out," or when measure performance is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (79 FR 66968). As we noted in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70527), the benefits of removing a measure from the ASCQR Program will be assessed on a case-by-case basis. We will evaluate all measures adopted for the ASCQR Program against these criteria as a whole in determining whether to suspend or remove a previously adopted measure from the ASCQR Program measure set.

Comment: One commenter urged CMS to ensure that the proposed ASC-13 measure population exclude procedures where propofol is administered because propofol is not general anesthesia. The commenter further recommended that CMS exclude non-surgical procedures, such as endoscopy, from this measure.

Response: Depending on the dose administered, propofol may in fact be used for moderate sedation, monitored anesthesia care, and the induction/maintenance of general anesthesia. The ASC-13 measure only includes procedures performed under general or neuraxial anesthesia of 60 minutes or more in duration and, as a result, only procedures in which propofol is used as a general anesthetic for 60 minutes or more would be included in this measure. We refer readers to the measure methodology where this is discussed, <http://www.ascquality.org/qualitymeasures.cfm>, under "ASC Quality Collaboration Measures Implementation Guide." While these instances may be rare, we believe it is appropriate to include procedures where propofol is used as a general anesthetic in this measure, because those procedures are subject to the same patient outcome concerns regarding maintenance of normothermia as procedures performed using other anesthetics. We also note that the majority of endoscopy procedures do not involve general anesthesia, and would, therefore, be excluded from the measure. However, nonsurgical procedures performed under general or neuraxial anesthesia of 60 minutes or more in duration would be included in the measure. Again, while these procedures may be rare, we believe it is important to capture patient outcome data for these procedures in order to incentivize quality improvement among ASCs in normothermia maintenance.

Comment: One commenter noted that the 2015 Surgical Standing Committee convened by NQF approved a change in the definition of normothermia from 36 degrees Celsius/96.8 degrees Fahrenheit to 35.5 degrees Celsius/95.9 degrees Fahrenheit, and that NQF endorsed this changed definition in September 2015. The commenter also expressed concern that adopting the Normothermia Outcome measure in the ASCQR Program using a less current definition of "normothermia" may result in misalignment in quality measurement across federal healthcare quality programs. The commenter therefore recommended CMS adopt the proposed Normothermia Outcome measure with one modification, to use the more current definition of "normothermia."

Response: We thank the commenter for its recommendation. We believe the commenter is referring to the 2014 Surgery Project at NQF, which released its final report in December of 2015. This report is available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81394>. We interpret the commenter's reference to a "change in the definition of normothermia" to refer to a different, recently endorsed measure, NQF #2681: Perioperative Temperature Management, which uses a temperature threshold of 35.5 degrees Celsius/95.9 degrees Fahrenheit, as opposed to the 36 degrees Celsius/96.8 degree Fahrenheit threshold used in the ASC-13 measure. We believe using the higher temperature threshold for normothermia is still clinically appropriate. This higher temperature threshold has been used as the definition of normothermia in a number of journal articles and best practices reviews,¹⁵⁹ and is maintained in the American Society of PeriAnesthesia Nurses' Clinical Guideline for the Prevention of Unplanned Perioperative Hypothermia.¹⁶⁰ Furthermore, we believe maintaining a higher temperature threshold for normothermia under the ASC-13 measure will provide greater incentive for ASCs to engage in quality improvement in this area by encouraging facilities to engage in more proactive perioperative temperature maintenance in order to shorten patients' time for return to normothermia. In addition, the MAP agreed that this measure "is highly impactful and meaningful to patients."

¹⁵⁹ Kurz, A. Thermal care in the perioperative period. *Best Pract Res Clin Anesthesiol.* 2008;22:39-62.

¹⁶⁰ Hoover VD et al. ASPAN's evidence-based clinical practice guideline for the promotion of perioperative normothermia: Second edition. *J Perianesth Nurs.* 2010 Dec; 25(6):346-365.

Therefore, we believe finalizing the measure along with the measure's definition of normothermia as proposed is appropriate. However, we appreciate commenters' concerns that this measure may have an unclear performance gap and that this measure's lower bound for normothermia does not match the lower bound for normothermia in NQF #2681, a measure we recently finalized for inclusion in the quality category of the Merit-based Incentive Payment System. We will engage the measure steward in harmonization efforts. We will discuss our continued evaluation of this measure in a future year's rulemaking.

After consideration of the public comments we received, we are finalizing our proposal to adopt the ASC-13: Normothermia Outcome measure for the ASCQR Program for the CY 2020 payment determination and subsequent years as proposed. We will discuss our continued evaluation of this measure in a future year's rulemaking.

b. ASC-14: Unplanned Anterior Vitrectomy

(1) Background

An unplanned anterior vitrectomy is performed when vitreous inadvertently prolapses into the anterior segment of the eye during cataract surgery. Cataracts are a leading cause of blindness in the United States, with 24.4 million cases in 2010.¹⁶¹ Each year, approximately 1.5 million patients undergo cataract surgery to improve their vision.¹⁶² While unplanned anterior vitrectomy rates are relatively low, complications from this procedure may result in poor visual outcomes and other complications, including retinal detachment.¹⁶³ Cataract surgery is the most common surgery performed in ASCs; therefore, this measure is of interest to the ASC Program.¹⁶⁴

(2) Overview of Measure

Based on the prevalence of cataract surgery in the ASC setting, we believe it is important to minimize adverse

patient outcomes associated with cataract surgery. Therefore, we proposed to adopt the ASC-14: Unplanned Anterior Vitrectomy measure in the ASCQR Program for the CY 2020 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 this unplanned procedure at ASCs more visible to both ASCs and patients and would incentivize ASCs to incorporate quality improvement activities to reduce the occurrence of unplanned anterior vitrectomies. The measure also addresses the MAP-identified priority measure area of procedure complications for the ASCQR Program.¹⁶⁵

The ASC-14 measure we proposed was included on a publicly available document entitled "List of Measures under Consideration for December 1, 2014."¹⁶⁶ The MAP reviewed this measure (MUC ID: X3720) and conditionally supported it for the ASCQR Program, pending completion of reliability testing and NQF review and endorsement.¹⁶⁷ The MAP agreed that this measure is highly impactful and meaningful to patients.¹⁶⁸ It stated that according to the National Eye Institute report in 2002, more than half of U.S. residents over 65 years have a cataract.¹⁶⁹ Furthermore, cataracts are a leading cause of blindness, with more than 1.5 million cataract surgeries performed annually to improve the vision of those with cataracts.¹⁷⁰ Unplanned anterior vitrectomy is a recognized adverse intraoperative event during cataract surgery occurring in two to four percent of all cases,¹⁷¹ with some

research showing that rates of unplanned anterior vitrectomy are higher among less experienced surgeons.¹⁷² The MAP continued to state that an anterior vitrectomy, the repair of a rupture in a mainly liquid portion of the eye, is generally an unplanned complication of a cataract surgery.¹⁷³ The MAP agreed that this is an outcome measure that fills the workgroup identified priority gap of procedure complications.¹⁷⁴

The proposed ASC-14 measure is not NQF-endorsed. However, this measure is maintained by the ASC Quality Collaboration,¹⁷⁵ an entity recognized within the community as an expert in measure development for the ASC setting of care. We believe that this measure is appropriate for the measurement of quality care furnished by ASCs, because cataract surgery is commonly performed in ASCs and, as discussed above, complications such as unplanned anterior vitrectomy can signify important issues in the care being provided by ASCs. While the Unplanned Anterior Vitrectomy 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 measure for use in the ASCQR Program. The MAP stated that the Unplanned Anterior Vitrectomy measure is "highly impactful and meaningful to patients" because cataracts are a leading cause of blindness among Americans and an unplanned anterior vitrectomy is a generally unplanned complication of the surgery intended to help restore patients' vision. Furthermore, we believe the measure is reliable because reliability testing performed by the measure steward found that the difference from originally submitted and re-abstracted vitrectomy rates was zero for 92 percent of ASCs reviewed. Therefore, we believe there is strong evidence that the Unplanned Anterior Vitrectomy measure is reliable.

vitrectomy—is it bad news?. *Eye*. 2002 March;16:117–120.

¹⁷² Tan JHY and Karawatowski. Phacoemulsification cataract surgery and unplanned anterior vitrectomy—is it bad news? *Eye*. 2002 March;16:117–120.

¹⁷³ National Quality Forum. *MAP 2015 Final Recommendations to HHS and CMS*. Rep. National Quality Forum, Jan. 2015. Available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711>.

¹⁷⁴ *Ibid.*

¹⁷⁵ ASC Quality Collaboration. "ASC Quality Collaboration." Available at: <http://www.ascquality.org/>.

¹⁶⁵ National Quality Forum. *MAP 2015 Considerations for Selection of Measures for Federal Programs: Hospitals*. Rep. National Quality Forum, Feb. 2015. Available at: http://www.qualityforum.org/Publications/2015/02/MAP_Hospital_Programmatic_Deliverable_-_Final_Report.aspx.

¹⁶⁶ National Quality Forum. *List of Measures under Consideration for December 1, 2014*. National Quality Forum, Dec. 2014. Available at: https://www.qualityforum.org/Setting_Priorities/Partnership/Measures_Under_Consideration_List_2014.aspx.

¹⁶⁷ National Quality Forum. *MAP 2015 Final Recommendations to HHS and CMS*. Rep. National Quality Forum, Jan. 2015. Available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711>.

¹⁶⁸ *Ibid.*

¹⁶⁹ *Ibid.*

¹⁷⁰ *Ibid.*

¹⁷¹ Schein OD, Steinberg EP, Javitt JC, et al. Variation in cataract surgery practice and clinical outcomes. *Ophthalmology* 1994;101:1142–1152; Tan JHY and Karawatowski. Phacoemulsification cataract surgery and unplanned anterior

¹⁶¹ National Eye Institute. "Cataracts." *Cataracts*. National Institutes of Health, n.d. Available at: <https://www.nei.nih.gov/eyedata/cataract#1>.

¹⁶² "Measure Application Partnership Hospital Workgroup", National Quality Forum. Dec. 2014. Transcript. Available at: <http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369>.

¹⁶³ Chen M, Lamattina KC, Patrianakos T, Dwarakanathan S. Complication rate of posterior capsule rupture with vitreous loss during phacoemulsification at a Hawaiian cataract surgical center: A clinical audit. *Clin Ophthalmol*. 2014 Feb 5;8:375–378.

¹⁶⁴ "Measure Application Partnership Hospital Workgroup", National Quality Forum. Dec. 2014. Transcript. Available at: <http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369>.

(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 proposed that the data collection period for the proposed ASC-14 measure would be the calendar year 2 years prior to the applicable payment determination year. For example, for the CY 2020 payment determination, the data collection period would be CY 2018. We also proposed 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 2020 payment determination, the submission period would be January 1, 2019 to May 15, 2019. We refer readers to section XIV.D.3.b. of this final rule with comment period 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-14 measure is the percentage of cataract surgery patients who have an unplanned anterior vitrectomy. The numerator for this measure is all cataract surgery patients who had an unplanned anterior vitrectomy. The denominator is all cataract surgery patients.

(5) Cohort

There are no additional inclusion or exclusion criteria for the proposed ASC-14 measure. 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

This measure is not risk-adjusted.

We invited public comments on our proposal to adopt the ASC-14: Unplanned Anterior Vitrectomy measure for the CY 2020 payment determination and subsequent years as discussed above.

Comment: Many commenters supported adoption of the proposed ASC-14 measure because cataract surgery is frequently performed in the ASC setting, and adoption of this measure will promote improvement in patient care over time and incentivize ASCs to engage in more quality improvement activities through public reporting of measure performance data. Some commenters asserted this measure has significant potential to reduce the

rate of unplanned vitrectomies by encouraging ASCs to arrange mentoring relationships between newer and more senior doctors practicing at the ASC in order to engage in knowledge-sharing and, in turn, improve performance. Commenters also noted there is little burden associated with reporting on the measure, because the patient is still in the ASC when the complication occurs and the patient's ASC record will include the relevant information that will be reported.

Response: We thank the commenters for their support.

Comment: Some commenters did not support adoption of the proposed ASC-14 measure because the commenters believe chart-abstracted measures are too burdensome for ASCs and the measure is not NQF-endorsed. One commenter recommended that CMS focus on higher priority measures that impact a greater number of ASC patients.

Response: In selecting measures for the ASCQR Program, we weigh the relevance and utility of measures against the potential burden to ASCs resulting from the measure's adoption. 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. While we understand the commenters' concerns regarding the burden of chart-abstracting measures, we believe the benefits of including the measure in the ASCQR Program and publicly reporting unplanned anterior vitrectomy data for use in patient decision-making and incentivizing ASCs to engage in quality improvement efforts to reduce rates of unplanned anterior vitrectomy outweigh the burden associated with collecting aggregate data on patients treated at an ASC.

In addition, as we discuss above, section 1833(t)(17)(C)(i) of the Act does not require that each measure we adopt for the ASCQR Program be endorsed by a national consensus building entity, or 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. While we strive to adopt NQF-endorsed measures when possible, we believe the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad acceptance and use of the measure, and through public comments. As noted in

the CY 2017 OPPTS/ASC proposed rule (81 FR 45730), ASC-14 is maintained by the ASC Quality Collaboration, an entity recognized within the community as an expert in measure development for the ASC setting. In addition, this measure is already publicly reported as part of the ASC Quality Collaboration's quarterly Quality Report. Furthermore, the MAP, which represents stakeholder groups, reviewed and conditionally supported the measure for use in the ASCQR Program. We therefore believe the measure reflects consensus among affected parties.

We further believe this measure addresses a high-priority concern affecting a large number of ASC patients. As noted previously, cataracts are a leading cause of blindness in the United States. As stated at in the proposed rule (81 FR 45729), each year, approximately 1.5 million patients undergo cataract surgery to improve their vision, and cataract surgery is the most common surgery performed in ASCs. In addition, as stated in the proposed rule (81 FR 45729), the MAP stated that the Unplanned Anterior Vitrectomy measure is "highly impactful and meaningful to patients" because cataracts are a leading cause of blindness among Americans and an unplanned anterior vitrectomy is a generally unplanned complication of the surgery intended to help restore patients' vision. While rates of unplanned anterior vitrectomy are relatively low, we believe that the severity of the complications associated with this unplanned procedure, combined with the frequency of cataract surgery in the ASC setting, highlights the importance of tracking and preventing these outcomes for patients treated in the ASC setting.

Comment: One commenter recommended CMS revise the CPT coding for this procedure to distinguish between planned and unplanned anterior vitrectomies rather than adopting a chart-abstracted measure on this issue.

Response: We appreciate the commenter's recommendation to collect unplanned anterior vitrectomy data through a set of modified CPT codes, but believe collecting this measure data through chart abstraction will enable us to provide patients with this data more quickly and without undertaking the time-intensive and resource-intensive process of modifying and implementing modified CPT codes.

After consideration of the public comments we received, we are finalizing our proposal to adopt the ASC-14: Unplanned Anterior Vitrectomy measure for the ASCQR

Program for the CY 2020 payment determination and subsequent years as proposed.

c. ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey Measures

(1) Background

Currently, there is no standardized survey available to collect information on the patient's overall experience for surgeries or procedures performed within an ASC. Some ASCs are conducting their own surveys and reporting these results on their Web sites, but there is not one standardized survey in use to assess patient experiences with care in ASCs that would allow valid comparisons across ASCs. Patient-centered experience of care measures are a component of the 2016 CMS Quality Strategy, which emphasizes patient-centered care by rating patient experience as a means for empowering patients and improving the quality of their care.¹⁷⁶ In addition, information on patient experience with care at a provider/facility is an important quality indicator to help providers and facilities improve services furnished to their patients and to assist patients in choosing a provider/facility at which to seek care.

(2) Overview of Measures

The OAS CAHPS Survey was developed as part of HHS' Transparency Initiative to measure patient experiences with ASC care.¹⁷⁷ In 2006, CMS implemented the Hospital CAHPS (HCAHPS) Survey, which collects data from hospital inpatients about their experience with hospital inpatient care (71 FR 48037 through 48039). The HCAHPS Survey, however, is limited to data from patients who receive inpatient care for specific diagnosis-related groups for medical, surgical, and obstetric services; it does not include patients who received outpatient surgical care from ASCs or HOPDs. Throughout the development of the OAS CAHPS Survey, CMS considered the type of data collected for HCAHPS and other existing CAHPS surveys as well as the terminology and question

¹⁷⁶ CMS National Quality Strategy 2016. Available at: <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/qualityinitiativesgeninfo/downloads/cms-quality-strategy.pdf>.

¹⁷⁷ U.S. Department of Health and Human Services. *HHS Strategic Plan, Strategic Goal 4: Ensure Efficiency, Transparency, Accountability, and Effectiveness of HHS Programs*. Feb. 2016. Available at: <http://www.hhs.gov/about/strategic-plan/strategic-goal-4/index.html>

wording to maximize consistency across CAHPS surveys. CMS has developed similar surveys for other settings of care that are currently used in other quality reporting and value-based purchasing programs, such as the Hospital IQR Program (71 FR 68203 through 68204), the Hospital VBP Program (76 FR 26497, 26502 through 26503, and 26510), the ESRD QIP (76 FR 70269 through 70270), the Home Health QRP (80 FR 68709 through 68710), and the Hospice QRP (80 FR 47141 through 47207).

The OAS CAHPS Survey contains 37 questions that cover topics such as access to care, communications, experience at the facility, and interactions with facility staff. The survey also contains two global rating questions and asks for self-reported health status and basic demographic information (race/ethnicity, educational attainment level, languages spoken at home, among others). The basic demographic information captured in the OAS CAHPS Survey are standard AHRQ questions used to develop case-mix adjustment models for the survey. Furthermore, the survey development process followed the principles and guidelines outlined by the AHRQ and its CAHPS® Consortium. The OAS CAHPS Survey received the registered CAHPS trademark in April 2015. OAS CAHPS Survey questions can be found at: <https://oascahps.org/Survey-Materials> under "Questionnaire."

We proposed to adopt five survey-based measures derived from the OAS CAHPS Survey for the CY 2020 payment determination and subsequent years: Three OAS CAHPS composite survey-based measures and two global survey-based measures (discussed below). We believe that these survey-based measures will be useful to assess aspects of care where the patient is the best or only source of information, and to enable objective and meaningful comparisons between ASCs. We note that we made similar proposals in the Hospital OQR Program in section XIII.B.5.c. of the proposed rule. The three OAS CAHPS composite survey-based measures are:

- ASC–15a: OAS CAHPS—About Facilities and Staff;
- ASC–15b: OAS CAHPS—Communication About Procedure; and
- ASC–15c: OAS CAHPS—Preparation for Discharge and Recovery.

Each of the three OAS CAHPS composite survey-based measures consists of six or more questions. Furthermore, the two global survey-based measures are:

- ASC–15d: OAS CAHPS—Overall Rating of Facility; and

- ASC–15e: OAS CAHPS—Recommendation of Facility.

The two global survey-based measures are comprised of a single question each and ask the patient to rate the care provided by the ASC and their willingness to recommend the ASC to family and friends. More information about these measures can be found at the OAS CAHPS Survey Web site (<https://oascahps.org>).

The five survey-based measures (MUC IDs: X3697; X3698; X3699; X3702; and X3703) we proposed were included on the CY 2014 MUC list,¹⁷⁸ and reviewed by the MAP.¹⁷⁹ The MAP encouraged continued development of these survey-based measures; however, we note that these measures had not been fully specified by the time of submission to the MUC List.¹⁸⁰ The MAP stated that these are high impact measures that will improve both quality and efficiency of care and be meaningful to consumers.¹⁸¹ Further, the MAP stated that given that these measures are also under consideration for the Hospital OQR Program, they help to promote alignment across care settings.¹⁸² It also stated that these measures would begin to fill a gap MAP has previously identified for this program including patient-reported outcomes and patient and family engagement.¹⁸³ Several MAP workgroup members noted that CMS should consider how these measures are related to other existing ambulatory surveys to ensure that patients and facilities aren't overburdened.¹⁸⁴

These measures have been fully developed since submission to the MUC List. The survey development process followed the principles and guidelines outlined by the AHRQ¹⁸⁵ and its CAHPS® Consortium¹⁸⁶ in developing a patient experience of care survey, such as: Reporting on actual patient experiences; standardization across the

¹⁷⁸ National Quality Forum. *List of Measures under Consideration for December 1, 2014*. National Quality Forum, Dec. 2014. Available at: https://www.qualityforum.org/Setting_Priorities/Partnership/Measures_Under_Consideration_List_2014.aspx.

¹⁷⁹ National Quality Forum. *MAP 2015 Final Recommendations to HHS and CMS*. Rep. National Quality Forum, Jan. 2015. Available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711>.

¹⁸⁰ *Ibid.*

¹⁸¹ *Ibid.*

¹⁸² *Ibid.*

¹⁸³ *Ibid.*

¹⁸⁴ *Ibid.*

¹⁸⁵ Agency for Healthcare Research and Quality. "Principles Underlying CAHPS Surveys." Available at: <https://cahps.ahrq.gov/about-cahps/principles/index.html>.

¹⁸⁶ Agency for Healthcare Research and Quality. "The CAHPS Program." Available at: <https://cahps.ahrq.gov/about-cahps/cahps-program/index.html>.

survey instrument, administration protocol, data analysis, and reporting; and extensive testing with consumers. Development also included: Reviewing surveys submitted under a public call for measures; reviewing existing literature; conducting focus groups with patients who had recent outpatient surgery; conducting cognitive interviews with patients to assess their understanding and ability to answer survey questions; obtaining stakeholder input on the draft survey and other issues that may affect implementation; and conducting a field test.

In addition, we received public input from several modes. We published a request for information in the **Federal Register** on January 25, 2013 (78 FR 5460) requesting information regarding publicly available surveys, survey questions, and measures indicating patient experience of care and patient-reported outcomes from surgeries or other procedures for consideration in developing a standardized survey to evaluate the care received in these facilities from the patient's perspective. Stakeholder input was also obtained through communications with a TEP comprised of experts on outpatient surgery, including clinicians, providers, patient advocates, and accreditation organizations. The TEP provided input and guidance on issues related to survey development, and reviewed drafts of the survey throughout development.

After we determined that the survey instrument was near a final form, we tested the effect of various data collection modes (that is, mail-only, telephone-only, or mail with telephone follow-up of nonrespondents) on survey responses. We began voluntary national implementation of the OAS CAHPS Survey in January 2016.¹⁸⁷

In addition, while the proposed OAS CAHPS Survey-based measures are not currently NQF-endorsed, they will be submitted to the NQF for endorsement under an applicable call for measures in the near future.

In section XIX. of the proposed rule (81 FR 45755 through 45757), for the Hospital VBP Program, we proposed to remove the three Pain Management dimension questions of the HCAHPS Survey from the total Hospital VBP Program performance score. For more information about the pain management questions captured in the HCAHPS Survey and their use in the Hospital VBP Program, we refer readers to

section XIX.B.3. of this final rule with comment period.

The OAS CAHPS Survey also contains two questions regarding pain management. We believe pain management is an important dimension of quality, but realize that there are concerns about these types of questions. However, the pain management questions in the OAS CAHPS Survey are very different from those contained in the HCAHPS Survey because they focus on communication regarding pain management rather than pain control and are part of a composite measure focusing on the preparation for discharge and recovery. Specifically, the OAS CAHPS Survey pain management communication questions read:

Q: Some ways to control pain include prescription medicine, over-the-counter pain relievers or ice packs. Did your doctor or anyone from the facility give you information about what to do if you had pain as a result of your procedure?

- A1: Yes, definitely.
- A2: Yes, somewhat.
- A3: No.

Q: At any time after leaving the facility, did you have pain as a result of your procedure?¹⁸⁸

- A1: Yes.
- A2: No.

Unlike the HCAHPS pain management questions, which directly address the adequacy of the hospital's pain management efforts, such as prescribing opioids, the OAS CAHPS pain management communication questions focus on the information provided to patients regarding pain management following discharge from an ASC. We continue to believe that pain control is an appropriate part of routine patient care that ASCs should manage and is an important concern for patients, their families, and their caregivers. We also note that appropriate pain management includes communication with patients about pain-related issues, setting expectations about pain, shared decision-making, and proper prescription practices. For these reasons, we proposed to adopt the OAS CAHPS Survey measures as described in this section, including the pain management communication questions, but will continue to evaluate the appropriateness and responsiveness of these questions to patient experience of care and public health concerns. We also welcomed feedback on these pain management communication questions

for use in future revisions of the OAS CAHPS Survey.

(3) Data Sources

As discussed in the Protocols and Guidelines Manual for the OAS CAHPS Survey (<https://oascahps.org/Survey-Materials>), the survey has three administration methods: Mail-only; telephone-only; and mixed mode (mail with telephone follow-up of non-respondents). We refer readers to section XIV.D.5. of this final rule with comment period for an in-depth discussion of the data submission requirements associated with the proposed OAS CAHPS Survey measures. To summarize, to meet the OAS CAHPS Survey requirements for the ASCQR Program, we proposed that ASCs contract with a CMS-approved vendor to collect survey data for eligible patients at the ASCs on a monthly basis and report that data to CMS on the ASC's behalf by the quarterly deadlines established for each data collection period. ASCs may elect to add up to 15 supplemental questions to the OAS CAHPS Survey. These could be questions ASCs develop or use from an existing survey. All supplemental questions must be placed after the core OAS CAHPS Survey questions (Questions 1 through 24). The list of approved vendors is available at: <https://oascahps.org>.

We also proposed to codify the OAS CAHPS Survey administration requirements for ASCs and vendors under the ASCQR Program at 42 CFR 416.310(e), and refer readers to section XIV.D.5. of this final rule with comment period for more details. It should be noted that non-discrimination requirements for effective communication with persons with disabilities and language access for persons with limited English proficiency should be considered in administration of the surveys. For more information, we refer readers to: <http://www.hhs.gov/civil-rights>.

We proposed that the data collection period for the OAS CAHPS Survey measures would be the calendar year 2 years prior to the applicable payment determination year. For example, for the CY 2020 payment determination, ASCs would be required to collect data on a monthly basis, and submit this collected data on a quarterly basis, for January 1, 2018–December 31, 2018 (CY 2018).

We further proposed that, as discussed in more detail below, ASCs will be required to survey a random sample of eligible patients on a monthly basis. A list of acceptable random sampling methods can be found in the OAS CAHPS Protocols and Guidelines

¹⁸⁷ Outpatient and Ambulatory Surgery CAHPS Survey. "National Implementation" Available at: <https://oascahps.org/General-Information/National-Implementation>.

¹⁸⁸ We note that this question is a control question only used to determine if the facility should have given a patient additional guidance on how to handle pain after leaving the facility. The facility is not scored based on this question.

Manual (<https://oascahps.org/Survey-Materials>). We also proposed that ASCs would be required to collect at least 300 completed surveys over each 12-month reporting period (an average of 25 completed surveys per month). We acknowledge that some smaller ASCs may not be able to collect 300 completed surveys during a 12-month period; therefore, we proposed an exemption for facilities with lower patient censuses. ASCs would have the option to submit a request to be exempted from performing the OAS CAHPS Survey if they treat fewer than 60 survey-eligible patients during the year preceding the data collection period. We refer readers to section XIV.B.4.c.(6) of this final rule with comment period for details on this proposal. However, we believe it is important to capture patients' experience of care at ASCs. Therefore, except as discussed in section XIV.B.4.c.(6) of this final rule with comment period, below, we also proposed that smaller ASCs that cannot collect 300 completed surveys over a 12-month reporting period will only be required to collect as many completed surveys as possible during that same time period, with surveying all eligible patients (that is, no sampling). For more information regarding these survey administration requirements, we refer readers to the OAS CAHPS Survey Protocols and Guidelines Manual (<https://oascahps.org/Survey-Materials>).

Furthermore, we proposed that ASC eligibility to perform the OAS CAHPS Survey would be determined at the

individual ASC level. In other words, an individual ASC that meets the exemption criteria outlined in section XIV.B.4.c.(6) of this final rule with comment period, below, may submit a participation exemption request form, regardless of whether it operates under an independent CCN or shares a CCN with other facilities. CMS will then assess that ASC's eligibility for a participation exemption due to facility size independent of any other facilities sharing its CCN. However, all data collection and submission, and ultimately, also public reporting, for the OAS CAHPS Survey measures would be at the CCN level. Therefore, the reporting for a CCN would include all eligible patients from all eligible ASCs covered by the CCN.

(4) Measure Calculations

As noted above, we proposed to adopt three composite OAS CAHPS Survey-based measures (ASC-15a, ASC-15b, and ASC-15c) and two global survey-based measures (ASC-15d and ASC-15e). An ASC's performance for a given payment determination year will be based upon the successful submission of all required data in accordance with the data submission requirements discussed in section XIV.D.5. of this final rule with comment period. Therefore, ASCs' scores on the OAS CAHPS Survey-based measures, discussed below, will not affect whether they are subject to the 2.0 percentage point payment reduction for ASCs that fail to meet the reporting requirements of the ASCQR Program.

$$\text{ASC Publicly Reported Score} = \frac{(0.5 + 0.8 + 1 + 0.7 + 0.9 + 0.8)}{6}$$

This calculation would give this example ASC a raw score of 0.78 or 78 percent for the ASC-15a measure for purposes of public reporting. We note that each percentage would then be adjusted for differences in the characteristics of patients across ASCs as described in section XIV.B.4.c.(7) of this final rule with comment period. As a result, the final ASC percentages may vary slightly from the raw percentage as calculated in the example above.

(B) Global Survey-Based Measures

We also proposed to adopt two global OAS CAHPS Survey measures. ASC-15d asks the patient to rate the care provided by the ASC on a scale of 0 to 10, and ASC-15e asks about the patient's willingness to recommend the

These measure calculations will be used for public reporting purposes only.

(A) Composite Survey-Based Measures

ASC rates on each composite OAS CAHPS Survey-based measure would be calculated by determining the proportion of "top-box" responses (that is, "Yes" or "Yes Definitely") for each question within the composite and averaging these proportions over all questions in the composite measure. For example, to assess ASC performance on the composite measure ASC-15a: OAS CAHPS—About Facilities and Staff, we would calculate the proportion of top-box responses for each of the measure's six questions, add those proportions together, and divide by the number of questions in the composite measure (that is, six).

As a specific example, we take an ASC that had 50 surveys completed and received the following proportions of "top-box" responses through sample calculations:

- 25 "top-box" responses out of 50 total responses on Question One
- 40 "top-box" responses out of 50 total responses on Question Two
- 50 "top-box" responses out of 50 total responses on Question Three
- 35 "top-box" responses out of 50 total responses on Question Four
- 45 "top-box" responses out of 50 total responses on Question Five
- 40 "top-box" responses out of 50 total responses on Question Six

Based on the above responses, we would calculate that facility's measure score for public reporting as follows:

ASC to family and friends on a scale of "Definitely No" to "Definitely Yes."

ASC performance on each of the two global OAS CAHPS Survey-based measures would be calculated by proportion of respondents providing high-value responses (that is, a 9–10 rating or "Definitely Yes") to the survey questions over the total number of respondents. For example, if an ASC received 45 9- and 10-point ratings out of 50 responses, this ASC would receive a 0.9 or 90 percent raw score, which would then be adjusted for differences in the characteristics of patients across ASCs as described in section XIV.B.4.c.(7) of this final rule with comment period, for purposes of public reporting.

(5) Cohort

The OAS CAHPS Survey is administered to all eligible patients—or a random sample thereof—who had at least one outpatient surgery/procedure during the applicable month. Eligible patients, regardless of insurance or method of payment, can participate. For purposes of each survey-based measure captured in the OAS CAHPS Survey, an "eligible patient" is a patient 18 years or older:

- Who had an outpatient surgery or procedure in an ASC, as defined in the OAS CAHPS Survey administration manual (<https://oascahps.org/Survey-Materials>);
- Who does not reside in a nursing home;

- Who was not discharged to hospice care following their surgery;
- Who is not identified as a prisoner; and
- Who did not request that ASCs not release their name and contact information to anyone other than ASC personnel.

There are a few categories of otherwise eligible patients who are excluded from the measure as follows:

- Patients whose address is not a U.S. domestic address;
- Patients who cannot be surveyed because of State regulations;
- Patient's surgery or procedure does not meet the eligibility CPT or G-codes as defined in the OAS CAHPS Survey Protocols and Guidelines Manual (<https://oascahps.org/Survey-Materials>) (referred to in the proposed rule as the "OAS CAHPS Survey Manual administration manual"); and
- Patients who are deceased.

(6) Exemption

We understand that facilities with lower patient censuses may be disproportionately impacted by the burden associated with administering the survey and the resulting public reporting of OAS CAHPS Survey results. Therefore, we proposed that ASCs may submit a request to be exempted from performing the OAS CAHPS Survey-based measures if they treat fewer than 60 survey-eligible patients during the "eligibility period," which is the calendar year before the data collection period. For example, for the CY 2020 payment determination, this exemption request would be based on treating fewer than 60 survey-eligible patients in CY 2017, which is the calendar year before the data collection period (CY 2018) for the CY 2020 payment determination. All exemption requests will be reviewed and evaluated by CMS.

To qualify for the exemption, we proposed that ASCs must submit a participation exemption request form, which will be made available on the OAS CAHPS Survey Web site (<https://oascahps.org>) on or before May 15 of the data collection year. For example, the deadline for submitting an exemption request form for the CY 2020 payment determination would be May 15, 2018. We determined the May 15 deadline in order to align with the deadline for submitting Web-based measures, and because we believe this deadline allows ASCs sufficient time to review the previous years' patient lists and determine whether they are eligible for an exemption based on patient population size.

We note that ASCs with fewer than 240 Medicare claims (Medicare primary

and secondary payer) per year during an annual reporting period for a payment determination year are not required to participate in the ASCQR Program for the subsequent annual reporting period for that applicable payment determination year (42 CFR 416.305(c)). For example, an ASC as identified by National Provider Identifier (NPI) with fewer than 240 Medicare claims in CY 2017 (for the CY 2019 payment determination year) would not be required to participate in the ASCQR Program in CY 2018 (for the CY 2020 payment determination year).

In addition, as discussed above, ASC eligibility to perform the OAS CAHPS Survey would be determined at the individual ASC level. In other words, an individual ASC that meets the exemption criteria outlined in section XIV.B.4.c.(6) of this final rule with comment period, below, may submit a participation exemption request form, regardless of whether it operates under an independent CCN or shares a CCN with other facilities. However, all data collection and submission, and ultimately, also public reporting, for the OAS CAHPS Survey measures would be at the CCN level. Therefore, the reporting for a CCN would include all eligible patients from all eligible ASCs covered by the CCN.

(7) Risk Adjustment

In order to achieve the goal of fair comparisons across all ASCs, we believe it is necessary and appropriate to adjust for factors that are not directly related to ASC performance, such as patient case-mix, for these OAS CAHPS Survey measures. The survey-based measures are adjusted for patient characteristics such as age, education, overall health status, overall mental health status, type of surgical procedure, and how well the patient speaks English. These factors influence how patients respond to the survey, but are beyond the control of the ASC and are not directly related to ASC performance. For more information about risk adjustment for these measures, we refer readers to: <https://oascahps.org/General-Information/Mode-Experiment>.

(8) Public Reporting

We will propose a format and timing for public reporting of OAS CAHPS Survey data in future rulemaking prior to implementation of the measures. Because CY 2016 is the first year of voluntary national implementation for the OAS CAHPS Survey, and we believe using data from this voluntary national implementation will help inform the displays for public reporting of OAS CAHPS Survey data for the ASCQR

Program, we did not propose a format or timing for public reporting of OAS CAHPS Survey data in the proposed rule.

As currently proposed, ASCs that share the same CCN must combine data for collection and submission for the OAS CAHPS Survey across their multiple facilities. These results would then be publicly reported on the *Hospital Compare* Web site as if they apply to a single ASC. To increase transparency in public reporting and improve the usefulness of the *Hospital Compare* Web site, we intend to note on the Web site instances where publicly reported measures combine results from two or more ASCs.

We invited public comments on our proposals as discussed above to adopt for the CY 2020 payment determination and subsequent years, the five survey-based measures: (1) ASC-15a: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS)—About Facilities and Staff; (2) ASC-15b: OAS CAHPS—Communication About Procedure; (3) ASC-15c: OAS CAHPS—Preparation for Discharge and Recovery; (4) ASC-15d: OAS CAHPS—Overall Rating of Facility; and (5) ASC-15e: OAS CAHPS—Recommendation of Facility.

Comment: Many commenters supported adoption of the proposed ASC-15a-e survey-based measures based on an understanding that these measures capture patient experience of care data, apply to ASCs broadly, and are also proposed for adoption in the ASCQR Program. Some commenters noted adopting these measures will establish a baseline for standardized collection of patient experience of care data, and allow for meaningful comparisons across ASCs on patient experience of care. Commenters also noted that the ASC-15a-e survey-based measures are important quality indicators that can be used in combination with other measures to assist patients in deciding where to seek care. One commenter expressed specific support for the inclusion of risk-adjustment factors in the OAS CAHPS Survey-based measures.

Response: We thank the commenters for their support.

Comment: One commenter requested additional information regarding the OAS CAHPS Survey development process.

Response: As discussed in the CY 2017 OPFS/ASC proposed rule (for example, 81 FR 45730 through 45732), background on the OAS CAHPS Survey, including the survey development process, is publicly available on the

OAS CAHPS Web site: <http://oascahps.org/>. The OAS CAHPS Survey development process followed the principles and guidelines outlined by the AHRQ¹⁸⁹ and its CAHPS Consortium¹⁹⁰ in developing a patient experience of care survey, such as: Reporting on actual patient experiences; standardization across the survey instrument; administration protocol; data analysis and reporting; and extensive testing with consumers. This process included reviewing existing literature; reviewing surveys submitted under a public call for measures; conducting focus groups with patients who had recent outpatient surgery; conducting cognitive interviews with patients to assess their understanding and ability to answer survey questions; obtaining stakeholder input on the draft survey and other issues that may affect implementation; conducting a field test; and conducting a test of the various data collection mode effects on survey responses.

We published a request for information on January 25, 2013 (78 FR 5459) requesting information regarding publicly available surveys, survey questions, and measures indicating patient experience of care and patient-reported outcomes from surgeries or other procedures for consideration in developing a standardized survey to evaluate the care received in these facilities from the patient's perspective. In 2013 and 2014, we conducted six focus groups with patients who had recent outpatient surgeries or procedures in a hospital outpatient department or ASC. Analysis of the focus group feedback¹⁹¹ led to development of the final domain structure for the survey, and identified the following topic areas for assessment under a patient experience of care survey for these procedures: (1) Preparations for surgery; (2) check-in process; (3) facility environment; (4) staff communication; (5) discharge; (6) recovery and outcomes; and (7) overall experience.

We convened and consulted with two TEPs throughout the development and

testing of the OAS CAHPS Survey.¹⁹² In 2013, we established a 10-member TEP consisting of experts on outpatient surgery, including clinicians, providers, patient advocates, and representatives from other stakeholder organizations to provide preliminary guidance in the establishment of relevant topics and to comment on the draft versions for cognitive testing and the field test. Information about the TEP was documented in materials supporting an information collection request for the voluntary national implementation of the OAS CAHPS Survey published in the **Federal Register** (80 FR 2430 through 2431).¹⁹³ We established a second TEP in 2015 to solicit input and guidance related to national implementation protocols and the survey mode experiment.

We conducted three rounds of cognitive testing among patients who received outpatient surgery at an ASC or hospital outpatient department before finalizing the field test version of the OAS CAHPS Survey. With each round of testing, we modified the survey to reflect the comments from the previous round.

The survey was tested in both the outpatient and ASC setting in 2014 (field testing) and 2015 (mode testing) and found to be reliable. We refer readers to 80 FR 2430 and the OAS CAHPS Information Collection Request Paperwork Reduction Act Package¹⁹⁴ for more information about field and mode testing for these measures. The field test collected data through a mixed-mode design, which consisted of a mail survey with telephone follow-up of non-respondents. We recruited a total of 36 facilities for the field test: 18 Hospital outpatient departments and 18 ASCs. Approximately 116 patient records were selected from each of the 36 facilities, for a total sample of 4,179 patients. The field test data collection yielded a 46 percent adjusted response rate, or 1,863 completed surveys (31 percent computer-assisted telephone interviewing, 68 percent mail, and 0.8 percent break-offs). Once partial surveys were removed from the analysis set, 1,849 total surveys were used in the evaluation. The field test data were

evaluated and analyzed to identify item-level refinements necessary for the survey instrument. The field test psychometric analysis included evaluations of individual items and composite item sets. Individual items were analyzed to report item-level missing data and item response distributions (including ceiling and floor effects), which included response variance. Composite item sets were analyzed using factor analysis and item response theory (IRT) analysis to assess dimensionality, discriminability, dimensional coverage, and subgroup response differences. Internal consistency statistics (reliability) and correlational checks for composite validity were performed to evaluate the final composite item sets. The item-level recommendations for the field test were based on the findings from the factor analyses, the internal consistency checks, and the IRT analysis. As a result, 10 questions were recommended for deletion. Reliability of the remaining measures was assessed using the Cronbach's alpha coefficient, with an estimate range from zero to one. An estimate of zero indicated no measurement consistency and one indicates perfect consistency. The cutoff criterion for the examination was 0.70, which indicated adequate consistency.¹⁹⁵ The composites analytically derived maintained adequate internal consistency even when reduced to Top-Box scoring and across the facility types and modes of administration.

In 2015, we conducted a mode experiment for the OAS CAHPS Survey. We refer readers to <https://oascahps.org/General-Information/Mode-Experiment> for more details. The facility sample included hospital outpatient departments and ASCs that reflect industry characteristics and was sorted to achieve implicit stratification by four facility characteristics: Single specialty or multispecialty; facility size (large, medium, or small), facility location (urban or rural), and facility ownership (public, private, or other). A total of 70 facilities (38 hospital outpatient departments and 32 ASCs) participated in the mode experiment by providing a monthly patient information file for patients served during one or more of the three sample months (July, August, and September 2015). The patient sample consisted of 13,576 patients who had an eligible surgery or procedure during a sample month and who met other survey eligibility criteria.

¹⁸⁹ Agency for Healthcare Research and Quality. "Principles Underlying CAHPS Surveys." Available at: <https://cahps.ahrq.gov/about-cahps/principles/index.html>.

¹⁹⁰ Agency for Healthcare Research and Quality. "The CAHPS Program." Available at: <https://cahps.ahrq.gov/about-cahps/cahps-program/index.html>.

¹⁹¹ Hospital Outpatient Surgery Department/ Ambulatory Surgery Center Experience of Care Survey Focus Group Report (Submitted to CMS June 2013).

¹⁹² Information about feedback from the first TEP was documented in the **Federal Register** at 80 FR 2430 (See Section A.1 of the Supporting Statement).

¹⁹³ Available at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10500.html>.

¹⁹⁴ OMB Control Number 0938-1240, "Consumer Assessment of Healthcare providers and Systems Outpatient and Ambulatory Surgery (OAS CAHPS) Survey (CMS-10500)." Available at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201510-0938-003.

¹⁹⁵ Aron, A. and Aron, E.N. *Statistics for Psychology*. (1999) 2nd ed. New Jersey: Prentice Hall.

Data collection for each sample month began approximately 21 days after the sample month closed and ended within a 6-week period after the survey was initiated. The overall response rate (for all three modes) was 39 percent. The response rate for the mail-only mode was 37 percent, the telephone-only response rate was 34 percent, and the mixed-mode response rate was 50 percent.

We began voluntary national implementation of the OAS CAHPS Survey in January 2016 and refer readers to <https://oascahps.org/General-Information/National-Implementation> for more details. Preliminary data from the voluntary reporting period (Quarter 1 data), which included 24,201 sampled patients from 74 facilities, indicate a response rate of 33 percent for both telephone and mail modes. Voluntary national implementation is ongoing.

Comment: Some commenters did not support adoption of the proposed ASC-15a-e survey-based measures because these measures have not been endorsed by a consensus-based measurement evaluation body. The commenters asserted that moving forward with the non-endorsed measures could result in publication of unreliable measure scores, and urged CMS to delay implementation of these measures until NQF endorsement is received. One commenter recommended CMS implement the OAS CAHPS Survey in the Hospital OQR Program first to demonstrate its reliability before requiring ASCs to implement the survey.

Response: We note that section 1833(t)(17)(C)(i) of the Act does not require that each measure we adopt for the ASCQR Program be endorsed by a national consensus building entity, or 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. While we strive to adopt NQF-endorsed measures when possible, we believe the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad acceptance and use of the measure, and through public comments. As discussed in the measure description above, the MAP has reviewed the measure.

In addition, we received public input from several modes. We published a request for information in the **Federal Register** on January 25, 2013 (78 FR 5460) requesting information regarding

publicly available surveys, survey questions, and measures indicating patient experience of care and patient-reported outcomes from surgeries or other procedures for consideration in developing a standardized survey to evaluate the care received in these facilities from the patient's perspective. As stated in more detail above, stakeholder input was also obtained through communications with a TEP comprised of experts on outpatient surgery, including clinicians, providers, patient advocates, and accreditation organizations. The TEP provided input and guidance on issues related to survey development, and reviewed drafts of the survey throughout development. Given these consensus-building efforts, we believe the measure reflects consensus among affected parties for a standardized instrument assessing patients' experience of care in the ASC setting. As such, we do not think it is necessary to delay implementation of the OAS CAHPS Survey until it achieves NQF endorsement. We also believe it is unnecessary to delay implementation of the OAS CAHPS Survey in the ASC setting until its reliability is demonstrated in the hospital outpatient department setting, because the survey was tested in both settings in 2014 (field testing) and 2015 (mode testing) and found to be reliable, as discussed above and again below. We also note, however, that we intend to submit the OAS CAHPS Survey-based measures to NQF for endorsement under an applicable call for measures in the near future.

We also disagree with the commenters' assertion that moving forward with a non-endorsed measure could result in publication of unreliable measure scores. The survey was tested in both the outpatient and ASC setting in 2014 (field testing) and 2015 (mode testing) and found to be reliable. We refer readers to <https://oascahps.org/> for more information about field and mode testing for these measures. The OAS CAHPS Survey development process followed the principles and guidelines outlined by AHRQ and its CAHPS Consortium.¹⁹⁶ This process included reviewing existing literature; reviewing surveys submitted under a public call for measures; conducting focus groups with patients who had recent outpatient surgery; conducting cognitive interviews with patients to assess their understanding and ability to answer survey questions; obtaining stakeholder input on the draft survey and other

issues that may affect implementation; conducting a field test; and conducting a test of the various data collection mode effects on survey responses.

In 2014, the field test data were evaluated and analyzed to identify item-level refinements necessary for the survey instrument. The field test psychometric analysis included evaluations of individual items and composite item sets. Individual items were analyzed to report item-level missing data and item response distributions (including ceiling and floor effects), which included response variance. Composite item sets were analyzed using factor analysis and item response theory (IRT) analysis to assess dimensionality, discriminability, dimensional coverage, and subgroup response differences. Internal consistency statistics (reliability) and correlational checks for composite validity were performed to evaluate the final composite item sets. The item-level recommendations for the field test were based on the findings from the factor analyses, the internal consistency checks, and the IRT analysis. As a result, 10 questions were recommended for deletion. Reliability of the remaining measures was assessed using the Cronbach's alpha coefficient, with an estimate range from zero to one. An estimate of zero indicated no measurement consistency and one indicates perfect consistency. The cutoff criterion for the examination was 0.70, which indicated adequate consistency.¹⁹⁷ The composites analytically derived maintained adequate internal consistency even when reduced to Top-Box scoring and across the facility types and modes of administration.

Based on the rigorous testing that was undertaken during the development process, we believe the OAS CAHPS Survey, and measure scores derived therefrom, are both reliable and valid. Therefore, we believe it is unnecessary to delay implementation of the OAS CAHPS Survey in the ASC setting.

Comment: Many commenters asserted that requiring ASCs to meet the proposed target minimum number of surveys (that is, 300 completed surveys) would be difficult for participating ASCs because they are small businesses and implementing a high target minimum will require ASCs to ramp up quickly to administer the OAS CAHPS Survey. Other commenters stated that past experience with facility-specific surveys indicates ASCs will experience

¹⁹⁶ Agency for Healthcare Research and Quality. "The CAHPS Program." Available at: <https://ahrq.gov/cahps/index.html>.

¹⁹⁷ Aron, A. and Aron, E.N. *Statistics for Psychology*. (1999) 2nd ed. New Jersey: Prentice Hall.

low completion rates on the OAS CAHPS Survey. The commenters therefore recommended CMS consider lowering this target minimum or, in the alternative, consider implementing scaled target minimums based on facility size. A number of commenters recommended that the target minimum instead be set at 100 completed surveys, in alignment with the requirements from the first year of the HCAHPS Survey's use in the inpatient setting. One commenter recommended CMS assess ASCs' performance based on the number of surveys sent to patients. A number of commenters recommended that CMS increase the threshold for an exception to administering the OAS CAHPS Survey based on a small patient population from 60 survey-eligible patients to 100 survey-eligible-patients in the year preceding the performance period.

Other commenters recommended that CMS remove the proposed 60 survey-eligible patient threshold from the OAS CAHPS Survey proposals. The commenters noted an ASC is exempt from the requirements of the ASCQR Program if it submits fewer than 240 Medicare primary and secondary claims per year, and requested CMS clarify the circumstances under which this proposal would exclude an ASC eligible to participate in the ASCQR Program from the requirement to administer the OAS CAHPS Survey.

Two commenters asserted that comparing an ASC with a small patient population to a sample of a much larger ASC's population may weaken the statistical reliability of the survey results and comparability of facilities' scores.

Response: We are committed to ensuring high reliability in publicly reported OAS CAHPS Survey results. To make abundantly clear our policies discussed in the proposed rule, ASCs will fall into one of three categories based on their past and projected total patient volume. In order to determine its projected total patient volume, we recommend ASCs review their accounts receivable and payable records. From these accounting documents, a facility can determine its past patient volume and project future patient volume. Acceptable methods of sampling survey-eligible patients can be found in Chapter IV-Sampling Procedures of the Protocols and Guidelines Manual at <https://oascahps.org/Survey-Materials>.

The first category includes ASCs that estimate receiving more than 300 completed surveys during the 12-month reporting period based on its past and projected total patient volume. We note that in the proposed rule (81 FR 45732),

we stated that "ASCs will be required to survey a random sample of eligible patients on a monthly basis." We also note that elsewhere in the proposed rule (81 FR 45733), we also stated that, "the OAS CAHPS Survey is administered to all eligible patients—or a random sample thereof—who had at least one outpatient surgery/procedure during the applicable month." We recognize that the language is confusing and are clarifying here that ASCs that anticipate receiving more than 300 surveys have a choice. They are required to either: (1) randomly sample their eligible patient population, or (2) survey their entire OAS CAHPS eligible patient population. In other words, random sampling is optional.

We calculated the number 300 by using the reliability criterion for the OAS CAHPS Survey measures, which is 0.8 or higher.¹⁹⁸ This which requires facilities with large patient populations to randomly sample a sufficient number of patients to yield at least 300 completed surveys over each 12-month reporting period. This criterion allows at least 80 percent power to detect a 10 percent difference for binary survey outcome at the 0.05 significance level.¹⁹⁹ A reliability criterion of 0.8 is the normal standard for random sample surveys.²⁰⁰ The 300 completed surveys translates into approximately 25 completed surveys per month (25 completes \times 12 months = 300 completes per year). At this time, there are no plans to adjust the threshold of the target minimum of 300 completed surveys for the OAS CAHPS Survey for larger facilities that have the option to undertake random sampling. To do so could decrease the reliability of the OAS CAHPS survey results. Survey data will be collected on a monthly basis and uploaded on a quarterly basis. Survey vendors will report the "total patient volume," "total eligible patients," "number of patients sampled," and the "number of completed surveys" for each reporting period.²⁰¹ These reported patient data will be used to ensure sampling requirements are followed.

Second, if an ASC does not anticipate receiving 300 completed surveys during the 12-month reporting period based on its past and projected total patient volume, it must survey all eligible patients served during the reporting

period. In other words, these smaller facilities must undertake a census of all eligible patients served; there is no option to randomly sample. Smaller facilities' OAS CAHPS survey results are not affected by the reliability issues underlying the target minimum policy because conducting a census—surveying all eligible patients in a population, as opposed to sampling and administering the survey to a portion of that eligible patient population—measures the true value of the patient population by including all eligible patients at the facility in the survey population. However, we will continue to review the data from the voluntary implementation to identify and address any issues related to the reliability and comparability of OAS CAHPS Survey-based measure rates across facilities. Thus, the OAS CAHPS results for the larger facilities and the smaller facilities both achieve the statistical precision of the reliability criterion. For example, if two different facilities with large patient volumes in a particular year both randomly sample their eligible patients and receive 300 completed surveys, they would both have met the reliability criterion during that year. If in a particular year one facility estimates it will receive more than 300 completed surveys in that year and samples and obtains 300 completed surveys while, during that same year, a different facility does not anticipate receiving 300 completed surveys and undertakes a census of its entire survey-eligible patients, both facilities would achieve the statistical precision of the reliability criterion for that year. As a third example, for a facility that obtained 300 completed surveys from their 1500 total eligible patients served in one year, but experienced a change in patient volume during the next year and surveyed their entire 200 total eligible patients served the next year, the facility would have met the reliability criterion during both years.

Third, if in the prior year an ASC serves less than 60 survey-eligible patients, the facility can request an exemption from the OAS CAHPS Survey administration requirement because these few surveys would not provide reliable data and the burden associated with administering the survey as well as the resulting public reporting of OAS CAHPS Survey results would be disproportionately burdensome. At this time, there are no plans to adjust the threshold for the exemption. This request and related deadlines will be available on the OAS CAHPS Survey Web site (<https://oascahps.org>) on or before May 15 of the

¹⁹⁸ Cohen, Jacob. 1977. *Statistical Power Analysis for the Behavioral Sciences*. New York: Academic Press.

¹⁹⁹ *Ibid.*

²⁰⁰ *Ibid.*

²⁰¹ Outpatient and Ambulatory Surgery CAHPS Survey: "Protocol and Guidelines Manual." Available for download at: <https://oascahps.org/Survey-Materials>.

data collection calendar year as discussed in the proposed rule (81 FR 45733).

However, we agree with the commenters that the proposed 60 survey-eligible patient threshold is unlikely to exclude ASCs that would otherwise be eligible for the ASCQR Program from the OAS CAHPS Survey administration requirements. As noted by commenters, ASCs with fewer than 240 Medicare claims (Medicare primary and secondary payer) per year during an annual reporting period for a payment determination year are not required to participate in the ASCQR Program for the subsequent annual reporting period for that applicable payment determination year (42 CFR 416.305(c)). Therefore, it is unlikely that an ASC would qualify for an exemption from the OAS CAHPS Survey without also being exempted from the ASCQR Program. However, this would also likely be the case if we adopted a 100 survey-eligible patient threshold. We currently lack data regarding the interaction between the ASCQR Program's programmatic threshold and the OAS CAHPS Survey's survey-eligible patient threshold. Because it may be possible for an ASC to treat enough patients to be eligible for the ASCQR Program but not treat 60 survey-eligible patients, we believe it is appropriate to maintain the OAS CAHPS Survey administration threshold at this time. To be clear, an ASC that would not need to report data for any measures in the ASCQR Program if it has less than 240 Medicare claims (Medicare primary and secondary payer) in the year prior to the data collection year for the applicable payment determination, would also not be required to submit a participation exemption request form or administer the OAS CAHPS Survey for the same time period.

The facility-level data for both large and small facilities will be adjusted to account for patient characteristics that impact response tendencies (that is, patient-mix) and ensure fair comparisons across all facilities. As discussed in the CY 2017 OPPS/ASC proposed rule (81 FR 45720), the survey-based measures are adjusted for patient characteristics such as age, education, overall health status, overall mental health status, type of surgical procedure, and how well the patient speaks English. We refer readers to the Protocols and Guidelines Manual, available at: <https://oascahps.org/Survey-Materials> for information regarding the patient-mix adjustment methodology. However, we do not adjust for facility-level characteristics

that are under control of the facility, for example, specialty or geographic location. During the voluntary implementation of the survey, we will continue to review the data collected to identify and address any issues related to the reliability and comparability of measure rates across facilities as appropriate. In addition, we believe the proposed 60 survey-eligible patient exemption policy appropriately balances the benefit of ensuring that patient experience of care data is collected and publicly reported for use by patients in making decisions about their health care against the burden of requiring facilities to administer the OAS CAHPS Survey. For this reason, we do not believe it would be appropriate to increase the exemption threshold at this time.

Comment: A number of commenters did not support adoption of the proposed OAS CAHPS Survey-based measures due to the administrative and financial burdens associated with implementing the OAS CAHPS Survey. The commenters asserted that ASCs, as small businesses, cannot afford the staff needed to gather the required measure data, and that diverting available resources to address these reporting requirements may result in diminishing quality of care for ASCs' patients or cause ASCs to withdraw from the ASCQR Program. One commenter noted that ASCs are already paid at lower rates than hospital outpatient departments for the same procedures and this requirement would further reduce ASCs' resources available for quality improvement activities. Commenters asserted that most ASCs will treat more than 60 but fewer than 300 survey-eligible patients in a given year, and as a result, smaller ASCs will incur significant costs to administer the survey and receive far fewer completed surveys than the target minimum.

Response: In selecting measures for the ASCQR Program, we weigh the relevance and utility of measures against the potential burden to ASCs resulting from the measure's adoption. We refer readers to the CY 2013 OPPS/ASC final rule with comment period for a discussion of our considerations in the selection of ASCQR Program quality measures (77 FR 68493 through 68494). While we understand the commenters' concerns regarding the administrative and financial burdens associated with implementing the OAS CAHPS Survey and OAS CAHPS Survey-based measures in the ASCQR Program, we believe the benefits of capturing patient experience of care data in the ASC setting outweigh the administrative burden associated with administering

the survey. We are dedicated to improving the quality of care provided to patients, and believe patients are a vital source of information in assessing the quality of care provided at an ASC.

Furthermore, collection of the patient's perspectives of care data is similar for other CAHPS surveys, such as the Home Health Care CAHPS (HHCAHPS) Survey,²⁰² In-Center Hemodialysis CAHPS (ICH CAHPS),²⁰³ and Hospice CAHPS.²⁰⁴ ASCs would follow the same model where providers contract with approved survey vendors for the data collection and implementation of the survey. We post the list of the approved OAS CAHPS vendors on <https://oascahps.org>, and we encourage ASCs to contact vendors for cost and service information pertaining to OAS CAHPS as there may be differences among vendors. In addition, as discussed in the proposed rule (81 FR 45737), the survey has three administration methods: mail-only; telephone-only; and mixed mode (mail with telephone follow-up of non-respondents). We refer readers to the Protocols and Guidelines Manual for the OAS CAHPS Survey (<https://oascahps.org/Survey-Materials>) for materials for each mode of survey administration. While ASCs/vendors must make multiple attempts to contact eligible patients unless the patient refuses or the ASC/vendor learns that the patient is ineligible to participate in the survey, ASCs/vendors may conduct the OAS CAHPS survey in one or more of the survey modes of telephone only, mail only, or mail with telephone follow-up. We note that generally, the mail only mode is the most economical choice.

Comment: Some commenters noted that many ASCs already have a different survey in place to assess patient satisfaction and quality of care, and stated their belief that adding another survey requiring the ASC to contract with a third party vendor would not improve the quality control measures already in place at the ASC. One commenter requested clarification as to whether ASCs may continue to administer their own facility-specific patient experience of care surveys using the same tools and administration

²⁰² Home Health Care CAHPS Survey: "Protocol and Guidelines Manual." Available for download at: <https://homehealthcahps.org/Portals/0/PandGManual.pdf>.

²⁰³ In-Center Hemodialysis CAHPS Survey: "Protocol and Guidelines Manual." Available for download at: https://ichcahps.org/Portals/0/ICH_SurveyAdminManual.pdf.

²⁰⁴ Hospice CAHPS Survey: "Quality Assurance Guidelines." Available for download at: <http://www.hospicecahpsurvey.org/en/quality-assurance-guidelines/>.

methods they use now if the ASC-15a-e survey-based measures are finalized.

Response: Currently, there is no standardized survey available to collect information on the patient's overall experience for surgeries or procedures performed within an ASC. Some ASCs are conducting their own surveys and reporting these results on their Web sites, but there is not one standardized survey in use to assess patient experiences with care in ASCs that would allow valid comparisons across ASCs. Patient-centered experience of care measures are a component of the 2016 CMS Quality Strategy, which emphasizes patient-centered care by rating patient experience as a means for empowering patients and improving the quality of their care.²⁰⁵

Through inclusion in the ASCQR Program and public reporting of survey results, both ASCs and patients will be able to learn. ASCs can assess their own quality and see how their quality compares to other ASCs, and patients can compare measures and make informed decisions about their healthcare. We believe this provides additional incentives for ASCs to engage in quality improvement activities.

While an ASC may continue to administer its own facility-specific patient experience of care survey, that survey administration would not satisfy the requirements of the ASC-15a-e survey-based measures. In order to meet the survey administration requirements for these measures, the ASC must administer the OAS CAHPS Survey in accordance with the requirements listed in the OAS CAHPS Survey Protocols and Guidelines Manual.²⁰⁶

We encourage ASCs to consider adding specific questions of interest to the OAS CAHPS Survey instead, rather than administering a second, standalone, survey to patients. As noted in the CY 2017 OPPI/ASC proposed rule (81 FR 45732), ASCs may elect to add up to 15 supplemental questions to the OAS CAHPS Survey. These could be questions ASCs develop specifically for use alongside the OAS CAHPS Survey, or questions from an existing survey. All supplemental questions must be placed after the core OAS CAHPS Survey questions (Questions 1 through 24).

Comment: Another commenter suggested that CMS delay public

reporting of ASC measure rates for at least one year to allow ASCs to become familiar with the measures and survey administration.

Response: As stated in the CY 2017 OPPI/ASC proposed rule (81 FR 45728), this measure was proposed for the CY 2020 payment determination and subsequent years. Therefore, ASCs would not be required to submit OAS CAHPS Survey results until CY 2018. This gives ASCs an additional year to become familiar with both the OAS CAHPS Survey and its administration requirements, as well as contract with a third-party vendor to administer the survey. We refer ASCs to the list of CMS-approved survey vendors available on the OAS CAHPS Web site (<https://oascahps.org/General-Information/Approved-Survey-Vendors>) and encourage ASCs to compare prices across vendors, as they may vary. We believe this additional year is sufficient time for ASCs to become familiar with the measures and survey administration before it is a requirement of the ASCQR Program and is publicly reported. Furthermore, we encourage ASCs to participate in the voluntary national implementation of the OAS CAHPS Survey to gain experience. More information can be found at: <https://oascahps.org>.

Moreover, as stated in the proposed rule (81 FR 45734), we will propose a format and timing for public reporting of OAS CAHPS Survey data in future rulemaking prior to implementation of the measures. Because CY 2016 is the first year of voluntary national implementation for the OAS CAHPS Survey, and we believe using data from this voluntary national implementation will help inform the displays for public reporting of OAS CAHPS Survey data for the ASCQR Program, we did not propose a format or timing for public reporting of OAS CAHPS Survey data in the proposed rule.

Comment: One commenter recommended that CMS instead provide ASCs with a sample survey document to use in their practices, which ASCs could enter into a CMS database for review. The commenter believed such an alternative would provide CMS with patient experience of care data without imposing undue burdens on ASCs, and give ASCs greater control over the data submission process.

Response: At present, there is no standardized survey available to collect information on the patient's overall experience for surgeries or procedures performed within an ASC. Implementing the OAS CAHPS Survey in the ASCQR Program will enable patients to compare patient experience

of care data across multiple ASCs as part of their healthcare decision-making. In addition, we believe implementing the OAS CAHPS Survey in the ASCQR Program will incentivize ASCs to factor patient experience of care into their quality improvement efforts more proactively. Implementing a shorter "sample survey" would not enable the same apples-to-apples comparison as a fully tested survey, and we believe allowing ASCs to administer the survey by any means chosen rather than according to the OAS CAHPS Protocol and Guidelines Manual²⁰⁷ could affect the reliability of a facility's scores. As currently specified, the OAS CAHPS Survey requires that the survey be administered by an approved survey vendor. This is to ensure that patients respond to the survey in a way that reflects their actual experiences with ASC care, and is not influenced by the ASC. Removing vendors, neutral third parties, could raise issues of objectivity and bias.

Comment: One commenter did not support adoption of the proposed ASC-15a-e survey-based measures because the commenter believes the OAS CAHPS Survey assesses only patient satisfaction with their care, not the quality of care provided, and is therefore inappropriate for use in the ASCQR Program.

Response: We disagree with the commenter's assertion that the OAS CAHPS Survey does not assess the quality of care provided at a facility. Studies show a relationship between the clinical quality of care provided at a facility and patients' experience of care.^{208 209} The OAS CAHPS Survey is specifically designed to measure patient experience of care in the hospital outpatient and ambulatory surgical center settings, and we believe patient experience of care is an important indicator of the quality of care provided at a facility. As noted above, patients are the best source for certain information about the quality of care.

Comment: One commenter requested additional information regarding the definition of "completed surveys" for the OAS CAHPS Survey.

Response: We refer readers to Exhibit 9.1 "Steps for Determining Whether a

²⁰⁷ Outpatient and Ambulatory Surgery CAHPS Survey: "Protocol and Guidelines Manual." Available for download at: <https://oascahps.org/Survey-Materials>.

²⁰⁸ Isaac, T., Zaslavsky, A.M., Cleary, P.D., and Landon, B.E. The Relationship Between Patients' Perception of Care and Measures of Hospital Quality and Safety. *Health Services Research*. 2010;45:1024-1040.

²⁰⁹ Anhang, P. et al. Examining the Role of Patient Experience Surveys in Measuring Health Care Quality. *Med Care Res Rev*. 2014;71(5):552-554.

²⁰⁵ CMS National Quality Strategy 2016. Available at: <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/qualityinitiativesgeninfo/downloads/cms-quality-strategy.pdf>.

²⁰⁶ Outpatient and Ambulatory Surgery CAHPS Survey: "Protocol and Guidelines Manual." Available for download at: <https://oascahps.org/Survey-Materials>.

Questionnaire Meets Completeness Criteria” on in the Protocol and

Guidelines manual, available at: <https://oascahps.org/Survey-Materials>.

Exhibit 9.1 Steps for Determining Whether a Questionnaire Meets Completeness Criteria

Sum the number of questions that have been answered by the respondent that are applicable to all patients. These include questions 1–10 and 13–24.

$R = \text{total number of questions answered}$

Divide the total number of questions answered by 22, which is the total number of questions applicable to all patients, and then multiple by 100 to determine the percentage.

Percentage Complete = $(R / 22) \times 100$

If the Percentage Complete is greater than or equal to 50 percent, then assign the applicable survey completed disposition code (code 110 or 120) to indicate that the case meets the definition of a completed survey. Otherwise, assign the disposition code for breakoff (code 310) to the case.

A survey administered under the OAS CAHPS Survey Protocols and Guidelines is considered to be “complete” if the patient answered at least half of the questions applicable to all patients.²¹⁰ There are a total of 22 questions that are applicable to all patients—Questions 1 through 10 and Questions 13 through 24. A survey is considered complete when at least 11 of these questions are answered by the patient.

Comment: One commenter expressed concerns about using the survey results in payment determinations, particularly in instances where a facility has a low response rate. A few commenters stated that patient response is out of the control of the facility, and asserted that facilities should not be penalized for patients’ decision not to complete the survey.

Response: We agree with commenters that patient response is largely out of the control of the facility. However, we clarify we did not propose to penalize ASCs for patients’ decision not to complete the survey. Payment implications under the ASCQR Program are tied to the successful and timely reporting of required quality measure data. An ASC will not receive a payment reduction based on performance under the ASC–15a–e measures if the ASC administers the survey according to the OAS CAHPS

Survey Protocol and Guidelines Manual²¹¹ and submits that data to CMS by the data submission deadline, regardless of the number of completed surveys the facility receives. Results will be used for public reporting only.

Comment: One commenter noted that the patient population for ASCs is different than that of hospitals, and there is little data available about this population’s willingness to complete CAHPS surveys.

Response: We acknowledge the commenter’s concern regarding the current lack of data on ASC patient response rates to patient experience of care surveys. As noted previously (81 FR 45730), before development of the OAS CAHPS Survey, there was no standardized survey available to collect information on the patient’s overall experience for surgeries or procedures performed within an ASC. However, the field and mode testing of the OAS CAHPS Survey, as discussed in the above responses, indicates that ASCs will receive a reasonable response rate. For the mode experiment in 2015, which included 13,576 patients from 70 facilities (38 hospital outpatient departments and 32 ASCs), the overall response rate across all modes tested was 39 percent. The response rate for ASCs was slightly higher (39.6 percent) than the response rates for the hospital outpatient departments (38.6 percent)

for the mode experiment. The response rate for the mail-only mode was 37 percent; the telephone-only response rate was 34 percent; and the mixed-mode response rate was 50 percent. For the field test in 2014, which was mixed-mode only and included 4,179 patients from 36 facilities (18 hospital outpatient departments and 18 ASCs), the response rate was 46 percent. The overall response rate for the 18 participating ASCs was slightly higher (47 percent) than the response rate for the hospital outpatient departments.²¹² Therefore, we believe ASCs will receive a reasonable response rate under the OAS CAHPS Survey.

Comment: One commenter expressed concern that the survey administration period for the OAS CAHPS Survey extends too far beyond the time after a patient’s procedure.

Response: Both the field test (2014) and the mode experiment (2015) were conducted using monthly survey administration. The monthly sampling ensures that patient records are evenly distributed throughout the year without possible seasonal bias. As stated in the proposed rule (81 FR 45738), to meet the OAS CAHPS Survey requirements for the ASCQR Program, we proposed that ASCs contract with a CMS approved vendor to collect survey data for eligible patients at the ASCs on a monthly basis and report that data to CMS on the ASC’s behalf by the

²¹⁰ Outpatient and Ambulatory Surgery CAHPS Survey: “Protocol and Guidelines Manual.” Available for download at: <https://oascahps.org/Survey-Materials>.

²¹¹ Outpatient and Ambulatory Surgery CAHPS Survey: “Protocol and Guidelines Manual.” Available for download at: <https://oascahps.org/Survey-Materials>.

²¹² <https://oascahps.org/General-Information/Mode-Experiment>.

quarterly deadlines established for each data collection period. While we require that the OAS CAHPS Survey be collected on a monthly basis, we are clarifying here that facilities can sample and implement the survey more frequently than monthly as long as the reporting of data is provided based on a monthly sampling plan. Information on sampling more frequently than monthly can be found in the OAS CAHPS Protocols and Guidelines Manual which is available at: <https://oascahps.org/Survey-Materials>. Under the OAS CAHPS Protocols and Guidelines Manual,²¹³ ASCs may choose to have their vendors select the sample and implement the survey more frequently as long as the monthly targets are met and the patient sample is distributed throughout the month. Therefore, if ASCs are concerned with the timeframe, they may survey more frequently.

Comment: One commenter recommended that CMS align the OAS CAHPS Survey with the HCAHPS Survey by: (1) Adopting the same four-point scale used in the HCAHPS Survey for ratings questions (that is, “Always; Usually; Sometimes; or Never” responses); and (2) adopting the same new medication questions used in the HCAHPS Survey to the OAS CAHPS Survey (Question 15: “During this hospital stay, were you given any medicine that you had not taken before?”; Question 16: “Before giving you any new medicine, how often did hospital staff tell you what the medicine was for?”; Question 17: “Before giving you any new medicine, how often did hospital staff describe possible side effects in a way you could understand?”).

Response: As part of the survey development process, the OAS CAHPS Survey was aligned as appropriate with other CAHPS Surveys, including the HCAHPS Survey. However, the OAS CAHPS Survey assesses patient experience of care for outpatient surgical procedures, and therefore, takes the outpatient/ambulatory setting into account and captures information about the appropriate experiences of care for this particular setting.

We note that the four-point scale response set used for some HCAHPS Survey questions, “Always; Usually; Sometimes; or Never,” is appropriate to use when a question includes the phrase “how often.” This is appropriate in the inpatient setting, where patients stay in

the hospital for a longer period of time. The OAS CAHPS Survey questions use a single point in time reference for an outpatient surgery or procedure because patients spend a significantly shorter period of time in the facility. Therefore, we believe the OAS CAHPS Survey questions and response options are worded appropriately (that is, for the majority of the OAS CAHPS Survey questions, the response categories are: “Yes, definitely,” “Yes, somewhat,” or “No.” Response categories for other questions are: “Yes” or “No” for this setting of care and treatment situation.

While there are no plans to add questions about new medications to the OAS CAHPS Survey at this time, we will take this recommendation into consideration during future updates to the survey.

Comment: One commenter expressed concern that the OAS CAHPS Survey groups patients’ assessment of care provided by doctors and nurses together because the commenter believes this will provide less meaningful information to providers and patients. The commenter recommended that CMS develop separate questions regarding nurses’ care, focusing on the nursing staff’s effect on the patient’s surgical experience and discharge instructions to better measure the role of nurses in patient experience of care.

Response: In the OAS CAHPS Survey, references to the doctors, nurses, and other staff at the facility are grouped together for two reasons. First, grouping assessment of the healthcare personnel at a facility helps reduce the overall length of the survey so that similar questions are not repeated separately for doctors and nurses. Second, the questions listed under sections I, II, III, and IV (Before Your Procedure; Facility and Staff; Communications; and Recovery) include aspects of the patient’s care that could be addressed by either the doctor or another healthcare professional at the facility. Combining these professionals under a single series of questions allows the patient to report that someone provided information and explained the process without having to recall the specific individual who gave the information. This is important because the OAS CAHPS Survey is intended to assess the patient’s experience of care at the facility, including, but not separating out, all the staff that work at the facility. For these reasons, we believe it is appropriate to ask these questions in a way that reflects the care provided by doctors, nurses, and other facility staff combined. We note that during the OAS CAHPS Survey field test conducted in 2014 and the mode experiment conducted in

2015, we did not receive any indications that the respondents had any difficulty answering these questions as they are currently written. The nonresponse, which is an indication of difficulty answering a question, was very low for the two questions that combine doctors and nurses (Question 7, which is about treating the patient with courtesy and respect and Question 8, which is about making sure the patient was a comfortable as possible). For the field test, less than 0.5 percent of the respondents did not respond to these questions while 99.5 percent were able to answer these questions. For the mode experiment just over 1 percent of the respondents did not respond to the questions while nearly 99 percent were able to answer them. These nonresponse rates were very similar to the questions that were about clerks and receptionists.

Comment: One commenter expressed concern that CMS did not propose to include the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey (S-CAHPS) in the ASCQR Program alongside the OAS CAHPS Survey. The commenter stated the S-CAHPS Survey, developed by AHRQ in collaboration with a broad array of surgical groups, addresses critical gaps in the assessment of surgical care such as informed consent, shared decision-making, anesthesia care, post-operative instructions, and access, all of which are issues consumers find to be very important in seeking surgical care. The commenter therefore recommended CMS include the S-CAHPS Survey in the ASCQR Program in addition to the OAS CAHPS Survey. Another commenter recommended CMS adopt the S-CAHPS Survey for the ASCQR Program instead of the OAS CAHPS Survey because the S-CAHPS Survey is NQF-endorsed for the measurement of patient experience of care before, during, and after surgery.

Response: The focus of S-CAHPS is to obtain a patient’s experience of care received from a surgeon,²¹⁴ whereas the focus of OAS CAHPS is to obtain data on a patient’s experience of care received from a facility, specifically from an ambulatory surgery center or an ASC. Therefore, the units of analyses are not the same. We also refer readers to our discussions above regarding non-NQF endorsed measures. Furthermore, in order for a measure to be proposed for adoption into the ASCQR Program, it must first be put on the MUC list and reviewed by the MAP. The S-CAHPS

²¹³ Outpatient and Ambulatory Surgery CAHPS Survey: “Protocol and Guidelines Manual.” Available for download at: <https://oascahps.org/Survey-Materials>.

²¹⁴ American College of Surgeons. “S-CAHPS (Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey).” Available at: <https://www.facs.org/advocacy/quality/cahps>.

Survey has not been submitted to the MAP for consideration as a measure for the ASCQR Program, and therefore, cannot be proposed or adopted for the program at this time. However, we will take these recommendations into consideration for the future.

Comment: Two commenters requested that CMS reconsider its position on respondent confidentiality for the OAS CAHPS Survey administration to align with the HCAHPS survey, which allows for the release of patient-level data for quality improvement purposes, with the stipulation that a patient's identity should not be shared with direct care staff. One commenter stated that very few patients return to an ASC for another surgical procedure within three months of the index surgery, and that ASC patients should therefore not be considered to have an "ongoing relationship" with the ASC where they received care. Another commenter noted that maintaining this confidentiality would pose challenges to identification and formal investigation of potential grievances and limit facilities' ability to map specific ratings to other patient-level encounter variables for quality improvement initiatives. Commenter asserted that ASCs must be able to work confidentially with the OAS CAHPS Survey results in order to study the patient experience and drive quality improvement efforts.

Response: The administration protocols for OAS CAHPS follow protocols for other more recent CAHPS® Surveys, restricting the release of patient-level data if the patient has not consented. For example, the Home Health Care CAHPS (HHCAPHS) Survey protocol states: "HHCAPHS Survey approved vendors can provide responses linked to a sample patient's name and other identifying information only if the sample patient gives his or her consent on the 'Consent to Share Identifying Information' question."²¹⁵ For the Hospital IQR Program, because hospitals can self-administer the HCAHPS Survey, we do not state that patients' responses and identifying information will not be shared with the hospital. However, HCAHPS Surveys administered via a third-party vendor are not linked to a sample patient's name unless the patient gives his or her consent, and we encourage hospitals to undertake measures to protect patient confidentiality when self-administering the survey. We note that facilities may choose to add the "Consent to Share"

question²¹⁶ to the OAS CAHPS Survey. This question asks whether a patient gives permission for their name to be linked to their survey responses. However, we note that each facility should consult with its own counsel to ensure compliance with applicable privacy and security laws.

Comment: Two commenters expressed concern that if the OAS CAHPS Survey results are reported at the CCN level, the results will be more difficult for patients to use in selecting a facility for their care, and of less value to individual facilities for performance improvement purposes. The commenters recommended that CMS collect and report ASC-15a-e measure data at the NPI level, as is done for other ASCQR Program measures.

Response: Survey results are collected and reported at the CCN level because the OAS CAHPS Survey was tested at the CCN level. However, we thank the commenters for their recommendation to report OAS CAHPS Survey-based measure data at the NPI level for patient ease and individual facility performance improvement purposes. We will consider the feasibility of requiring ASCs to collect and report OAS CAHPS Survey data at the NPI level in future rulemaking.

Comment: Many commenters expressed concerns regarding the length of the OAS CAHPS Survey. A number of commenters asserted that the OAS CAHPS Survey's length impairs ASCs' ability to add their own questions to the survey because the resulting survey would be too long to receive a reasonable response rate. The commenters also expressed concern that the OAS CAHPS Survey's length will limit the number of completed surveys an ASC receives because patients will be overwhelmed by the number of questions in the survey or otherwise unable to complete the survey, and in turn impact the ability of the ASC to use the survey data in quality improvement activities.

These commenters recommended CMS shorten the OAS CAHPS Survey in order to increase survey completion rates, and further recommended CMS allow each facility to have more choice in the questions they include in their survey. A number of commenters specifically recommended that CMS shorten the required patient experience items to allow ASCs to add their own questions and collect targeted information to enhance patient experience at their own facilities.

Numerous commenters also recommended that CMS shorten the "About You" section of the OAS CAHPS Survey to include only those items either required by law or collected for use in patient-mix adjustment.

Response: The OAS CAHPS Survey is comparable in length and survey response rate to other patient experience of care surveys. For example, the HCAHPS Survey is 32 questions long,²¹⁷ and the response rate for the HCAHPS Survey has generally been 32 to 33 percent.²¹⁸ By comparison, the OAS CAHPS Survey is 37 questions long, and the survey's 2015 mode experiment showed an overall response rate of 39 percent.²¹⁹ The mode experiment was conducted to test the OAS CAHPS Survey questions when administered by mail-only, telephone-only, and mixed-mode (mail with telephone follow-up).

With regard to the concern that response rates would be negatively affected by any supplemental questions, we found that the response rates for the field test in 2014 were good for ASCs (47 percent for the mixed-mode) and that earlier version of the survey included 12 additional questions that have since been removed from the OAS CAHPS Survey.

While we appreciate commenters' recommendation that facilities be allowed to choose which questions to administer, the survey instrument was developed in order to provide a more complete picture of patients' experience of care in the ASC setting. We believe allowing facilities to administer a selection of the survey items to patients would impair the assessment of a facility's quality of care, and would also inhibit the comparison of performance across facilities and the reliability of a facility's scores. As currently specified, the OAS CAHPS Survey requires that the survey be administered by an approved survey vendor. As previously discussed, this is to ensure that patients respond to the survey in a way that reflects their actual experiences with ASC care, and is not influenced by the ASC. Removing vendors, neutral third parties, could raise issues of objectivity and bias. In addition, the 24 core questions of the OAS CAHPS Survey are either directly actionable (that is, give feedback to hospitals) or inform the need for patients to answer subsequent

²¹⁷ <http://www.hcahpsonline.org/survey/instrument.aspx>.

²¹⁸ For example, see: <https://www.medicare.gov/hospitalcompare/details.html?msrCd=prnt1grp1&ID=220066&stCd=MA&stName=Massachusetts>.

²¹⁹ Outpatient and Ambulatory Surgery CAHPS Survey: "Mode Experiment." Available at: <https://oascahps.org/General-Information/Mode-Experiment>.

²¹⁵ Home Health Care CAHPS Survey: "Protocols and Guidelines Manual." Available at: <https://homehealthcahps.org/Portals/0/PandGManual.pdf>.

²¹⁶ Outpatient and Ambulatory Surgery CAHPS Survey: "Survey Materials." Available at: <https://oascahps.org/Survey-Materials>.

questions that are actionable. For example, Question 10, which asks whether a patient received anesthesia, establishes whether a patient should respond to Questions 11 and 12, which provide actionable feedback to ASCs regarding their communication with the patient about the anesthesia process and possible side effects. We also encourage ASCs to consider adding specific questions of interest to the OAS CAHPS Survey. As noted in the CY 2017 OPPS/ASC proposed rule (81 FR 45732), ASCs may elect to add up to 15 supplemental questions to the OAS CAHPS Survey. These could be questions ASCs develop specifically for use alongside the OAS CAHPS Survey, or questions from an existing survey.

However, we also acknowledge commenters' concerns about the length of the OAS CAHPS Survey and their recommendations to shorten 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 are contemplating removing two demographic questions—the "gender" and "age" questions—from the OAS CAHPS Survey in its next update, if we determine that it is feasible, when collecting information on survey-eligible patients from facility records, that gender and age information could also be collected via these records.

Comment: One commenter requested that CMS remove or revise two questions on the OAS CAHPS Survey asking whether a doctor or anyone from the facility: (1) Gave the patient all the information needed about their procedure; and/or (2) gave the patient easy to understand instructions about preparing for their procedure. The commenter asserted that patient education is solely within the purview of the doctor's office, not the facility, and should therefore be removed from a survey assessing patients' experience of care at the facility.

Response: We disagree with the commenter's assertion that patient education is solely within the purview of the doctor's office. We believe it is the facility's responsibility to ensure that a doctor, nurse, or other facility staff member provides the patient with information about preparing for their procedure, the procedure itself, and what to expect following discharge from the ASC. The OAS CAHPS Survey-based measures were reviewed by two 10-member TEPs comprised of experts

on outpatient surgery, including clinicians, providers, patient advocates, and representatives from other stakeholder organizations. These TEPs provided guidance in the establishment of relevant topics for assessing patient experience of care at an outpatient facility, and commented on draft versions of the survey for cognitive and field testing. These TEPs agreed with the questions as drafted, including those regarding the facility's communication with patients. Therefore, we believe it is appropriate to include these important communications between the patient and the facility about their care in the OAS CAHPS Survey.

The OAS CAHPS Survey is focused on patients' experience of care received for their ambulatory surgery or procedure. A physician/surgeon who performs surgeries/procedures at a facility is a member of that facility with both rights and responsibilities. We believe it is the facility's responsibility to ensure that someone—whether the doctor, nurse, or other facility staff member—provide patients with information about preparing for their procedure, about the procedure itself, as well as what to expect following the procedure/surgery. Therefore, we believe it is appropriate to include these important communications with patients in the OAS CAHPS Survey.

Comment: One commenter requested clarification from CMS regarding the inclusion of pain management-related questions in the OAS CAHPS Survey. The commenter expressed concern that the pain management communication questions may negatively influence patient perceptions about their overall care and, in turn, result in negative responses throughout the survey. Another commenter expressed concern that the OAS CAHPS Survey's questions regarding communication about pain management may not reflect the true perception patients have of their experience relative to pain management, and recommended CMS continue to explore ways to ensure better measurement of patients' experience with pain management.

Response: The OAS CAHPS Survey pain management communication questions focus on the information provided to patients regarding pain management following discharge from an ASC, not the ASC's direct control or management of patients' pain. The ASC is responsible for providing the patient with this information if there is a possibility that the patient might have pain as a result of the procedure. Communication about possible effects during recovery is an important factor for patients. As discussed previously,

the OAS CAHPS Survey underwent a rigorous survey development process, the results of which did not indicate any negative impact to overall survey responses resulting from the inclusion of these questions regarding pain management communication. In addition, we have no reason to believe that patients' responses to the pain management communication questions would not accurately reflect their experience with the facility. Therefore, we do not believe that the pain management communication question would negatively influence patient perceptions about their overall care, resulting in negative responses throughout the survey. However, as noted in the CY 2017 OPPS/ASC proposed rule (81 FR 45732), we will continue to evaluate the appropriateness and responsiveness of these questions to patient experience of care and public health concerns.

Comment: A number of commenters expressed concern regarding the OAS CAHPS Survey pain management communication question, "Some ways to control pain include prescription medicine, over-the-counter pain relievers or ice packs. Did your doctor or anyone from the facility give you information about what to do if you had pain as a result of your procedure?" One commenter recommended that CMS refine this question to be clear the survey is asking whether patients received pain management information that could be applied once they left the facility, and that the information could include, but is not limited to, information about pain management using appropriate medications. Another commenter recommended reorganizing the pain management methods listed in the first question to run from non-medication pain management to prescription pain medication treatment. One commenter recommended that CMS expand this question to include other methods of pain management, such as physical therapy, because the commenter believed using a more inclusive list of pain control methods would help to further combat the over prescription of opioids for pain management.

Some commenters also expressed concerns regarding the pain management communication control question, "At any time after leaving the facility, did you have pain as a result of your procedure?" Specifically, a few commenters requested that CMS revise the pain management communication control question to ask whether, at any time after leaving the facility, the patient experienced pain as a result of their procedure that they felt they could

not manage based on the information they received from the facility or treating physician.

Response: We thank the commenters for their recommendations. As discussed previously, the OAS CAHPS Survey underwent a rigorous survey development process, the results of which indicated that patients understand these questions as presented, and that the questions sufficiently developed for use in the survey.²²⁰ As discussed previously, the OAS CAHPS Survey-based measures were reviewed by two 10-member TEPs comprised of experts on outpatient surgery, including clinicians, providers, patient advocates, and representatives from other stakeholder organizations. These TEPs provided guidance in the establishment of relevant topics for assessing patient experience of care at an ASC, and commented on draft versions of the survey for cognitive and field testing. The possible treatments for pain included in the survey reflect what is tested and reflected to work, and their order is not intended to reflect a preference for any single pain treatment method, only to provide examples of types of pain management a facility may discuss with a patient prior to discharge. The examples provided in this question are also not intended to be an exhaustive list, and we acknowledge that there are many methods for addressing pain following a procedure performed at an ASC, including physical therapy. Because this is not an exhaustive list, we do not believe it is necessary to exclude, expand, or reorganize these questions at this time. However, we will take these suggestions, including reorganizing the pain management methods, into consideration for future iterations of the survey.

Comment: Two commenters expressed concerns that the pain management communication control question raises an unrealistic expectation regarding pain control, and may potentially encourage over prescription of opioids. These commenters therefore recommended removing the pain management communication control question from the OAS CAHPS Survey.

Response: We also note that Question 16 “At any time after leaving the facility, did you have pain as a result of your procedure?” is a control question;

in other words, an answer of “yes” or of “no” would not affect provider scores on the OAS CAHPS survey questions. The scores are based on the previous Question 15, which asked if the doctor or anyone from the facility gave the patient information about what to do if the patient had pain as a result of the procedure. We will not publicly report the data from the control question that asks if the patient had pain as a result of the procedure, rather, that question is only used to determine if the previous question should be included in the score or not. For example, if the patient reported having had pain in Question 16, then the response to Question 15 would be included in the score that is reported for the ASC.

For example, the focus of Questions 15 and 16 is to determine whether a patient who is expected to experience pain as a result of a procedure was given information from the doctor or anyone from the facility about what to do about pain. If a patient experiences pain as a result of a procedure (Question 16), it is important that the patient was provided information as to what to do about the pain (Question 15). In these instances, the response to Question 15 would be included in the score. However, for some procedures conducted in an ASC (for example colonoscopies), there is little expectation of the patient experiencing pain. In these instances, a doctor or anyone from the facility may not have given a patient information about what to do about pain as such information would not be relevant. In these latter instances, the response to Question 15 would not be included in the score unless the patient response is a top-box (that is, “Yes, definitely”) response.

We do not believe a question asking whether patients experienced pain would have an undue influence on patients’ responses to the OAS CAHPS Survey or warrant its removal from the OAS CAHPS Survey. As stated above, the OAS CAHPS Survey underwent a rigorous survey development process, the results of which did not indicate any negative impact to overall survey responses resulting from the inclusion of these questions regarding pain management communication. In addition, we have no reason to believe that patients’ responses to the pain management communication questions would not accurately reflect their experience with the facility. Therefore, we do not believe that the pain management communication question would negatively influence patient perceptions about their overall care, resulting in negative responses throughout the survey.

Furthermore, as stated in the proposed rule (81 FR 45732), this control question will not affect scores on the OAS CAHPS survey. Rather, scores are based on the previous Question 15, which asks if the doctor or anyone from the facility gave the patient information about what to do if the patient had pain as a result of the procedure. However, we will review the data from the voluntary national implementation and continue to evaluate the appropriateness and responsiveness of these questions, particularly for any unintended consequences.

Comment: One commenter requested clarification about whether CMS intends to publicly report ASC scores on the pain management communication control question.

Response: We interpret the comment to refer to Question 16, “At any time after leaving the facility, did you have pain as a result of your procedure?” As stated above, this question is a control question, meaning that an answer of “yes” or “no” would not affect scores on the OAS CAHPS survey questions. Rather, scores are based on the previous Question 15, which asks if the doctor or anyone from the facility gave the patient information about what to do if the patient had pain as a result of the procedure.

Comment: One commenter recommended that CMS remove the questions on the OAS CAHPS Survey asking patients whether they experienced pain, nausea, or bleeding following a procedure, because the commenter believes this information is not useful to facilities in quality improvement activities, as these are all risks associated with surgery.

Response: Question 17 (“Before you left the facility, did your doctor or anyone from the facility give you information about what to do if you had nausea or vomiting?”) and Question 18 (“At any time after leaving the facility, did you have nausea or vomiting as a result of either your procedure or the anesthesia?”) are intended to assess the information provided to patients regarding what to expect following a surgery/procedure. We believe it is the facility’s responsibility to ensure that the patient is aware of the potential side effect of their treatment, and, therefore, believe these questions are indicative of quality of care. As above, we note that Question 18 is a control question, so an affirmative or negative response would not be included in the provider scores on the OAS CAHPS Survey, but rather is used to determine if the provider should have given guidance on how to handle nausea or vomiting (Question

²²⁰ A description of the field test analysis of the survey questions was documented in the **Federal Register** notice on January 16, 2015 (80 FR 2430 through 2431). Available at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10500.html>.

17). The information will be useful to facilities because they will be able to ensure that the information that patients need during recovery is adequately addressed by the facility staff. These questions are not reporting whether the patients experienced pain, nausea, vomiting, bleeding or signs of infection; the questions are reporting if the patients were informed what to do if they had these outcomes.

For example, the focus of questions 17 and 18 is to determine whether a patient who might likely experience nausea or vomiting as a result of a procedure was given information from the doctor or anyone from the facility about what to do to manage these outcomes. If a patient experiences these outcomes as a result of a procedure, it is important that the patient was provided information on how to manage these outcomes. In these instances, the response to Question 17 would be included in the score. However, for some procedures conducted in an ASC (for example laser surgeries), there is little expectation of the patient experiencing nausea or vomiting and in these instances a doctor or anyone from the facility may not have given a patient information on how to

manage these outcomes as such information would not be relevant. In these latter instances the responses to Question 17 would not be included in the score unless the patient response is a top-box (that is, “Yes, definitely”) response.

Furthermore, as stated in the proposed rule (81 FR 45732), this control question will not affect scores on the OAS CAHPS survey. Rather, scores are based on the previous Question 17, which asks if the doctor or anyone from the facility gave information about what to do if the patient had nausea or vomiting. However, we will review the data from the voluntary national implementation and continue to evaluate the appropriateness and responsiveness of these questions, particularly for any unintended consequences.

Comment: One commenter recommended that CMS include an item in the OAS CAHPS Survey assessing whether patients felt they were provided sufficient and timely access to medical innovation and technology during their care in the ASC setting.

Response: We thank the commenter for its recommendation as well as

similar concerns from other commenters and will take this recommendation into consideration while balancing the survey’s length during the next OAS CAHPS Survey update.

After consideration of the public comments we received, we are finalizing our proposal to adopt the ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures for the ASCQR Program for the CY 2020 payment determination and subsequent years as proposed with a clarification that ASCs that anticipate receiving more than 300 surveys are required to either: (1) randomly sample their eligible patient population, or (2) survey their entire OAS CAHPS eligible patient population. We note that these measures are also being finalized in the Hospital OQR Program and refer readers to section XIII.B.5.c. of this final rule with comment period for more details.

Including the proposals we are finalizing, the measure set for the ASCQR Program CY 2020 payment determination and subsequent years is listed below.

ASCQR PROGRAM MEASURE SET PREVIOUSLY FINALIZED AND NEWLY FINALIZED FOR THE CY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

ASC #	NQF #	Measure name
ASC–1	0263	Patient Burn.
ASC–2	0266	Patient Fall.
ASC–3	0267	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant.
ASC–4	† 0265	All-Cause Hospital Transfer/Admission.
ASC–5	† 0264	Prophylactic Intravenous (IV) Antibiotic Timing.
ASC–6	N/A	Safe Surgery Checklist Use.
ASC–7	N/A	ASC Facility Volume Data on Selected ASC Surgical 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	N/A	Normothermia Outcome.***
ASC–14	N/A	Unplanned Anterior Vitrectomy.***
ASC–15a	N/A	OAS CAHPS—About Facilities and Staff.***
ASC–15b	N/A	OAS CAHPS—Communication About Procedure.***
ASC–15c	N/A	OAS CAHPS—Preparation for Discharge and Recovery.***
ASC–15d	N/A	OAS CAHPS—Overall Rating of Facility.***
ASC–15e	N/A	OAS CAHPS—Recommendation of Facility.***

† We note that NQF endorsement for this measure was removed.

* Procedure categories and corresponding HCPCS codes are located at: <http://qualitynet.org/docs/ContentServer?c=Page&pagename=QnetPublic%2FPPage%2QnetTier2&cid=1228772475754>.

** Measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in section XIV.E.3.c. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).

***New measure finalized for the CY 2020 payment determination and subsequent years.

5. ASCQR Program Measure for Future Consideration

In the CY 2013 OPPS/ASC final rule with comment period, we set forth our considerations in the selection of

ASCQR Program quality measures (77 FR 68493 through 68494). 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 OPPTS/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 the CY 2017 OPPTS/ASC proposed rule (81 FR 45735), we invited public comments on one measure developed by the ASC Quality Collaboration for potential inclusion in the ASCQR Program in future rulemaking: the Toxic Anterior Segment Syndrome (TASS) measure.

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.²²¹ The TASS measure assesses the number of ophthalmic anterior segment surgery patients diagnosed with TASS within 2 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.²²² Prevention requires careful attention to solutions, medications, and ophthalmic devices and to cleaning and sterilization of surgical equipment because of the numerous potential etiologies.²²³ Despite a recent focus on prevention, cases of TASS continue to occur, sometimes in clusters.²²⁴ 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.

This issue 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.

The TASS measure was included on the 2015 MUC list²²⁵ and reviewed by the MAP. The MAP conditionally supported the measure (MUC ID: 15–1047), noting 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 cautioned that the measure should 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.²²⁶ A summary of the MAP recommendations can be found at: http://www.qualityforum.org/Projects/im/MAP/2016_Final_Recommendations.aspx.

The TASS measure is used to assess 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://www.ascquality.org/qualitymeasures.cfm>, under “Implementation Guide.”

We invited public comments on the possible inclusion of this measure in the ASCQR Program measure set in the future.

Comment: A number of commenters agreed that TASS is a serious complication of anterior segment eye surgery, and that the high volume of eye procedures performed in the United States each year highlights the importance of measures that can support best practices in instrument sterilization and reprocessing. The commenters also noted that incidences of TASS are attributable to the ASC, prevention is actionable by the facility, and published guidelines regarding cleaning and sterilizing of surgical instruments to help improve quality and

prevent TASS are available. The commenters also stated that measuring the incidence of TASS may aid in better tracking and understanding the prevalence of TASS.

Response: We thank the commenters for their comments and insights regarding future inclusion of the TASS measure in the ASCQR Program. We will take these comments into consideration if we propose to adopt the TASS measure for the ASCQR Program in the future.

Comment: A few commenters did not support future adoption of the TASS measure because the occurrence of TASS is not necessarily attributable to the ASC, and as a result ASCs may lack the ability to reduce cases of TASS. Some commenters recommended that CMS wait until the NQF has reviewed and endorsed the TASS measure before adopting this measure for the ASCQR Program.

Response: We thank the commenters for sharing their concerns regarding future inclusion of the TASS measure in the ASCQR Program. As stated above, we believe that ASCs could reduce cases of TASS by prevention, which requires careful attention to solutions, medications, and ophthalmic devices and to cleaning and sterilization of surgical equipment because of the numerous potential etiologies.²²⁷ With millions of anterior segment surgeries being performed in the United States each year, we believe that measurement and public reporting have the potential to serve as an additional tool to drive further preventive efforts. However, we will take these comments into consideration if we propose to adopt the TASS measure for the ASCQR Program in the future.

6. Maintenance of Technical Specifications for Quality Measures

We refer readers to the CY 2012 OPPTS/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 OPPTS/ASC final rule with comment period (77 FR 68496 through 68497), the CY 2014 OPPTS/ASC final rule with comment period (78 FR 75131), and the

²²¹ 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.

²²² 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.

²²³ 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 Instruments. J Cataract Refract Surg. 2007 Jun;33(6):1095–1100.

²²⁴ 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.

²²⁵ Available at: http://www.qualityforum.org/2015_Measures_Under_Consideration.aspx, under “2015 Measures Under Consideration List (PDF).”

²²⁶ Available at: <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593>.

²²⁷ 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 Instruments. J Cataract Refract Surg. 2007 Jun;33(6):1095–1100.

CY 2015 OPPTS/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 OPPTS/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. In the CY 2017 OPPTS/ASC proposed rule (81 FR 45735), we did not propose any changes to our policies regarding the maintenance of technical specifications for the ASCQR Program.

7. Public Reporting of ASCQR Program Data

In the CY 2012 OPPTS/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 OPPTS/ASC final rule with comment period (80 FR 70531 through 70533), we finalized our policy to publicly display data by the National Provider Identifier (NPI) when the data are submitted by the NPI and to publicly display data by the CCN when the data are submitted by the CCN. In addition, we codified our policies regarding the public reporting of ASCQR Program data at 42 CFR 416.315 (80 FR 70533). In this final rule with comment period, we are formalizing our current public display practices regarding timing of public display and the preview period, as discussed in more detail below and finalizing how we will announce the preview period timeframes.

Our regulations at 42 CFR 416.315 state that data that an ASC submits for the ASCQR Program will be made publicly available on a CMS Web site. We currently make the data available on at least a yearly basis and strive to publicly display data as soon as possible. Furthermore, as previously stated in the CY 2012 OPPTS/ASC final rule with comment period (76 FR 74514 through 74515), we are required to give ASCs an opportunity to preview their data before it is made public. Historically, preview for the April

Hospital Compare data release typically occurs in January, preview for the July *Hospital Compare* data release typically occurs in April, preview for the October *Hospital Compare* data release typically occurs in July, and the preview for the December *Hospital Compare* data release typically occurs in October. During the preview period, ASCs have generally had approximately 30 days to preview their data. In the CY 2017 OPPTS/ASC proposed rule (81 FR 45735 through 45736), therefore, we proposed to publicly display data on the *Hospital Compare* Web site, or other CMS Web site, as soon as possible after measure data have been submitted to CMS, consistent with current practice. In addition, we proposed that ASCs will generally have approximately 30 days to preview their data, also consistent with current practice.

Lastly, moving forward, we proposed 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.

We invited public comments on our proposals regarding the timing of public display and the preview period as discussed above.

Comment: A number of commenters supported CMS' proposal to give ASCs 30 days to preview their quality data before it is publicly reported on Hospital Compare because commenters agree doing so will increase data transparency and better educate patients and providers regarding ASC's performance under the ASCQR Program. The commenters encouraged CMS to publicly display ASCQR Program data as soon as possible, because doing so will help consumers make more informed decisions about their care and encourage facilities to ensure high quality of care.

Response: We thank the commenters for their support.

Comment: One commenter urged CMS to align preview period policies across its inpatient and outpatient quality reporting programs in order to reduce confusion and frustration of providers participating in more than one quality reporting program.

Response: By adopting a 30-day preview period, the ASCQR Program will align the duration of its preview period for publicly reporting program data with the Hospital IQR Program (77 FR 53505), the Hospital Readmissions Reduction Program (76 FR 51672 through 51673), the Hospital-Acquired Condition Reduction Program (78 FR 50727 through 50728), the PPS-Exempt Cancer Hospital Quality Reporting Program (77 FR 53562 through 53563),

and the Inpatient Psychiatric Facility Quality Reporting Program (77 FR 53654). We also note that we are finalizing a similar proposal under the Hospital OQR Program and refer readers to section XIII.C.8. of this final rule with comment period for more details.

Comment: One commenter urged CMS to finalize a preview period that is reliably and consistently 30 days in length because ASCs need predictability in the preview period in order to appropriately plan staffing and ensure the data are accessed quickly and distributed to the appropriate parties for review in a timely fashion. Another commenter recommended that CMS establish a set timeline for the release of preview reports and consistent preview periods, because doing so will ensure greater quality in data reporting and reduce unnecessary costs for facilities in reviewing program data.

Response: We agree with the commenters, and believe adopting a consistent preview period will benefit ASCs' planning and review of ASCQR Program measure data. We also understand commenters' concern that allowing variability in the duration of the preview period may impact ASCs' ability to plan and prepare for the preview period. While we currently intend to provide a consistent 30-day preview period for ASCQR Program data year-after-year, we believe that retaining some flexibility in this timeline is important in order to ensure that measure data are available for public reporting in a timely fashion. While there may be some variability in the specific dates of a preview period due to data processing and report development issues, we currently publish notifications regarding the availability of preview reports for facilities' review before publication of ASCQR Program measure data through the QualityNet Web site (<https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPPage%2FQnetTier1&cid=1138115987249>) and direct communication to ASCs. We intend to continue providing ASCs with this advance notice of the preview period because we believe doing so provides ASCs with sufficient time to identify and procure resources needed to ensure timely and accurate review of their ASCQR Program data.

Comment: One commenter suggested that CMS allow a preview period of 60 days for ASCs, rather than the proposed 30-day preview period, because ASCs are generally small providers without dedicated quality measurement personnel on staff. The commenter stated that a 60-day preview period would allow a more appropriate amount

of time for ASCs to retrieve reports and review their data before its publication.

Response: While we understand that a 60-day preview period would allow ASCs more time to review their ASCQR Program data prior to its publication, we believe 30 days provides balance between sufficient time for ASCs to review their data and timely publication. Implementing a longer preview period would affect our ability to publish ASCQR Program data in a timely manner, and likely result in longer delays between ASC performance and public reporting of measure data. We believe that implementing a 30-day preview period, in conjunction with the revised May 15 data submission deadline for data submitted via a CMS online data submission tool (discussed in more detail below), will enable us to publicly report ASCs' performance data significantly faster, providing patients with the most up-to-date information for use in making decisions about their care. Furthermore, 30 days aligns the ASCQR Program with other CMS quality reporting programs as discussed above.

Comment: One commenter requested that CMS provide additional information on the length of time it takes to appeal a misclassification and how CMS intends to address misclassifications within the 30-day preview period.

Response: We interpret the commenter's reference to "misclassifications" to mean errors in an ASC's ASCQR Program data. With regards to errors spotted during the preview period, ASCs are directed to contact CMS if there are inaccuracies with regards to measure calculations. ASCs are responsible for ensuring that the underlying measure data are accurate, however, because the preview period is not an opportunity to make corrections to the underlying data.

While the preview period does not serve as a corrections period, ASCs can edit any measure data submitted via an online data submission tool up until the data submission deadline for that measure (80 FR 70533). In addition, although we understand that ASCs cannot currently change QDCs on claims once submitted, or edit measure quality data submitted via an online data submission tool after the submission deadline was passed, we believe it is the responsibility of each ASC to ensure that its data, as reported to CMS, are accurate (80 FR 70533).

After consideration of the public comments we received, we are finalizing our proposals regarding the timing of public display and the preview period for the ASCQR Program as proposed.

C. Administrative Requirements

1. Requirements Regarding QualityNet Account and Security Administrator

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75132 through 75133) for a detailed discussion of the QualityNet security administrator requirements, including setting up a QualityNet account, and the associated timelines, for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70533), we codified the administrative requirements regarding maintenance of a QualityNet account and security administrator for the ASCQR Program at 42 CFR 416.310(c)(1)(i). In the CY 2017 OPPS/ASC proposed rule (81 FR 45736), we did not propose any changes to these policies.

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75133 through 75135) for a complete discussion of the participation status requirements for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70534), we codified these requirements regarding participation status for the ASCQR Program at 42 CFR 416.305. In the CY 2017 OPPS/ASC proposed rule (81 FR 45736), we did not propose any changes to these policies.

D. Form, Manner, and Timing of Data Submitted for the ASCQR Program

1. Requirements Regarding Data Processing and Collection Periods for Claims-Based Measures Using Quality Data Codes (QDCs)

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75135) for a complete summary of the data processing and collection periods for the claims-based measures using QDCs for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70534), we codified the requirements regarding data processing and collection periods for claims-based measures using QDCs for the ASCQR Program at 42 CFR 416.310(a)(1) and (2). In the CY 2017 OPPS/ASC proposed rule (81 FR 45736), we did not propose any changes to these requirements.

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) for a complete discussion of the minimum thresholds, minimum case volume, and data completeness for successful reporting for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 75035), we codified our policies regarding the minimum threshold and data completeness for claims-based measures using QDCs for the ASCQR Program at 42 CFR 416.310(a)(3). We also codified our policy regarding the minimum case volume at 42 CFR 416.305(c). In the CY 2017 OPPS/ASC proposed rule (81 FR 45736), we did not propose any changes to these policies.

3. Requirements for Data Submitted Via an Online Data Submission Tool

In the CY 2017 OPPS/ASC proposed rule (81 FR 45736 through 45737), we proposed changes to requirements for data submitted via a CMS online data submission tool (*QualityNet.org*). In the CY 2017 OPPS/ASC proposed rule (81 FR 45736), we did not propose any changes to our policies regarding data submitted via a non-CMS online data submission tool (CDC NHSN Web site), but are summarizing those policies for context below.

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.

In the CY 2015 OPPS/ASC final rule with comment period, we finalized a submission deadline of May 15 of the year when the influenza season ends for ASC-8: Influenza Vaccination Coverage among Healthcare Personnel (79 FR 66985 through 66986). In the CY 2017

OPPS/ASC proposed rule (81 FR 45736), we did not propose any changes to these requirements.

b. 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) 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 the CY 2014 OPPS/ASC final rule with comment period (78 FR 75137 through 75139), we finalized the data collection time period for quality measures for which data are submitted via a CMS online data submission tool to cover services furnished during the calendar year 2 years prior to the payment determination year. We also finalized our policy that these data will be submitted during the time period of January 1 to August 15 in the year prior to the affected payment determination year. In the CY 2016 OPPS/ASC final rule with comment period, 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 CMS online data submission tool at 42 CFR 416.310(c)(1)(ii). In the CY 2017 OPPS/ASC proposed rule (81 FR 45737), we proposed to change the submission deadline from August 15 in the year prior to the affected payment determination year to May 15 in the year prior to the affected payment determination year for all data submitted via a CMS online data submission tool in the ASCQR Program for the CY 2019 payment determination and subsequent years. We also proposed to make a corresponding change to the regulation text at § 416.310(c)(1)(ii) to reflect this policy.

We previously proposed a similar policy to adopt a May 15 submission deadline for all data submitted via a CMS online data submission tool in the CY 2016 OPPS/ASC proposed rule (80 FR 38345). However, we did not finalize that proposal due to public comments received indicating that a May 15 deadline would increase ASC administrative burden by giving ASCs less time to collect and report data, and noting previous technical issues with data submission that required extension of the data submission deadline (80 FR 70535).

However, we believe the May 15 data submission deadline would align the ASCQR Program with the Hospital OQR Program submission deadline (80 FR 70521 through 70522) for data submitted via a CMS online data submission tool. Furthermore, the proposed submission deadlines for measures submitted via a CMS online data submission tool would align the above-listed measures with the submission deadline for ASC-8, resulting in a single deadline for all data submitted via an online data submission tool by ASCs (via CMS and non-CMS online data submission tools). We believe this single deadline would reduce the administrative burden associated with submitting and tracking multiple data submission deadlines for the ASCQR Program. In addition, we believe implementing the proposed May 15 deadline will enable public reporting of these data by December of the same year, thereby enabling us to provide the public with more up-to-date information for use in making decisions about their care. Thus, we believe the benefits of implementing the proposed May 15 submission deadline for data submitted via a CMS online data submission tool outweigh previously stated stakeholder concerns with this deadline.

Therefore, we proposed that data collected for a quality measure for which data are submitted via a CMS online data submission tool must be submitted during the time period of January 1 to May 15 in the year prior to the payment determination year for the CY 2019 payment determination and subsequent years. For example, for the CY 2017 data collection period, ASCs have January 1, 2018 through May 15, 2018 to submit their data for the CY 2019 payment determination.

This policy would apply to the following measures for the CY 2019 payment determination and subsequent years:

- ASC-6: Safe Surgery Checklist Use;
- ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures;
- ASC-9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658);
- ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use (NQF #0659); and
- ASC-11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536).²²⁸

²²⁸ We note that ASC-11 is a voluntary measure for the CY 2017 payment determination and

In addition, this policy would apply to the following measures for the CY 2020 payment determination and subsequent years that we finalized above:

- ASC-13: Normothermia Outcome, and
- ASC-14: Unplanned Anterior Vitrectomy.

Lastly, we also proposed to make corresponding changes to the regulation at 42 CFR 416.310(c)(1)(ii) to replace the date "August 15" with the date "May 15."

We invited public comments on our proposals to change the data submission time period and make corresponding changes to the regulation text for data submitted via a CMS online data submission tool as discussed above.

Comment: Some commenters supported CMS' proposal to move the reporting deadlines for data submitted via a CMS online data submission tool to May 15 because doing so would make ASC quality data available to the public as soon as possible each year and would therefore help stakeholders compare quality among facilities.

Response: We thank the commenters for their support.

Comment: Some commenters did not support the proposal to adopt a May 15 deadline for all data submitted via a CMS online data submission tool for the CY 2019 payment determination and subsequent years, because the commenters believe shortening the data submission time period for these measures will increase ASCs' burden and lead to confusion for ASCs. These commenters further asserted that changing the longstanding data submission deadline for measure data submitted during CY 2017 in this rulemaking may lead to ASCs inadvertently missing the earlier deadline and thereby forfeiting their full payment update. Commenters recommended that CMS retain the current data submission deadlines for data submitted via a CMS online data submission tool or, in the alternative, align the data submission deadline for measures submitted via a CMS online data submission tool on August 15.

Response: While we acknowledge that ASCs may undergo a period of adjustment while changing their reporting processes to meet the May 15 data submission deadline, we believe that aligning the data submission deadlines for measure data submitted via a CMS online data submission tool

subsequent years. This proposal would mean that ASCs that choose to submit data for this measure also would need to submit such data between January 1 and May 15 for the CY 2019 payment determination and subsequent years.

will ultimately streamline and reduce administrative burden on ASCs by reducing the total number of data submission deadlines under the ASCQR Program. Furthermore, one of the primary goals of the ASCQR Program is to publicly report ASC performance data, and moving the data submission deadline for all data submitted via a CMS online data submission tool to May 15 will enable us to publicly report ASCs' performance data by December of the same year. We believe this modified public reporting timeline will provide patients with the most up-to-date information for use in making decisions about their care. Therefore, we believe that any associated burden will be outweighed by the importance of making the public aware of performance data as timely as possible.

We also understand commenters' concerns that shortening the data submission time period for these measures may lead to some confusion for ASCs, but note that this policy affects data submitted for CY 2019 payment determinations, which will be reported during CY 2018. To be clear, this policy will not affect data collected during CY 2016 data collection period and reported during CY 2017 for CY 2018 payment determinations. Therefore, ASCs have an additional year under the current August 15 data submission deadline before the updated May 15 deadline will go into effect. As stated in the CY 2017 OPPS/ASC proposed rule (81 FR 45737), for example, for the CY 2017 data collection period, ASCs have January 1, 2018 through May 15, 2018 to submit their data for the CY 2019 payment determination. We believe this delay will provide ASCs with sufficient time to become familiar with the updated deadline and adjust their data reporting processes accordingly.

Comment: One commenter noted that technical difficulties have delayed ASC reporting in the past, and this commenter was concerned that similar issues could arise each time new measures are incorporated into ASC reporting.

Response: We acknowledge that we have delayed reporting deadlines for the ASCQR Program in the past due to technical issues.²²⁹ However, we have

since resolved those concerns, and do not anticipate any further technical issues as a result of expanding the ASCQR Program measure set.

After consideration of the public comments we received, we are finalizing our proposals to change the submission deadline to May 15 in the year prior to the affected payment determination year for all data submitted via a CMS online data submission tool in the ASCQR Program for the CY 2019 payment determination and subsequent years as proposed. We are also finalizing corresponding changes to the regulation at 42 CFR 416.310(c)(1)(ii) to replace the date "August 15" with the date "May 15" as proposed.

4. Claims-Based Measure Data Requirements for the CY 2019 Payment Determination and Subsequent Years

We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66985) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70536) for our previously adopted policies regarding data processing and 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). In the CY 2017 OPPS/ASC proposed rule (81 FR 45737), we did not propose any changes to these requirements.

5. Data Submission Requirements for ASC-15a-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

As discussed in section XIV.B.4.c. of this final rule with comment period, above, we are adopting five survey-based measures derived from the OAS CAHPS Survey for the CY 2020 payment determination and subsequent years: Three OAS CAHPS composite survey-based measures and two global survey-based measures. In this section of the CY 2017 OPPS/ASC proposed rule (81 FR 45737 through 45738), we proposed requirements related to survey administration and vendors. We note that we are adopting similar policies in the Hospital OQR Program in section XIII.B.5.c. of this final rule with comment period.

Available at: <https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228774593984>. (Delay because program is in initial implementation years).

a. Survey Requirements

The survey has three administration methods: mail-only; telephone-only; and mixed mode (Mail with telephone follow-up of non-respondents). We refer readers to the Protocols and Guidelines Manual for the OAS CAHPS Survey (<https://oascahps.org/Survey-Materials>) for materials for each mode of survey administration.

For all three modes of administration, we proposed that data collection must be initiated no later than 21 days after the month in which a patient has a surgery or procedure at an ASC and completed within 6 weeks (42 days) after initial contact of eligible patients begins. We proposed that ASCs, via their CMS-approved vendors (discussed below), must make multiple attempts to contact eligible patients unless the patient refuses or the ASC/vendor learns that the patient is ineligible to participate in the survey. In addition, we proposed that ASCs, via their CMS-approved survey vendor, collect survey data for all eligible patients—or a random sample thereof—using the timeline established above and report that data to CMS by the quarterly deadlines established for each data collection period unless the ASC has been exempted from the OAS CAHPS Survey requirements under the low volume exemption discussed in section XIV.B.4.c.(6) of this final rule with comment period, above. These submission deadlines will be posted on the OAS CAHPS Survey Web site (<https://oascahps.org>). Late submissions will not be accepted.

Compliance with the OAS CAHPS Survey protocols and guidelines, including this monthly reporting requirement, will be overseen by CMS or its contractor that will receive approved vendors' monthly submissions, review the data, and analyze the results. As stated previously, all data collection and submission for the OAS CAHPS Survey measures is done at the CCN level, and all eligible ASCs in a CCN would be required to participate in the OAS CAHPS Survey. Therefore, the survey data reported for a CCN must include all eligible patients from all eligible ASCs covered by the CCN. Survey vendors acting on behalf of ASCs must submit data by the specified data submission deadlines. If an ASC's data are submitted after the data submission deadline, it will not fulfill the OAS CAHPS quality reporting requirements. Therefore, we encourage ASCs to be fully appraised of the methods and actions of their survey vendors—especially the vendors' full compliance

²²⁹ "2013-16-ASC: ASC Web-Based Measures Deadline Extended to August 23." Published July 18, 2013. Available at: <https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772879036>. (Delay due to obtaining access to the QualityNet Secure Portal and going through security requirements. Deadline extended by seven days). "2015-39-ASC: Important Update—Submission Deadline Extended for Reporting Data Online into QualityNet and NHSN." Published July 31, 2015.

with OAS CAHPS Survey Administration protocols—and to carefully inspect all data warehouse reports in a timely manner.

We note that the use of predictive or auto dialers in telephonic survey administration under certain circumstances is governed by the Telephone Consumer Protection Act (TCPA) (47 U.S.C. 227) and subsequent regulations promulgated by the Federal Communications Commission (FCC) (47 CFR 64.1200) and Federal Trade Commission. We refer readers to the FCC's declaratory ruling released on July 10, 2015 further clarifying the definition of an auto dialer, available at: https://apps.fcc.gov/edocs_public/attachmatch/FCC-15-72A1.pdf. In the telephone-only and mixed mode survey administration methods, ASCs and vendors must comply with the regulations discussed above, and any other applicable regulations. To the extent that any existing CMS technical guidance conflicts with the TCPA or its implementing regulations regarding the use of predictive or auto dialers, or any other applicable law, CMS expects vendors to comply with applicable law.

b. Vendor Requirements

To ensure that patients respond to the survey in way that reflects their actual experiences with outpatient surgical care, and are not influenced by the ASC, we proposed that ASCs must contract with a CMS-approved OAS CAHPS Survey vendor to conduct or administer the survey. We believe that a neutral third-party should administer the survey for ASCs and it is our belief that an experienced survey vendor will be best able to ensure reliable results. OAS CAHPS Survey-approved vendors are also already used or required in the following CMS quality programs: The Hospital IQR Program (71 FR 68203 through 68204), the Hospital VBP Program (76 FR 26497, 26502 through 26503, and 26510), the ESRD QIP (76 FR 70269 through 70270), the HH QRP (80 FR 68709 through 68710), and the HQR (70 FR 47141 through 47207).

Information about the list of approved survey vendors and how to authorize a vendor to collect data on an ASC's behalf is available through the OAS CAHPS Survey Web site at: <https://oascahps.org>. The Web portal has both public and secure (restricted access) sections to ensure the security and privacy of selected interactions. ASCs will need to register on the OAS CAHPS Survey Web site (<https://oascahps.org>) in order to authorize the CMS-approved vendor to administer the survey and submit data on their behalf. Each ASC must then administer (via its vendor)

the survey to all eligible patients treated during the data collection period on a monthly basis according to the guidelines in the Protocols and Guidelines Manual (<https://oascahps.org/Survey-Materials>) and report the survey data to CMS on a quarterly basis by the deadlines posted on the OAS CAHPS Survey Web site as stated above.

Moreover, we also proposed to codify these OAS CAHPS Survey administration requirements for ASCs and survey vendors under the ASCQR Program at 42 CFR 416.310(e).

As stated previously, we encourage ASCs to participate in voluntary national implementation of the OAS CAHPS Survey that began in January 2016. This will provide ASCs the opportunity to gain first-hand experience collecting and transmitting OAS CAHPS data without the public reporting of results or ASCQR Program payment implications. For additional information, we refer readers to: <https://oascahps.org/General-Information/National-Implementation>.

We invited public comments on our proposals for the data submission requirements for the five proposed OAS CAHPS Survey-based measures for the CY 2020 payment determination and subsequent years as discussed above.

Comment: One commenter expressed concern that under the proposed ASC-15a-e survey-based measures, an ASC could meet its obligations under the measure by contracting with a CMS-approved, third-party vendor to administer the survey but still receive a reduction in their reimbursements if that vendor does not administer the survey properly or submit the required data to CMS by the data submission deadline.

Response: We acknowledge that it is possible an ASC could fail to meet the requirements under the ASC-15a-e survey-based measures if its vendor fails to administer the survey properly or submit the required data to CMS by the data submission deadline. However, we continue to believe that a neutral third-party should administer the survey for ASCs and it is our belief that an experienced survey vendor will be best able to ensure reliable results. We encourage all ASCs to be fully apprised of the methods and actions of their survey vendors—especially the vendors' full compliance with the OAS CAHPS Survey Administration protocols—and to carefully inspect all data warehouse reports in a timely manner. After the survey vendor submits the data to the OAS CAHPS Data Center, we strongly recommend that hospitals promptly review their two OAS CAHPS feedback

reports and submit corrections under the process outlined in the OAS CAHPS Protocol and Guidelines Manual.²³⁰ These reports enable a hospital to ensure that its survey vendor has submitted the data on time, the data has been accepted into the OAS CAHPS Data Center, and the data accepted into the OAS CAHPS Data Center are complete and accurate.

Finally, we note that submission of complete, accurate, and timely data is the responsibility of the ASC. ASCs should check-in regularly with survey vendors to ensure that vendors are properly submitting timely survey data.

Comment: Many commenters recommended that CMS include an electronic method of administration, such as portal messages and/or email, for the OAS CAHPS Survey because electronic methods of survey administration would be more cost effective for ASCs and more convenient for patients than administration via phone or standard mail. One commenter noted electronic survey administration has allowed many ASCs to achieve significant cost savings in the administration of patient surveys, and asserted electronic administration may increase patient response rates. Another commenter noted that recent releases by the U.S. Census Bureau and the National Telecommunications & Information Administration of the U.S. Department of Commerce show that the use of information technology is already prevalent and expanding rapidly amongst all Americans regardless of age, sex, educational attainment, household income, and employment status. One commenter noted that many survey vendors already offer electronic survey options to their customers.

One commenter expressed concern that the proposed OAS CAHPS Survey administration methods may result in biased reporting because older patients are more likely to respond to mail-based or telephone-based surveys than younger patients. The commenter also noted electronic survey administration can reduce facility costs with the reduction of paper use and postage requirements, while also decreasing the time to receiving feedback from patients following their treatment at an ASC. The commenter therefore recommended CMS include electronic administration methods, portal messages and/or email as a method of administration for the OAS CAHPS Survey.

²³⁰ Outpatient and Ambulatory Surgery CAHPS Survey: "Protocol and Guidelines Manual." Available for download at: <https://oascahps.org/Survey-Materials>.

Response: While email and Web-based survey administration modes are not available at this time, we are actively investigating these modes as possible new options for the future. This ongoing investigation includes, among other things, determining whether ASCs receive reliable email addresses from patients, whether there is adequate access to the Internet across all types of patients, and whether implementing a Web-based survey administration method would introduce bias into the survey administration process. However, we note that a previous study investigating the suitability of speech-enabled interactive voice response (SE-IVR) and Web modes for publicly reported surveys of patients' experience of hospital care found lower response rates for mixed-mode administrations including a Web-based option than for mail-only and SE-IVR administration modes.²³¹ Portal messaging, like systems that are sometimes used to address patient questions, would require a Web portal that patients can access. If this were housed at the facility, patient confidentiality could potentially be an issue. Furthermore, as currently specified, the OAS CAHPS Survey requires that the survey be administered by an approved survey vendor. This is to ensure that patients respond to the survey in a way that reflects their actual experiences with outpatient surgical care, and is not influenced by the hospital. Removing vendors, neutral third parties, could raise issues of objectivity and bias. However, as stated above, we are actively investigating new modes of conducting this survey as possible options for the future. We believe that the data collected by this measure is so significant and important that collecting data and publicly reporting it sooner rather than later outweighs waiting for a Web-based survey administration method to be developed, tested, and implemented nationwide.

Comment: A few commenters expressed concerns regarding the proposed survey administration requirements. One commenter stated that requiring survey vendors make multiple calls to patients regarding the OAS CAHPS Survey may be excessively intrusive to patients, particularly when coupled with a mailed survey. Another commenter asserted that requiring multiple mailings would add

considerable expense to survey costs incurred by ASCs in administering the OAS CAHPS Survey. One commenter expressed concern that the OAS CAHPS Survey administration requirement that ASCs, via their CMS-approved vendor, contact a patient multiple times would be very burdensome for ASCs with a diminishing return. These commenters recommended that CMS remove the requirement that ASCs attempt to contact a patient multiple times from the survey administration requirements in order to minimize the burden imposed on ASCs.

Response: As stated in the proposed rule (81 FR 45737), we proposed that ASCs, via their CMS-approved vendors, must make multiple attempts to contact eligible patients unless the patient refuses or the ASC/vendor learns that the patient is ineligible to participate in the survey. We are finalizing this proposal in section XIV.C.5.a. of this final rule with comment period, above. This is also reflected in the OAS CAHPS Survey Protocols and Guidelines. Under the telephone-only and mixed mode survey administration requirements, the vendor does not leave a message for the patient when calling to administer the survey. Further, under the mixed mode with telephone follow-up survey administration, only one follow-up telephone call is made. We believe these administration requirements impose minimal survey response burdens on patients or burdens on ASCs.

The use of a second mailing to improve response rates and reduce survey error comes from survey methodological literature,²³² and is the standard for CAHPS Survey implementation.²³³ Data from the OAS CAHPS Survey Mode Experiment in 2015 showed that in a sample size of 3,510 patients, including both mail-only and mixed-mode survey administration, the response rate to the first mailing was approximately 25 percent. By contrast, the final response rate for the mail-only sample after the second mailing was 37 percent. We believe this 12-percent increase highlights the importance of requiring a second mailing in improving survey response rates. In addition to lowering response rates, which can lead to potential bias in the data, we believe implementing a single mailing survey administration option would require increases in the initial sample size for survey administration in order to achieve 300 completed surveys. Thus,

we believe the cost savings from not requiring a second mailing would be reduced due to the need for an increased sample size for the initial mailing for reliability.

After consideration of the public comments we received, we are finalizing our proposals for the data submission requirements for the five OAS CAHPS Survey-based measures for the CY 2020 payment determination and subsequent years, as proposed. We also are finalizing, as proposed, to codify these OAS CAHPS Survey administration requirements for ASCs and survey vendors under the ASCQR Program at 42 CFR 416.310(e).

6. Extraordinary Circumstances Extensions or Exemptions for the CY 2019 Payment Determination and Subsequent Years

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53642 through 53643) and the CY 2014 OPSS/ASC final rule with comment period (78 FR 75140 through 75141) for a complete discussion of the ASCQR Program's procedures for extraordinary circumstance extensions or exemptions (ECE) requests for the submission of information required under the ASCQR Program.²³⁴ In the CY 2016 OPSS/ASC final rule with comment period (80 FR 70537), we codified our policies regarding extraordinary circumstances extensions or exemptions at 42 CFR 416.310(d).

In the CY 2017 OPSS/ASC proposed rule (81 FR 45738 through 45739), we proposed one modification to the ASCQR Program's extraordinary circumstances extensions or exemptions policy for the CY 2019 payment determination and subsequent years. Specifically, we proposed to extend the time to submit a request form from within 45 days of the date that the extraordinary circumstance occurred to within 90 days of the date that the extraordinary circumstance occurred. We believe this extended deadline is necessary, because in certain circumstances it may be difficult for ASCs to timely evaluate the impact of an extraordinary event within 45 calendar days. We believe that extending the deadline to 90 calendar days will allow ASCs more time to determine whether it is necessary and appropriate to submit an ECE request and to provide a more comprehensive account of the "event" in their forms to

²³¹ Elliott MN, Brown JA, Lehrman WG, Beckett MK, Hambarsoomian K, Giordano LA, Goldstein EH. A Randomized Experiment Investigating the Suitability of Speech-Enabled IVR and Web Modes for Publicly Reported Surveys of Patients' Experience of Hospital Care. *Med Res Rev*. 2013 April;70(2):165-184.

²³² Dillman, D. A. 1978. *Mail and Telephone Surveys: The Total Design Method*. New York: Wiley & Sons.

²³³ "Outpatient and Ambulatory Surgery." Available at: <https://oascahps.org>.

²³⁴ In 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.

CMS. For example, if an ASC has suffered damage due to a hurricane on January 1, it would have until March 31 (90 days) to submit an ECE form via the QualityNet Secure Portal, mail, email, or secure fax as instructed on the ECE form. This proposed timeframe (90 calendar days) also aligns with the ECE request deadlines for the Hospital VBP Program (78 FR 50706), the HAC Reduction Program (80 FR 49580), and the Hospital Readmissions Reduction Program (80 FR 48542). We note that, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57181 through 57182; 81 FR 57231), we finalized a deadline of 90 days following an event causing hardship for the Hospital IQR Program (in non-eCQM circumstances) and for the LTCH QRP Program. In section XIII.D.8. of this final rule with comment period, we are also finalizing a similar deadline of 90 days following an event causing hardship for the Hospital OQR Program.

In addition, we proposed to make a corresponding change to the regulation text at 42 CFR 416.310(d)(1). Specifically, we proposed to state that ASCs may request an extension or exemption within 90 days of the date that the extraordinary circumstance occurred.

We invited public comments on our proposals to extend the submission deadline for an extraordinary circumstances extension or exemption and make corresponding changes to the regulation text to reflect this policy as discussed above.

Comment: Commenters supported CMS' proposal to extend the deadline for submission of an ECE request from within 45 days of the extraordinary event to within 90 days of the extraordinary event because this proposal would give ASCs more time to determine whether it is appropriate to submit a request and would align the ASCQR Program with many of CMS' other quality reporting and value-based purchasing programs.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal to extend the time to submit a request form to within 90 days of the date that the extraordinary circumstance occurred for the CY 2019 payment determination and subsequent years as proposed. We also are finalizing, as proposed, a corresponding change to the regulation text at 42 CFR 416.310(d)(1).

7. ASCQR Program Reconsideration Procedures

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53643 through 53644) and the CY 2014 OPSS/ASC final rule with comment period (78 FR 75141) for a complete discussion of the ASCQR Program's requirements for an informal reconsideration process. In the CY 2016 OPSS/ASC final rule with comment period (80 FR 70537), we finalized one modification to these requirements: that ASCs must submit a reconsideration request to CMS by no later than the first business day on or after March 17 of the affected payment year. We codified this policy at 42 CFR 416.330. In the CY 2017 OPSS/ASC proposed rule (81 FR 45736), we did not propose 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 XV.C.1. of the CY 2014 OPSS/ASC final rule with comment period (78 FR 75131 through 75132) 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 73397), if the CPI-U is a negative number, the CPI-U would be held to zero. Under the ASCQR Program, any annual update will 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. For a complete discussion of the calculation of the ASC conversion factor, we refer readers to

section XII.G. of this final rule with comment period.

In the CY 2013 OPSS/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." 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.

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 OPSS 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. 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.

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 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized our proposal that payment for the new category of covered ancillary services (that is, certain diagnostic test codes within the medical range of CPT codes for which separate payment is allowed under the OPPS and when they are integral to an ASC covered surgical procedure) will be at the lesser of the MPFS nonfacility PE RVU-based amounts or the rate calculated according to the standard ASC ratesetting methodology. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the standard ASC ratesetting methodology for this type of comparison would use the ASC conversion factor that has been calculated using the full ASC update adjusted for productivity. This is necessary so that the resulting ASC payment indicator, based on the comparison, assigned to these procedures or services is consistent for each HCPCS code, regardless of whether payment is based on the full update conversion factor or the reduced update conversion factor.

For ASCs that receive the reduced ASC payment for failure to meet the ASCQR Program requirements, we believe that it is both equitable and appropriate that a reduction in the payment for a service should result in proportionately reduced coinsurance liability for beneficiaries. Therefore, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the Medicare beneficiary's national unadjusted coinsurance for a service to which a reduced national unadjusted payment rate applies will be based on the reduced national unadjusted payment rate.

In that final rule with comment period, we finalized our proposal that all other applicable adjustments to the ASC national unadjusted payment rates would apply in those cases when the annual update is reduced for ASCs that fail to meet the requirements of the ASCQR Program (77 FR 68500). For example, the following standard adjustments would apply to the reduced

national unadjusted payment rates: the wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; and the adjustment for devices furnished with full or partial credit or without cost. We believe that these adjustments continue to be equally applicable to payment for ASCs that do not meet the ASCQR Program requirements.

In the CY 2014, CY 2015, and CY 2016 OPPS/ASC final rules with comment periods (78 FR 75132; 79 FR 66981 through 66982; and 80 FR 70537 through 70538, respectively), we did not make any changes to these policies.

In the CY 2017 OPPS/ASC proposed rule (81 FR 45739 through 45740), we did not propose any changes to these policies.

XV. Transplant Outcomes: Restoring the Tolerance Range for Patient and Graft Survival

A. Background

Solid organ transplant programs in the United States are subject to a specialized system of oversight that includes: (1) An organized national system of organ donation and allocation, including a national database that allows for the tracking of transplants and transplant outcomes; (2) formalized policy development, program inspection, and peer review processes under the aegis of the Organ Procurement and Transplantation Network (OPTN); (3) Medicare Conditions of Participation (CoPs) that hold transplant programs accountable for patient and graft (organ) survival for at least 1 year after each recipient's transplant; and (4) a CMS system of onsite survey and certification for Medicare-participating transplant centers. These features mean that transplant programs have been in the vanguard of efforts to hold health care providers accountable not only for acceptable processes, but for patient outcomes as well.

Congress established the framework for a national organ transplantation system in 1984, and the Health Resources and Services Administration (HRSA) and CMS then operationalized the system as a national model of accountable care in the area of solid organ transplantation.²³⁵ The 1984 National Organ and Transplantation Act (NOTA)²³⁶ created the OPTN and Organ Procurement Organizations (OPOs),

²³⁵ Hamilton, T.E. 2009, "Accountability in Health Care—Transplant Community Offers Leadership," *American Journal of Transplantation*, Vol. 9, pp. 1287–1293.

²³⁶ National Organ Transplant Act (NOTA; Pub. L. 98–507), codified at 42 U.S.C. 274, "Organ procurement and transplantation network."

among other provisions. NOTA also required the establishment of a registry that includes such information respecting patients and transplant procedures as the Secretary deems necessary to an ongoing evaluation of the scientific and clinical status of organ transplantation.²³⁷ The Scientific Registry of Transplant Recipients (SRTR) has served this purpose since 1987. The registry supports the ongoing evaluation of the scientific and clinical status of solid organ transplantation, including kidney, heart, liver, lung, intestine, and pancreas. Data in the SRTR are collected by the OPTN from hospitals and OPOs. The SRTR contains current and past information about the full continuum of transplant activity related to organ donation and wait-list candidates, transplant recipients, and survival statistics. This information is used to help develop evidence-based policy, to support analysis of transplant programs and OPOs, and to encourage research on issues of importance to the transplant community.²³⁸

The SRTR contains detailed information regarding: (1) Donor characteristics (for example, age, hypertension, diabetes, stroke, and body mass index); (2) organ characteristics (for example, both warm and cold ischemic time); and (3) recipient characteristics (for example, age, race, gender, body mass index, and hypertension status). The SRTR is administered by the Chronic Disease and Research Group of the Minneapolis Medical Research Foundation under a contract with HRSA. The SRTR data are then used to construct the risk profile of a transplant program's organ transplants. The risk models allow the SRTR to calculate an expected survival rate for both patients and grafts (organs) over various periods of time.

Every 6 months, the SRTR publishes a Program Specific Report (PSR) for each transplant program. Each report covers a rolling, retrospective, 2.5-year period. For example, the PSR reports the aggregate number of patient deaths and graft failures that occurred within 1 year after each transplant patient's receipt of an organ. The PSR also compares the actual number of such events with the risk-adjusted number that would be expected, and reports the resulting ratio of observed to expected events (O/E). An O/E ratio of 1.0, for example, means that the transplant program's outcomes were equal to the national outcomes for a patient, donor, and organ risk profile that reasonably matched the risk profile of that particular transplant program, for

²³⁷ 42 U.S.C. 274a, "Scientific registry."

²³⁸ Available at: <http://srtr.org/who.aspx>.

the time period under consideration. An O/E ratio of 1.5 means that the patient deaths or graft failures were 150 percent of the risk-adjusted expected number.²³⁹

On March 30, 2007, we issued a final rule that set out CoPs for solid organ transplant programs (“Medicare Program: Hospital Conditions of Participation: Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplants” (72 FR 15198)). The CoPs for data submission, clinical experience, and outcome requirements are codified at 42 CFR 482.80 and 482.82. The regulations specified that a program would not be in compliance with the CoPs for patient and graft survival if three thresholds were all crossed: (1) The O/E ratio exceeded 1.5; (2) the results were statistically significant ($p < .05$); and (3) the results were numerically meaningful (that is, the number of observed events minus the expected number is greater than 3). If all three thresholds were crossed over in a single SRTR report, the program was determined to not be in compliance with the CMS standard.

The above three criteria were the same as those used at that time by the OPTN to “flag” programs that the OPTN considered to merit deeper inquiry with regard to transplant program performance. However, we implemented the Medicare outcomes requirements in a manner that would assure that a flagged transplant program would first have an opportunity to become engaged with the OPTN peer review process, and improve outcomes, before there was significant CMS involvement. We did so by classifying outcomes that crossed over all three thresholds in a single (most recent) SRTR report (that is, a “single flag”) as a lower level deficiency (that is, a “standard-level” deficiency in CMS terms). A standard-level deficiency requires a hospital to undertake improvement efforts, but continued Medicare participation is not at risk solely due to a single standard-level deficiency. Only programs flagged twice (in two SRTR reports, including the most recent report) within a 2.5-year period have been cited for a “condition-level” deficiency where Medicare termination is at risk. Approximately 79 (29.3 percent) of the 270 transplant programs (of all types of solid organs) that were flagged once in the 8-year period from the July 2007 SRTR report through the July 2015 report were not flagged again within a 2.5-year period.

The CMS “two-flag” approach for citation of a condition-level deficiency allowed an opportunity for the OPTN to take timely action after the first time a program was flagged, and allowed the transplant programs some time to work with the OPTN peer review process and possibly improve outcomes quickly. As a result, almost a third of once flagged programs (29.3 percent) did not require any significant CMS involvement because they were not flagged a second time within a rolling 2.5 year period.

We also determined to make quality improvement the cornerstone of CMS’ enforcement of the outcomes standard.²⁴⁰ Through the “mitigating factors” provisions in the regulations for transplant programs at 42 CFR 488.61(g), we allowed a 210-day period for transplant programs with a condition-level outcomes deficiency to implement substantial improvements and demonstrate compliance with more recent data than the data in the available SRTR reports. Further, for programs that were unable to demonstrate compliance by the end of the 210-day period, but were on the right track and had strong institutional support from the hospital to make the necessary improvements for achieving compliance, we generally offered to enter into a voluntary “Systems Improvement Agreement” (SIA) with that hospital. An SIA provides a transplant program with additional time (generally 12 months) during which the hospital engages in a structured regimen of quality improvement. The transplant program also has an opportunity to demonstrate compliance with the CMS outcomes requirements before the end of the SIA period. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50334 through 50344 and 50359 through 50361), we further defined the mitigating factors and SIA processes at 42 CFR 488.61(f), (g), and (h). (We note that, in section XVII.B. of this final rule with comment period, we discuss finalization of a proposal to make additional revisions to § 488.61(h)(2) to clarify provisions relating to a signed SIA remaining in force.)

Through July 2015, we completed the mitigating factors review process for 145 programs that had been cited for condition-level patient or graft volume or outcome requirements that fell below the relevant CMS standards. Of that number, 83 programs (57.2 percent) were approved by the end of the 210-day review process on the basis of

program improvements, combined with recent outcomes from which CMS concluded that the program was in present-day compliance. Another 45 programs (31.0 percent) were offered and completed a year-long SIA, while 17 programs (11.7 percent) terminated Medicare participation. CMS tracking data indicate that approximately 90 percent of programs that engaged in an SIA were able to complete the quality improvement regimen and continue Medicare participation after the end of the SIA period.

One-year post-transplant outcomes have improved since 2007 for all organ types, resulting in 1-year post-transplant survival rates that are among the highest in U.S. history for all types of solid organs. For adult kidneys, 1-year graft survival increased nationally from 92.9 percent in CY 2007 to 94.8 percent in 2014, while 1-year patient survival increased nationally from 96.4 percent to 96.9 percent. During this time, 1-year patient survival increased nationally for heart recipients from 88.5 percent to 89.5 percent, for liver recipients from 87.7 percent to 90.8 percent, and for lung recipients from 80.4 percent to 85.7 percent.

Because the CMS outcomes requirement is based on a transplant program’s outcomes in relation to the risk-adjusted national average, as national outcomes have improved, it has become much more difficult for an individual transplant program to meet the CMS outcomes standard. This is explained in more detail in section XVI. of this final rule with comment period. We are concerned that transplant programs may elect not to use certain available organs out of fear that such use would adversely affect their outcome statistics, despite the risk adjustment model accounting for differences in both donor organ quality and recipient health. We observed, for example, that the percent of adult kidneys donated and recovered—but not used—increased from 16.6 percent in CY 2006 to 18.3 percent in CY 2007 to 18.7 percent in CY 2014 and 19.3 percent in CY 2015. Even if the number of recovered adult kidneys had remained the same, these percentages of unused kidneys would be of concern. However, the number of recovered kidneys is also increasing, thereby enlarging the impact of the discard rate. The combined effect of (a) more recoveries and (b) a higher percent of unused organs means that the absolute number of recovered but unused adult kidneys increased from 2,632 in CY 2007, for example, to 2,888 in CY 2014 and to 3,159 in CY 2015.

We appreciate that some of the single-year sharp increase in the percent of

²³⁹ Dickinson, D.M., Arrington, C.J., et al., 2008, “SRTR program-specific reports on outcomes: A guide for the new reader,” *American Journal of Transplantation*, Vol. 8 (4 PART 2), pp. 1012–1026.

²⁴⁰ Hamilton, T.E. 2008, “Improving Organ Transplantation in the U.S.—A Regulatory Perspective,” *American Journal of Transplantation*, Vol. 8 (12), pp. 2404–2405.

unused adult kidneys that occurred between CY 2006 and CY 2007 (from a previously consistent 16.6 percent rate in the 3 years prior to 2007, to 18.3 percent in 2007) may have been due to many factors, and not just any potential impact that the new CMS outcomes CoP may have had. The CMS regulation, for example, was gradually phased in. The regulation did not take effect until June 28, 2007, and transplant programs had until December 26, 2007 to register with CMS for certification under the new regulation. Other changes also occurred in 2007 that may have had a substantial impact.

In particular, in December 2006, the UNOS, under contract with HRSA, made a new OPTN organ donor data collection and matching system available for voluntary use and improved the data in the system. The OPTN voted to make such use mandatory effective April 30, 2007. The stated goal of the system was to “facilitate and expedite organ placement.”²⁴¹ The system provided for a national list to be generated for each organ, with offers made to patients at transplant centers based on the order of patients on this list. The design of the system made it possible to send multiple offers simultaneously to different transplant programs, in priority order. As the authors of a later study concluded, “This initially led to an extraordinary increase in the volume of unwanted offers to many centers.”²⁴²

However, with substantial feedback from transplant programs, the system was improved and provided transplant programs with much more information regarding the available organs and donor characteristics. For example, the system allowed for programs to add more screening criteria, such as differentiation between local and import (for example, national) values, and screening for donors after cardiac death (DCD) with differentiation between local and import offers. In 2008, additional screening features were added, such as maximum acceptable cold ischemic time (CIT), maximum donor body mass index (BMI), and donor history of hypertension, diabetes, and coronary artery disease, among others. Such improvements were designed to allow centers to restrict organ offers to those

individuals who the program was most likely to accept. After the introduction of such additional system improvements, the percent of adult kidneys from deceased donors, that were not used, held at an average of 18.2 percent over the next 4 years. More recently, however, the average discard rate has resumed an upward trend, rising to 18.7 percent in CY 2014 and 19.3 percent in CY 2015. We are not aware of any studies that have specifically examined transplant program organ acceptance and discard patterns in relation to their perceptions regarding the CMS organ transplant CoPs. However, we believe that the increased percent of unused adult kidneys, combined with an increase in the number of recovered organs, creates an imperative to action, given the lifesaving benefits of organ transplantation.

Further concerns arise when we examine the use of what historically have been known as “expanded criteria donor (ECD)” organs. ECD organs are organs that are deemed transplantable but experience lower rates of functional longevity compared to most other organs. For instance, with the ECD kidneys, characteristics that historically defined an ECD kidney include age of donor at or greater than 60 years, or kidneys from donors who were aged 50–59 years who also had experienced two of the following: Cerebrovascular accident as the cause of death; preexisting hypertension; or terminal serum creatinine greater than 1.5 mg/dl.

Although the SRTR risk-adjustment methods take into account the factors that comprise an ECD designation, ECD kidneys have been the only category of adult kidneys that experienced a decline in the number that were recovered for organ transplantation, from 3,249 in CY 2007 to 2,833 in CY 2015. Acceptance rates for ECD kidneys also declined, from 56.2 percent in CY 2007 to 51.0 percent in CY 2015. There is some evidence that this decline is influenced by other factors, such as the higher costs to the hospital that are associated with ECD kidney use. ECD kidney selection also requires greater sophistication on the part of a transplant program to be able, in a timely manner, to distinguish between the finer features of an ECD kidney that might be appropriate to use compared with one that involves too much risk. Therefore, ECD kidney use may have been a particularly sensitive indicator of risk aversion. We note that, in 2014, the OPTN replaced the ECD kidney designations and implemented a more sophisticated system of adult kidney classification (the kidney donor profile index, KDPI). We believe this

new system should help in the decision-making process for kidney acceptance, but may have limited effect on undue risk aversion.

B. Revisions to Performance Thresholds

For the reasons described above, in the CY 2017 OPPS/ASC proposed rule (81 FR 45742 through 45743), we proposed to change the performance threshold at §§ 482.80(c)(2)(ii)(C) and 482.82(c)(2)(ii)(C) from 1.5 to 1.85. We stated in the preamble of the March 30, 2007 final rule (72 FR 15220) that “If we determine in the future that any of the three thresholds is too low or too high, we will propose changes in the threshold through the rulemaking process.” In the proposed rule, we followed through on that commitment.

The current relevant standard specifies that outcomes would not be acceptable if the ratio of observed patient deaths or graft failures divided by the risk-adjusted expected number, or “O/E,” exceeds 1.5. The expected number is based on the national average, adjusted for the patient, organ, and donor risk profile of a transplant program’s actual clientele for individuals who received a transplant in the 2.5-year period under consideration in each SRTR report. As the national performance has improved, it has become more difficult for transplant programs to maintain compliance with this CoP. In 2007, for example, an adult kidney transplant program was in compliance with the CMS outcomes standard if there were no more than 10.7 graft losses within 1 year out of 100 transplants. By 2014, that number had decreased to 7.9, a 26-percent reduction in graft losses 7 years later. Similarly, the number of patient deaths that could occur while maintaining compliance with the CoP declined from 5.4 to 4.6 out of every 100 adult kidney transplant recipients. We believe that a change in the threshold from 1.5 to 1.85 would restore the approximate compliance levels for adult kidney transplants that were allowed in 2007 when national performance was not so high. More specifically, a 1.85 threshold would mean that up to 9.7 graft losses out of 100 transplants (within 1 year of transplant) would remain within the new CMS outcomes range (which is slightly fewer than the 10.7 allowed in 2007 but more than the 7.9 allowed in 2015), and up to 5.7 patient deaths out of 100 transplants (within 1 year of transplant) would remain within the CMS range (compared to 5.4 in 2007 and 4.6 in 2015). Through restoring rough parity to 2007 graft failure rates, we hope to encourage transplant centers

²⁴¹ Massie AB, Zeger SL, Montgomery RA, Segev DL. The effects of DonorNet 2007 on kidney distribution equity and efficiency. *American Journal of Transplantation*, Vol. 9, pp. 1550–1557.

²⁴² Gerber DA., Arrington CJ, Taranto SE., Baker T, Sung RS. DonorNet and the Potential Effects on Organ Utilization. *American Journal of Transplantation*, Vol. 10, pp. 1081–1089. Article first published online: 22 MAR 2010. DOI: 10.1111/j.1600-6143.2010.03036.x.

to use more of the increasing number of viable organs.

For consistency and to avoid unneeded complexity, we proposed to use the same 1.85 threshold for all organ types and for both graft and patient survival. We appreciate that a case could instead be made for having different thresholds for different organ types, or a different threshold for graft versus patient survival. For example, if the only consideration was to restore the 2007 effective impact, the threshold for patient survival on the part of heart transplant recipients would be changed to 1.63, while the liver and lung threshold would be 2.00. Similarly, the new threshold for adult kidney graft survival would be 2.02 but for adult kidney patient survival a new threshold would be 1.77. Arguments also may be made for a variety of other thresholds, such as keeping the 1.5 threshold for heart, liver, and lung, on the grounds that there is more statistical room for improvement in outcomes for those types of organs compared to rates for adult kidney survival (which are already quite high). However, instead of a myriad of thresholds, we proposed to adopt a consistent 1.85 threshold for all organ types, and for both graft and patient survival. This is a number that is approximately mid-range between the number that would restore the adult kidney graft tolerance range to the 2007 level, and the number that would do so for adult kidney patient survival. We believe this approach is less confusing than the alternatives, and that it would be advisable to implement the new 1.85 threshold now in a consistent and clear manner, and then to study the effects, before proceeding further. For future consideration, we also may explore other approaches that are aimed at optimizing the effective use of available organs instead of adjusting the CMS outcomes threshold further, such as the potential that a balancing measure (focused specifically on effective use of organs) may be appropriate (which we discuss in section XXIII. (Economic Analyses) of this final rule with comment period).

We also note that the OPTN is examining its own flagging criteria under its new Bayesian methodology, out of concern that the OPTN may be flagging an excessive number of programs for review and contributing to undue risk aversion. The OPTN flagging criteria, both before and after adoption of the new Bayesian methodology, have resulted in more programs being flagged than are cited by CMS. We view this as a purposeful and desirable positioning of CMS as a backstop to the OPTN. We believe that our proposed change would

help ensure that, if OPTN also changed its criteria for outcomes review and as a result flagged fewer programs, those programs that are then flagged would still have the opportunity to first engage with the peer review process of the OPTN and might never be in a situation of being cited by CMS.

We invited public comment on this issue. Specifically, we invited comment on whether this proposal is effectively balancing our dual goals of improved beneficiary outcomes and increased beneficiary access. We also reiterate our statement from the March 30, 2007 final rule, that if we find that the thresholds are too low or too high, we will propose changes in future rulemaking.

Comment: Many commenters supported CMS' proposal to raise the threshold for observed/expected events (1-year patient deaths and graft failures) from 1.5 to 1.85 for all organ types. One commenter believed that changing the threshold to 1.85 would appropriately balance the need for outcome requirements standards in the transplant CoPs, while ensuring that the thresholds do not hinder beneficiary access to available organs. Other commenters stated that the proposed change would encourage greater access to transplantation for higher-risk patients who could still benefit from a transplant, thereby improving health outcomes and quality of life and decreasing costs. One commenter stated that the change would help to make solid organs available to patients who need them by not penalizing hospitals that perform higher-risk transplant procedures. Another commenter stated that this proposal is consistent with the OPTN's evaluation of proposed revisions to its criteria for performance review as part of an effort to reduce disincentives to transplant and encourage innovation. One commenter stated that the original threshold was based on the threshold for OPTN Membership and Professional Standards Committee (MPSC) peer review of potentially underperforming transplant centers, was never intended as a regulatory criterion, and that the threshold has always been too stringent, resulting in a high number of false positive citations. This commenter also supported CMS' decision not to adopt the SRTR Bayesian methodology for flagging underperforming transplant centers.

Response: We appreciate the commenters' support for our proposal to increase the threshold for observed/expected events from 1.5 to 1.85 for all organ types in the transplant outcome requirements standards.

Comment: One commenter believed that the proposed changes would bring relevant OPTN policies and CMS standards into alignment. The commenter urged CMS to continue to develop policies and requirements that align current or future standards in an expeditious manner and/or develop regulatory provisions in alignment with OPTN policy that would ensure that changes to OPTN policy are automatically reflected in CMS' standards. The commenter believed that this action would allow the transplant community to ensure that limited resources are focused more on efforts to successfully complete transplants for candidates on a waiting list than on ensuring compliance with multiple, inconsistent standards and requirements.

Response: We appreciate the commenter's support. We agree that future coordination between CMS and OPTN, where appropriate, will support efforts toward more successful transplantations.

Comment: A few commenters stated that a recent study documented a "survival benefit" for transplants as opposed to dialysis, even in transplant centers with low performance ratings. One commenter requested that CMS acknowledge this study and use the information to support the development of policies that reduce barriers that currently limit transplant centers in this and future rulemakings. Another commenter believed that transplant outcomes should be considered in the context of patient outcomes in the absence of transplantation. The commenter opined that variations in transplant center performance ratings are clinically insignificant when compared with the outcomes of patients who are not transplanted. The commenter further stated that, for this reason, any regulation that has the potential to reduce access to transplantation, whether by increasing risk aversion or otherwise, warrants careful scrutiny.

Response: We acknowledge the significant issues that are associated with dialysis treatment. We note that the outcome measures within the CoPs establish minimum quality standards for protecting the health and safety of transplant recipients in Medicare-certified facilities.

Comment: A few commenters believed that the proposed increase in the O/E threshold to 1.85 continues to limit access to transplantations. One commenter expressed concern that the proposed change would only impact a few transplant programs and that the increase in the threshold would not

provide a meaningful increase in access to transplantations. Some commenters requested that CMS increase the threshold to at least 2.0. One commenter stated that the threshold of 2.0 more closely approximates the performance threshold for graft survival in 2007. Other commenters opined that the O/E threshold adopted in 2007 has always been too stringent, and that a threshold of at least 2.0 strikes a suitable balance.

Response: At this time, we believe that it is most advisable to implement the proposed 1.85 threshold and study the impacts and effects of that revision. We will consider further changes in the future if data suggest that the threshold is too low or too high.

Comment: A few commenters expressed support for a recent Survey and Certification Memorandum (S & C 16–24—Hospitals) that provided guidance that Medicare approval will generally not be at risk solely due to noncompliance with the outcome standards at 42 CFR 482.80 and 482.82, as long as a transplant program's O/E ratio is within 185 percent of the risk-adjusted expected number.

Response: We believe that this comment is outside the scope of the proposed rule. However, we note that the requirements of this finalized provision will supersede this Survey and Certification Memorandum, and we will consider issuing an updated memorandum in the future if necessary.

Comment: A few commenters stated that, while they supported the proposal to revise the transplant outcome requirements standards, clear data will be required to assess the effects of this change both on organ utilization and patient outcomes. Another commenter noted that future analysis will be required to assess whether the change results in increases in the number of organs transplanted and decreases in organ wastage.

Response: We agree with the commenters.

Comment: One commenter stated that multiple published reports highlight the impact of regulatory thresholds on risk aversion and reduced rates of transplantation and patient listing. The commenter also stated that reports of regulatory oversight reveal a sustained negative impact on transplant activity with no identified decrease in outcomes based on the flagging methodologies.

Response: We understand that these perceptions are present in the transplant community. We proposed the change to the outcome requirements standard in part to address and acknowledge these perceptions regarding risk aversion. However, on a whole, the outcome measures for transplant centers do

provide minimal standards of acceptable quality to protect the health and safety of beneficiaries.

Comment: One commenter stated that CMS should work with HRSA to ensure that less egregious deviations from expected practice are handled through the OPTN review process.

Response: We appreciate the commenter's recommendation. However, we believe this comment is outside the scope of the proposed rule.

Comment: One commenter appreciated that CMS acknowledged the need to ensure that SRTR and CMS' requirements are consistent and supported the proposed changes. The commenter recommended that additional attention be given to the current "disconnect" between OPO and transplant center outcome measures. The commenter believed that CMS' regulations indirectly discourage OPOs from increasing the recovery of organs from older, "marginal donors" because this practice reduces organs transplanted per donor, which will reduce the incentive to aggressively pursue all donors. The commenter stated that these regulations incentivize OPOs to maximize organ retrieval from multi-organ donors, without consideration of whether the organs retrieved are appropriate for transplantation or whether transplantation of these organs will result in positive patient outcomes. The commenter stated that, by contrast, transplant centers are required to meet stringent post-transplant recipient outcome requirements, regardless of donor organ quality. The commenter believed that acceptance of these organs that result in a higher transplant rate, while good for OPOs and patients, may actually hurt the centers if the rate of graft failure is excessive.

Response: We appreciate the commenter's observations. However, we believe that these issues and observations are outside the scope of the proposed rule.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to revise the performance threshold specified at §§ 482.80(c)(2)(ii)(C) and 482.82(c)(2)(ii)(C) from 1.5 to 1.85.

XVI. Organ Procurement Organizations (OPOs): Changes to Definitions; Outcome Measures; and Documentation Requirements

A. Background

1. Organ Procurement Organizations (OPOs)

Organ procurement organizations (OPOs) are vital partners in the procurement, distribution, and transplantation of human organs in a safe and equitable manner for all potential transplant recipients. The role of OPOs is critical to ensuring that the maximum possible number of transplantable human organs are available to seriously ill patients who are on a waiting list for an organ transplant. OPOs are responsible for the identification of eligible donors, recovering organs from deceased donors, reporting information to the UNOS and OPTN, and compliance with all CMS outcome and process performance measures.

2. Statutory Provisions

Section 1138(b) of the Act provides the statutory qualifications and requirements that an OPO must meet in order for organ procurement costs to be paid under the Medicare program or the Medicaid program. Among other provisions, section 1138(b) of the Act also specifies that an OPO must operate under a grant made under section 371(a) of the Public Health Service Act (PHS Act) or must be certified or recertified by the Secretary as meeting the standards to be a qualified OPO within a certain time period. Congress has provided that payment may be made for organ procurement cost "only if" the OPO meets the performance related standards prescribed by the Secretary. Under these authorities, we established Conditions for Coverage (CfCs) for OPOs that are codified at 42 CFR part 486 and set forth the certification and recertification processes for OPOs.

Section 1102 of the Act gives the Secretary the authority to make and publish such rules and regulations as may be necessary to the efficient administration of the functions that the Secretary is charged with performing under the Act. Moreover, section 1871 of the Act gives the Secretary broad authority to establish regulations that are necessary to carry out the administration of the Medicare program.

3. HHS Initiatives Related to OPO Services

The Advisory Committee on Organ Transplantation (ACOT) was established under the authority of section 222 of the

PHS Act, as amended, and regulations under 42 CFR 121.12. A 2012 recommendation by ACOT stated: “ACOT recognizes that the current CMS and HRSA/OPTN structure creates unnecessary burdens and inconsistent requirements on transplant centers (TCs) and organ procurement organizations (OPOs) and that the current system lacks responsiveness to advances in TC and OPO performance metrics. The ACOT recommends that the Secretary direct CMS and HRSA to confer with the OPTN, SRTR, the OPO community, and TC representatives to conduct a comprehensive review of regulatory and other requirements, and to promulgate regulatory and policy changes to requirements for OPOs and TCs that unify mutual goals of increasing organ donation, improving recipient outcomes, and reducing organ wastage and administrative burden on TCs and OPOs. These revisions should include, but not be limited to, improved risk adjustment methodologies for TCs and a statistically sound method for yield measures for OPOs.”²⁴³

4. Requirements for OPOs

To be an OPO, an entity must meet the applicable requirements of both the Social Security Act and the PHS Act. Among other requirements, the OPO must be certified or recertified by the Secretary as an OPO. To receive payment from the Medicare and Medicaid programs for organ procurement costs, the entity must have an agreement with the Secretary. In addition, under section 1138(b) of the Act, an OPO must meet performance standards prescribed and designated by the Secretary. Among other things, the Secretary is required to establish outcome and process performance measures based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of the qualified OPO. An OPO must be a member of and abide by the rules and requirements of the OPTN that have been approved by the Secretary (section 1138(b)(1)(D) of the Act; 42 CFR 486.320).

B. Proposed and Finalized Provisions

1. Definition of “Eligible Death”

Transplant hospitals and OPOs report data to the OPTN and those data are transmitted on a monthly basis to the SRTR contractor. The OPTN establishes the types and frequencies of the data to be submitted by the OPOs to the SRTR through its policies. The OPTN and

SRTR collect and analyze the data pursuant to the HRSA mission to increase organ donation and transplantation. Periodically, the OPTN revises its OPO data reporting policies based on methodologies and clinical practice improvements that enable them to draw more accurate conclusions about donor and organ suitability for transplantation. When the CMS OPO regulations were published on May 31, 2006, the definition for “eligible death” at § 486.302 was in alignment with the OPTN definitions at that time. This “eligible death” definition has been used by CMS since May 31, 2006 to calculate and determine compliance with the OPO outcomes measures at § 486.318.

The OPTN has approved changes to its “eligible death” definition, which is scheduled to go into effect on January 1, 2017. The changes to the OPTN definition²⁴⁴ are predicted to increase the availability of transplantable organs by: increasing the maximum age for donation from 70 years of age to 75; replacing the automatic exclusion of patients with Multi-System Organ Failure (MSOF) with clinical criteria for each organ type that specifies such type’s suitability for procurement; and implementing policies allowing recovery and transplantation of organs from an HIV positive donor into an HIV positive recipient, consistent with the HIV Organ Policy Equity Act (HOPE Act) (November 21, 2013, Pub. L. 113–51).

The existing definition of “eligible death” under the May 31, 2006 CFCs (71 FR 31046 through 31047; 42 CFR 486.302) would not be consistent with this OPTN revised definition. Existing § 486.302 defines this term as “the death of a patient 70 years old or younger, who ultimately is legally declared brain dead according to hospital policy, independent of family decision regarding donation or availability of next-of-kin, independent of medical examiner or coroner involvement in the case, and independent of local acceptance criteria or transplant center practice . . . ,” and who does not exhibit active infections or other conditions, including HIV. The definition also sets out several additional general exclusion criteria, including MSOF. If there are inconsistent definitions, the resultant changes in data reported to the OPTN by the OPOs, would inhibit the SRTR’s ability to produce the data required by

CMS to evaluate OPOs’ conformance with § 486.318.

Therefore, in order to ensure more consistent requirements, in the CY 2017 OPPS/ASC proposed rule (81 FR 45743 through 45744), we proposed to replace the current definition for “eligible death” at § 486.302 with the upcoming revised OPTN definition of “eligible death.” The CMS definition would be revised to include donors up to the age of 75 and replace the automatic exclusion of potential donors with MSOF with the clinical criteria listed in the definition, that specify the suitability for procurement. We requested public comments on our proposed definition. We indicated that if, as a result of the public comments we receive on the proposal, additional changes are necessary to this definition, we will work with the OPTN to harmonize the definition.

Comment: One commenter noted that the changes to the “eligible death” definition were approved by the OPTN Board of Directors in June 2013. According to the commenter, following the passage of the HOPE Act on November 21, 2013, a workgroup was formed to review OPTN policies and make recommendations for policy changes to allow for research as outlined in the HOPE Act. The commenter stated that this workgroup considered including patients with HIV as part of the “eligible death” definition. However, according to the commenter, because the components of the “eligible death” definitions were developed as a comparative metric for OPO performance and are not intended to affect acceptance or allocation, the workgroup recommended no changes to the “eligible death” definition components. The commenter believed that the definitions will not impact the use of HIV organs within a HOPE Act research study.

Response: We appreciate the commenter’s input. We have retained an exclusion for HIV if the organ is not being recovered for an HIV positive transplant recipient under the definition of “eligible death.” We have added the phrase “consistent with the HIV Organ Policy Equity Act (the HOPE Act)” to paragraph (8) of the definition of “eligible death” under § 486.302 for clarity.

Comment: Several commenters supported the proposed revision to the definition of “eligible death” at § 486.302 to be consistent with the revised OPTN definition of “eligible death.”

Response: We appreciate the commenters’ support.

²⁴³ Available at: <http://www.organdonor.gov/legislation/acotrecs55.html>.

²⁴⁴ Alcorn, James B. (2013). “Summary of actions taken at OPTN/UNOS Board of Directors Meeting: June 24–25, 2013.” Available at: https://optn.transplant.hrsa.gov/media/1277/policynotice_20130701.pdf.

Comment: One commenter, while supporting the overall effort to align definitions, stated that the new definition of “eligible death” is intended to improve reporting consistency and clinical refinement in determination of organ suitability for transplantation. However, the commenter believed that the associated measure itself falls short of meeting the statutory requirements for recertification based on performance measures because the commenter believed that the proposed outcome measures may not be based on empirical data as required by the statute.

Response: We appreciate the commenter’s overall support. However, we do not agree that adoption of the OPTN yield metric falls short of statutory requirements for performance measures for OPOs. We believe that the revised measure is based on empirical evidence and will enable more precise measurement of OPO performance because of the multiple risk adjustments that are applied to each individual donation service area (DSA), including environmental factors and patient population.

Comment: Several commenters supported CMS’ proposed regulatory changes, which would extend the benefits of transplantation to individuals with both HIV and ESRD by allowing recovery and transplantation of kidneys from HIV positive donors into HIV positive recipients. One commenter stated that the possibility of renal transplantation in HIV donors was explored by an association several years ago and that it was recently suggested that there is potential for approximately 500 people on the donor list who are HIV positive to receive organs from HIV positive people every year.

Response: We appreciate the commenters’ support.

Comment: One commenter believed that the proposed changes will promote consistency in requirements between OPTN and CMS and ultimately allow for more transplantable organs and clear requirements between the two organizations. Several commenters stated that the proposed changes to the “eligible death” definition (as well as the proposed aggregate donor yield metric and transport documentation) are necessary updates to reflect advances in technology and promote greater utilization of organs.

Response: We appreciate the commenters’ support.

Comment: One commenter stated that the donation rate metric is a fundamentally appropriate measure of OPO performance and supported efforts to identify a measure that is an accurate

and validated measure. The commenter also supported data collection under the new definition of “eligible death,” but disagreed with the proposed adoption of this measure for OPO performance assessment.

Response: We appreciate the commenter’s input. The commenter did not provide specifics as to why the commenter disagreed with the proposed adoption of the measure. Therefore, we are unable to respond to the commenter’s disagreement.

Comment: One commenter recommended that CMS adopt a donation rate metric defined as a ratio of actual donors over a surrogate measure for the pool of possible organ donors. The commenter believed that the best donation rate measure currently available is the proposed OPTN measure of donation rate and supported the use of this measure while current efforts of OPTN, SRTR, and AOPO members are completed. The commenter noted that the potential for stronger measures of donation rate are on the horizon, and suggested that the measure be named, but not defined in the regulations. The commenter believed that this would allow for a more fluid adoption of improved measures once completed and established by the donation and transplant community.

Response: We appreciate the commenter’s recommendation. However, we did not propose to include a donation rate metric as a new outcome measure, and therefore consider this comment to be outside the scope of the proposed rule. We will continue to evaluate the effectiveness of the performance measures for OPOs and will propose changes to the regulations if necessary.

Comment: One commenter supported any regulatory proposals for OPOs that would encourage or expect them to evaluate all potential deaths as a possibility for organ donation regardless of the definition of “eligible death” or the number of organs that can be recovered. The commenter requested that CMS continue to reevaluate OPO metrics for performance because organ recovery is so variable throughout the country.

Response: We appreciate the commenter’s support. We will continue to evaluate OPO performance measures.

After consideration of the public comments we received, we are finalizing our proposal to replace the current definition of “eligible death” at § 486.302 with the revised OPTN definition of “eligible death.” The CMS revised definition includes donors up to the age of 75 and replaces the automatic exclusion of potential donors with

MSOF with the clinical criteria listed in the definition, that specify the suitability for procurement.

2. Aggregate Donor Yield for OPO Outcome Performance Measures

At the time of publication of the May 31, 2006 OPO regulations, outcome measures specified at §§ 486.318(a)(3)(i) and (ii) and §§ 486.318(b)(3)(i) and (ii) were consistent with yield calculations then utilized by the SRTR. These CMS standards measure the number of organs transplanted per standard criteria donor and expanded criteria donor (donor yield). We have received feedback that the use of this measure has created a hesitancy on the part of OPOs to pursue donors for only one organ due to the impact on the CMS yield measure.

In 2012 (incorrectly referenced in the proposed rule as “2014”), the SRTR, based upon the use of empirical data, changed the way it calculates aggregate donor yield after extensive research and changes to risk-adjustment criteria. The revised metric, currently in use by the OPTN/SRTR, risk-adjusts based on 29 donor medical characteristics and social complexities. We believe the OPTN/SRTR yield metric accurately predicts the number of organs that may be procured per donor, and each OPO is measured based on the donor pool in its DSA. This methodology is a more accurate measure for organ yield performance and accounts for differences between donor case-mixes across DSAs.

Therefore, in the CY 2017 OPPS/ASC proposed rule (81 FR 45744), we proposed to revise our regulations at § 486.318(a)(3) and § 486.318(b)(3) to be consistent with the current OPTN/SRTR aggregate donor yield metric. We also stated that we intend to revisit and revise the other OPO measures at a future date.

Comment: One commenter noted that the date for the implementation of SRTR’s OPO donor yield models was incorrect and stated that this was first produced and used by the OPTN in 2012.

Response: We appreciate the commenter for recognizing the misstatement. We have revised the preamble language of this final rule with comment period to reflect the 2012 date.

Comment: Several commenters supported consistency between the OPTN and CMS in the use of the current SRTR donor yield metric to evaluate OPO performance. The commenters encouraged CMS to operationalize the use of these measures in a way that would provide the OPTN sufficient time to work with an OPO to improve donor yield after they are initially flagged, but

prior to engagement with CMS. The commenters believed that this action would be consistent with the current application of CMS' performance requirements for transplant programs.

Response: We appreciate the commenters' support. While we also appreciate the suggested operationalization for use of these measures, we must measure OPO performance as specified by the regulations. There is delay between our publication of the final rule and its effective date in order to provide an opportunity for OPOs to prepare for the new standard. In addition to the aggregate donor yield measure, there are two other outcome measures pertaining to the donation rate within the OPO CfCs. Measure one is the donation rate of eligible donors as a percentage of eligible deaths, and measure two is the observed donation rate compared to the expected donation rate. We will continue to evaluate our OPO performance measures and will propose additional changes in the future if we believe additional changes are warranted.

Comment: Several commenters supported the proposed methodology for more accurate measures for organ yield performance and accounting for differences between donor case-mixes across DSAs.

Response: We appreciate the commenters' support.

Comment: One commenter expressed concern regarding the utilization of the OPTN proposed definition of "eligible death" as a measure of donation potential. The commenter stated that the utilization of these data as part of an overall donation metric does not adhere to the requirement to use empirical evidence to measure OPO potential and performance.

Response: We disagree that the OPTN Yield Metric does not meet the statutory requirement for the development of OPO measures utilizing empirical data. The OPTN Yield Metric was developed based upon, and utilizes, actual data submitted by the OPOs to the OPTN and, therefore, is based on observation or experience.

Comment: One commenter noted that current OPO outcome measures one and two utilize eligible death as part of the calculation and believed the implementation of a revised definition mid-cycle impairs the ability for an OPO to track and adjust its performance as needed to remain compliant. The commenter supported inclusion of the proposed donation metric outlined, but requested that this measure be defined in subregulatory documents to allow for refinement as needed based on changes

in the donation and transplantation community.

Response: We appreciate the commenter's support. While we also appreciate the suggested operationalization for use of these measures, we must measure OPO performance as specified in the regulations. There is a delay between our publication of the final rule and its effective date in order to provide an opportunity for OPOs to prepare for the new standard. In addition to the aggregate donor yield measure, there are two other outcome measures pertaining to the donation rate within the OPO CfCs. Measure one is the donation rate of eligible donors as a percentage of eligible deaths, and measure two is the observed donation rate compared to the expected donation rate. We will continue to evaluate our OPO performance measures and will propose additional changes in the future if we believe additional changes are warranted.

Comment: One commenter stated that the current certification cycle for OPOs will be complete in 2018 and, therefore, the new definitions will be implemented within an existing performance cycle. The commenter believed that the required timeframes for data review and evaluation would not be met, based on the adoption of a new definition of "eligible death" and a new yield metric for the current certification cycle. The commenter requested clarification on how the data collection timeframes and designation cycle would be reconciled.

Response: We understand that the OPO community has concerns with the implementation of a new definition in the middle of a certification cycle. However, we believe that the change is imperative to support increased organ availability, and we will make any needed adjustments in interpretation through the mid-cycle change. OPOs will continue to receive 6-month data reports indicating compliance and noncompliance with the outcome measures. Each OPO's performance will be measured based on the current definition and yield measures for the time period ending December 31, 2016. The new definition and yield measure will be effective on January 1, 2017. The June 2017 OPO data reports will be based on the new definition and yield metric. OPOs will receive two data reports based on the new definition and yield measure prior to the 2018 survey cycle. We will review both reports during the 2018 survey cycle.

Comment: One commenter requested clarification of the update to the final rule published in December 2013,

which changed requirements for OPOs to meet only two of the three outcome measures. The commenter stated that it was unclear if this requirement will remain in place for this next review certification cycle with the proposed revised measures and requested that these facts be considered prior to formalizing changes that may impact the donation and transplantation community in a negative manner.

Another commenter questioned whether, under the proposed revisions, the existing requirement to meet two of the three measures would continue. The commenter supported the CMS 2013 final rule (78 FR 74826) that modified the requirement at § 486.318 to specify that two of the three measures must be met for recertification. The commenter agreed with CMS' statement in that final rule that the requirement to automatically decertify an OPO for failure to meet all three measures was unnecessarily stringent. The commenter stated that, in the absence of a process to review mitigating factors or consider corrective action, as well as given ongoing concerns about the outcome measures themselves, a threshold of compliance with two of the three measures was appropriate.

Response: We appreciate the commenters' concern. The proposed change to Measure 3 will not impact the requirement at § 486.318(a) that states that "with the exception of OPOs operating exclusively in noncontiguous States, Commonwealths, Territories, or possessions, an OPO must meet two out of the three outcome measures." The proposed change also will not impact the requirement at § 486.318(b) that states that "for OPOs operating exclusively in noncontiguous States, Commonwealths, Territories, or possessions, an OPO must meet two out of the three outcome measures."

Comment: One commenter believed that CMS intended to replace the three current yield measures with one proposed O/E measure and requested that this be clarified in the final rule with comment period. The commenter noted that current regulations require OPOs to meet two out of three yield measures defined as: (1) The number of organs transplanted per standard criteria donor; (2) the number of organs transplanted per expanded criteria donor; and (3) the number of organs used for research per donor. The commenter supported the concept of replacing these three yield measures with an aggregate O/E measure. However, the commenter also urged CMS to adopt larger regulatory reform that includes process improvement and corrective action opportunities. The

commenter supported, in the context of such a regulatory structure, a CMS requirement that OPOs meet both the donation rate and the yield measures to remain in compliance.

Response: We thank the commenter for expressing this concern. In the proposed rule, we did not clearly articulate our intention to retain the requirement that the number of organs for research per donor continues to be included as one of the yield measure criteria. It was not our intention to eliminate this requirement, and we have revised the regulation text in this final rule with comment period to retain the number of organs for research per donor as a yield measure criterion. The requirements in the 2006 final rule at §§ 486.318(a)(3)(iii) and (b)(3)(iii) have been renumbered as §§ 486.318(a)(3)(ii) and (b)(3)(ii), respectively, in this final rule with comment period due to the reduction in the total number of yield measure criteria included in §§ 486.318(a)(3) and (b)(3). Because there will only be two yield measure criteria under §§ 486.318(a)(3) and (b)(3), the language in the proposed rule that “at least 2 of the 3 yield measures specified are more than 1 standard deviation below the national mean” has been removed and replaced with language that now reads “The OPO data reports, averaged over the 4 years of the recertification cycle, must meet the rules and requirements of the most current OPTN aggregate donor yield measure.” In response to the commenter’s request for CMS to adopt larger regulatory reform, while we understand the concerns raised by the commenter, we believe that the recommendations are outside the scope of the proposed rule.

Comment: One commenter recommended that CMS’ definition of the yield measure refer to the OPTN Observed to Expected Risk-Adjusted Process and not to a detailed description of the current methodology.

Response: We appreciate the commenter’s observation regarding the detailed description of the components of the revised definition. In accordance with statutory requirements, we must include outcome measures as a regulation.

Comment: One commenter recommended that the number of organs used for research be eliminated from the performance measures. The commenter stated that the measure is imprecisely defined, influenced by physical proximity to research clearinghouse agencies, and conflicts with the organ yield measure.

Response: We appreciate the commenter’s input. In the proposed rule

(81 FR 45776), our proposed amendments to §§ 486.318(a)(3) and (b)(3) did not propose to eliminate the performance measure on research. Our regulation is consistent with the Pancreatic Islet Cell Transplantation Act which requires that pancreata used for islet cell research be counted for OPO certification.

Comment: One commenter stated that the current proposed changes present modest progress in improving definitions for and measures of OPO performance. However, the commenter believed that the most pressing and significant components of regulatory reform have not been addressed. The commenter further stated that regulatory change was needed to develop and implement outcome measures that have technical integrity, are meaningful and understandable, and drive towards increasing the number of transplants that save more lives, through a defined process for continuous improvement in establishing risk-adjusted, verifiable and meaningful measures of performance, that are not misaligned with transplant program outcome measures.

Specifically, the commenter recommended that CMS:

- Establish a process of continuous OPO performance measurement and monitoring over a rolling 36-month period, updated in 6 month intervals.
- Establish a preemptive review and corrective action process to be implemented before an OPO falls out of compliance with outcome measures.
- Establish a process for OPOs that fall out of compliance with outcome measures, to include the ability to request a review of mitigating factors and/or the ability to enter a formal corrective action process.
- Define two distinct OPO outcome measures in the regulation (the Donation Measure and the Yield Measure). Define the methodology for calculating the outcome measures outside of the regulation to allow for future refinement and adjustment of the calculation as needed and as the data and science advance.
- Establish OPTN/SRTR oversight responsibilities for development, ongoing review and refinement of the two OPO outcome measure algorithms and calculations, with enhanced OPO representation. This oversight group should include equal OPO and transplant representation.

Response: While we understand the concerns raised by the commenter, we believe that the recommendations are outside the scope of the proposed rule. However, we will consider these comments for future rulemaking.

Comment: One commenter stated that the current yield metrics provide alternative performance thresholds for OPOs operating exclusively in noncontiguous U.S. States, commonwealths, territories, or possessions. The commenter expressed concern that, while the proposed OPTN/SRTR yield metric includes in the risk model a variable for geographic location, the unique challenges faced by these OPOs may not be sufficiently identified and accounted for in the current risk model. The commenter asked what provisions CMS would include for appropriate evaluation for OPOs operations exclusively in these regions.

Response: Due to the specificity of the risk adjustments in the proposed yield metric, which are based on 29 risk factors regarding donor medical characteristics and social complexities, the metric accurately predicts the number of organs that may be procured per donor, and each OPO is measured based on the donor pool in its DSA. This methodology is a more accurate measure for organ yield performance and accounts for differences among donor case-mixes across DSAs.

Comment: One commenter stated that the proposed changes would further advance efforts to foster quality improvement by modernizing the quantitative criteria for both performance standards for transplant centers and the conditions of participation for OPOs.

Response: We appreciate the commenter’s support.

Comment: One commenter noted that the OPTN system compares each OPO’s actual donor yield with its expected donor yield, given the characteristics of the OPO’s donor pool and that the OPTN’s Membership and Professional Standards Committee will monitor results and review OPOs that meet each of the following three criteria:

- Observed (O) transplants per 100 donors minus Expected (E) transplants per 100 donors is less than -10 , that is, more than 10 fewer organs transplanted than expected per 100 donors.
- O divided by E (O/E) is less than 0.9, that is, more than 10 percent fewer transplanted organs than expected.
- O/E is statistically significantly lower than 1.0 using a two-sided p -value of less than 0.05.

Response: We appreciate the commenter’s input.

Comment: One commenter recommended that measures be defined outside of the regulations to allow for refinement as needed, based on changes in the donation and transplantation community. The commenter also

requested that donor yield measures and its utilization of this measure should include the ability for OPOs to submit corrective action plans similar to what is allowed in the OPTN construct, noting mitigating factors as needed if found to be noncompliant.

Response: We appreciate the commenter's input. However, in order to ensure adequate notice and to provide the public an opportunity to participate in establishing the legal standards, we establish the OPO performance measures by regulation.

After consideration of the public comments we received, we are finalizing our proposal to revise our regulations at §§ 486.318(a)(3) and (b)(3) to be consistent with the current OPTN/SRTR aggregate donor yield metric.

3. Organ Preparation and Transport—Documentation With the Organ

In the CY 2017 OPPS/ASC proposed rule (81 FR 45744), we proposed to revise § 486.346(b), which currently requires that an OPO send complete documentation of donor information to the transplant center along with the organ. The regulation specifically lists documents that must be copied and sent by the OPO to include: Donor evaluations; the complete record of the donor's management; documentation of consent; documentation of the pronouncement of death; and documentation for determining organ quality. This requirement has resulted in an extremely large volume of donor record materials being copied and sent to the transplant centers by the OPOs with the organ. However, all these data can now be accessed by the transplant center electronically. The OPOs utilize an intercommunicative Web-based system to enter data that may be received and reviewed electronically by transplant centers.

Therefore, we proposed to revise § 486.346(b) to no longer require that paper documentation, with the exception of blood typing and infectious disease information, be sent with the organ to the receiving transplant center. We also proposed a revision to § 486.346(b) to make it consistent with current OPTN policy which requires that blood type source documentation and infectious disease testing results be physically sent in hard copy with the organ. The reduction in the amount of hard copy documentation that is packaged and shipped with each organ would increase OPO transplant coordinators' time, allowing them to focus on donor management and organ preparation. This proposal would not restrict the necessary donor information sent to transplant hospitals because all

other donor information could be accessed electronically by the transplant center.

Comment: One commenter noted a discrepancy pertaining to the entity to which OPOs submit data and advised CMS that transplant hospitals and OPOs report data to the OPTN and those data are transmitted on a monthly basis to the SRTR contractor.

Response: We appreciate the commenter's recognition of the discrepancy. We have revised the preamble language in this final rule with comment period to provide that transplant hospitals and OPOs report data to the OPTN and that those data are transmitted on a monthly basis to the SRTR contractor.

Comment: One commenter noted a policy citation discrepancy between OPTN and CMS' proposal to revise § 486.346(b) to make it consistent with current OPTN policy at 16.5.A. Organ Documentation, which requires that blood type source documentation and infectious disease testing results be physically sent in hard copy with the organ. The commenter applauded CMS' proposal to align both OPTN and CMS requirements. The commenter stated that the issues of not utilizing current technology, inefficient use of time, and unnecessary misdirection of resources away from donors and their families were brought to light during numerous discovery observations made during the development of the OPTN electronic tracking and transport project. According to the commenter, the OPTN policy change was designed to limit physical paperwork sent with the organ down to key elements, ABO results and infectious disease results, and expressed full support for the proposed CMS change.

Response: We appreciate the commenter's input and clarification. We have revised the preamble language of this final rule with comment period to remove the specific reference citations to an OPTN policy.

Comment: Several commenters supported the proposal to revise § 486.346(b) to no longer require that paper documentation, with the exception of blood typing and infectious disease information, be sent with the organ to the receiving transplant center. In addition, one commenter supported the revision for documentation requirements for donor records to be in alignment with OPTN policy.

Response: We appreciate the commenters' support.

Comment: One commenter supported the provisions to reduce the administrative burden of copying records that are available electronically.

The commenter suggested that CMS require a minimum timeframe for preservation of electronic access to the records for the transplant centers. The commenter also suggested that the OPOs complete a specified data set in the electronic system and that transplant centers have access to any of the records that have been typically included in the packet accompanying the organ. Another commenter also supported the proposal and stated its appreciation for CMS' efforts to streamline the process by reducing paperwork burdens.

Response: We appreciate the commenters' support. The commenter's suggestion regarding a retention timeframe is outside the scope of the proposed rule.

After consideration of the public comments we received, we are adopting as final without modification the revision of § 486.346(b) to make it consistent with current OPTN policy, which requires that blood type source documentation and infectious disease testing results be the only records required to be physically sent in hard copy with the organ.

XVII. Transplant Enforcement Technical Corrections and Other Revisions to 42 CFR 488.61

A. Technical Correction to Transplant Enforcement Regulatory References

In the CY 2017 OPPS/ASC proposed rule (81 FR 45744), we proposed a technical correction to preamble and regulatory language we recently adopted regarding enforcement provisions for organ transplant centers. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50338), we inadvertently made a typographical error in the final citations in a response to a commenter and stated, “[i]n the final regulation, at § 488.61(f)(1) and elsewhere, we therefore limit the mitigating factors provision to deficiencies cited for noncompliance with the data submission, clinical experience, or outcomes requirements specified at § 488.80 and § 488.82.” However, the transplant center data submission, clinical experience, and outcomes requirements are actually specified at 42 CFR 482.80 and 482.82, and not within Part 488; moreover, Part 488 does not contain a § 488.80 or § 488.82. We wish to correct this typographical error; the response should read as follows: “In the final regulation, at § 488.61(f)(1) and elsewhere, we therefore limit the mitigating factors provision to deficiencies cited for noncompliance with the data submission, clinical experience, or outcomes requirements specified at § 482.80 and § 482.82.”

We also proposed to amend § 488.61(f)(1) which was added in that final rule (79 FR 50359) to correct the same incorrect citations.

Comment: One commenter supported CMS' vigilance to address needed technical corrections and clarifications.

Response: We appreciate the commenter's support.

After consideration of the public comments we received, we are finalizing our proposals to make technical corrections to the preamble language and regulatory text of § 488.61(f) in the FY 2015 IPPS/LTCH PPS final rule regarding enforcement provisions for organ transplant centers described above.

B. Other Revisions to 42 CFR 488.61

Under current § 488.61(f)(3), transplant programs must notify CMS of their intent to request mitigating factors approval within 10 days and the time period for submission of mitigating factor materials is 120 days. Current § 488.61(f)(3) does not specify how these time periods are to be computed.

In the CY 2017 OPPS/ASC proposed rule (81 FR 45745), we proposed to amend § 488.61(f)(3) to extend the due date for programs to notify CMS of their intent to request mitigating factors approval from 10 days to 14 calendar days, and to clarify that the time period for submission of the mitigating factors information is calculated in calendar days (that is, 120 calendar days).

In addition, as part of our improvement efforts, in the proposed rule, we proposed to revise § 488.61(h)(2) to clarify that a signed SIA with a transplant program remains in force even if a subsequent SRTR report indicates that the transplant program has restored compliance with the Medicare CoPs, except that CMS, in its sole discretion, may shorten the timeframe or allow modification to any portion of the elements of the SIA in such a case.

Comment: One commenter opposed the proposal that a signed Systems Improvement Agreement remain in force even if a subsequent SRTR report indicates that the program has regained compliance with the CoPs because continuing the SIA would result in staff and financial implications and possible loss of referrals. One commenter supported the proposal and one commenter indicated that it understood CMS' proposal to revise § 488.61(h)(2) to provide that a signed SIA remains in force even if a subsequent SRTR report indicates that the transplant program has regained compliance.

Response: We believe that our estimated cost for a transplant SIA

program of \$250,000 is reasonable, as it is based on reports from programs that have actually completed such agreements in the past. We appreciate that the costs may be higher (or lower), depending on the extent of the improvements the hospital identifies as needed and chooses to undertake. We believe that the additional portion of the proposed rule, which includes the ability for CMS to shorten or modify the timeframes of the SIA provides an opportunity for CMS to end the SIA early if the program has regained compliance and has procedures in place to ensure that compliance is maintained. We will determine whether the program has procedures for maintaining compliance on a case-by-case basis prior to ending the SIA.

Comment: A few commenters supported the proposed revisions to 42 CFR 488.61 to clarify and extend the timeframe to submit a letter of intent and other materials to apply for mitigating factors.

Response: We appreciate the commenters' support.

Comment: One commenter supported CMS' proposal to extend and clarify the timeframes for transplant centers to notify the agency of the intent to request a mitigating factors approval and submit the relevant data for review. Specifically, the commenter agreed that CMS should extend the notification period from 10 days to 14 calendar days and clarify that the timeframe to submit mitigating factors materials is 120 calendar days.

Response: We appreciate the commenter's support.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to amend § 488.61(f)(3) to extend the due date for programs to notify CMS of their intent to request mitigating factors approval from 10 days to 14 calendar days, and to clarify that the time period for submission of the mitigating factors information is calculated in calendar days (that is, 120 calendar days). In addition, we are finalizing our proposal to revise § 488.61(h)(2) to clarify that a signed SIA with a transplant program remains in force even if a subsequent SRTR report indicates that the transplant program has restored compliance with the Medicare CoPs, except that CMS, in its sole discretion, may shorten the timeframe or allow modification to any portion of the elements of the SIA in such a case.

XVIII. Changes to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs

A. Background

The American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5), which included the Health Information Technology for Economic and Clinical Health Act (HITECH Act), amended Titles XVIII and XIX of the Act to authorize incentive payments and Medicare payment adjustments for eligible professionals (EPs), eligible hospitals, critical access hospitals (CAHs), and Medicare Advantage (MA) organizations to promote the adoption and meaningful use of certified EHR technology (CEHRT). Sections 1848(o), 1853(l) and (m), 1886(n), and 1814(l) of the Act provide the statutory basis for the Medicare incentive payments made to meaningful EHR users. These provisions govern EPs, MA organizations (for certain qualifying EPs and hospitals that meaningfully use CEHRT), subsection (d) hospitals and CAHs respectively.

Sections 1848(a)(7), 1853(l) and (m), 1886(b)(3)(B), and 1814(l) of the Act also establish downward payment adjustments, beginning with calendar or fiscal year 2015, for EPs, MA organizations, subsection (d) hospitals, and CAHs that are not meaningful users of CEHRT for certain associated EHR reporting periods.

In the October 16, 2015 **Federal Register**, we published a final rule titled “Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017” (80 FR 62761 through 62955), hereinafter referred to as the “2015 EHR Incentive Programs Final Rule,”²⁴⁵ which in part aligned the Modified Stage 2 measures with Stage 3 measures, aligned EHR reporting periods with the calendar year, and aligned aspects of the EHR Incentive Programs with other CMS quality reporting programs.

On October 14, 2016, we posted on our Web site the Medicare Program; Merit-based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models final rule with comment period (CMS–5517–FC) (hereinafter referred to as the “2016 MIPS and APMs final rule with

²⁴⁵ We also published two correction notices for the 2015 EHR Incentive Programs Final Rule, making corrections and correcting amendments (81 FR 11447 through 11449; 81 FR 34908 through 34909).

comment period”).²⁴⁶ The 2016 MIPS and APMs final rule with comment period establishes the MIPS, a new program for certain Medicare-enrolled practitioners. MIPS consolidates components of three existing programs, the Physician Quality Reporting System (PQRS), the Physician Value-Based Payment Modifier (VM), and the Medicare EHR Incentive Program for EPs, and focuses on quality—both a set of evidence-based, specialty-specific standards as well as practice-based improvement activities; cost; and use of CEHRT to support interoperability and advanced quality objectives in a single, cohesive program that avoids redundancies.

B. Summary of Final Policies Included in This Final Rule With Comment Period

In this final rule with comment period, we are adopting final policies based on the proposals in the CY 2017 OPPI/ASC proposed rule (81 FR 45745 through 45753) to continue advancement of certified EHR technology utilization, focusing on interoperability and data sharing. We proposed to eliminate the Clinical Decision Support (CDS) and Computerized Provider Order Entry (CPOE) objectives and measures for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for Modified Stage 2 and Stage 3 for 2017 and subsequent years. We also proposed to reduce the thresholds of a subset of the remaining objectives and measures in Modified Stage 2 for 2017 and in Stage 3 for 2017 and 2018 for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program. In addition, we proposed to update the Modified Stage 2 and Stage 3 measures with a new naming convention to allow for easier reference to a given measure (81 FR 45748 and 45752). These proposed changes would not apply to eligible hospitals and CAHs that attest to meaningful use under their State’s Medicaid EHR Incentive Program. These eligible hospitals and CAHs would continue to attest to their State Medicaid agencies on the measures and objectives finalized in the 2015 EHR Incentive Programs Final Rule.

In the CY 2017 OPPI/ASC proposed rule, we did not expressly address the effect these proposals would have on eligible hospitals and CAHs that are

eligible to participate in both the Medicare and Medicaid EHR Incentive Programs. These hospitals may be eligible for an incentive payment under Medicare for meaningful use of CEHRT or subject to the Medicare payment reduction for failing to demonstrate meaningful use; in addition, they may be eligible to earn a Medicaid incentive payment for meaningful use. We refer to these hospitals in this section of the final rule with comment period as “dual-eligible” hospitals. As discussed in our responses to the comments below, we are finalizing these proposed changes to the objectives and measures for 2017 and 2018 for all eligible hospitals and CAHs that submit an attestation to CMS, including dual-eligible hospitals that are eligible to participate in both the Medicare and Medicaid EHR Incentive Programs. We also are making further, minor, refinements to the new naming conventions.

We proposed to change the EHR reporting period in 2016 to any continuous 90 day period within CY 2016 for all returning EPs, eligible hospitals and CAHs that have previously demonstrated meaningful use in the Medicare and Medicaid EHR Incentive Programs (81 FR 45753). For the reasons discussed in section XVIII.D.1. of this final rule with comment period, we are finalizing a 90-day EHR reporting period in both CYs 2016 and 2017 for all returning participants.

We proposed to require EPs, eligible hospitals and CAHs that have not successfully demonstrated meaningful use in a prior year and are seeking to demonstrate meaningful use for the first time in 2017 to avoid the 2018 payment adjustment by attesting by October 1, 2017 to the Modified Stage 2 objectives and measures (81 FR 45753 through 45754). In this final rule with comment period, we are adopting this requirement as proposed.

We proposed a one-time significant hardship exception from the 2018 payment adjustment for certain EPs who are new participants in the EHR Incentive Program in 2017 and are transitioning to MIPS in 2017, as well as an application process (81 FR 45754 through 45755). In this final rule with comment period, we are finalizing this policy as proposed.

We proposed to change the policy on measure calculations for actions outside the EHR reporting period for the Medicare and Medicaid EHR Incentive Programs (81 FR 45755). We are adopting a final policy that, for all meaningful use measures, unless otherwise specified, actions included in

the numerator must occur within the EHR reporting period if that period is a full calendar year, or if it is less than a full calendar year, within the calendar year in which the EHR reporting period occurs. In addition, we are finalizing that this requirement applies beginning in calendar year 2017.

C. Revisions to Objectives and Measures for Eligible Hospitals and CAHs

In the CY 2017 OPPI/ASC proposed rule (81 FR 45746 through 45753), we made two proposals regarding the objectives and measures of meaningful use for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program. One of these proposals would eliminate the Clinical Decision Support (CDS) and Computerized Provider Order Entry (CPOE) objectives and measures for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for 2017 and subsequent years in an effort to reduce reporting burden for eligible hospitals and CAHs. The second proposal would reduce the reporting thresholds for a subset of the remaining Modified Stage 2 objectives and measures for 2017 and Stage 3 objectives and measures for 2017 and 2018 to Modified Stage 2 thresholds. We note that the Stage 3 Request/Accept Summary of Care measure under the Health Information Exchange objective is a new measure in Stage 3, therefore the proposed reduction in the threshold is not based on Modified Stage 2 thresholds.

In the proposed rule, our goal was to propose changes to the objectives and measures of meaningful use that we expect would reduce administrative burden and enable hospitals and CAHs to focus more on patient care.

We invited public comment on our proposals.

Comment: Commenters stated that having two different sets of meaningful use requirements, one for State Medicaid and one for Medicare would be a reporting burden for health systems that have providers that participate in both the Medicare and Medicaid EHR Incentive Programs. They stated that the best way to reduce the administrative burden would be to align all programs to the same threshold requirements and the same measures (or as close as possible) because there are many different programs to report to now, including the EHR Incentive Program for Medicaid providers and MIPS, for Medicare EPs, and each is proposed to have similar, but different measures.

Response: The MACRA requires the establishment of the MIPS for eligible clinicians, which is a new program that

²⁴⁶ The 2016 MIPS and APMs final rule with comment period also has been posted on the *Regulations.gov* Web site at: <https://www.regulations.gov/document?D=CMS-2016-0060-3921>, and is expected to be published in the *Federal Register* on November 4, 2016.

includes aspects of three existing programs (PQRS, VM, and the Medicare EHR Incentive Program for EPs) and will have an effect on Part B payments to MIPS eligible clinicians beginning in CY 2019. Under section 101(b) of the MACRA, the payment adjustment for EPs under the Medicare EHR Incentive Program will end after CY 2018. The MACRA did not make changes to the Medicare EHR Incentive Program for eligible hospitals and CAHs or to the Medicaid EHR Incentive Program, and thus our ability to adopt modifications to this program for hospitals remains constrained by the relevant provisions of the HITECH Act. Both the MIPS and the Medicare EHR Incentive Program for eligible hospitals and CAHs have different statutory requirements, which limit our ability to align the measures and thresholds between these two programs.

Comment: Several commenters supported the flexibility proposed but believed the requirements remained burdensome and complicated, which could have a negative effect on the quality of patient care.

Some commenters expressed concerns about meeting the requirements through relatively untested technology and functionalities related to application programming interfaces (APIs) and continue to have concerns about practicability of the Modified Stage 2 objectives and measures as well as the Stage 3 objectives and measures, including the ability of providers to satisfy the objectives and measures. Some commenters recommended allowing for a testing period in which providers would not incur penalties, thereby allowing new technologies to become more widely available and facilitate greater use.

Many commenters also expressed concern about the potential impact the timing of the rule will have on their success and indicated there may be a heavy reporting burden for providers.

Response: We recognize clinical workflows and maintaining documentation may require modifications upon implementation of the requirements in this final rule with comment period for eligible hospitals and CAHs attesting under Medicare and Medicaid. However, we believe the modifications will be minimal and the reporting burden may be reduced, as we are eliminating the CDS and CPOE objectives and associated measures (although the functionalities supporting these measures are still required in CEHRT). In addition, we are reducing the thresholds for a subset of remaining measures. We believe these final policies will help reduce administrative

burdens and allow providers to focus more on patient care.

We believe that interoperability and EHR functionalities will continue to advance prior to and after implementation of the technology certified to the 2015 Edition, which should increase providers' success in meeting the objectives and associated measures of the program. Furthermore, healthcare providers that experience significant issues with their technology vendors may submit an application for a significant hardship exception from the Medicare payment adjustment.

We also recognize the commenters' concerns regarding the timing of the publication of this final rule with comment period. For 2016, we proposed to shorten the EHR reporting period based on stakeholders' concerns that additional time was needed to update CEHRT systems, implement APIs for Stage 3 and transition to MIPS for certain EPs. In addition, we proposed certain Medicare EPs who are new participants in 2017 and who are transitioning to MIPS in 2017 may apply for a one-time significant hardship exception from the 2018 payment adjustment.

Comment: A few commenters requested confirmation on whether dual-eligible hospitals will be able to attest to the Medicare meaningful use requirements with CMS, and if State Medicaid programs will be able to rely on the Medicare attestations to determine Medicaid EHR Incentive Program payment eligibility.

Response: Dual-eligible hospitals attesting to CMS via such systems as the Hospital IQR Program reporting portal (81 FR 45754) will attest based on the revised objectives and measures established in this final rule with comment period for 2017 and 2018. State Medicaid agencies will be able to rely on these Medicare attestations to determine whether these hospitals qualify for incentive payments under the Medicaid EHR Incentive Program. Medicaid-only hospitals and dual-eligible hospitals that choose to attest directly to a State for the State's Medicaid EHR Incentive Program will continue to attest to the measures and objectives as finalized in the 2015 EHR Incentive Programs Final Rule (80 FR 62762 through 62955).

Comment: One commenter recommended that the proposed changes to meaningful use should apply in 2016 instead of 2017 as proposed.

Response: We disagree that the removal of the CDS and CPOE objectives and measures or reduction of thresholds for a subset of the remaining objectives and measures should begin in CY 2016

as this would require upgrades to our attestation system within a short period of time, which would be costly and difficult to implement.

We also note that we received a few comments indicating opposition to CMS having direct access to a facility's EHR for data abstraction, the States' inability to confirm duplicate payment status and obtain national data necessary to run and monitor the Medicaid EHR Incentive Program, and application of the same proposed advancing care information requirements for both Medicare clinicians participating in MIPS and Medicaid clinicians participating in the Medicaid EHR Incentive Program. We are not addressing these comments because we consider them to be outside the scope of the proposed rule.

1. Removal of the Clinical Decision Support (CDS) and Computerized Provider Order Entry (CPOE) Objectives and Measures for Eligible Hospitals and CAHs

We proposed to amend 42 CFR 495.22 (by revising § 495.22(e) and by adding a new § 495.22(f)) and by revising 42 CFR 495.24 to eliminate the CDS and CPOE objectives and associated measures (currently found at 42 CFR 495.22(e)(2)(iii) and (e)(3)(iii)) and 42 CFR 495.24(d)(3)(ii) and (d)(4)(ii) for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program beginning with the EHR reporting period in calendar year 2017. In the proposed rule (81 FR 45745), we indicated this proposal would not apply to eligible hospitals and CAHs attesting under a State's Medicaid EHR Incentive Program due to the burden of updating technology and reporting systems which would incur both additional costs and time. In the 2015 EHR Incentive Programs Final Rule (80 FR 62782 through 62783), we finalized a methodology for evaluating whether objectives and measures have become topped out and, if so, whether a particular objective or measure should be considered for removal from the EHR Incentive Program. We applied the following two criteria, which are similar to the criteria used in the Hospital IQR and Hospital VBP Programs (79 FR 50203): (1) Statistically indistinguishable performance at the 75th and 99th percentile, and (2) performance distribution curves at the 25th, 50th, and 75th percentiles are compared to the required measure threshold. Through this analysis it was determined the CPOE objective and measures were topped out (81 FR 45746).

We also proposed to remove the CDS objective and its associated measures which do not have percentage-based thresholds (hospitals attest “yes/no” to these measures) and therefore, cannot be measured by statistical analysis. However, we noted that 99 percent of eligible hospitals and CAHs have successfully attested “yes” to meeting these measures based on attestation data for 2015 and believe that the high level of successful attestation indicates achievement of widespread adoption of this objective and its associated measures among eligible hospitals and CAHs.

In the 2015 EHR Incentive Programs Final Rule, we also established that, for measures that were removed, the technology requirements would still be a part of the definition of CEHRT. We noted in the proposed rule (81 FR 45746) that the CDS and CPOE objectives and associated measures that we proposed to remove for eligible hospitals and CAHs would still be required as part of the eligible hospital’s or CAH’s CEHRT. However, eligible hospitals and CAHs attesting to meaningful use under Medicare would not be required to report on those measures under this proposal.

We invited public comment on our proposals.

Comment: Several commenters supported the elimination of the CDS and CPOE objectives and associated measures as they agreed that it would decrease administrative burden, improve provider satisfaction, and would no longer provide useful performance information.

Response: We thank the commenters for their support. As we stated in the proposed rule (81 FR 45746), we proposed the removal of these objectives and associated measures to reduce the reporting burden on providers for measures already achieving widespread adoption and with the goal to reduce administrative burden and allow a greater focus on patient care. As noted in the proposed rule (81 FR 45746), performance data for the objectives and associated measures have already achieved widespread adoption and are now considered topped out based on high performance.

Comment: One commenter suggested that CMS consider “sidelining” CDS as a temporary measure. A few commenters disagreed with the proposal to eliminate the CDS measure because it contributes to improving quality and patient care. The commenters expressed concern that the functionality would no longer be used, which would jeopardize other patient centered uses associated with CDS leading to regression in

facilities which made progress in this area.

Response: We reiterate that the technology requirements for CDS would still be a required part of the definition of CEHRT for provider use. We encourage providers to continue to use functionalities that are important to their patient base or practice even if reporting on performance is no longer required for the EHR Incentive Programs.

Comment: A few commenters requested clarification on whether dually eligible hospitals need to attest to the CPOE and CDS measures in order to receive their Medicaid EHR Incentive payment.

Response: As previously mentioned, in this final rule with comment period we are aligning the removal of the CPOE and CDS objectives and measures for dual-eligible hospitals that attest to CMS for both Medicare and Medicaid. Therefore, dual-eligible hospitals attesting to CMS will attest based on the revised objectives and measures established in this final rule with comment period and will not attest to the CPOE and CDS objectives and measures. However, eligible hospitals and CAHs attesting to a State Medicaid agency will attest to the objectives and measures as established in the 2015 EHR Incentive Programs Final Rule, which include the CDS and CPOE objectives and measures.

After consideration of the public comments we received, we are finalizing our proposal to remove the CDS and CPOE objectives and measures. In summary, we are finalizing the removal of the CDS and CPOE objectives and measures beginning in 2017 for eligible hospitals and CAHs attesting to CMS, including dual-eligible hospitals that are attesting to CMS for both the Medicare and Medicaid EHR Incentive Programs.

2. Reduction of Measure Thresholds for Eligible Hospitals and CAHs for 2017 and 2018

In the CY 2017 OPPS/ASC proposed rule (81 FR 45746 through 45748), we proposed to reduce a subset of the thresholds for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for EHR reporting periods in calendar year 2017 for Modified Stage 2 and in calendar years 2017 and 2018 for Stage 3. As previously noted, this proposal would not apply to eligible hospitals and CAHs attesting under a State’s Medicaid EHR Incentive Program. We believe this proposal would reduce the hospital and CAH reporting burden, allowing eligible hospitals and CAHs attesting under the

Medicare EHR Incentive Program to focus more on providing quality patient care, as well as focus on updating and optimizing CEHRT functionalities to sufficiently meet the requirements of the EHR Incentive Program and prepare for Stage 3 of meaningful use. In addition, we proposed to update the Modified Stage 2 measures with a new naming convention to allow for easier reference to a given measure (81 FR 45747).

We note that section 1886(n)(3)(A) of the Act requires the Secretary to seek to improve the use of EHRs and health care quality over time by requiring more stringent measures of meaningful use. We intend to adopt more stringent measures in future rulemaking and will continue to evaluate the program requirements and seek input from eligible hospitals and CAHs on how the measures could be made more stringent in future years of the EHR Incentive Programs.

We invited public comment on our proposals.

Comment: Many commenters agreed with reducing thresholds for eligible hospitals for the remaining Modified Stage 2 measures in 2017 and Stage 3 measures in 2017 and 2018 because it would reduce administrative burden, resolve some of the challenges in meeting thresholds, and allow providers to best utilize health IT in their practice.

Response: We thank the commenters for their support. As we stated in the proposed rule (81 FR 45746 through 45753), we believe that reducing thresholds would decrease administrative burdens in order for the healthcare providers to focus on providing more quality patient care and updating and optimizing CEHRT functionalities to meet the requirements and prepare for Stage 3. We agree with commenters regarding some of the threshold challenges that hospitals have experienced, and therefore considered the concerns via written correspondence and proposed a reduction in thresholds accordingly.

Comment: A few commenters expressed concern that the threshold reduction proposals for Stage 2 and 3 objectives will slow progress to improve health care quality through use of CEHRT. A few commenters stated the threshold reduction proposals for selected objectives and measures may not be sufficient and hospitals will still struggle to meet them, such as objectives and measures that require patient action.

Response: We disagree that the threshold reduction proposals will slow progress in terms of improving health care quality or advancements in the use of CEHRT. Our proposal was intended

to be responsive to concerns we have received from various stakeholders regarding the additional work required to effectively implement technologies and workflows to meet current thresholds. We note the threshold reductions are generally at the Modified Stage 2 level, which would maintain current requirements and are not believed to hinder progress on interoperability or improving patient care. Instead, we believe this will allow for greater focus on updating and optimizing EHR functionalities in preparation for Stage 3 and the implementation of technology certified to the 2015 Edition. As we stated in the proposed rule (81 FR 45747), we recognize the fact that eligible hospitals and CAHs may need additional time to educate patients on how to use health information technology and we believe that reducing the thresholds for 2017 and 2018 would provide additional time for eligible hospitals and CAHs to determine the best ways to communicate the importance for patients to access their medical information. If we reduce these measures even further, we believe this would stifle innovation in health IT and not encourage the widespread adoption of CEHRT.

a. Changes to the Objectives and Measures for Modified Stage 2 (42 CFR 495.22) in 2017

In the proposed rule, for EHR reporting periods in calendar year 2017, we proposed to modify the threshold of the Modified Stage 2 View, Download or Transmit (VDT) measure under the Patient Electronic Access objective established in the 2015 EHR Incentive Programs Final Rule (80 FR 62846 through 62848), and this proposed modification would apply to eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program. We also proposed to update the Modified Stage 2 measures with a new naming convention to allow for easier reference to a given measure, and to align with the measure nomenclature proposed for the MIPS. For the reasons previously stated, these proposals would not apply to eligible hospitals and CAHs attesting under a State's Medicaid EHR Incentive Program.

Specifically, we proposed to revise section 495.22(e) to specify that the current Modified Stage 2 meaningful use objectives and measures apply for EPs for 2015 through 2017, for eligible hospitals and CAHs attesting under a State's Medicaid EHR Incentive Program for 2015 through 2017, and for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for

2015 and 2016. We proposed to add a new § 495.22(f) that includes the meaningful use objectives and measures with the proposed modifications discussed below that would be applicable only to eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for an EHR reporting period in calendar year 2017. We also proposed a new naming convention for certain measures (shown in the table at 81 FR 45748) as well as minor conforming changes to §§ 495.22(a), (c)(1), and (d)(1).

We did not receive any public comments specific to the proposed updated naming conventions for those measures in Modified Stage 2, and therefore are finalizing the proposed updated naming conventions with further minor refinements. The naming conventions are included in the table below.

Patient Electronic Access (VDT) (42 CFR 495.22(f)(8)(ii)(B))

View, Download or Transmit (VDT): At least 1 patient (or patient-authorized representative) who is discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH during the EHR reporting period views, downloads or transmits to a third party his or her health information during the EHR reporting period.

- **Denominator:** Number of unique patients discharged from the inpatient or emergency department (POS 21 or 23) of the eligible hospital or CAH during the EHR reporting period.

- **Numerator:** The number of patients (or patient-authorized representatives) in the denominator who view, download, or transmit to a third party their health information.

- **Threshold:** The numerator and denominator must be reported and the numerator must be equal to or greater than 1.

- **Exclusion:** Any eligible hospital or CAH that is located in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period.

- **Proposed Modification to the VDT Measure Threshold**

For eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program, we proposed to reduce the threshold of the VDT measure from more than 5 percent to at least one patient. We proposed to reduce the threshold because we have heard from stakeholders including hospitals and hospital associations that they have faced significant challenges in

implementing the objectives and measures that require patient action. These challenges included, but are not limited to, patients who have limited knowledge of, proficiency with, and access to information technology, as well as patients declining to access the portals provided by the eligible hospital or CAH to view, download, and transmit their health information via this platform.

We invited public comment on our proposals.

Comment: Several commenters supported the reduction in this threshold to at least one patient because it provides additional time to accustom patients to electronic access of their health information and enhance their portal with additional functionalities.

Response: We thank commenters for their support. As we stated in the proposed rule (81 FR 45747), we recognize the fact that eligible hospitals and CAHs may need additional time to educate patients on how to use health information technology, and we believe that reducing the thresholds for 2017 and 2018 would provide additional time for eligible hospitals and CAHs to determine the best ways to communicate the importance for patients to access their medical information.

Comment: One commenter expressed concern about this measure because it requires patient action and it includes factors outside of the commenter's control because some patients do not want to view their information or have access to the Internet.

Response: We thank the commenter for the feedback. We believe that providers do have a role in educating patients about the importance of engaging with their health information to build understanding and more informed decision making about their health and their care. We believe providers can also play an essential role in improving patients' health literacy. We also acknowledged the concerns stakeholders have had with patient action measures in the proposed rule, which led us to propose a reduction in threshold for measures such as VDT. We believe the reduction in threshold will allow providers additional time to determine the best ways to educate patients on the importance of accessing their health care information, and assist them to access their health information electronically. As technology continues to advance, we believe that more patients will have access to the Internet, allowing them to access their health information through the various formats provided by the eligible hospitals and CAHs.

After consideration of the public comments we received, we are finalizing the proposed reduction to the VDT measure threshold. Specifically, we are finalizing the VDT measure threshold as equal to or greater than one patient for Modified Stage 2 in 2017 for eligible hospitals and CAHs attesting to CMS. This includes dual-eligible hospitals that are attesting to CMS for both the Medicare and Medicaid EHR Incentive Programs. This reduced threshold does not apply to eligible hospitals and CAHs attesting to a State for the Medicaid EHR Incentive Program.

The objective and measure are as follows:

Patient Electronic Access (VDT) (42 CFR 495.22(f)(8)(ii)(B))

Objective: Provide patients the ability to view online, download, or transmit their health information within 36 hours of hospital discharge.

View, Download or Transmit (VDT): At least 1 patient (or patient-authorized representative) who is discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH during the EHR reporting period views, downloads or transmits to a third party his or her health information during the EHR reporting period.

- Denominator: Number of unique patients discharged from the inpatient or emergency department (POS 21 or 23)

of the eligible hospital or CAH during the EHR reporting period.

- Numerator: The number of patients (or patient-authorized representatives) in the denominator who view, download, or transmit to a third party their health information.

- Threshold: The numerator and denominator must be reported and the numerator must be equal to or greater than 1.

- Exclusion: Any eligible hospital or CAH that is located in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period.

MODIFIED STAGE 2 OBJECTIVES AND MEASURES IN 2017 FOR ELIGIBLE HOSPITALS AND CAHS ATTESTING TO CMS

Objective	Previous measure name/reference	Measure name	Threshold requirement
Protect Patient Health Information CDS (Clinical Decision Support) * ..	Measure	Security Risk Analysis	Yes/No attestation. Five CDS.
	Measure 1	Clinical Decision Support Interventions.	
CPOE (Computerized Provider Order Entry) *.	Measure 2	Drug Interaction and Drug-Allergy Checks.	Yes/No.
	Measure 1	Medication Orders	
Electronic Prescribing**	Measure 2	Laboratory Orders	>30%
	Measure 3	Radiology Orders	>30%
Health Information Exchange	Measure	e-Prescribing	>10%
Patient Specific Education	Measure	Health Information Exchange	>10%
Medication Reconciliation	Eligible Hospital/CAH Measure ...	Patient-Specific Education	>10%
Patient Electronic Access	Measure	Medication Reconciliation	>50%
	Eligible Hospital/CAH Measure 1	Provide Patient Access	>50%
Public Health Reporting	Eligible Hospital/CAH Measure 2	View, Download or Transmit (VDT)***	At least 1 patient.
	Immunization Reporting	Immunization Registry reporting ...	Public Health Reporting to 3 Registries.
	Syndromic Surveillance Reporting	Syndromic Surveillance Reporting.	
	Specialized Registry Reporting	Specialized Registry Reporting.	
	Electronic Reportable Laboratory Result Reporting.	Electronic Reportable Laboratory Result Reporting.	

* We note that we are finalizing our policy to remove CDS and CPOE for eligible hospitals and CAHs attesting to CMS in section XVIII.C. of this final rule with comment period.

** We note that, in the proposed rule (81 FR 45748), we referred to this objective as “eRx (electronic prescribing)”.

*** We note that in the proposed rule (81 FR 45748), we referred to this measure as the “View Download Transmit Measure”.

b. Changes to the Objectives and Measures for Stage 3 (42 CFR 495.24) in 2017 and 2018

For EHR reporting periods in 2017 and 2018, we proposed to modify a subset of the Stage 3 measure thresholds established in the 2015 EHR Incentive Programs Final Rule (80 FR 62829 through 62871) that are currently codified at 42 CFR 495.24, and these proposed modifications would apply to eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program. For the reasons previously stated, these proposed modifications would not apply to eligible hospitals and CAHs attesting under a State’s Medicaid EHR Incentive Program. We

also proposed, beginning in 2017, in proposed 42 CFR 495.24(c) and (d), to update the measures for EPs, eligible hospitals and CAHs with a new naming convention to allow for easier reference to a given measure, and to align with the measure nomenclature proposed for the MIPS (we refer readers to the table in the proposed rule at 81 FR 45752).

We did not receive any public comments specific to the updated naming conventions for those measures in Stage 3, and therefore are finalizing the proposed updated naming conventions with further minor refinements. The naming conventions are included in the table below.

We invited public comment on our proposals.

Comment: A few commenters stated that the electronic prescribing threshold is too high and recommended that it remain at 10 percent for Stage 3 as the measure is still extremely new for hospitals.

One commenter stated that including controlled substances should continue to be optional since provider and vendor readiness issues are still being addressed. The commenter sought clarification on the flexibility to include or exclude controlled substances depending on a provider’s situation. The commenter also expressed disappointment that CMS did not

propose revisions to the additional Stage 3 measure thresholds, specifically electronic prescribing and patient-generated health data. The commenter urged CMS to modify these thresholds in the final rule with comment period.

Response: We are not maintaining the Stage 2 10 percent threshold for the electronic prescribing measure for eligible hospitals and CAHs for Stage 3 because the attestation data through March 2015 indicates that eligible hospitals in Stage 2 met the threshold in the 1st (30 percent), 2nd (53 percent) and 3rd (80 percent) quartile (https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/AttestationPerformanceData_Feb2015.pdf (page 27)). We believe an increase is warranted based on this attestation data indicating hospitals were successful in meeting the threshold.

We would like to clarify that providers have flexibility to include or exclude controlled substances in the denominator for the Stage 3 electronic prescribing objective and measure. We refer commenters to the discussion in the 2016 MIPS and APMs proposed rule (81 FR 28227) regarding this topic, which was finalized as proposed in the 2016 MIPS and APMs final rule with comment period.

(1) Objective: Patient Electronic Access to Health Information (42 CFR 495.24(c)(5))

Objective: The eligible hospital or CAH provides patients (or patient-authorized representatives) with timely electronic access to their health information and patient-specific education.

Provide Patient Access: For more than 50 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23): (1) The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and (2) the provider ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the application programming interfaces (APIs) in the provider's CEHRT.

- Denominator: The number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

- Numerator: The number of patients in the denominator (or patient-authorized representatives) who are

provided timely access to health information to view online, download, and transmit to a third party and to access using an application of their choice that is configured meet the technical specifications of the API in the provider's CEHRT.

- Threshold: The resulting percentage must be more than 50 percent in order for a provider to meet this measure.

- Exclusion: Any eligible hospital or CAH that is located in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period.

- Proposed Modification to the Provide Patient Access Threshold for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program

We proposed to reduce the threshold for the Provide Patient Access measure for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program from more than 80 percent to more than 50 percent. In the 2015 EHR Incentive Programs Final Rule (80 FR 62846), we finalized that providers in Stage 3 would be required to offer all four functionalities (view, download, transmit and access through an API) to their patients.

We continued to hear from health IT vendors through correspondence regarding concerns about the implementation of APIs for Stage 3, indicating, in part that application development is in a fledgling state, and thus it might be very difficult for hospitals to be ready to achieve the 80 percent threshold by the time Stage 3 is required starting in January 2018 and that API requirements outlined in the 2015 EHR Incentive Programs Final Rule could place an excessive burden on hospitals because application development has not been entirely market tested and widely accepted amongst the entire industry. Vendors also expressed concerns around the likely issues surrounding compatibility and varying API interface functionalities that could possibly hinder interoperability among certified EHR technology. We proposed to reduce the threshold based on the concerns voiced by these vendors and believe the Modified Stage 2 threshold of more than 50 percent is reasonable.

We invited public comment on our proposals.

Comment: Many commenters supported the reduction of the Provide Patient Access threshold to greater than 50 percent because it would provide greater flexibility.

Response: We thank commenters for their support. We believe through reducing the threshold to greater than 50 percent we are providing eligible hospitals and CAHs with increased flexibility and additional time needed to communicate and educate the importance for patients to access their medical information.

Comment: One commenter requested clarification on whether providers are obligated to make only the API available, and not also the application(s) that could use the API.

Response: For health care providers to implement an API under this measure, they would need to fully enable the API functionality in such a way that any application chosen by a patient would enable them to gain access to their individual health information. The information provided in the application should be configured to meet the technical specifications of the API. We refer the commenter to the 2015 EHR Incentive Programs Final Rule (80 FR 64842) for additional information on API requirements.

Comment: A few commenters stated that not all patients electronically access their health information based on a variety of factors such as technology literacy and access of technology, and the provider should be able to make the decision on how health information is communicated to their patients. The commenters recommended that CMS propose additional methods of meeting this objective that better reflect differences in patient literacy and levels of access.

Response: We acknowledged in the proposed rule the difficulties stakeholders had with the Provide Patient Access measure which led us to propose a reduction in this threshold. We do not believe we need to propose additional methods of meeting this objective. We previously stated in the 2015 EHR Incentive Programs Final Rule that providers may still provide patients with paper based educational materials and information, if the provider deems such an action beneficial and of use to the patient. We would simply no longer require or allow providers to manually count and report on these paper-based exchanges beginning in Stage 3 (80 FR 62783 through 62784).

Patient-Specific Education: The eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 10 percent of unique patients discharged from the eligible hospital or CAH inpatient or emergency department

(POS 21 or 23) during the EHR reporting period.

- Denominator: The number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.
- Numerator: The number of patients in the denominator who were provided electronic access to patient-specific educational resources using clinically relevant information identified from CEHRT during the EHR reporting period.
- Threshold: The resulting percentage must be more than 10 percent in order for a provider to meet this measure.
- Exclusions: Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.
- Proposed Modification to the Patient Specific Education Measure threshold for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program

We proposed to reduce the threshold for the Patient-Specific Education measure for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program from more than 35 percent to more than 10 percent. We continued to receive written correspondences from hospitals and hospital associations expressing their concerns that the vast majority of patients ask for and are given patient education materials at the time of discharge, usually in print form. These stakeholders indicated that they believe patients benefit from this information at the time of their interaction with the healthcare professionals in the inpatient or emergency department settings of the hospital. Requiring hospitals to make patient education materials available electronically, which would be accessed after the patient is discharged, requires hospitals to set up a process and workflow that these stakeholders describe as administratively burdensome and the benefit would be diminished for patients who have limited knowledge of, proficiency with or access to information technology or patients who request paper based educational resources.

We invited public comment on our proposal.

Comment: Several commenters supported the reduction of the threshold to greater than 10 percent and indicated this will reduce reporting burden.

Response: We thank commenters for their support. As noted in the proposed

rule (81 FR 45749), we believe this reduction in threshold will provide hospitals the ability to continue to meet the needs of their patients while allowing additional time for advancements on workflows and processes to make patient-educational materials available electronically after discharge.

Comment: A few commenters believed that the reduction in the threshold does not address concerns that patient education must be tailored to meet the needs of the patients, which may not include electronic methods, and urged CMS to consider alternative methods of meeting this objective.

Response: As previously stated, we do not believe we need to propose additional methods for meeting this objective. We previously stated in the 2015 EHR Incentive Programs Final Rule that providers may still provide patients with paper based educational materials and information, if the provider deems such an action beneficial and of use to the patient. We would simply no longer require or allow providers to manually count and report on these paper-based exchanges beginning in Stage 3 (80 FR 62783 through 62784).

After consideration of the public comments we received, we are finalizing the reduction to the thresholds. Specifically, we are finalizing for the Provide Patient Access measure a threshold of more than 50 percent and for the Patient-Specific Education measure a threshold of more than 10 percent for eligible hospitals and CAHs attesting to CMS, including dual-eligible hospitals that are attesting to CMS for both the Medicare and Medicaid EHR Incentive Programs. These reduced thresholds do not apply to eligible hospitals and CAHs attesting to a State for the Medicaid EHR Incentive Program.

The objective and measures are as follows:

Objective: Patient Electronic Access to Health Information (42 CFR 495.24(c)(5))

Objective: The eligible hospital or CAH provides patients (or patient-authorized representatives) with timely electronic access to their health information and patient-specific education.

Provide Patient Access: For more than 50 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23): (1) The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her

health information; and (2) the provider ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the application programming interfaces (APIs) in the provider's CEHRT.

- Denominator: The number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.
- Numerator: The number of patients in the denominator (or patient-authorized representatives) who are provided timely access to health information to view online, download, and transmit to a third party and to access using an application of their choice that is configured to meet the technical specifications of the API in the provider's CEHRT.
- Threshold: The resulting percentage must be more than 50 percent in order for a provider to meet this measure.
- Exclusion: Any eligible hospital or CAH that is located in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period.

Patient-Specific Education: The eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 10 percent of unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Provide Patient Access: For more than 50 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

- Denominator: The number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.
- Numerator: The number of patients in the denominator who were provided electronic access to patient-specific educational resources using clinically relevant information identified from CEHRT during the EHR reporting period.
- Threshold: The resulting percentage must be more than 10 percent in order for a provider to meet this measure.
- Exclusions: Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

(2) Objective: Coordination of Care Through Patient Engagement (42 CFR 495.24(c)(6))

Objective: Use CEHRT to engage with patients or their authorized representatives about the patient's care.

As finalized in the 2015 EHR Incentive Programs Final Rule (80 FR 62861), we maintain that providers must attest to the numerator and denominator for all three measures, but would only be required to successfully meet the threshold for two of the three measures to meet the Coordination of Care through Patient Engagement Objective.

We invited public comment on our proposals.

Comment: One commenter stated it is premature to include measure 3 (Patient Generated Health Data measure) as a requirement which requires provider use of certified EHR functionality that supports receiving patient-generated data or data from nonclinical settings and recommended that CMS either remove this measure or reduce the threshold to at least one patient.

Response: We are not removing or reducing the threshold for this measure. We note that, for the Coordination of Care through Patient Engagement objective, providers must attest to the numerators and denominators for all three measures, but must only meet the thresholds for two of three measures, which provides flexibility in meeting the objective. We also refer readers to the 2015 EHR Incentive Programs Final Rule in which we state the types of data that will count in the numerator are broad, which we believe will assist providers in meeting the threshold of greater than 5 percent.

View, Download or Transmit (VDT): During the EHR reporting period, at least one unique patient (or their authorized representatives) discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engages with the electronic health record made accessible by the provider and engages in one of the following: (1) View, download or transmit to a third party their health information; or (2) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT; or (3) a combination of (1) and (2).

- Denominator: The number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

- Numerator: The number of unique patients (or their authorized representatives) in the denominator who

have viewed online, downloaded, or transmitted to a third party the patient's health information during the EHR reporting period and the number of unique patients (or their authorized representatives) in the denominator who have accessed their health information through the use of an API during the EHR reporting period.

- Threshold: The numerator must be at least one patient in order for an eligible hospital or CAH to meet this measure.

- Exclusion: Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

- Proposed Modification to the View, Download or Transmit (VDT) Threshold

As discussed above, under the Modified Stage 2 Objectives and Measures, we proposed to reduce the threshold of the View, Download or Transmit (VDT) measure for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program from more than 5 percent to at least one patient. We proposed to reduce the threshold for Stage 3 because we had heard from stakeholders including hospitals and hospital associations that they have faced significant challenges in implementing the objectives and measures that require patient action. These challenges included, but are not limited to, patients who have limited knowledge of, proficiency with and access to information technology as well as patients declining to access the portals provided by the eligible hospital or CAH to view, download, and transmit their health information via this platform.

We invited public comment on our proposal.

Comment: Several commenters supported the reduction of the threshold to at least one patient because it provides eligible hospitals and CAHs with greater flexibility.

Response: We thank commenters for their support. The reduction of this threshold takes into consideration the challenges voiced by providers on "patient action" including "opting out," limitation of knowledge, and limitation of access. We believe the reduction will allow additional time for providers to teach patients the importance of accessing their health information while increasing participation.

Comment: A few commenters disagreed with CMS' proposal to retain the Stage 3 requirements which included use of APIs to connect any app

of the patient's choice to the EHR in support of patient engagement and coordination of care through patient engagement objectives and believed the use of APIs was premature. The commenters requested that CMS make the API an option or not require it as part of the measure.

Response: We proposed to reduce the threshold for the VDT measure under the Coordination of Care Through Patient Engagement objective and the Provide Patient Access measure under the Patient Electronic Access to Health Information objective in response to concerns voiced by stakeholders and specific to concerns voiced about implementation of APIs in Stage 3 and difficulty in implementing objectives and measures that require patient action. We continue to believe that patient access to their electronic health information is a high priority for the EHR Incentive Programs and enabling an API will generate innovation and allow patients to access information in a manner that best suits their needs. We also note that for the Coordination of Care through Patient Engagement Objective (which includes the VDT measure and Patient Generated Health Data measure), providers must attest to the numerators and denominators of all three measures, but must only meet the thresholds for two of three measures, providing flexibility. We are not making changes to the current requirement of providing API functionality as part of the measure. However, due to the concerns voiced by stakeholders on the implementation of this technology, we are extending the 90-day EHR reporting period to include 2017 to allow additional time to test and implement this Stage 3 requirement. We address the extension of a 90-day EHR reporting period for 2017 in further detail in section XVIII.D.1. of this final rule with comment period.

Secure Messaging: For more than 5 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative).

- Denominator: The number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

- Numerator: The number of patients in the denominator for whom a secure electronic message is sent to the patient

(or patient-authorized representative) or in response to a secure message sent by the patient (or patient-authorized representative), during the EHR reporting period.

- **Threshold:** The resulting percentage must be more than 5 percent in order for an eligible hospital or CAH to meet this measure.

- **Exclusion:** Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

- **Proposed Modification to the Secure Messaging Threshold for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program**

We proposed to reduce the threshold of the Secure Messaging measure for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program from more than 25 percent to more than 5 percent.

We proposed to reduce the threshold because we had heard from stakeholders, including hospitals and hospital associations, that for patients who are in the hospital for an isolated incident the hospital may not have significant reason for a follow up secure message. In addition, we had heard concerns from these same stakeholders that these same patients may decline to access the messages received through this platform. They have expressed concern over not being able to meet this threshold as a result of their patients' limited knowledge of, proficiency with, and access to information technology.

We invited public comment on our proposal.

Comment: Several commenters supported the reduction of the threshold to more than 5 percent because it would provide greater flexibility and agree that it would take more time for patients to become more willing to use secure messaging.

Response: We thank commenters for their support. As we stated in the proposed rule (81 FR 45750), we believe that, with time, patients will become more willing to use secure messaging as a means to communicate and eligible hospitals and CAHs will be able to positively influence their patients in their use.

Comment: A few commenters expressed concerns with the limitations of existing vendor tools and systems used in secure messaging, as well as patient capabilities to comply with the requirements of secure messaging including patient technology literacy which could result in a patient not

receiving critical care. A few commenters requested that CMS eliminate this measure for hospitals as the expectation for the hospital to follow up with patients is inefficient and an administrative burden.

Response: We acknowledge the concerns expressed by commenters on being able to meet the threshold. We proposed to reduce the threshold to more than 5 percent which we believe is attainable and allows providers additional time to educate patients on the benefits of secure messaging as a form of healthcare provider to patient communication. We also believe that EHR technology will continue to evolve and produce innovative functionalities to benefit providers and patients alike.

We decline to eliminate this measure for hospitals because we believe there is value in communication between members of the care team and a patient post discharge. This provides an opportunity to enhance coordination of care, transitions of care between providers, and improve health outcomes.

After consideration of the public comments we received, we are finalizing the reduction to the thresholds. Specifically, for Stage 3 in 2017 and 2018, we are finalizing the threshold for the View, Download or Transmit (VDT) measure as at least one patient and the threshold for the Secure Messaging Measure as more than 5 percent for eligible hospitals and CAHs attesting to CMS, including dual-eligible hospitals that are attesting to CMS for both the Medicare and Medicaid EHR Incentive Programs. These reduced thresholds do not apply to eligible hospitals and CAHs attesting to a State for the Medicaid EHR Incentive Program.

The objective and measures are as follows:

Objective: Coordination of Care Through Patient Engagement (42 CFR 495.24(c)(6))

Objective: Use CEHRT to engage with patients or their authorized representatives about the patient's care.

Providers must attest to the numerator and denominator for all three measures, but are only required to successfully meet the threshold for two of the three measures to meet the Coordination of Care through Patient Engagement Objective.

View, Download or Transmit (VDT): During the EHR reporting period, at least one unique patient (or their authorized representatives) discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engages with the

electronic health record made accessible by the provider and engages in one of the following: (1) View, download or transmit to a third party their health information; or (2) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT; or (3) a combination of (1) and (2).

- **Denominator:** The number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

- **Numerator:** The number of unique patients (or their authorized representatives) in the denominator who have viewed online, downloaded, or transmitted to a third party the patient's health information during the EHR reporting period and the number of unique patients (or their authorized representatives) in the denominator who have accessed their health information through the use of an API during the EHR reporting period.

- **Threshold:** The numerator must be at least one patient in order for an eligible hospital or CAH to meet this measure.

- **Exclusion:** Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

Secure Messaging: For more than 5 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative).

- **Denominator:** The number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

- **Numerator:** The number of patients in the denominator for whom a secure electronic message is sent to the patient (or patient-authorized representative) or in response to a secure message sent by the patient (or patient-authorized representative), during the EHR reporting period.

- **Threshold:** The resulting percentage must be more than 5 percent in order for an eligible hospital or CAH to meet this measure.

- **Exclusion:** Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

(3) **Objective:** Health Information Exchange (HIE) (42 CFR 495.24(c)(7))

Objective: The eligible hospital or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of CEHRT.

As finalized in the 2015 EHR Incentive Programs Final Rule (80 FR 62861), we maintain that providers must attest to the numerator and denominator for all three measures, but are only required to successfully meet the threshold for two of the three measures to meet the Health Information Exchange Objective.

Comment: Many commenters supported the exchange of patient data to ensure better coordination of care between providers.

Response: We thank the commenters for their support. We agree that technology and access will continue to increase over time, which we believe will lead to expansion in the exchange of patient health information between health care providers.

Comment: A few commenters noted that the threshold reduction for each measure is not sufficient to address core concerns which are outside the control of hospitals such as functionality, data blocking and interoperability issues, as adoption of health IT is not universal among all care providers.

Response: We acknowledged the concerns in the proposed rule and believe the reduction in threshold is reasonable. We are encouraged by the continued advancement in health information exchange, as well as feedback by various stakeholders providing that the majority of hospitals are involved in some form of health information exchange. In May 2016, ONC published a report noting that the percentage of hospitals engaging in health information exchange through electronic means has increased from 50 percent in 2011 to over 80 percent in 2015 with more than 85 percent of hospitals sending patient health information electronically in CY

2015.²⁴⁷ However, the report also notes that one primary barrier to increasing health information exchange identified by hospitals is a lack of trading partners that have adopted and implemented certified health IT systems. To support flexibility in this transition, we note that hospitals exchanging health information may leverage a wide range of exchange methods to accommodate the range of health IT adoption in the industry. We further note that CMS and ONC continue to support the expansion of health information exchange in the industry and are in alignment with other CMS programs, to continue to increase adoption among a wider range of healthcare providers. In addition, we refer readers to the new EHR contracting guide on the ONC Web site which is a resource that will help providers address data blocking and other challenges as they continue to adopt and leverage health IT to improve the way they deliver care.²⁴⁸

Finally, we reiterate the fact that providers continue to have the option to apply for a hardship exception for circumstances related to health IT issues that are outside of a provider's control and impact their ability to demonstrate meaningful use.

Send a Summary of Care: For more than 10 percent of transitions of care and referrals, the eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care: (1) Creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.

- **Denominator:** Number of transitions of care and referrals during the EHR reporting period for which the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) was the transferring or referring provider.

- **Numerator:** The number of transitions of care and referrals in the denominator where a summary of care record was created using certified EHR technology and exchanged electronically.

- **Threshold:** The percentage must be more than 10 percent in order for an eligible hospital or CAH to meet this measure.

- **Exclusion:** Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not

have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

- **Proposed Modification to the Send a Summary of Care Measure for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program**

We proposed to reduce the threshold for the Send a Summary of Care measure for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program from more than 50 percent to more than 10 percent.

Hospital and hospital association feedback on the 2015 EHR Incentive Programs Final Rule, as well as recent reports and surveys of hospital participants showed that there were still challenges to achieving wide scale interoperable health information exchange.²⁴⁹ Specifically, more than 50 percent of hospital stakeholders identified a lack of health IT adoption to support electronic exchange among trading partners as a key barrier, especially for provider types and settings of care where wide spread adoption may be slower. Stakeholders have emphasized that while the majority of hospitals are now engaging in health IT supported health information exchange, achieving high performance will require further saturation of these health IT supports throughout the industry.

We invited public comment on our proposal.

Comment: Several commenters supported the reduction of the threshold to greater than 10 percent.

Response: We thank the commenters for their support. We continue to believe that technology and access will continue to increase as more healthcare providers implement EHR systems and there is greater focus on interoperability. In addition, we agree that the creation and electronic exchange of a summary of care is beneficial to delivery system reform and facilitating coordination of care.

Comment: A few commenters stated hospitals should not be penalized for interacting with other healthcare providers who are still in the process of implementing health IT.

A few commenters stated that primary care physicians are at a disadvantage in attempting to meet the Health Information Exchange requirements. The commenters believed that it is difficult to find other providers with which they could successfully exchange

²⁴⁷ ONC Data Brief 36: May 2016 "Interoperability among U.S. Non-federal Acute Care Hospitals in 2015: <http://dashboard.healthit.gov/evaluations/data-briefs/non-federal-acute-care-hospital-interoperability-2015.php>.

²⁴⁸ EHR Contracts Untangled: Selecting Wisely, Negotiating Terms, and Understanding the Fine Print—https://www.healthit.gov/sites/default/files/EHR_Contracts_Untangled.pdf.

²⁴⁹ ONC Data Brief: No. 36; May 2016. Available at: https://www.healthit.gov/sites/default/files/briefs/onc_data_brief_36_interoperability.pdf.

a patient's summary of care and requested that CMS consider excluding this objective until widespread adoption could be achieved.

Other commenters stated there is room for both CMS and healthcare providers to improve data sharing as a way to improve patient care and safety.

Response: We understand the difficulties that providers have in health information exchange requirements. However, the majority of hospitals are engaging in health information exchange as indicated in the ONC data brief (https://www.healthit.gov/sites/default/files/briefs/onc_data_brief_36_interoperability.pdf). We believe advancement in health information exchange will increase trading partners and allow for greater ability to meet the thresholds. We decline to remove this measure based on the comment that there is a lack of trading partners. We have provided flexibility in that providers must attest to the numerator and denominator for all three measures, but are only required to successfully meet the threshold for two of the three measures to meet the Health Information Exchange objective.

We agree that data sharing will continue to progress as interoperability and health information exchanges improve in number and innovation.

Request/Accept Summary of Care: For more than 10 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH incorporates into the patient's EHR an electronic summary of care document.

- Denominator: Number of patient encounters during the EHR reporting period for which an eligible hospital or CAH was the receiving party of a transition or referral or has never before encountered the patient and for which an electronic summary of care record is available.

- Numerator: Number of patient encounters in the denominator where an electronic summary of care record received is incorporated by the provider into the certified EHR technology.

- Threshold: The percentage must be more than 10 percent in order for an eligible hospital or CAH to meet this measure.

- Exclusions:
 - Any eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period is excluded from this measure.

- Any eligible hospital or CAH will be excluded from the measure if it is

located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

- Proposed Modification to the Request/Accept Summary of Care Threshold for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program

We proposed to reduce the threshold for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for the Request/Accept Summary of Care measure from more than 40 percent to more than 10 percent. Hospital and hospital association feedback on the 2015 EHR Incentive Programs Final Rule, as well as recent reports and surveys of hospital participants showed that there were still challenges to achieving wide scale interoperable health information exchange.²⁵⁰ Specifically, more than 50 percent of hospital stakeholders identified a lack of health IT adoption to support electronic exchange among trading partners as a key barrier, especially for provider types and settings of care where wide spread adoption may be slower. Stakeholders have emphasized that while the majority of hospitals are now engaging in health IT supported health information exchange, achieving high performance will require further saturation of these health IT supports throughout the industry.

We invited public comment on our proposal.

Comment: Several commenters supported the reduction of the threshold to greater than 10 percent.

Response: We thank the commenters for their support. We believe the reduction of this threshold will allow additional time for focus on interoperability and an increase in trading partners. We are encouraged by the state of interoperable exchange activity among U.S. non-Federal acute care hospitals found in ONC's data brief and believe this trend will continue.²⁵¹

Comment: A few commenters recommended lowering this threshold from 10 percent to at least one patient due to significant technical problems with receiving an electronic summary-of-care document.

Response: A review of the Stage 2 eligible hospital summary of care performance data through March 2015 found that eligible hospitals met the

²⁵⁰ Ibid.

²⁵¹ ONC Data Brief: No. 36 ■ May 2016. Available at: https://www.healthit.gov/sites/default/files/briefs/onc_data_brief_36_interoperability.pdf.

requirements at the 1st (19 percent) 2nd (29 percent) and 3rd (48 percent) quartile at a threshold of 10 percent for measure 2 under the Stage 2 Summary of Care objective (https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/AttestationPerformanceData_Feb2015.pdf) (page 25)). We believe the data support the proposed threshold reduction to more than 10 percent and indicate that providers have been successful with meeting this threshold.

Clinical Information Reconciliation: For more than 50 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH performs a clinical information reconciliation. The provider must implement clinical information reconciliation for the following three clinical information sets: (1) Medication. Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy. Review of the patient's known allergic medications; and (3) Current Problem list. Review of the patient's current and active diagnoses.

- Denominator: Number of transitions of care or referrals during the EHR reporting period for which the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) was the recipient of the transition or referral or has never before encountered the patient.

- Numerator: The number of transitions of care or referrals in the denominator where the following three clinical information reconciliations were performed: Medication list; medication allergy list; and current problem list.

- Threshold: The resulting percentage must be more than 50 percent in order for an eligible hospital or CAH to meet this measure.

- Exclusions: Any eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period is excluded from this measure.

- Proposed Modification to the Clinical Information Reconciliation Threshold for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program.

We proposed to reduce the threshold for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for the Clinical Information Reconciliation measure from more than 80 percent to more than 50 percent. As

mentioned in both the Send a Summary of Care measure and the Request/Accept Summary of Care measure, there are challenges to achieving wide scale interoperable health information exchange. Specifically, more than 50 percent of hospital stakeholders identified a lack of health IT adoption to support electronic exchange among trading partners as a key barrier, especially for provider types and settings of care where wide spread adoption may be slower. We will continue to review adoption and performance and consider increasing the threshold in future rulemaking.

We invited public comment on our proposal.

Comment: A few commenters supported the reduction of the threshold to greater than 50 percent.

Response: We thank commenters for their support and note that our intent in maintaining a 50-percent threshold for this measure is to allow providers to continue to improve on reconciliation workflows both involving HIE and through other methods as well as to provide flexibility, as providers continue to move toward reconciliation of a wider range of information beyond medications alone.

Comment: A few commenters stated that the proposed 50-percent threshold is not reasonably achievable as the industry has no experience implementing technology capable of clinical information reconciliation.

A few commenters suggested that the threshold for pulling the record and reconciling the information should be the same. The commenters stated that 10 percent is reasonable, given that this is the initial year of this objective and that a minority of patients are likely to have this information electronically available.

Response: We note that this measure builds on the existing Medication Reconciliation Objective for the EHR Incentive Programs in 2015 through 2017 (we refer readers to section II.B.2.a. of the preamble to the 2015 EHR Incentive Programs Final Rule (80 FR 62809 through 62811)). We further stated in the 2015 EHR Incentive Programs Final Rule that this process may include electronic and manual reconciliation through use of certified EHR technology and discussion with the patient. In addition, we stated the process of reconciliation may consist of simply verifying that fact or reviewing a record received on referral and determining that such information is merely duplicative of existing information in the patient record (80 FR 62861).

A review of the Stage 2 eligible hospital summary of care performance data through March 2015 found that eligible hospitals met the requirements for Medication Reconciliation at the 1st (81 percent) 2nd (91 percent) and 3rd (97 percent) quartile at a threshold of 50 percent (https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/AttestationPerformanceData_Feb2015.pdf (page 23)). We believe the data support the proposed threshold reduction to 50 percent and indicate providers have been successful with meeting this threshold. We believe the success of the medication reconciliation measure, shown in our data, will transcend to the Clinical Information Reconciliation measure because it builds on the medication reconciliation measure and allows for the provider's clinical judgment on what information is included in the process.

We stated in the 2015 EHR Incentive Programs Final Rule (80 FR 62861) that we believe many providers may conduct some form of reconciliation in conjunction with measure 2, or that providers in certain specialties may elect to conduct reconciliation of clinical information even beyond our requirement. We do not believe that the thresholds for measures 2 and 3 should both be at greater than 10 percent, and reiterate that while providers must attest to the numerator and denominator of all three measures, they are only required to successfully meet the threshold for two of three measures, providing additional flexibility.

After consideration of the public comments we received, we are finalizing the reduction to the thresholds. Specifically, for Stage 3 in 2017 and 2018, we are finalizing the Send a Summary of Care measure threshold as more than 10 percent, Request/Accept Summary of Care measure threshold as more than 10 percent, and Clinical Information Reconciliation measure threshold as more than 50 percent for eligible hospitals and CAHs attesting to CMS, including dual-eligible hospitals that are attesting to CMS for both the Medicare and Medicaid EHR Incentive Programs. These reduced thresholds do not apply to eligible hospitals and CAHs attesting to a State for the Medicaid EHR Incentive Program.

The objective and measures are as follows:

Objective: Health Information Exchange (HIE) (42 CFR 495.24(c)(7))

Objective: The eligible hospital or CAH provides a summary of care record when transitioning or referring their

patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of CEHRT.

Send a Summary of Care: For more than 10 percent of transitions of care and referrals, the eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care: (1) Creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.

- **Denominator:** Number of transitions of care and referrals during the EHR reporting period for which the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) was the transferring or referring provider.

- **Numerator:** The number of transitions of care and referrals in the denominator where a summary of care record was created using certified EHR technology and exchanged electronically.

- **Threshold:** The percentage must be more than 10 percent in order for an eligible hospital or CAH to meet this measure.

- **Exclusion:** Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

Request/Accept Summary of Care: For more than 10 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH incorporates into the patient's EHR an electronic summary of care document.

- **Denominator:** Number of patient encounters during the EHR reporting period for which an eligible hospital or CAH was the receiving party of a transition or referral or has never before encountered the patient and for which an electronic summary of care record is available.

- **Numerator:** Number of patient encounters in the denominator where an electronic summary of care record received is incorporated by the provider into the certified EHR technology.

- **Threshold:** The percentage must be more than 10 percent in order for an eligible hospital or CAH to meet this measure.

- **Exclusions:**

- Any eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period is excluded from this measure.

- Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

Clinical Information Reconciliation: For more than 50 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH performs a clinical information reconciliation. The provider must implement clinical information reconciliation for the following three clinical information sets: (1) Medication. Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy. Review of the patient's known allergic medications; and (3) Current Problem list. Review of the patient's current and active diagnoses.

- Denominator: Number of transitions of care or referrals during the EHR reporting period for which the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) was the recipient of the transition or referral or has never before encountered the patient.

- Numerator: The number of transitions of care or referrals in the denominator where the following three clinical information reconciliations were performed: Medication list; medication allergy list; and current problem list.

- Threshold: The resulting percentage must be more than 50 percent in order for an eligible hospital or CAH to meet this measure.

- Exclusions: Any eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period is excluded from this measure.

(4) Objective: Public Health and Clinical Data Registry Reporting (42 CFR 495.24(c)(8))

Objective: The eligible hospital or CAH is in active engagement with a public health agency (PHA) or clinical data registry (CDR) to submit electronic public health data in a meaningful way

using CEHRT, except where prohibited, and in accordance with applicable law and practice.

Immunization Registry Reporting (42 CFR 495.24(c)(8)(A))

Syndromic Surveillance Reporting (42 CFR 495.24(c)(8)(B))

Electronic Case Reporting (42 CFR 495.24(c)(8)(C))

Public Health Registry Reporting (42 CFR 495.24(c)(8)(D))

Clinical Data Registry Reporting (42 CFR 495.24(c)(8)(E))

Electronic Reportable Laboratory Result Reporting (42 CFR 495.24(c)(8)(F))

- Proposed Modification to the Public Health and Clinical Data Registry Reporting Requirements for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program.

We proposed to reduce the reporting requirement for eligible hospitals and CAHs attesting to CMS for Public Health and Clinical Data Registry Reporting, to the Modified Stage 2 requirement of any combination of three measures from any combination of six measures in alignment with Modified Stage 2 requirements (80 FR 62870). We received written correspondence from hospitals and hospital associations indicating that it is often difficult to find registries that are able to accept data that will allow them to successfully attest. Hospitals and hospital associations had indicated that it is administratively burdensome to seek out registries in their jurisdiction, contact the registries to determine if they are accepting data in the standards required, then determine if they meet the exclusion criteria if they are unable to send data to a registry. In addition, we had received written correspondence from hospitals indicating that in some instances additional technologies were required to transmit data, which prevented them from doing so.

We invited public comment on our proposal.

Comment: Several providers supported the reduction of Public Health and Clinical Data Registry Reporting requirements for Stage 3 because they believed there is a lack of entities ready to accept the electronic reporting data.

Response: We thank the commenters for their support. As we discussed in the proposed rule (81 FR 45751 through 45752), we have received written communication regarding the difficulty in finding registries that are able to accept data that will allow hospitals to successfully attest. We believe the number of available registries will increase over time. In addition, we are in the process of developing a

centralized repository for public health agency and clinical data registry reporting, which should be available early in 2017. The repository will assist eligible professionals, eligible hospitals and CAHs in finding entities that accept electronic public health data. We further note that the lack of an available registry capable of receiving electronic data remains an acceptable reason for exclusion from a given measure under this objective.

Comment: A few commenters disagreed with reducing the reporting requirement for eligible hospitals and CAHs to three measures for the Public Health and Clinical Data Registry Reporting objective. A few commenters noted that providers still struggle to identify the certified clinical registries to which they must submit measures and suggested that CMS maintain a list of clinical and public health registries that can support the active engagement requirement.

Response: We proposed to reduce the threshold for the Public Health and Clinical Data Registry Reporting objective based on concerns voiced by stakeholders who were having difficulty finding registries to report to. We believe a reduction in the reporting requirement will relieve the administrative burden providers indicated they were experiencing with this objective. We note that, for the 2015 and 2016 EHR reporting periods, we implemented alternate exclusions based on the issues associated with the specialized registry measure including acquisition of additional technologies they did not already have. We also note that providers that wish to attest to additional measures may do so.

We are developing a centralized repository for public health agency and clinical data registry reporting to help EPs, eligible hospitals, and CAHs find entities that accept electronic public health data as discussed in the 2015 EHR Incentive Programs Final Rule (80 FR 62863).

After consideration of the public comments we received, we are finalizing the reduction of the reporting requirements for Stage 3 Public Health and Clinical Data Registry Reporting to any combination of three measures out of six total measures for eligible hospitals and CAHs attesting to CMS, including dual-eligible hospitals that are attesting to CMS for both the Medicare and Medicaid EHR Incentive Programs. This reduction does not apply to eligible hospitals and CAHs attesting to a State for the Medicaid EHR Incentive Program.

STAGE 3 OBJECTIVES AND MEASURES FOR 2017 AND 2018 FOR ELIGIBLE HOSPITALS AND CAHS ATTESTING TO CMS

Objective	Previous measure name/reference	Measure name	Threshold requirement
Protect Patient Health Information Electronic Prescribing CDS (Clinical Decision Support) * ..	Measure Eligible hospital/CAH Measure	Security Risk Analysis	Yes/No attestation.
	Measure 1	e-Prescribing	>25%
CPOE (Computerized Provider Order Entry)*.	Measure 2	Clinical Decision Support Interventions.	Five CDS.
	Measure 1	Drug Interaction and Drug-Allergy Checks.	Yes/No.
	Measure 2	Medication Orders	>60%
Patient Electronic Access to Health Information.	Measure 3	Laboratory Orders	>60%
	Measure 1	Diagnostic Imaging Orders	>60%
Coordination of Care through Patient Engagement.	Measure 2	Provide Patient Access	>50%
	Measure 1	Patient-Specific Education**	>10%
Health Information Exchange	Measure 2	View, Download or Transmit (VDT)**.	At least 1 patient.
	Measure 3	Secure Messaging	>5%
	Measure 1	Patient Generated Health Data	>5%
	Measure 2	Send a Summary of Care***	>10%
Public Health and Clinical Data Registry Reporting.	Measure 3	Request/Accept Summary of Care***.	>10%
	Immunization Registry Reporting	Clinical Information Reconciliation**.	>50%
	Syndromic Surveillance Reporting	Immunization Registry Reporting	Report to 3 Registries or claim exclusions.
	Case Reporting	Syndromic Surveillance Reporting	
	Public Health Registry Reporting	Electronic Case Reporting	
Clinical Data Registry Reporting ..	Public Health Registry Reporting		
Electronic Reportable Laboratory Result Reporting.	Clinical Data Registry Reporting .. Electronic Reportable Laboratory Result Reporting.		

* We note that we are finalizing the removal of CDS and CPOE for eligible hospitals and CAHs attesting to CMS section XVIII.C.1. of this final rule with comment period. These objectives are included in the table to demonstrate what their measures and thresholds would have been if we were not finalizing our proposal to remove them.

** We note that, in the proposed rule (81 FR 45752), we referred to this measure as the "View Download Transmit Measure."

*** We note that, in the proposed rule (81 FR 45752), we referred to this measure as the "Patient Care Record Exchange Measure."

** We note that, in the proposed rule (81 FR 45752), we referred to this measure as the "Request/Accept Patient Care Record Measure."

We sought public comments on how measures of meaningful use under the EHR Incentive Program can be made more stringent in future years, consistent with the requirements of section 1886(n)(3)(A) of the Act. In addition, we sought public comments on new and more stringent measures for future years of the EHR Incentive Program and will consider these comments for future enhancements of the EHR Incentive Program in future rulemaking. We intend to reevaluate the objectives, measures, and other program requirements for Stage 3 in 2019 and subsequent years. We noted that our proposed revisions to the regulation text at § 495.24 would only include objectives and measures for eligible hospitals and CAHs for Stage 3 in 2017 and 2018. We requested comments on any changes that hospitals and other stakeholders believe should be made to the objectives and measures for Stage 3 in 2019 and subsequent years.

Comment: One commenter disagreed with CMS making further changes to meaningful use objectives and measures in 2019 and subsequent years as this conflicted with the 2015 EHR Incentive

Programs Final Rule that indicated meaningful use Stage 3 requirements would continue unchanged in 2018, 2019, and through future years (80 FR 62776) and that Stage 3 is intended to be the last stage of the program (80 FR 62766). The commenter indicated confusion on whether an additional stage was planned or if the intention was to make changes without the distinction of a separate stage and disagreed with same-stage changes to requirements. In addition, the commenter stated if CMS intends to make changes in 2019, vendors and healthcare organizations need sufficient advance notice to plan and prepare for those changes. Based on the timeline of previous rulemaking for Stage 2 and Stage 3, the commenter believed CMS would need to issue a proposed rule by March 2017 to allow for public comments and a final rule by August 2017 so there is enough time to implement changes before the start of the 2019 EHR reporting period.

Response: We previously stated that there would be three stages of meaningful use. However, we do not want to hinder advancement of health

information technology and additional program revisions are likely necessary in achieving widespread adoption of CEHRT. Therefore, continual advancements, changes and evolution in technology and other aspects of the program such as privacy, security, and practice standards will impact the EHR Incentive Program and may spur additional rulemaking, possibly resulting in additional stages to the EHR Incentive Program.

We understand the concern regarding the timeline for any changes we might make for 2019 and intend to work with stakeholders to ensure sufficient time is provided for updates and implementation of requirements in future rulemaking.

As stated in the previous sections, in the proposed rule, we did not propose any changes to the objectives and measures for Modified Stage 2 for 2017 or Stage 3 for 2017 and 2018 for eligible hospitals and CAHs that attest to a State's Medicaid EHR Incentive Program. We considered proposing the same changes for both Medicare and Medicaid, but based upon our concerns that States would incur additional cost

and time burdens in having to update their technology and reporting systems within a short period of time, we proposed these changes only for eligible hospitals and CAHs attesting to the Medicare EHR Incentive Program. We requested comments on whether these proposed changes should also apply for eligible hospitals and CAHs attesting to a State's Medicaid EHR Incentive Program. Specifically, we requested comments on whether the proposed changes to eliminate the CPOE and CDS objectives and measures and reduce a subset of the measure thresholds for Modified Stage 2 in 2017 and Stage 3 in 2017 and 2018 should also apply for eligible hospitals and CAHs that seek to qualify for an incentive payment for meaningful use under Medicaid. We requested comments from State Medicaid agencies concerning our assumptions about the additional cost and time burdens they would face in accommodating these changes, and whether those burdens would exist for both 2017 and 2018.

Comment: The majority of commenters requested that the proposed changes to the objectives and measures, including removal of the CDS and CPOE objectives beginning in 2017 and a reduction in thresholds for a subset of the remaining objectives and measures, also be applied to the Medicaid EHR Incentive Program for eligible hospitals, CAHs, and EPs. The commenters indicated that differing requirements vastly increase the burden of reporting and complexity, especially for hospitals that participate in both the Medicare and Medicaid EHR Incentive Programs. A few commenters suggested that CMS collect all data through the Medicare attestation process and pass the results to the appropriate State Medicaid program indicated by the participant or that CMS could assess its ability to intake Medicaid-only attestations and communicate them to the States because it currently does for hospitals participating in both the Medicare and Medicaid EHR Incentive Programs. This would leverage existing reporting and communication capabilities to ensure alignment across Medicare and Medicaid.

A few commenters believed that dual-eligible hospitals are required to attest to both the Medicare and Medicaid programs.

Some commenters proposed that, for objectives proposed for elimination, hospitals attesting under Medicaid should be able to attest with either 0 percent or NO as appropriate for 2017 and 2018 without penalty.

Response: We recognize the challenges associated with the proposal

to require different sets of objectives and measures for hospitals participating in the Medicaid EHR Incentive Program versus the Medicare EHR Incentive Program beginning in 2017. The vast majority of commenters supported aligning the proposed changes for dual-eligible hospitals participating in both the Medicare EHR Incentive Program and the Medicaid EHR Incentive Program because doing so will eliminate the need for additional attestation and reporting requirements. Section 1903(t)(8) of the Act provides that a State and the Secretary shall seek, to the maximum extent practicable, to avoid duplicative requirements to demonstrate meaningful use of certified EHR technology under Medicaid and Medicare.

Based on this statutory directive and for the reasons identified by the commenters, under our final policy, eligible hospitals and CAHs participating in both the Medicare and Medicaid EHR Incentive Programs that attest to CMS will attest based on the revised objectives and measures that we are adopting in this final rule with comment period, including the changes to eliminate the CPOE and CDS objectives and measures and reduce a subset of the measure thresholds for Modified Stage 2 in 2017 and Stage 3 in 2017 and 2018. Dual-eligible hospitals may submit one attestation for both the Medicare and Medicaid EHR Incentive Programs to CMS and the attestation data will be shared with the appropriate State Medicaid agency to process the Medicaid incentive payment. Medicaid-only hospitals and dual-eligible hospitals that attest directly to a State for the State's Medicaid EHR Incentive Program will continue to attest based on the measures and objectives as finalized in the 2015 EHR Incentive Programs Final Rule (80 FR 62793 through 80 FR 62871).

Comment: One commenter stated that Medicare providers should have to meet the higher standards for objectives and measures in the 2015 EHR Incentive Programs Final Rule that would apply for Medicaid providers.

Response: We thank the commenter for its input. We have previously stated that the proposals were meant to reduce reporting burden and allow providers to focus more on patient care. In addition, under our final policies stated above, the changes to the objectives and measures that we are adopting in this final rule with comment period apply to dual-eligible hospitals that participate in both the Medicare and Medicaid EHR Incentive Programs that submit an attestation to CMS, in addition to Medicare-only hospitals. In addition, we

requested public comments on how we could make the measures more stringent in future years. We did not receive any public comments on how to make the measures more stringent in future years.

After consideration of the public comments we received, we are finalizing that eligible hospitals and CAHs participating in both the Medicare and Medicaid EHR Incentive Programs that attest to CMS will attest based on the revised objectives and measures that we are adopting in this final rule with comment period, including the changes to eliminate the CPOE and CDS objectives and measures and reduce a subset of the measure thresholds for Modified Stage 2 in 2017 and Stage 3 in 2017 and 2018. Dual-eligible hospitals may submit one attestation for both the Medicare and Medicaid EHR Incentive Programs to CMS. Medicaid-only hospitals and dual-eligible hospitals that attest directly to a State for the State's Medicaid EHR Incentive Program will continue to attest based on the measures and objectives as finalized in the 2015 EHR Incentive Programs Final Rule (80 FR 62793 through 80 FR 62871).

D. Changes to the EHR Reporting Period in 2016 for EPs, Eligible Hospitals and CAHs

1. Definition of "EHR Reporting Period" and "EHR Reporting Period for a Payment Adjustment Year"

In the CY 2017 OPPTS/ASC proposed rule (81 FR 45753), we proposed to change the EHR reporting periods in 2016 for returning participants from the full CY 2016 to any continuous 90-day period within CY 2016. This would mean that all EPs, eligible hospitals and CAHs may attest to meaningful use for an EHR reporting period of any continuous 90-day period from January 1, 2016 through December 31, 2016. The applicable incentive payment year and payment adjustment years for the EHR reporting period in 2016, as well as the deadlines for attestation and other related program requirements, would remain the same as established in prior rulemaking. We proposed corresponding changes to the definition of "EHR reporting period" and "EHR reporting period for a payment adjustment year" at 42 CFR 495.4.

We invited public comment on our proposals.

Comment: Several commenters supported the 90-day EHR reporting period because they believed it would reduce the burden of reporting and meeting all the thresholds for a 12-month period, increase program flexibility, and allow clinicians to spend

more time on patient care and implement new program requirements without affecting clinician workflow. These commenters also stated that this additional time would allow health care providers to focus more time and attention on preparing for the upcoming implementation of MACRA/MIPS and train new physicians on the use of a group's EHR, including work flows and processes, and allows the extra time needed to upgrade to the 2015 Edition CEHRT.

Several commenters also requested CMS to extend the 90-day EHR reporting period for 2017 and 2018. These commenters believed that this reduction from a full calendar year reporting to a 90-day EHR reporting period will increase flexibility and prepare them for success in MIPS starting in 2017. Some commenters also expressed concerns about implementing APIs and other functionalities for Stage 3 and encouraged CMS to adopt a 90-day EHR reporting period in 2017 to allow for extra time needed to upgrade to the 2015 Edition CEHRT.

Response: We agree with the commenters that the change in the EHR reporting period will reduce burden on all EPs, eligible hospitals and CAHs preparing for Stage 3, as well as for EPs who will begin participating in MIPS in 2017. We also agree with health care providers that allowing a 90-day EHR reporting period does allow clinicians to spend more time on patient care and implement new requirements without negatively affecting clinician workflow.

Comment: Several commenters urged CMS to adopt the 90-day EHR reporting period as expeditiously as possible. Some commenters further urged the rapid launch of the Web site to prepare for these attestations.

Response: We note that after this final rule with comment period is published, we will work on a rapid implementation of this policy.

Comment: Several commenters recommended that CMS permanently keep the 90-day EHR reporting period for hospitals and EPs to avoid having to make yearly changes and streamline the attestation process.

Response: We disagree that we should permanently retain a 90-day EHR reporting period for returning participants. We do understand that it can cause uncertainty when we change the EHR reporting period in rulemaking from year to year. However, considering the implementation of MIPS in 2017 for EPs, as well as Stage 3 and the 2015 Edition for all EPs, eligible hospitals and CAHs in 2018 (optional in 2017), we believe adopting a 90-day EHR reporting period in 2016 for all

participants will reduce the burden of reporting for a full year and assist healthcare providers in establishing and testing their processes and workflows for the new requirements and implementation functionalities required for EHR technology certified to the 2015 Edition. We believe a full year EHR reporting period is the most effective way to ensure that all actions related to patient safety that leverage CEHRT are fully enabled for the duration of the year. This is one of the primary considerations of our continued push for a full year EHR reporting period, in addition to promoting greater alignment with other CMS quality reporting programs.

Comment: Some commenters stated that they are concerned with the proposed rule's late notice of the proposed change to the EHR reporting period in 2016 because they will have to monitor EPs and eligible hospitals for both 365-day reporting periods and 90-day reporting periods because they will not know if CMS will finalize the proposed change until the fourth quarter of 2016.

Response: We thank the commenters for their views on this proposal. While we understand the concerns of these commenters, we believe that we have provided EPs, eligible hospitals, and CAHs sufficient time to report on any continuous 90-day EHR reporting period from January 1, 2016–December 31, 2016.

Comment: Several commenters welcomed having a longer EHR reporting period because it allows them opportunity to evaluate their progress and improve in subsequent months.

Response: We thank the commenters for their feedback. We note that we are establishing in this final rule with comment period an EHR reporting period of any continuous 90 days from January 1, 2016 through December 31, 2016. However, we note that health care providers are required to report on a minimum of 90 days, but may choose to report on the full calendar year in 2016.

Comment: Some commenters stated that they need more time to implement and upgrade technology in order to meet the complex Stage 3 requirements, which they stated adds to the existing challenges they face. In addition, some commenters disagreed with the proposed changes in the proposed rule because they stated they must adapt to new changes every year.

Response: We thank the commenters for their feedback. We believe that reducing the EHR reporting period from the full CY 2016 to any continuous 90-day period from January 1, 2016 through December 31, 2016, in fact, reduces

challenges because it allows for the EPs, eligible hospitals and CAHs to report based on a shorter period of time.

Comment: Some commenters suggested that CMS issue guidance notifying physicians of the 90-day EHR reporting period and begin educating physicians about the change as quickly as possible.

Response: We thank the commenters for their feedback. This final rule with comment period serves as the notice to all EPs, eligible hospitals, and CAHs. We understand the need to implement the policies adopted in this rule as quickly as possible.

Comment: Some commenters were unclear if they should prepare for a 90-day or 365-day EHR reporting period in 2016.

Response: We are finalizing an EHR reporting period of any continuous 90-day period within CY 2016. Therefore, EPs, eligible hospitals, and CAHs should prepare for a 90-day EHR reporting period.

After consideration of the public comments we received, we are finalizing a change to the EHR reporting periods in 2016 and 2017 for returning participants, from the full calendar year to any continuous 90-day period within the CY. For all EPs, eligible hospitals and CAHs, the EHR reporting period in CY 2016 is any continuous 90-day period from January 1, 2016 through December 31, 2016, and the EHR reporting period in CY 2017 is any continuous 90-day period from January 1, 2017 through December 31, 2017. The applicable incentive payment year and payment adjustment years for the EHR reporting periods in 2016 and 2017, as well as the deadlines for attestation and other related program requirements, will remain the same as established in prior rulemaking. We are finalizing corresponding changes to the definitions of "EHR reporting period" and "EHR reporting period for a payment adjustment year" in the regulations under § 495.4.

2. Clinical Quality Measurement

In connection with the proposal to establish a 90-day EHR reporting period in 2016, we also proposed a 90-day reporting period for CQMs (81 FR 45753) which would have no impact on the requirements for CQM data that are electronically reported as established in prior rulemaking. In 2016, we proposed that providers may:

- Report CQM data by attestation for any continuous 90-day period during calendar year 2016 through the Medicare EHR Incentive Program registration and attestation site; or

- Electronically report CQM data in accordance with the requirements established in prior rulemaking.

We noted that, for EPs, eligible hospitals and CAHs, CQM data submitted via attestation can be submitted for a different 90-day period than the EHR reporting period for the meaningful use objectives and measures.

Comment: Several commenters agreed with a 90-day EHR reporting period because it would allow EPs, eligible hospitals, and CAHs the opportunity to implement the changes from the 2015 Final Rule for CQMs and urged CMS to finalize this change.

Response: We believe that this change will reduce provider burden and further simplify the program through alignment of the EHR reporting period and CQM reporting period for CY 2016.

We are finalizing our policy to allow a 90-day reporting period for clinical quality measures (CQMs) for all EPs, eligible hospitals, and CAHs that choose to report CQMs by attestation in 2016.

We intend to continue to allow the States to determine the form and manner of reporting CQMs for their respective State Medicaid EHR Incentive Programs subject to CMS approval.

E. Policy To Require Modified Stage 2 for New Participants in 2017

After the publication of the 2015 EHR Incentive Programs Final Rule, we determined that, due to cost and time limitation concerns related specifically to 2015 Edition CEHRT updates in the EHR Incentive Program Registration and Attestation System, it is not technically feasible for EPs, eligible hospitals, and CAHs that have not successfully demonstrated meaningful use in a prior year (new participants) to attest to the Stage 3 objectives and measures in 2017 in the EHR Incentive Program Registration and Attestation System. For this reason, in the CY 2017 OPPTS/ASC proposed rule (81 FR 45753 through 45754), we proposed that any EP or eligible hospital new participant seeking to avoid the 2018 payment adjustment by attesting for an EHR reporting period in 2017 through the EHR Incentive Program Registration and Attestation system, or any CAH new participant seeking to avoid the FY 2017 payment adjustment by attesting for an EHR reporting period in 2017 through the EHR Incentive Program Registration and Attestation System, would be required to attest to the Modified Stage 2 objectives and measures. This proposal does not apply to EPs, eligible hospitals, and CAHs that have successfully demonstrated meaningful use in a prior

year (returning participants) attesting for an EHR reporting period in 2017. In early 2018, these returning eligible hospitals and CAHs will be transitioned to other reporting systems to attest for 2017, such as the Hospital IQR Program reporting portal. Eligible professionals who have successfully demonstrated meaningful use in a prior year would not be attesting to the Medicare EHR Incentive Program for 2017, because the applicable EHR reporting period for the 2018 payment adjustment is in 2016 (80 FR 62906), and 2016 is also the final year of the incentive payment under section 1848(o)(1)(A)(ii) of the Act.

We further note that providers using 2014 Edition, 2015 Edition, or any combination of 2014 and 2015 Edition certified EHR technology in 2017 would have the necessary technical capabilities to attest to the Modified Stage 2 objectives and measures.

We proposed corresponding revisions to the regulations at proposed 42 CFR 495.40(a)(2)(i)(F) and 42 CFR 495.40(b)(2)(i)(F) to require new participants to attest to the Modified Stage 2 objectives and measures for 2017.

We note that we also proposed an editorial correction to the introductory language to 42 CFR 495.40(b), to correct the inadvertent omission of the word “satisfy” after the term “CAH must.” We invited public comment on our proposals.

Comment: Several commenters agreed that new participants to the Medicare EHR Incentive program should attest to Modified Stage 2 objectives and measures in 2017 and stated that the proposed requirements protect new participants from having to attest to Stage 3 requirements which they believe are challenging and unattainable.

Response: We agree that allowing for new participants to attest to Modified Stage 2 objectives and measures provide them an opportunity to successfully participate in the EHR Incentive Program. We reiterate that we are requiring new participants seeking to avoid the payment adjustment in 2018 by attesting early in 2017 to attest to only the Modified Stage 2 objectives and measures and will not allow these providers to attest to the Stage 3 objectives and measures. We are adopting this policy because as we are transitioning EPs to the advancing care information category of MIPS in 2017 and eligible hospitals will be reporting under the Hospital IQR Program in 2017 as well. Therefore, it is not feasible for providers attesting early in 2017 to avoid the payment adjustment in 2018 to attest to the Stage 3 objectives and measures and they will instead be

allowed to attest to only the Modified Stage 2 objectives and measures.

We believe this requirement will prepare these participants for success in MIPS and Stage 3 of the EHR Incentive Program in 2018. Also, while we agree that the objectives and measures for Stage 3 are challenging, we do not believe that they are unattainable.

Comment: Several commenters recommended that the Modified Stage 2 attestation date for new participants be pushed back from October 1, 2017 to a later date. One commenter disagreed with CMS’ statement that new participants attesting to Stage 3 is not technically feasible, and stated it would be beneficial for health care organizations if CMS could technically support Stage 3 attestation for new participants in 2017. One commenter stated that CMS should establish modified criteria for new program participants that will prepare them to meet subsequent stages successfully, stating that Modified Stage 2 requirements place an unfair burden on new participants.

Response: We thank the commenters for their recommendations. However, we do not agree that we should push the date back later. The reason for having an October 1, 2017 attestation deadline is to accommodate all the changes to the new systems that will occur specifically to the technology certified to the 2015 edition updates in the attestation system.

We also believe that developing modified requirements for new participants would further create confusion among health care providers and would create undue administrative burden, in addition to not being technically feasible. In addition, requiring new participants to attest to Modified Stage 2 in 2017 provides new participants with the experience necessary to attest to future stages of meaningful use and prepares those EPs who will transition to MIPS in 2017.

Comment: One commenter asked whether the proposals extend to the Medicaid EHR Incentive Program.

Response: The proposal to require attestation to Modified Stage 2 is for all new participants, including those who participate in the Medicaid EHR Incentive Program.

Comment: One commenter asked CMS to present the proposal in a table or grid format for clarity.

Response: We will provide guidance materials on our Web page at: <https://www.cms.gov/EHRIncentivePrograms/> after this final rule with comment period is published.

After consideration of the public comments we received, we are

finalizing our proposed policy at 42 CFR 495.40(a)(2)(i)(F) and 42 CFR 495.40(b)(2)(i)(F) to require new participants to attest to the Modified Stage 2 objectives and measures for 2017.

We did not receive any public comments specific to our proposed editorial correction to 42 CFR 495.40(b), and we are finalizing the correction as proposed.

F. Significant Hardship Exception for New Participants Transitioning to MIPS in 2017

In the 2016 MIPS and APMs proposed rule (81 FR 28161 through 28586), we proposed calendar year 2017 as the first MIPS performance period. As established in the 2015 EHR Incentive Programs Final Rule (80 FR 62904 through 62908), 2017 is also the last year in which new participants may attest to meaningful use (for a 90-day EHR reporting period in 2017) to avoid the 2018 payment adjustment. For the reasons stated in the CY 2017 OPPI/ASC proposed rule (81 FR 45754), we proposed to allow certain EPs to apply for a significant hardship exception from the 2018 payment adjustment as authorized under section 1848(a)(7)(B) of the Act. We limited this proposal only to EPs who have not successfully demonstrated meaningful use in a prior year, intend to attest to meaningful use for an EHR reporting period in 2017 by October 1, 2017, to avoid the 2018 payment adjustment, and intend to transition to MIPS and report on measures specified for the advancing care information performance category under the MIPS in 2017.

To apply for this significant hardship exception, we proposed an EP would submit an application by October 1, 2017 (or a later date specified by CMS) to CMS that includes sufficient information to show that they are eligible to apply for this particular category of significant hardship exception. The application must also explain why, based on their particular circumstances, demonstrating meaningful use for the first time in 2017 under the EHR Incentive Program and also reporting on measures specified for the advancing care information performance category under the MIPS in 2017 would result in a significant hardship. EPs should retain all relevant documentation of this hardship for 6 years post attestation.

We stated in the proposed rule that we believed this new category of significant hardship exception would allow the EPs who are new to certified EHR technology to focus on their transition to MIPS, and allow them to

work with their EHR vendor to build out an EHR system focused on the goals of patient engagement and interoperability, which are important pillars of patient-centered care and expected to be highly emphasized in the MIPS. It would also allow EPs to identify which objectives and measures are most meaningful to their practice which is a key feature of the proposed MIPS advancing care information performance category. We also proposed to amend the regulations by adding new § 495.102(d)(4)(v) to include this new category of significant hardship exception.

We invited public comment on our proposals.

Comment: Several commenters agreed with limiting the hardship exception to certain EPs by allowing new program participants to focus on meeting the requirements of MIPS instead of meeting the requirements of a program that will end soon.

Response: We thank the commenters for their support of the hardship exception for certain EPs. As stated in the propose rule (81 FR 45753), we want to provide first time participants who are new to meaningful use and will participate in MIPS ample time to adjust to the new reporting requirements. We believe that limiting this hardship exception to these new EPs, who would otherwise have to report to the Medicare EHR Incentive Program and MIPS, will provide these EPs more time to get adjusted to MIPS.

Comment: Several commenters supported the proposal. They also requested that CMS adopt a hardship exception application process that is as simple and readily available as possible for EPs affected by this policy.

Response: We thank the commenters for their support in this one-time significant hardship exception. Once this proposal is finalized, we will develop an application process that will be accessible for those who are applying for such an exception.

Comment: Several commenters appreciated CMS' flexibility in proposing to allow certain EPs to apply for a one time significant hardship exception. Commenters agreed that the hardship exception will help new participants focus on preparing for and successfully participating in MIPS.

Response: We thank the commenters for their support. As discussed previously we are providing this one-time hardship exception to improve chances of successful participation in MIPS.

Comment: Several commenters requested that the application deadline for a hardship exception be extended.

Response: We thank the commenters for their suggestion. However, as provided in the proposed rule the first time participants to the EHR Incentive Program have to attest by October 1, 2017. Therefore, it would not be desirable to extend the application deadline beyond this date.

Comment: Several commenters urged CMS not to finalize the hardship exception because they believed it provides incentives for procrastination and noncompliance.

Response: We thank the commenters for their views. However, we disagree with the commenters. We believe that, with this one-time hardship exception, we are providing new EPs an opportunity to prepare for the work to follow under MIPS. We believe that, through providing this hardship exception, we are improving the chances of successful participation under the MIPS.

Comment: Several commenters recommended that CMS include all new participants, rather than just certain EPs, in the hardship exception.

Response: We disagree that this policy should be extended to all new participants, as only EPs are transitioning to MIPS. This policy is to help those participants transitioning to MIPS to not have to attest to two different programs in order for them to focus their efforts on the new requirements under MIPS.

Comment: Several commenters stated that the hardship application requirement is unnecessary and too burdensome on physicians. Commenters suggested that EPs who have not previously participated in meaningful use automatically be granted a hardship exception from the meaningful use payment adjustment in 2018.

Response: We believe an application process is warranted for this significant hardship exception because we do not know how else we would verify that an EP meets the criteria for this exception, including the requirement that the EP show that, based on their particular circumstances, demonstrating meaningful use for the first time in 2017 under the EHR Incentive Program and also reporting on measures specified for the advancing care information performance category under the MIPS in 2017 would result in a significant hardship. We also believe that for some EPs this may not be a significant hardship, and thus we do not want to take the opportunity away for them to successfully participate in both the EHR Incentive Program and MIPS in 2017.

Comment: Several commenters urged CMS to communicate clearly the availability of the hardship exception to

all program participants prior to the 2017 EHR reporting period. These commenters stated that it is important that new participants who intend to transition into MIPS have the opportunity to focus on the measures and requirements specified for the proposed advancing care information performance category in 2017.

Response: We thank the commenters for their suggestion and rationale. We will work with our stakeholders to clearly communicate the availability of the hardship exception application once available. We plan to do this early enough in 2017 to ensure these new participants can focus on the relevant categories under MIPS.

After consideration of the public comments we received, we are finalizing the significant hardship exception for new participants transitioning to MIPS in 2017 as proposed. We are codifying this final policy at § 495.102(d)(4)(v).

G. Modifications To Measure Calculations for Actions Outside the EHR Reporting Period

In the CY 2017 OPPI/ASC proposed rule (81 FR 45755), we proposed that, for all meaningful use measures, unless otherwise specified, actions included in the numerator must occur within the EHR reporting period if that period is a full calendar year, or if it is less than a full calendar year, within the calendar year in which the EHR reporting period occurs. For example, if the EHR reporting period is any continuous 90-day period within CY 2017, the action must occur between January 1 and December 31, 2017, but does not have to occur within the 90-day EHR reporting period timeframe.

We note that FAQ 8231 was intended to help providers who initiate an action in their EHR after December 31 that is related to a patient encounter that occurred during the year of the EHR reporting period. We understand that a small number of actions may occur after December 31 of the year in which the EHR reporting period occurs.

However, we believe that the reduced measure thresholds proposed in the proposed rule would significantly reduce the impact that these actions would have on performance. In addition, we note that actions occurring after December 31 of the reporting year would count toward the next calendar year's EHR reporting period.

We invited public comment on our proposals.

Comment: Several commenters agreed with the proposal to require for all actions included in the numerator to occur within the EHR reporting period.

Response: We thank the commenters for their support. We believe that actions which occur outside of the EHR reporting period should be kept within the same calendar year because it could lead to attesting more than once on the same action but for different calendar year reporting periods.

Comment: Several commenters suggested that CMS revise FAQ 8231 in order to further clarify this change if it is finalized.

Response: We plan to update FAQ 8231 to explain the new policy.

Comment: Several commenters suggested that if CMS were to make a change to the reporting logic, it should be implemented as part of Stage 3, not to the Stage 2 modification.

Response: We thank the commenters for their suggestion. We do not believe that this change should be implemented as part of Stage 3 only. We believe that the intention of this policy is to be inclusive of both Modified Stage 2 objectives and measures and Stage 3 objectives and measures in order to accurately measure how EPs, eligible hospitals and CAHs are performing on the measures affected by this policy.

Comment: Several commenters suggested clarifying and maintaining the current policy to allow physicians to count actions that take place from the beginning of the calendar year of the EHR reporting period.

Response: We do not agree with the suggestion that we maintain the current policy. The goal of the new policy is to require all actions that occur during an EHR reporting period to only be counted once. We note that with the previous policy there was potential that some actions could be counted during two separate EHR reporting periods.

Comment: Several commenters requested that CMS clarify reporting timelines, specifically related to actions outside of the EHR reporting period.

Response: We clarify that the action do not have to occur within the 90 day EHR reporting period timeframe, but must occur between January 1 and December 31 (or within the calendar year).

Comment: Several commenters asked CMS to clarify whether this proposed policy applies to all EPs, eligible hospitals, and CAHs.

Response: The proposed policy for actions outside the EHR reporting period applies to all EPs, eligible hospitals and CAHs beginning January 1, 2017.

After consideration of the public comments we received, we are finalizing that, for all meaningful use measures, unless otherwise specified, actions included in the numerator must

occur within the EHR reporting period if that period is a full calendar year, or if that period is less than a calendar year, actions included in the numerator must occur within the calendar year in which the EHR reporting period occurs. This policy applies beginning with EHR reporting periods in CY 2017.

XIX. Additional Hospital Value-Based Purchasing (VBP) Program Policies

A. Background

Section 1886(o) of the Act, as added by section 3001(a)(1) of the Affordable Care Act, requires the Secretary to establish a hospital value-based purchasing program (the Hospital Value-Based Purchasing (VBP) Program) under which value-based incentive payments are made in a fiscal year to hospitals that meet performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary. We refer readers to the FY 2017 IPPS/LTCH PPS final rule for a full discussion of the Hospital VBP Program and its finalized policies (81 FR 56979 through 57011).

B. Removal of the HCAHPS Pain Management Dimension From the Hospital VBP Program

1. Background of the HCAHPS Survey in the Hospital VBP Program

Section 1886(o)(2)(A) of the Act requires the Secretary to select for the Hospital VBP Program measures, other than readmission measures, for purposes of the program. CMS partnered with the Agency for Healthcare Research and Quality (AHRQ) to develop the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient experience of care survey (NQF #0166) (hereinafter referred to as the HCAHPS Survey). We adopted the HCAHPS Survey in the Hospital VBP Program beginning with the FY 2013 program year (76 FR 26510), and we added the 3-Item Care Transition Measure (CTM-3) (NQF #0228) as the ninth dimension in the HCAHPS Survey beginning with the FY 2018 program year (80 FR 49551 through 49553). The HCAHPS Survey scores for the Hospital VBP Program are the basis for the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain.

The HCAHPS Survey is the first national, standardized, publicly reported survey of patients' experience of hospital care. The HCAHPS Survey asks discharged patients 32 questions about their recent hospital stay. Survey results are used to score nine

dimensions of the patient's experience of care for the Hospital VBP Program, as the table below illustrates.

HCAHPS SURVEY DIMENSIONS FOR THE FY 2018 PROGRAM YEAR

Communication with Nurses.
 Communication with Doctors.
 Responsiveness of Hospital Staff.
 Pain Management.
 Communication About Medicines.
 Hospital Cleanliness & Quietness.
 Discharge Information.
 3-Item Care Transition.
 Overall Rating of Hospital.

The HCAHPS Survey is administered to a random sample of adult patients who receive medical, surgical, or maternity care between 48 hours and 6 weeks (42 calendar days) after discharge and is not restricted to Medicare beneficiaries. Hospitals must survey patients throughout each month of the year. The HCAHPS Survey is available in official English, Spanish, Chinese, Russian, Vietnamese, and Portuguese versions. The HCAHPS Survey and its protocols for sampling, data collection and coding, and file submission can be found in the current HCAHPS *Quality Assurance Guidelines*, which is available on the official HCAHPS Web site at: <http://www.hcahponline.org/qaguidelines.aspx>. AHRQ carried out a rigorous, scientific process to develop and test the HCAHPS instrument. This process entailed multiple steps, including: A public call for measures; literature reviews; cognitive interviews; consumer focus groups; multiple opportunities for additional stakeholder input; a 3-State pilot test; small-scale field tests; and notice-and-comment rulemaking. In May 2005, the HCAHPS Survey was endorsed by the NQF (#0166).

2. Background of the Patient- and Caregiver-Centered Experience of Care/ Care Coordination Domain Performance Scoring Methodology

As previously finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49565 through 49566), beginning with the FY 2018 program year, for each of the 9 dimensions of the HCAHPS Survey that we have adopted for the Hospital VBP Program, we calculate Achievement Points (0 to 10 points) and Improvement Points (0 to 9 points), the larger of which is summed across the nine dimensions to create a prenormalized HCAHPS Base Score (0 to 90 points). The prenormalized HCAHPS Base Score is then multiplied by 8/9 (0.88888) and rounded according to standard rules (values of 0.5 and

higher are rounded up; values below 0.5 are rounded down) to create the normalized HCAHPS Base Score. Each of the nine dimensions is weighted equally, so that the normalized HCAHPS Base Score would range from 0 to 80 points. HCAHPS Consistency Points are then calculated and range from 0 to 20 points. The Consistency Points consider scores across all nine of the dimensions. The final element of the scoring formula is the sum of the HCAHPS Base Score and the HCAHPS Consistency Points, and that sum will range from 0 to 100 points. The Patient- and Caregiver-Centered Experience of Care/Care Coordination domain accounts for 25 percent of a hospital's Total Performance Score (TPS) for the FY 2018 program year (80 FR 49561).

3. Removal of the HCAHPS Pain Management Dimension From the Hospital VBP Program Beginning With the FY 2018 Program Year

As noted above, one of the HCAHPS Survey dimensions that we have adopted for the Hospital VBP Program is Pain Management. Three survey questions are used to construct this dimension,²⁵² as follows:

- 12. During this hospital stay, did you need medicine for pain?
 - Yes
 - No (If No, Go to Question 15)
- 13. During this hospital stay, how often was your pain well controlled?
 - Never
 - Sometimes
 - Usually
 - Always
- 14. During this hospital stay, how often did the hospital staff do everything they could to help you with your pain?
 - Never
 - Sometimes
 - Usually
 - Always

We have received feedback that some stakeholders are concerned about the Pain Management dimension questions being used in a program where there is any link between scoring well on the questions and higher hospital payments. Some stakeholders believe that the linkage of the Pain Management dimension questions to the Hospital VBP Program payment incentives creates pressure on hospital staff to prescribe more opioids in order to achieve higher scores on this dimension. Many factors outside the control of CMS quality program requirements may contribute to the

²⁵² Available at: <http://www.hcahponline.org/surveyinstrument.aspx>.

perception of a link between the Pain Management dimension and opioid prescribing practices, including misuse of the survey (such as using it for outpatient emergency room care instead of inpatient care, or using it for determining individual physician performance) and failure to recognize that the HCAHPS Survey excludes certain populations from the sampling frame (such as those with a primary substance use disorder diagnosis).

Because some hospitals have identified patient experience as a potential source of competitive advantage, we have heard that some hospitals may be disaggregating their raw HCAHPS data to compare, assess, and incentivize individual physicians, nurses, and other hospital staff. Some hospitals also may be using the HCAHPS Survey to assess their emergency and outpatient departments. The HCAHPS Survey was never intended to be used in these ways.²⁵³

We continue to believe that pain control is an appropriate part of routine patient care that hospitals should manage and is an important concern for patients, their families, and their caregivers. It is important to note that the HCAHPS Survey does not specify any particular type of pain control method. In addition, appropriate pain management includes communication with patients about pain-related issues, setting expectations about pain, shared decision-making, and proper prescription practices. Although we are not aware of any scientific studies that support an association between scores on the Pain Management dimension questions and opioid prescribing practices, we are developing alternative questions for the Pain Management dimension in order to remove any potential ambiguity in the HCAHPS Survey. We are following our standard survey development processes, which include drafting alternative questions, cognitive interviews and focus group evaluation, field testing, statistical analysis, stakeholder input, the Paperwork Reduction Act, and NQF endorsement. HHS is also conducting further research to help better understand these stakeholder concerns and determine if there are any unintended consequences that link the Pain Management dimension questions to opioid prescribing practices. In addition, we are in the early stages of developing an electronically specified

²⁵³ L. Tefera, W.G. Lehrman, and P. Conway. "Measurement of the Patient Experience: Clarifying Facts, Myths, and Approaches." *Journal of the American Medical Association*. Published online, 3–10–16. <http://jama.jamanetwork.com/article.aspx?articleid=2503222>.

process measure for the inpatient and outpatient hospital settings that would measure concurrent prescribing of an opioid and benzodiazepine. We also are in the early stages of developing a process measure that would assess whether inpatient psychiatric facilities are regularly monitoring for adverse drug events of opioid and psychotropic drugs. The measure specifications for any future measures will be posted on the CMS Web page and the public will have an opportunity to provide feedback before we make any proposal to adopt it for quality reporting purposes.

Due to some potential confusion about the appropriate use of the Pain Management dimension questions in the Hospital VBP Program and the public health concern about the ongoing prescription opioid overdose epidemic, while we await the results of our ongoing research and the above-mentioned process for developing modifications to the Pain Management dimension questions, we proposed in the CY 2017 OPPS/ASC proposed rule (81 FR 45755 through 45757) to remove 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. The FY 2018 program year uses HCAHPS

performance period data from January 1, 2016 to December 31, 2016 to calculate each hospital's TPS, which affects FY 2018 payments. When modified Pain Management questions for the HCAHPS Survey become available for use in the Hospital VBP Program, and subject to the statutory requirements listed in sections 1886(o)(2)(A) and 1886(o)(2)(C)(i) of the Act, we intend to propose to adopt them in future rulemaking.

In the proposed rule, we stated that finalizing our proposal to remove the Pain Management dimension would leave eight dimensions in the HCAHPS Survey, as the table below illustrates.

PROPOSED HCAHPS SURVEY DIMENSIONS FOR THE FY 2018 PROGRAM YEAR

- Communication with Nurses.
- Communication with Doctors.
- Responsiveness of Hospital Staff.
- Communication About Medicines.
- Hospital Cleanliness & Quietness.
- Discharge Information.
- 3-Item Care Transition.
- Overall Rating of Hospital.

In order to adjust for the removal of the Pain Management dimension from the HCAHPS Survey, we proposed to continue to assign Achievement Points

(0 to 10 points) and Improvement Points (0 to 9 points) to each of the remaining eight dimensions in order to create the HCAHPS Base Score (0 to 80 points) (81 FR 45756). Each of the remaining eight dimensions would be of equal weight, so that the HCAHPS Base Score would range from 0 to 80 points. HCAHPS Consistency Points would then be calculated, and would range from 0 to 20 points. The Consistency Points would consider scores across the remaining eight dimensions, and would not include the Pain Management dimension. The final element of the scoring formula would be the sum of the HCAHPS Base Score and the HCAHPS Consistency Points and would range from 0 to 100 points.

For the FY 2018 program year, we finalized performance standards for the HCAHPS measures in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49566). In the CY 2017 OPPS/ASC proposed rule (81 FR 45757), we proposed to remove the Pain Management dimension of the HCAHPS Survey in the calculation of the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain score beginning with the FY 2018 program year. The performance standards for the other eight dimensions would remain unchanged, as the table below illustrates.

PERFORMANCE STANDARDS FOR THE FY 2018 PROGRAM YEAR

HCAHPS survey dimension	Floor* (percent)	Achievement threshold** (percent)	Benchmark*** (percent)
Communication with Nurses	55.27	78.52	86.68
Communication with Doctors	57.39	80.44	88.51
Responsiveness of Hospital Staff	38.40	65.08	80.35
Pain Management	N/A	N/A	N/A
Communication about Medicines	43.43	63.37	73.66
Hospital Cleanliness & Quietness	40.05	65.60	79.00
Discharge Information	62.25	86.60	91.63
3-Item Care Transition	25.21	51.45	62.44
Overall Rating of Hospital	37.67	70.23	84.58

* Floor is defined as the 0th percentile of the baseline (76 FR 26519).

** Achievement threshold is defined as the 50th percentile of hospital performance in the baseline period (76 FR 26519).

*** Benchmark is defined as the mean of the top decile of hospital performance on each dimension (76 FR 26517).

For the FY 2019 program year, we proposed performance standards in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25114), and finalized performance standards in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57006 through 57007). The table below reflects the finalized performance standards for the FY 2019 program year. In the CY

2017 OPPS/ASC proposed rule (81 FR 45757), we proposed to remove the Pain Management dimension of the HCAHPS Survey in the calculation of the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain score beginning with the FY 2018 program year. (In section IV.H.3.b. of the FY 2017 IPPS/LTCH PPS final rule, we also

finalized our proposal to change the name of this domain to the Person and Community Engagement domain beginning with the FY 2019 program year (81 FR 56984)). The performance standards for the other eight dimensions would remain unchanged, as the table below illustrates.

PERFORMANCE STANDARDS FOR THE FY 2019 PROGRAM YEAR

HCAHPS survey dimension	Floor * (percent)	Achievement threshold ** (percent)	Benchmark *** (percent)
Communication with Nurses	28.10	78.69	86.97
Communication with Doctors	33.46	80.32	88.62
Responsiveness of Hospital Staff	32.72	65.16	80.15
Pain Management	N/A	N/A	N/A
Communication about Medicines	11.38	63.26	73.53
Hospital Cleanliness & Quietness	22.85	65.58	79.06
Discharge Information	61.96	87.05	91.87
3-Item Care Transition	11.30	51.42	62.77
Overall Rating of Hospital	28.39	70.85	84.83

* Floor is defined as the 0th percentile of the baseline (76 FR 26519).

** Achievement threshold is defined as the 50th percentile of hospital performance in the baseline period (76 FR 26519).

*** Benchmark is defined as the mean of the top decile of hospital performance on each dimension (76 FR 26517).

We invited public comments on these proposals.

Comment: Many commenters supported CMS’ proposal to remove the Pain Management dimension of the HCAHPS Survey from the Hospital VBP Program based on their concern that the survey questions may inadvertently create incentives and undue pressure for providers to prescribe opioids in order to achieve higher scores on the HCAHPS Survey, which may contribute to the opioid epidemic. Commenters also noted that removing the Pain Management dimension will resolve the perceived conflict between appropriate management of opioid use and patient satisfaction by allowing practitioners to use their best judgment in managing patients’ pain and providing effective, appropriate patient care. Some of these commenters believed that removing these questions from hospitals’ scores will reduce providers’ fear of negative feedback on the HCAHPS Survey and, in turn, reduce inappropriately high opioid prescription dosages and durations.

Other commenters supported removing the Pain Management dimension of the HCAHPS Survey from the Hospital VBP Program based on a belief that scoring hospitals on patients’ perception of the adequacy of their pain management unfairly penalizes providers by inappropriately linking clinical decision-making to payment. These commenters also expressed concern that linking assessment of patient experience of care with pain management has led to an increase in opioid prescription when other pain management, such as use of nonsteroidal anti-inflammatory drugs, has failed.

A number of commenters noted the importance of measuring patients’ experience of pain management despite these concerns with the current Pain Management dimension questions, and

urged CMS to develop alternative questions to assess patients’ pain management as soon as practicable. A few of these commenters also encouraged CMS to act to ensure that patients receive an appropriate level of pain control through methods that do not encourage excessive opioid prescription.

Response: We thank the commenters for their support. We are not aware of any scientific studies that support an association between scores on the Pain Management dimension questions and opioid prescribing practices. In addition, we continue to believe that many factors outside the control of CMS quality program requirements may contribute to the perception of a link between the Pain Management dimension and opioid prescribing practices; that pain control is an appropriate part of routine patient care that hospitals should manage; and that pain control is an important concern for patients, their families, and their caregivers.²⁵⁴ However, we believe that removing the Pain Management dimension from the Hospital VBP Program scoring calculations will address potential confusion about the appropriate use of the Pain Management dimension, and provide us with an opportunity to further refine the pain management questions used in the HCAHPS Survey.

Comment: A number of commenters disagreed with the assertion that the HCAHPS Survey Pain Management questions influence clinical decision-making, citing the lack of empirical evidence to support this position, but supported CMS’ proposal to remove the Pain Management dimension of the

HCAHPS Survey from the Hospital VBP Program because it will provide CMS and the hospital community with an opportunity to refine the pain management questions on the HCAHPS Survey.

Response: We thank the commenters for their support. As noted above, we are not aware of any scientific studies that support an association between scores on the Pain Management dimension questions and opioid prescribing practices. Nevertheless, we believe that removing the Pain Management dimension from the Hospital VBP Program scoring calculations will address potential confusion about the appropriate use of the Pain Management dimension, and provide us with an opportunity to further refine the pain management questions used in the HCAHPS Survey.

Comment: Several commenters supported CMS’ proposal to remove the Pain Management dimension of the HCAHPS Survey from the Hospital VBP Program because the current questions focus on pain control rather than pain communication, which the commenters believe could create a perverse incentive to inappropriately prescribe opioids and other pain medication. One commenter supported removal of the Pain Management dimension based on concerns regarding the wording of the pain management questions and how it may influence patient responses to these questions. Specifically, the commenter expressed concern that the current question wording may imply that pain is only an issue if the patient needed medicine, that medicine is the only means to reduce pain, and that medication should be administered to the point of cessation of all pain. Another commenter expressed concern that the current pain management questions may not accurately reflect the quality of care received at the hospital because they do not factor in all

²⁵⁴ L. Tefera, W.G. Lehrman, and P. Conway. “Measurement of the Patient Experience: Clarifying Facts, Myths, and Approaches.” *Journal of the American Medical Association*. Published online, 3–10–16. <http://jama.jamanetwork.com/article.aspx?articleid=2503222>.

elements of clinical decision-making and the individual circumstances of a patient's episode of care.

Response: We acknowledge commenters' concerns about the current Pain Management questions, and we will take the feedback into consideration as we continue to develop, test, and empirically assess potential alternative questions that focus on communication with patients about pain management as potential replacements for the Pain Management questions currently included in the HCAHPS Survey. As discussed in the CY 2017 OPPI/ASC proposed rule, we are following our standard survey development processes, which include drafting alternative questions, cognitive interviews and group evaluation, field testing, statistical analysis, and soliciting stakeholder input.

Comment: One commenter supported CMS' proposal to remove the Pain Management dimension from the Hospital VBP Program because the commenter believed that only the most reliable and valid measures should be included when Medicare payment is at risk.

Response: We thank the commenter for the support of our proposal. We continue to believe the HCAHPS Survey Pain Management questions, and the HCAHPS Survey as a whole, are valid and reliable measures of hospital quality that encourage hospitals to assess and improve patient experience. We further note that the HCAHPS Survey, including the Pain Management questions, is NQF-endorsed (NQF #0166). However, we believe that removing the Pain Management dimension from the Hospital VBP Program scoring calculations will address potential confusion about the appropriate use of the Pain Management dimension, and provide us with an opportunity to further refine the pain management questions used in the HCAHPS Survey.

Comment: One commenter recommended that hospitals continue to survey patients about their inpatient pain management experience because pain management is an important aspect of quality care.

Response: We agree with commenter that management of patients' pain is an important aspect of quality care. We note that the administration and reporting of the full HCAHPS Survey, including the current Pain Management questions, remains part of the Hospital IQR Program. In addition, we will continue to make publicly available the data reported under the Hospital IQR Program on our *Hospital Compare* Web site.

Comment: Some commenters did not support CMS' proposal to remove the HCAHPS Survey Pain Management dimension from the Hospital VBP Program due to the lack of evidence linking these questions to opioid overprescribing. Specifically, commenters stated that there is a lack of evidence that the HCAHPS Survey has inappropriately influenced providers' prescribing patterns; that there is no evidence that prescribed opioids are primarily responsible for opioid abuse or opioid-related deaths; and that there is no evidence to suggest that assessing and controlling pain in hospitalized inpatients is responsible for initiating or perpetuating the opioid epidemic. One commenter expressed concern that removing these pain management questions from hospitals' scores in the Hospital VBP Program would eliminate an important driver of progress to develop improved means of acute pain assessment. Another commenter expressed concern that removing the Pain Management dimension from the Hospital VBP Program may result in pain management issues being excluded from hospitals' quality improvement efforts. These commenters recommended that CMS explore opportunities to modify the Pain Management dimension questions in the HCAHPS Survey, but not remove these questions from the HCAHPS Survey or the Hospital VBP Program's scoring calculations until alternative questions are available to replace them.

Other commenters did not support CMS' proposal to remove the Pain Management dimension from the Hospital VBP Program because they believe doing so ignores the needs of patients who require treatment for pain. These commenters also expressed their concern that removing these questions may result in inadequate pain treatment for patients in need of such treatment.

Response: We remain dedicated to improving the quality of care provided to patients, including the appropriate management of pain and communication between patients and their providers regarding pain. We continue to believe that pain control is an appropriate part of routine patient care that hospitals should manage and is an important concern for patients, their families, and their caregivers. Furthermore, we are unaware of any empirical evidence demonstrating that failing to prescribe opioids lowers a hospital's HCAHPS Survey scores. However, we believe the potential confusion about the appropriate use of the Pain Management dimension questions, coupled with the public health concern about the opioid

epidemic, warrants removing these questions from Hospital VBP Program scoring calculations until alternative pain management questions are available. We note that hospitals would continue to administer the full HCAHPS Survey, including the current Pain Management questions, to eligible patients. In addition, we note that hospital performance rates on all HCAHPS Survey measures will still be publicly reported under the Hospital IQR Program on *Hospital Compare* and used in calculating HCAHPS star ratings and *Hospital Compare* overall ratings. We believe continued public reporting of Pain Management performance rates appropriately balances the need to provide the public with important quality data for use in health care decision-making and to incentivize quality improvement regarding pain management and communication with our desire to address the perceived conflict between appropriate management of opioid use and patient satisfaction by relieving the pressure physicians may feel to overprescribe opioids. We further believe continued public reporting of Pain Management performance rates will provide important information to patients and consumers and encourage hospitals to appropriately manage patients' pain and continue engaging in quality improvement efforts.²⁵⁵

Comment: One commenter recommended that CMS make concerted efforts to inform Medicare providers of the CDC's recently published "Guideline for Prescribing Opioids for Chronic Pain."

Response: We thank the commenter for the recommendation and note that this information is publicly available on the CDC's Web site at: <http://www.cdc.gov/drugoverdose/prescribing/guideline.html>. The guideline provides recommendations that focus on the use of opioids in treating chronic pain (defined as pain lasting longer than 3 months or past the time of normal tissue healing) outside of active cancer treatment, palliative care, and end-of-life care. We encourage prescribing clinicians to follow this guideline for prescribing opioids for chronic pain.

Comment: Many commenters supported the development of alternative questions regarding pain management for the HCAHPS Survey and recommended that CMS submit the revised survey to NQF for endorsement

²⁵⁵ L. Tefera, W.G. Lehrman, and P. Conway. "Measurement of the Patient Experience: Clarifying Facts, Myths, and Approaches." *Journal of the American Medical Association*. Published online, 3–10–16. <http://jama.jamanetwork.com/article.aspx?articleid=2503222>.

following a rigorous survey development process. A large number of commenters provided specific recommendations regarding the context and content of these alternative questions. Numerous commenters recommended that the alternative questions should include whether a patient's pain was assessed; whether treatment options were discussed with the patient, including discussion of the risks and benefits associated with opioid prescription and the potential for use of alternative, non-opioid pain management therapy, and interventions made; and whether the patient's pain was reassessed following intervention to determine its effectiveness. Other commenters recommended that the alternative questions focus on effective provider communication with patients about pain management-related issues, appropriate expectations about pain relief, patient understanding of interventions offered to address pain, and shared decision-making and proper prescription practices. Some commenters specifically recommended that CMS assess patients' understanding of the interventions offered to address the patient's pain. Some commenters urged CMS to pay particular attention to the difference between acute and chronic pain treatment, individual patient's pain management goals, and the risks of the particular clinical situation in pain management decision-making. Commenters also urged CMS to acknowledge the role of palliative care in pain management decision-making.

One commenter recommended that CMS define a high-quality patient experience as one in which the health care provider discussed pain management treatment options with patients and patients believed they had the opportunity to engage in the discussion to determine the most appropriate treatment option. Another commenter recommended the development of alternative questions regarding pain management for the HCAHPS Survey that align with the pain control and communication questions in the OAS CAHPS Survey. Other commenters recommended that these alternative questions be studied for their potential effect on clinical behavior and patient outcomes, including any unintended consequences such as creating barriers to access opioids when they are clinically appropriate.

Response: We thank the commenters for their recommendations regarding the alternative questions for the HCAHPS Survey. We will take these recommendations into consideration as we continue to develop, test, and

empirically assess potential alternative questions that focus on communication with patients about pain management as potential replacements for the Pain Management questions currently included in the HCAHPS Survey. As discussed in the CY 2017 OPPS/ASC proposed rule, we are following our standard survey development processes, which include drafting alternative questions, cognitive interviews and group evaluation, field testing, statistical analysis, and soliciting stakeholder input. Any specific Pain Management questions that would be considered for use in a CMS program will proceed through the prerulemaking process, including listing of measures on the "Measures Under Consideration" list and review by the Measures Application Partnership, as well as notice-and-comment rulemaking in the future. In addition, we intend to seek NQF endorsement for the alternative questions we decide to propose to use in the HCAHPS Survey once these survey development processes are complete.

Comment: Several commenters recommended that CMS exclude all patients with substance use disorders on their problem list, not just those patients admitted with a primary diagnosis of a substance use disorder, from the HCAHPS Survey because the commenters believed these patients' survey responses are affected by their underlying conditions, which in turn creates a perverse incentive for providers to prescribe opioids rather than referring patients for substance use disorder treatment.

Response: We thank the commenters for their comments. Since its inception in 2006, HCAHPS has classified eligible patients into three service line categories: Medical, surgical, or maternity care.²⁵⁶ The recommended method of assignment to service line is the patient's MS-DRG at discharge; if unavailable, CMS permits several alternative methods of service line assignment. Due to methodological considerations, the requirements of national standardization, and the data collection burden placed on hospitals and their HCAHPS Survey vendors, CMS does not collect or employ patients' secondary diagnoses or any other codes, designations, or notes, including "problem lists." We note that patients whose primary diagnosis MS-DRG is substance abuse are ineligible for the HCAHPS Survey under the current HCAHPS Quality Assurance

Guidelines.²⁵⁷ We will take into consideration public comments received as we continually seek to improve our quality measures.

Comment: One commenter encouraged CMS to conduct further assessments of whether, and to what extent, removal of the Pain Management dimension from the Hospital VBP Program scoring calculations influences providers' management of pain. Another commenter urged CMS to study the impact of the HCAHPS Pain Management questions (both the current and alternative questions) on clinician behavior, use of other approaches to pain management, and patient outcomes.

Response: We thank the commenter for the recommendations and will take these concerns into consideration as we continue to develop and test the alternative pain management questions. We note that HHS is also conducting further research to help better understand stakeholder concerns regarding the current HCAHPS Survey Pain Management dimension questions and to determine whether there are any unintended consequences that link the Pain Management dimension questions to opioid prescribing practices.

Comment: One commenter recommended that CMS conduct mode testing for an electronic administration option for the HCAHPS Survey.

Response: We thank the commenter for its recommendation. While email and a Web-based survey are not available survey modes at present, we are actively investigating these modes as possible new options for the future. This ongoing investigation includes exploring whether hospitals receive reliable email addresses and whether there is adequate access to the Internet across all types of inpatients. Ultimately, the purpose of the investigation is to ensure that any new survey administration method does not introduce bias to the survey process.

Comment: One commenter believed that if the HCAHPS Survey can be used for public reporting, the data should also have the ability to be used to change the behavior of individual providers. Furthermore, the commenter believed that individual and groups of providers should be held accountable for HCAHPS Survey results.

Response: While we agree that the HCAHPS Survey can be used to identify general areas for improvement within a hospital, some of which may be addressed through changes in provider

²⁵⁶ HCAHPS Quality Assurance Guidelines, V11.0, pp. 53–55; 75–76 (2016). <http://www.hcahpsonline.org/qaguidelines.aspx>.

²⁵⁷ HCAHPS Quality Assurance Guidelines, V11.0, p. 75 (2016). <http://www.hcahpsonline.org/qaguidelines.aspx>.

behavior generally, we disagree with the commenter's assertion that individual providers or provider groups should be held "accountable" for hospital scores on the HCAHPS Survey. The HCAHPS Survey is designed to evaluate the performance of a hospital as a whole, not individuals or groups within the larger hospital setting;²⁵⁸ therefore, its use for evaluating or incentivizing individual providers or groups within the hospital is contrary to the survey's design and policy aim.²⁵⁹

Comment: One commenter sought clarification regarding CMS' concerns about hospitals' use of disaggregated HCAHPS Survey results to evaluate individual provider performance on a given question or domain, and whether those concerns are limited to use of disaggregated results on the Pain Management questions. Specifically, the commenter believed that HCAHPS Survey data should be used to improve clinician-patient communication, which is important in quality of care.

Response: We agree with the commenter that clinician-patient communication about pain and pain management are important aspects of quality care. However, disaggregation of HCAHPS Survey results for use in evaluating individual providers' performance on any dimension within the HCAHPS Survey, not just the Pain Management dimension, is not how the HCAHPS Survey was intended to be used. As noted above, the HCAHPS Survey is designed to assess hospital-level performance and is not suitable for evaluating or incentivizing individual providers or provider groups within a hospital. Hospitals can and should use HCAHPS Survey results to identify general areas for improvement within the hospital setting, but should not ascribe those results to individual providers within the hospital.²⁶⁰

Comment: A few commenters expressed concern regarding the application of the HCAHPS Survey to the emergency department (ED) setting. These commenters stated that the available evidence indicates ED physicians are most affected by low ratings on patient experience of care surveys, particularly on questions

regarding the adequacy of pain medication prescriptions. One commenter asserted that the use of the HCAHPS Survey in the ED setting is inappropriate and urged CMS to refine the pain management questions included in the Emergency Department Patient Experience of Care Survey currently under development and implement the survey in order to better capture patient experience of care in the ED setting.

Response: We agree that use of the HCAHPS Survey in the ED setting to assess outpatient ED care instead of inpatient care is inappropriate. HCAHPS was designed, developed, and intended for hospital level measurement for inpatient stays, not EDs or other individual hospital departments. Other uses of the HCAHPS Survey are not consistent with its design or validation metrics. Accordingly, we encourage hospitals and HCAHPS Survey vendors to review the HCAHPS Survey specifications in order to avoid such instances of misuse. We are continuing our evaluation of the Emergency Department Patient Experience of Care Survey in an effort to develop a survey that will provide patient experience data that enable comparison of EDs across the nation and promote effective communication and coordination, and we intend to address its potential use in CMS' quality programs in the future. We also note that, in section XIII.B.5.c. of this final rule with comment period, we are finalizing adoption of five survey-based measures in the Hospital OQR Program utilizing the OAS CAHPS Survey, a patient experience of care survey developed for use with selected outpatient surgical procedures.

Comment: A number of commenters expressed concern about the continued public reporting of the HCAHPS Pain Management measure in other CMS quality reporting programs, specifically the Hospital IQR Program, including HCAHPS star ratings and *Hospital Compare* overall ratings. Commenters stated that use of these questions in these quality reporting programs may still lead to potential overprescribing of opioids to at-risk patients. Some commenters also expressed concern that public reporting of these scores could distort the public's perception of the quality of care provided at certain hospitals. Commenters recommended that CMS remove or exclude hospital scores on the HCAHPS Survey's Pain Management questions from *Hospital Compare* reporting, including HCAHPS star ratings and *Hospital Compare* overall ratings, until alternative questions are developed and adopted for these programs.

Response: Pain management is an important component of the quality of care provided at a hospital, and we believe continued public reporting of hospital rates on the HCAHPS Survey Pain Management questions, without linkage to payment, properly balances these concerns with our desire to provide patients with critical information for use in selecting a hospital setting for their care, ensure hospitals continue to appropriately manage patients' pain, and encourage hospitals to engage in quality improvement efforts addressing pain management and communication. We continue to believe that pain control is a critical part of routine patient care that hospitals should manage and is an important concern for patients, their families, and their caregivers. Therefore, we believe there is continued benefit to publicly reporting the HCAHPS Survey Pain Management questions in other CMS quality programs. As noted previously, we are not aware of any empirical evidence that failing to prescribe opioids lowers a hospital's HCAHPS rates. We also continue to believe that many factors outside the control of CMS quality program requirements may contribute to the perception of a link between the Pain Management dimension and opioid prescribing practices, such as misuse of the survey, disaggregation of surveys results to assess the performance of individual hospital staff, and/or failure to recognize that the HCAHPS Survey excludes certain populations from the sampling frame.

Comment: A number of commenters supported continued collection and public reporting of the current HCAHPS Survey Pain Management questions in the Hospital IQR Program until alternative pain management questions are developed and adopted. Commenters noted that these questions are currently the only source of nationally comparable data on pain management, and stated that the importance of pain management to patient care and experience during a hospital stay makes this information useful for the public. One commenter supported continued collection of these data because hospitals can use the information to improve patient quality of care as new survey questions are developed and tested. One commenter recommended that CMS provide a notation on the publicly reported HCAHPS Survey Pain Management dimension rates, stating that CMS is reviewing the pain management questions for possible revision.

Response: We thank the commenters for their support and note that, in July

²⁵⁸ 80 FR 49551 through 49552.

²⁵⁹ L. Tefera, W.G. Lehrman, and P. Conway. "Measurement of the Patient Experience: Clarifying Facts, Myths, and Approaches." *Journal of the American Medical Association*. Published online, 3-10-16. <http://jama.jamanetwork.com/article.aspx?articleid=2503222>.

²⁶⁰ L. Tefera, W.G. Lehrman, and P. Conway. "Measurement of the Patient Experience: Clarifying Facts, Myths, and Approaches." *Journal of the American Medical Association*. Published online, 3-10-16. <http://jama.jamanetwork.com/article.aspx?articleid=2503222>.

2016, we began displaying a footnote on the *Hospital Compare* Web site along with the Pain Management measure information, which reads: “Note: CMS is reviewing the pain management questions on the HCAHPS Survey for possible revision.”

After consideration of the public comments we received, we are finalizing our proposal to remove the Pain Management dimension of the HCAHPS Survey in the Patient- and Caregiver-Centered Experience of Care/ Care Coordination domain of the Hospital VBP Program beginning with the FY 2018 program year.

XX. 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 final rule with comment period pertaining to CY 2017 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 “1656-FC” from the list of regulations. All OPPTS Addenda to this final rule with comment period are contained in the zipped folder entitled “2017 OPPTS 1656-FC Addenda” at the bottom of the page. To view the Addenda to this final rule with comment period pertaining to the CY 2017 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 “1656-FC” from the list of regulations. All ASC Addenda to this final rule with comment period are contained in the zipped folders entitled “Addendum AA, BB, DD1, DD2, and EE”.

XXI. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the CY 2017 OPPTS/ASC proposed rule (81 FR 45758 through 45761), we solicited 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

As we stated in section XIV. of the CY 2012 OPPTS/ASC final rule with comment period, the Hospital OQR Program has been generally modeled after the quality data reporting program for the Hospital IQR Program (76 FR 74451). We refer readers to the CY 2011 through CY 2016 OPPTS/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; and 80 FR 70580 through 70582, respectively) for detailed discussions of Hospital OQR Program information collection requirements we have previously finalized. The information collection requirements associated with the Hospital OQR Program are currently approved under OMB control number 0938-1109.

Below we discuss only the changes in burden resulting from the provisions in this final rule with comment period.

2. Estimated Burden of Hospital OQR Program Newly Finalized Proposals for the CY 2018 Payment Determination and Subsequent Years

In section XIII.B.8. of this final rule with comment period, we are finalizing our proposal to publicly display data on the *Hospital Compare* Web site, or other CMS Web site, as soon as possible after measure data have been submitted to CMS. In addition, we are finalizing our proposal that hospitals will generally have approximately 30 days to preview their data. Both of these policies are consistent with current practice. Lastly, we are finalizing our proposal to announce the timeframes for the preview period starting with the CY 2018 payment determination on a CMS Web site and/or on our applicable listservs. We do not anticipate additional burden to hospitals as a result of these changes to the public

display policies because hospitals will not be required to submit additional data or forms to CMS.

3. Estimated Burden of Hospital OQR Program Newly Finalized Proposals for the CY 2019 Payment Determination and Subsequent Years

a. Extraordinary Circumstances Extension or Exemptions Process

In section XIII.D.8. of this final rule with comment period, we are finalizing our proposal to extend the submission deadline for requests under our “Extraordinary Circumstances Extension or Exemptions” (ECE) process from 45 days from the date that the extraordinary circumstance occurred to 90 days from the date that the extraordinary circumstance occurred. For a complete discussion of our ECE process under the Hospital OQR Program, we refer readers to the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68489), the CY 2014 OPPTS/ASC final rule with comment period (78 FR 75119 through 75120), the CY 2015 OPPTS/ASC final rule with comment period (79 FR 66966), and the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70524).

We believe that the updates to the ECE deadlines will have no effect on burden for hospitals, because we are not making any changes that will increase the amount of time necessary to complete the form. We do not anticipate that there will be any additional burden as the materials to be submitted related to an ECE request are unchanged and the deadline does not result in a change in time necessary to submit an extension or exemption request. The burden associated with submitting an Extraordinary Circumstances Extension/Exemption Request is accounted for in OMB Control Number 0938-1022.

b. Reconsideration and Appeals

In section XIII.D.9. of this final rule with comment period, we are finalizing a clarification to our reconsideration and appeals procedures. While there is a burden associated with filing a reconsideration request, 5 CFR 1320.4 of OMB’s implementing regulations for the Paperwork Reduction Act of 1995 excludes collection activities during the conduct of administrative actions such as reconsiderations.

4. Estimated Burden of Hospital OQR Program Newly Finalized Proposals for the CY 2020 Payment Determination and Subsequent Years

In sections XIII.B.5.a. and XIII.B.5.b. of this final rule with comment period, we are finalizing our proposals to add

two new claims-based measures for the CY 2020 payment determination and subsequent years: (1) OP–35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy; and (2) OP–36: Hospital Visits after Hospital Outpatient Surgery (NQF #2687). In section XIII.B.5.c. of this final rule with comment period, we also are finalizing our proposal to add five new 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: (1) OP–37a: OAS CAHPS—About Facilities and Staff; (2) OP–37b: OAS CAHPS—Communication About Procedure; (3) OP–37c: OAS CAHPS—Preparation for Discharge and Recovery; (4) OP–37d: OAS CAHPS—Overall Rating of Facility; and (5) OP–37e: OAS CAHPS—Recommendation of Facility.

OP–35 and OP–36 are claims-based measures. As noted in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68530), we calculate claims-based measures using Medicare FFS claims data that do not require additional hospital data submissions. As a result, as we stated in the CY 2017 OPPS/ASC proposed rule (81 FR 45758), we do not anticipate that the proposed OP–35 or OP–36 measures will create any additional burden to hospital outpatient departments for the CY 2020 payment determination and subsequent years.

The information collection requirements associated with the five newly adopted 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 proposed rule (81 FR 45758), we did not provide an independent estimate of the burden associated with OAS CAHPS Survey-based measures for the Hospital OQR Program.

We invited public comment on the burden associated with these information collection requirements. We did not receive any public comments on our estimates of the burden associated with these information collection requirements. Therefore, we are finalizing our burden estimates as discussed above.

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 and CY 2016 OPPS/ASC final rules with comment periods (77 FR 68532 through 68533; 78 FR 75172 through 75174; 79 FR 67015 through 67016; and 80 FR 70582 through 70584, 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 final rule with comment period.

2. Changes in Burden Calculation for the ASCQR Program

To better align this program with our other quality reporting and value-based purchasing programs, we are finalizing our proposal to update our burden calculation methodology to standardize elements within our burden calculation. Specifically, we are finalizing our proposals to utilize: (1) A standard estimate of the time required for abstracting chart data for measures based on historical data from other quality reporting programs; and (2) a standard hourly labor cost for chart abstraction activities.

a. Estimate of Time Required to Chart-Abstract Data

In the past, we have used 35 minutes as the time required to chart-abstract and report data for each chart-abstracted Web-based measure in the ASCQR Program (76 FR 74554). However, we have studied other programs' estimates for this purpose and believe that 15 minutes is a more reasonable number. Specifically, the Hospital IQR Program possesses historical data from its data validation contractor. This contractor chart-abstracts each measure set when charts are sent to CMS for validation. Based on this contractor's validation activities, we believe that the average time required to chart-abstract data for each measure is approximately 15 minutes. We believe that this estimate is reasonable because the ASCQR Program uses measures similar to those of the Hospital IQR Program, such as the surgery safety measures and immunization measures. Accordingly, in the CY 2017 OPPS/ASC proposed rule (81 FR 45759), we proposed to use 15 minutes in calculating the time required to chart-abstract data, unless we have historical data that indicate that this approximation is not accurate.

b. Hourly Labor Cost

Previously, we used \$30 as our hourly labor cost in calculating the burden associated with chart-abstraction activities. This labor cost is different from those used in other quality reporting and value-based purchasing programs, and we do not believe there is a justification for these different numbers given the similarity in quality measures and required staff. Therefore, in the CY 2017 OPPS/ASC proposed rule (81 FR 45759), we proposed to align these numbers and use one hourly labor cost across programs for purposes of burden calculations. Specifically, we proposed to use an hourly labor cost (hourly wage plus fringe and overhead, as discussed below) of \$32.84. This labor cost is based on the Bureau of Labor Statistics (BLS) 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.”²⁶¹ Acting as an independent agency, the BLS provides objective information for not only the government, but also for the public. The BLS describes Medical Records and Health Information Technicians as those responsible for organizing and managing health information data. Therefore, we believe it is reasonable to assume that these individuals will be tasked with abstracting clinical data for these measures. According to the BLS, the median pay for Medical Records and Health Information Technicians is \$16.42 per hour.²⁶²

However, obtaining data on other overhead costs is challenging because overhead costs may vary greatly across ASCs. In addition, the precise cost elements assigned as “indirect” or “overhead” costs, as opposed to direct costs or employee wages, are subject to some interpretation at the facility level. Therefore, in the CY 2017 OPPS/ASC proposed rule (81 FR 45759), we proposed to calculate the cost of overhead 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. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method. We note that in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57260, 57266, and 57339), we used

²⁶¹ <http://www.bls.gov/bls/infhome.htm>.

²⁶² <http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm>.

a similar adjustment for a couple other quality reporting programs. Therefore, we proposed to apply an hourly labor cost of \$32.84 (\$16.42 base salary + \$16.42 fringe and overhead) to our burden calculations.

We did not receive any public comments on our proposals to utilize: (1) A standard estimate of the time required for abstracting chart data for measures based on historical data from other quality reporting programs, specifically, 15 minutes; and (2) a standard hourly labor cost for chart abstraction activities, specifically, \$32.84. Therefore, we are finalizing our proposals as proposed.

3. Estimated Burden of ASCQR Program Newly Finalized Proposals for the CY 2018 Payment Determination

For the CY 2018 payment determination and subsequent years, we are finalizing a few proposals. In section XIV.B.7 of this final rule with comment period, we are finalizing our proposal to publicly display data on the *Hospital Compare* Web site, or other CMS Web site, as soon as possible after measure data have been submitted to CMS. In addition, we are finalizing our proposal that ASCs will generally have approximately 30 days to preview their data. Both of these finalized proposals are consistent with current practice. Lastly, we are finalizing our proposal to announce the timeframes for the preview period starting with the CY 2018 payment determination on a CMS Web site and/or on our applicable listservs. We believe that these finalized changes to the ASCQR Program public reporting policies will have no effect on burden for ASCs because these changes will not require participating ASCs to submit additional data to CMS.

4. Estimated Burden of ASCQR Program Newly Finalized Proposals for the CY 2019 Payment Determination

For the CY 2019 payment determination and subsequent years, we are finalizing two new proposals. In section XIV.D.3. of this final rule with comment period, we are finalizing our proposal to implement a submission deadline with an end date of May 15 for all data submitted via a CMS Web-based tool beginning with the CY 2019 payment determination as proposed. (For all data submitted via a non-CMS Web-based tool, ASCs are already required to submit by May 15 of the year prior to the affected payment determination year (79 FR 66985 through 66986).) We do not anticipate additional burden as the data collection and submission requirements have not changed; only the deadline will be

moved to a slightly earlier date that we anticipate will alleviate burden by aligning data submission deadlines. We also are finalizing our proposal to make corresponding changes to the regulations at 42 CFR 416.310(c)(1)(ii) to reflect this change in submission deadline, as proposed. We do not anticipate any additional burden to ASCs as a result of codifying this policy.

In addition, in section XIV.D.6. of this final rule with comment period, we are finalizing our proposal to extend the time for filing an Extraordinary Circumstance Exception or Exemption from within 45 days of the date that the extraordinary circumstance occurred to within 90 days of the date that the extraordinary circumstance occurred as proposed. We do not anticipate that there will be any additional burden as the materials to be submitted are unchanged and the deadline does not result in reduced time to submit an extension or exemption. We also are finalizing our proposal to make corresponding changes to the regulations at 42 CFR 416.310(d)(1) to reflect this change to 90 days, as proposed. We do not anticipate any additional burden to ASCs as a result of codifying this policy.

5. Estimated Burden of ASCQR Program Newly Finalized Proposals for the CY 2020 Payment Determination

For the CY 2020 payment determination and subsequent years, we are finalizing our proposals to add two new measures collected via a CMS online data submission tool and five survey-based measures to the ASCQR Program measure set. In section XIV.B.4. of this final rule with comment period, we are finalizing our proposals, as proposed, to add the following measures collected via a CMS online data submission tool: ASC-13: Normothermia Outcome and ASC-14: Unplanned Anterior Vitrectomy. In the same section, we are finalizing our proposals to adopt the following survey-based measures: (1) ASC-15a: OAS CAHPS—About Facilities and Staff; (2) ASC-15b: OAS CAHPS—Communication About Procedure; (3) ASC-15c: OAS CAHPS—Preparation for Discharge and Recovery; (4) ASC-15d: OAS CAHPS—Overall Rating of Facility; and (5) ASC-15e: OAS CAHPS—Recommendation of Facility.

We believe ASCs will incur a financial burden associated with abstracting numerators, denominators, and exclusions for the two newly adopted measures collected and reported via a CMS online data submission tool (ASC-13 and ASC-14). Using the burden estimate values for

chart-abstracted measures discussed in section XXI.C.2. of this final rule with comment period, we estimate that each participating ASC will spend 15 minutes per case to collect and submit the data, making the total estimated burden for all ASCs with a single case per ASC of 1,315 hours (5,260 ASCs × 0.25 hours per case per ASC), and 82,845 hours for each measure across all ASCs based on a historic average of 63 cases. Therefore, we estimate that the reporting burden for all ASCs with a single case per ASC for newly finalized ASC-13 and ASC-14 will be 1,315 hours and \$43,185²⁶³ (1,315 hours × \$32.84 per hour), and 82,845 hours (1,315 × 63 cases) and \$2,720,630 (82,845 hours × \$32.84 per hour) for each measure across all ASCs based on an historic average of 63 cases for the CY 2020 payment determination. The additional burden associated with these requirements is available for review and comment under OMB Control Number 0938-1270.

The information collection requirements associated with the five newly adopted 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, in the CY 2017 OPPS/ASC proposed rule (81 FR 45760), we did not provide an independent estimate of the burden associated with OAS CAHPS Survey administration for the ASCQR Program.

6. Reconsideration

For a complete discussion of the ASCQR Program's reconsideration processes, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53643 through 53644), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75141), and the CY 2016 final rule with comment period (80 FR 75141). In the CY 2017 OPPS/ASC proposed rule, we did not propose any changes to this process.

While there is burden associated with filing a reconsideration request, 5 CFR 1320.4 of OMB's implementing regulations for the Paperwork Reduction Act of 1995 excludes collection activities during the conduct of administrative actions such as reconsiderations.

We invited public comment on the burden associated with these information collection requirements. We did not receive any public comments on

²⁶³ We note that in the CY 2017 OPPS/ASC proposed rule (81 FR 45760) this value appeared as \$42,185. This was a typographical error; the correct value for this burden estimate is \$43,185, the product of 1,315 hours multiplied by \$32.84 per hour.

our estimates of the burden associated with these information collection requirements. Therefore, we are finalizing our burden estimates as discussed above.

D. ICRs Relating to Changes in Transplant Enforcement Performance Thresholds

In section XV. of this final rule with comment period, we discuss changes to the enforcement performance thresholds relating to patient and graft survival outcomes. The changes will impose no new burdens on transplant programs. The changes do not impose any new information collection or recordkeeping requirements. Consequently, review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 is not required.

E. ICRs for Changes Relating to Organ Procurement Organizations (OPOs)

In section XVI. of this final rule with comment period, we are finalizing several proposed changes to definitions, outcome measures and documentation requirements for OPOs. In section XVI.B.1. of this final rule with comment period, we are revising the definition of "eligible death." In section XVI.B.2 of this final rule with comment period, we are finalizing our proposal to adjust the outcome performance yield measure to align CMS with the SRTR yield metric. In section XVI.B.3. of this final rule with comment period, we are finalizing our proposal to reduce the amount of hard copy documentation that is packaged and shipped with each organ. These finalized changes do not impose any new information collection or recordkeeping requirements. Consequently, review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 is not required.

Finally, in section XVII. of this final rule with comment period, we are finalizing our proposal to make a technical correction to the enforcement provisions for transplant centers and to clarify our policy regarding SIAs. These changes do not impose information collection and recordkeeping requirements. Consequently, review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 is not required.

F. ICRs Relating to Changes to the Electronic Health Record (EHR) Incentive Program

In section XVIII. of this final rule with comment period, we discuss our proposed and finalized policy changes for eligible hospitals and CAHs attesting to CMS for Modified Stage 2 and Stage

3 to eliminate the Clinical Decision Support (CDS) and Computerized Provider Order Entry (CPOE) objectives and measures and reduce the reporting thresholds for a subset of the remaining objectives and measures, generally to the Modified Stage 2 thresholds. We believe that there will be a reduction in burden by not reporting for the CDS (1 minute) and CPOE (10 minutes) objectives and measures. This will reduce the total burden associated with these measures by a total of 11 minutes. This will reduce the time to attest to objectives and measures for Modified Stage 2 (495.22) from 6 hours and 48 minutes to 6 hours and 37 minutes and for the Stage 3 from 6 hours and 52 minutes to 6 hours and 41 minutes. We refer readers to the 2015 EHR Incentive Programs Final Rule for the detailed analysis of the burden associated with the objectives and measures (80 FR 62916 through 62924).

While we do believe that eliminating requirements will decrease the associated information collection burden, we believe that the reduction detailed below falls within an acceptable margin of error, and therefore we will not be revising the information collection request currently approved under 0938–1158.

We discuss our proposed and finalized policies to change the EHR reporting period in 2016 and 2017 from the full calendar year to any continuous 90-day period within the calendar year for all returning EPs, eligible hospitals and CAHs in the Medicare and Medicaid EHR Incentive Programs; require new participants in 2017 who are seeking to avoid the 2018 payment adjustment by attestation by October 1, 2017 to attest to the Modified Stage 2 objectives and measures. We do not believe that modifying the EHR reporting period will cause an increase in burden as the reporting requirements for a 90 day reporting period are the same for a full calendar year reporting period. Instead, the burden is associated with data capture and measure calculations on the objectives and measures not the reporting period to which one will attest for.

We discuss our proposed and finalized policy changes to allow for a one-time significant hardship exception from the 2018 payment adjustment for certain EPs who are new participants in the EHR Incentive Program in 2017 and are transitioning to MIPS in 2017. The hardship exception process involves participants completing an application form for an exception. While the form is standardized, we believe it is exempt from the PRA. The form is structured as an attestation. Therefore, we believe it is

exempt under 5 CFR 1320.3(h)(1) of the implementing regulations of the PRA. The form is an attestation that imposes no burden beyond what is required to provide identifying information and to attest to the applicable information.

G. ICRs Relating to Additional Hospital VBP Program Policies

In section XIX. of this final rule with comment period, we discuss finalizing our proposal to change the scoring methodology for the Patient- and Caregiver-Centered Experience of Care/ Care Coordination domain in the Hospital VBP Program by removing the HCAHPS Pain Management dimension. As required under section 1886(o)(2)(A) of the Act, the HCAHPS Survey is used in the Hospital IQR Program. Therefore, the removal of the Pain Management dimension from the survey for purposes of the Hospital VBP Program does not change the reporting burden for hospitals because the data will still be used for the Hospital IQR Program. The finalized change to the scoring methodology for the Patient- and Caregiver-Centered Experience of Care/ Care Coordination domain in the Hospital VBP Program also will not result in any change to the reporting burden.

H. ICRs for Payment for Off-Campus Provider-Based Departments Policy Changes for CY 2017

In section X.A. of this final rule with comment period, we discuss finalized proposals for the implementation of section 603 of the Bipartisan Budget Act of 2015. The finalized proposals will impose no new information collection requirements for CY 2017. Consequently, review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 is not required.

Any public comments on estimates of the burden associated with implementation of section 603 of the Bipartisan Budget Act of 2015 are summarized and addressed in section X.A. of this final rule with comment period.

XXII. Waiver of Proposed Rulemaking and Response to Comments

A. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on a proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This

procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We utilize HCPCS codes for Medicare payment purposes. The HCPCS is a national coding system comprised of Level I codes (CPT codes) and Level II codes that are intended to provide uniformity to coding procedures, services, and supplies across all types of medical providers and suppliers. CPT codes are copyrighted by the AMA and consist of several categories, including Category I codes which are 5-digit numeric codes, and Category III codes which are temporary codes to track emerging technology, services, and procedures. The AMA issues an annual update of the CPT code set each Fall, with January 1 as the effective date for implementing the updated CPT codes. The HCPCS codes, including both CPT codes and Level II codes, are similarly updated annually on a calendar year basis. Annual Level II coding changes are not available to the public until the Fall immediately preceding the annual January update of the OPSS and the ASC payment system. Because of the timing of the release of these new codes, it is impracticable for us to provide prior notice and solicit comment on the Level II codes and the payments assigned to them in advance of publication of the final rule that implements the OPSS and the ASC payment system. However, it is imperative that these coding changes be accounted for and recognized timely under the OPSS and the ASC payment system for payment because services represented by these codes will be provided to Medicare beneficiaries in hospital outpatient departments and ASCs during the calendar year in which they become effective. Moreover, regulations implementing the HIPAA (42 CFR parts 160 and 162) require that the HCPCS codes be used to report health care services, including services paid under the OPSS and the ASC payment system. We assign interim payment amounts and status indicators to any new codes according to our assessment of the most appropriate APC based on clinical and resource homogeneity with other procedures and services in the APC. If we did not assign payment amounts to new codes on an interim basis, the alternative would be to not pay for these services during the initial calendar year in which the codes become effective. We believe it would be contrary to the public interest to

delay establishment of payment amounts for these codes.

Therefore, we find good cause to waive the notice of proposed rulemaking for the establishment of payment amounts for selected HCPCS codes identified with comment indicator "NI" in Addendum B and Addendum BB to this final rule with comment period. We are providing a 60-day public comment period.

B. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this final rule with comment period, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

XXIII. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this final rule with comment period, as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995, Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Contract with America Advancement Act of 1996 (Pub. L. 104-121) (5 U.S.C. 804(2)). This section of the final rule with comment period contains the impact and other economic analyses for the provisions that we are finalizing for CY 2017.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule with comment period has been designated as an economically significant rule under section 3(f)(1) of Executive Order 12866 and a major rule

under the Contract with America Advancement Act of 1996 (Pub. L. 104-121). Accordingly, this final rule with comment period has been reviewed by the Office of Management and Budget. We have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of this final rule with comment period. In the CY 2017 OPSS/ASC proposed rule (81 FR 45761), we solicited public comments on the regulatory impact analysis in the proposed rule, and we are addressing any public comments we received in this final rule with comment period as appropriate.

2. Statement of Need

This final rule with comment period is necessary to make updates to the Medicare hospital OPSS rates. It is necessary to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2017. 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 revising the APC relative payment weights using claims data for services furnished on and after January 1, 2015, through and including December 31, 2015, and processed through June 30, 2016, and updated cost report information.

This final rule with comment period also is necessary to make updates to the ASC payment rates for CY 2017, 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 2017. 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 OPPS and ASC Payment Provisions

We estimate that the total increase in Federal government expenditures under the OPPS for CY 2017, compared to CY 2016 due to the changes in this final rule with comment period, will be approximately \$773 million. Taking into account our estimated changes in enrollment, utilization, and case-mix, we estimate that the OPPS expenditures for CY 2017 will be approximately \$5.0 billion higher relative to expenditures in CY 2016. We note that this estimate of \$5.0 billion does not include the implementation of section 603 of the Bipartisan Budget Act of 2015 in CY 2017, which we estimate will reduce Part B expenditures by \$50 million in CY 2017. Because this final rule with comment period 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 52 displays the distributional impact of the CY 2017 changes in OPPS payment to various groups of hospitals and for CMHCs.

We estimate that the update to the conversion factor and other adjustments (not including the effects of outlier payments, the pass-through estimates, and the application of the frontier State wage adjustment for CY 2016) will increase total OPPS payments by 1.7 percent in CY 2017. The changes to the APC relative payment weights, the changes to the wage indexes, the continuation of a payment adjustment for rural SCHs, including EACHs, and the payment adjustment for cancer hospitals will not increase OPPS payments because these changes to the OPPS are budget neutral. However, these updates will change the distribution of payments within the budget neutral system. We estimate that the total change in payments between CY 2016 and CY 2017, considering all payments, 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, will increase total estimated OPPS payments by 1.7 percent.

We estimate the total increase (from changes to the ASC provisions in this final rule with comment period as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures under the ASC payment

system for CY 2017 compared to CY 2016 to be approximately \$177 million. Because the provisions for the ASC payment system are part of a final rule that is economically significant as measured by the \$100 million threshold, we have prepared a regulatory impact analysis of the changes to the ASC payment system that, to the best of our ability, presents the costs and benefits of this portion of this final rule with comment period. Table 53 and 54 of this final rule with comment period display the redistributive impact of the CY 2017 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

4. Detailed Economic Analyses

a. Estimated Effects of OPPS Changes in This Final Rule With Comment Period

(1) Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the CY 2017 policy changes on various hospital groups. We post on the CMS Web site our hospital-specific estimated payments for CY 2017 with the other supporting documentation for this final rule with comment period. 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–1656–FC” from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this final rule with comment period. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 52 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 final rule with comment period for a discussion of the hospitals whose claims we do not use for ratesetting and impact purposes.

We estimate the effects of the individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our policy changes. In addition, we have not made adjustments for future changes in variables such as service volume, service-mix, or number of encounters.

In the CY 2017 OPPS/ASC proposed rule (81 FR 45762), we solicited public comment and information about the

anticipated effects of the proposed changes included in the proposed rule on providers and our methodology for estimating them. Any public comments that we receive are addressed in the applicable sections of this final rule with comment period that discuss the specific policies.

(2) Estimated Effects of OPPS Changes on Hospitals

Table U1 below shows the estimated impact of this final rule with comment period on hospitals. Historically, the first line of the impact table, which estimates the change in payments to all facilities, has always included cancer and children’s hospitals, which are held harmless to their pre-BBA amount. We also include CMHCs in the first line that includes all providers. We now include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 52, 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 2017, we are paying CMHCs for partial hospitalization services under only one APC 5853 (Partial Hospitalization for CMHCs), and we are paying hospitals for partial hospitalization services under only one APC 5863 (Partial Hospitalization for Hospital-Based PHPs).

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor as discussed in detail in section II.B. of this final rule with comment period. Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The IPPS market basket percentage increase for FY 2017 is 2.7 percent (81 FR 56938). Section 1833(t)(3)(F)(i) of the Act reduces that 2.7 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is 0.3 percentage point for FY 2017 (which is also the MFP adjustment for FY 2017 in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56939)), 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 OPD fee schedule increase factor of 1.65 percent. We are using the OPD fee schedule increase factor of 1.65 percent in the calculation of the CY 2017 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 2017 estimates in Table 52.

To illustrate the impact of the CY 2017 changes, our analysis begins with a baseline simulation model that uses the CY 2016 relative payment weights, the FY 2016 final IPPS wage indexes that include reclassifications, and the final CY 2016 conversion factor. Table 52 shows the estimated redistribution of the increase or decrease in payments for CY 2017 over CY 2016 payments to hospitals and CMHCs as a result of the following factors: the impact of the APC reconfiguration and recalibration changes between CY 2016 and CY 2017 (Column 2); the wage indexes and the provider adjustments (Column 3); the combined impact of all of the changes described in the preceding columns plus the 1.65 percent OPD fee schedule increase factor update to the conversion factor; and the estimated impact taking into account all payments for CY 2017 relative to all payments for CY 2016, including the impact of changes in estimated outlier payments, the frontier State wage adjustment, and changes to the pass-through payment estimate (Column 5).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are maintaining the current adjustment percentage for CY 2017. Because the updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected pass-through payment for CY 2017 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services will change), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this final rule with comment period will redistribute money during implementation also will depend on

changes in volume, practice patterns, and the mix of services billed between CY 2016 and CY 2017 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the rates for CY 2017 will increase Medicare OPPS payments by an estimated 1.7 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in an estimated 1.8 percent increase in Medicare payments to all other hospitals. These estimated payments will not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table U1 shows the total number of facilities (3,906), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2015 hospital outpatient and CMHC claims data to model CY 2016 and CY 2017 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 2016 or CY 2017 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A. of this final rule with comment period. At this time, we are unable to calculate a 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 OPPS hospitals (3,789), 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 50 CMHCs at the bottom of the impact table and discuss that impact separately below.

Column 2: APC Recalibration—All Changes

Column 2 shows the estimated effect of APC recalibration. Column 2 also reflects any changes in multiple procedure discount patterns or conditional packaging that occur as a result of the changes in the relative magnitude of payment weights. As a result of APC recalibration, we estimate that urban hospitals will experience no change, with the impact ranging from an increase of 0.2 percent to a decrease of 0.3 percent, depending on the number of beds. Rural hospitals will experience a 0.2 percent increase, with the impact ranging from an increase of 0.1 percent to 0.3 percent, depending on the number of beds. Major teaching hospitals will experience a decrease of 0.2 percent overall.

Column 3: Wage Indexes and the Effect of the Final Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the APC recalibration; the updates for the wage indexes with the FY 2017 IPPS post-reclassification wage indexes; the rural adjustment; and the cancer hospital payment adjustment. We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase factor by using the relative payment weights and wage indexes for each year, and using a CY 2016 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indexes.

Column 3 reflects the independent effects of the updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis. This column excludes the effects of the 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 rural adjustment for SCHs because we are continuing the rural payment adjustment of 7.1 percent to rural SCHs for CY 2017, as described in section II.E. of this final rule with comment period.

We modeled the independent effect of updating the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the CY 2017 scaled weights and a CY 2016 conversion factor that included a budget neutrality adjustment for the effect of the changes to the wage indexes between CY 2016 and CY 2017. The FY 2017 wage policy results in modest redistributions.

There is a slight increase of less than 0.1 in Column 3 for the CY 2017 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 2017 of 0.91, compared to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70362 through 70363) payment-to-cost ratio target of 0.92.

Column 4: All Budget Neutrality Changes Combined With the Market Basket Update

Column 4 demonstrates the combined impact of all of the changes previously described and the update to the conversion factor of 1.65 percent. Overall, these changes will increase payments to urban hospitals by 1.7 percent and to rural hospitals by 2.2 percent. Most classes of hospitals will receive an increase in line with the 1.7 percent overall increase after the update is applied to the budget neutrality adjustments. Additionally, this column includes a slight increase of less than 0.1 to account for our final policy to package unrelated laboratory tests into OPPS payment.

Column 5: All Changes for CY 2017

Column 5 depicts the full impact of the CY 2017 policies on each hospital group by including the effect of all of the changes for CY 2017 and comparing them to all estimated payments in CY 2016. Column 5 shows the combined budget neutral effects of Column 2 and 3; the OPD fee schedule increase; the impact of the frontier State wage index adjustment; the impact of estimated OPPS outlier payments as discussed in section II.G. of this final rule with comment period; the change in the Hospital OQR Program payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XIII.

of this final rule with comment period); and the difference in total OPPS payments dedicated to transitional pass-through payments.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2016 update (and assumed, for modeling purposes, to be the same number for CY 2017), we included 50 hospitals in our model because they had both CY 2015 claims data and recent cost report data. We estimate that the cumulative effect of all of the changes for CY 2017 will increase payments to all facilities by 1.7 percent for CY 2017. We modeled the independent effect of all of the changes in Column 5 using the final relative payment weights for CY 2016 and the final relative payment weights for CY 2017. We used the final conversion factor for CY 2016 of \$73.725 and the final CY 2017 conversion factor of \$75.001 discussed in section II.B. of this final rule with comment period.

Column 5 contains simulated outlier payments for each year. We used the 1-year charge inflation factor used in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57286) of 4.8 percent (1.0481) to increase individual costs on the CY 2015 claims, and we used the most recent overall CCR in the July 2016 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2016. Using the CY 2015 claims and a 4.8 percent charge inflation factor, we currently estimate that outlier payments for CY 2016, using a multiple threshold of 1.75 and a fixed-dollar threshold of \$3,250 will be approximately 0.96 percent of total payments. The estimated current outlier payments of 0.96 percent are incorporated in the comparison in Column 5. We used the same set of claims and a charge inflation factor of 9.8 percent (1.0984) and the CCRs in the July 2016 OPSF, with an adjustment of 0.9688, to reflect relative changes in cost and charge inflation between CY 2015 and CY 2017, to

model the CY 2017 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of \$3,825. The charge inflation and CCR inflation factors are discussed in detail in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57286).

Overall, we estimate that facilities will experience an increase of 1.7 percent under this final rule with comment period in CY 2017 relative to total spending in CY 2016. This projected increase (shown in Column 5) of Table 52 reflects the 1.65 percent OPD fee schedule increase factor, plus 0.04 percent to account for our finalized policy to package unrelated laboratory tests into OPPS payment, plus 0.02 percent for the change in the pass-through estimate between CY 2016 and CY 2017, plus 0.04 percent for the difference in estimated outlier payments between CY 2016 (0.96 percent) and CY 2017 (1.0 percent). We estimate that the combined effect of all of the changes for CY 2017 will increase payments to urban hospitals by 1.8 percent. Overall, we estimate that rural hospitals will experience a 2.2 percent increase as a result of the combined effects of all of the changes for CY 2017.

Among hospitals by teaching status, we estimate that the impacts resulting from the combined effects of all changes will include an increase of 1.5 percent for major teaching hospitals and an increase of 2.0 percent for nonteaching hospitals. Minor teaching hospitals will experience an estimated increase of 1.9 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals will experience an increase of 1.9 percent, proprietary hospitals will experience an increase of 1.8 percent, and governmental hospitals will experience an increase of 1.6 percent.

TABLE 52—ESTIMATED IMPACT OF THE CY 2017 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

	Number of hospitals	APC recalibration (all changes)	New wage index and provider adjustments	All budget neutral changes (combined cols 2, 3) with market basket update	All changes
	(1)	(2)	(3)	(4)	(5)
ALL FACILITIES *	3,906	0.0	0.0	1.7	1.7
ALL HOSPITALS (excludes hospitals permanently held harmless and CMHCs)	3,789	0.0	0.0	1.8	1.8
URBAN HOSPITALS	2,958	0.0	0.0	1.7	1.8
LARGE URBAN (GT 1 MILL.)	1,616	0.0	-0.1	1.6	1.7
OTHER URBAN (LE 1 MILL.)	1,342	0.1	0.1	1.8	1.8
RURAL HOSPITALS	831	0.2	0.3	2.2	2.2
SOLE COMMUNITY	376	0.2	0.4	2.3	2.2
OTHER RURAL	455	0.2	0.2	2.1	2.1

TABLE 52—ESTIMATED IMPACT OF THE CY 2017 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM—Continued

	Number of hospitals	APC recalibration (all changes)	New wage index and provider adjustments	All budget neutral changes (combined cols 2, 3) with market basket update	All changes
	(1)	(2)	(3)	(4)	(5)
BEDS (URBAN):					
0–99 BEDS	1,045	–0.3	0.2	1.6	1.7
100–199 BEDS	834	0.2	–0.1	1.8	1.8
200–299 BEDS	465	0.2	0.0	1.9	1.9
300–499 BEDS	405	0.1	0.0	1.8	1.9
500+ BEDS	209	–0.2	0.0	1.5	1.5
BEDS (RURAL):					
0–49 BEDS	340	0.3	0.5	2.5	2.5
50–100 BEDS	299	0.2	0.4	2.4	2.3
101–149 BEDS	108	0.1	–0.2	1.6	1.7
150–199 BEDS	45	0.1	0.5	2.3	2.2
200+ BEDS	39	0.2	0.2	2.1	2.1
REGION (URBAN):					
NEW ENGLAND	146	0.0	–1.1	0.6	0.6
MIDDLE ATLANTIC	350	0.0	0.1	1.7	1.7
SOUTH ATLANTIC	465	0.0	0.0	1.7	1.8
EAST NORTH CENT	473	0.1	0.1	1.8	1.9
EAST SOUTH CENT	177	–0.3	0.3	1.7	1.7
WEST NORTH CENT	182	–0.1	0.0	1.6	1.5
WEST SOUTH CENT	527	–0.2	0.3	1.8	1.9
MOUNTAIN	206	0.2	1.0	2.9	3.0
PACIFIC	383	0.4	–0.3	1.7	1.8
PUERTO RICO	49	0.4	–0.3	1.8	1.8
REGION (RURAL):					
NEW ENGLAND	21	0.9	0.5	3.0	2.9
MIDDLE ATLANTIC	55	0.1	1.2	3.0	3.0
SOUTH ATLANTIC	126	0.3	–0.3	1.7	1.7
EAST NORTH CENT	121	0.2	0.4	2.3	2.3
EAST SOUTH CENT	158	0.0	0.2	1.9	1.9
WEST NORTH CENT	100	0.0	0.4	2.2	2.0
WEST SOUTH CENT	168	0.1	0.7	2.6	2.6
MOUNTAIN	58	0.3	–0.1	1.9	1.8
PACIFIC	24	0.3	–0.3	1.7	1.7
TEACHING STATUS:					
NON-TEACHING	2,712	0.1	0.1	1.9	2.0
MINOR	731	0.1	0.0	1.9	1.9
MAJOR	346	–0.2	–0.1	1.4	1.5
DSH PATIENT PERCENT:					
0	10	–1.7	–0.2	–0.3	–0.2
GT 0–0.10	305	–0.4	0.0	1.2	1.3
0.10–0.16	270	0.0	0.1	1.8	1.8
0.16–0.23	600	0.1	0.1	1.9	2.0
0.23–0.35	1,135	0.1	0.1	1.9	1.9
GE 0.35	895	0.1	–0.1	1.7	1.8
DSH NOT AVAILABLE**	574	–1.4	–0.2	0.1	0.1
URBAN TEACHING/DSH:					
TEACHING & DSH	975	0.0	0.0	1.6	1.7
NO TEACHING/DSH	1,425	0.1	0.1	1.9	1.9
NO TEACHING/NO DSH	10	–1.7	–0.2	–0.3	–0.2
DSH NOT AVAILABLE**	548	–1.4	–0.3	0.0	0.1
TYPE OF OWNERSHIP:					
VOLUNTARY	1,983	0.1	0.1	1.8	1.9
PROPRIETARY	1,306	0.0	0.1	1.7	1.8
GOVERNMENT	500	–0.1	–0.1	1.5	1.6
CMHCs	50	–15.1	–0.4	–13.9	–13.7

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all CY 2017 OPPS policies and compares those to the CY 2016 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the final FY 2017 hospital inpatient wage index, including all hold harmless policies and transitional wages. The rural adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the cancer hospital adjustment is 1.0003 because the target payment-to-cost ratio target changes from 0.92 in CY 2016 to 0.91 in CY 2017 (80 FR 70362 through 70364).

Column (4) shows the impact of all budget neutrality adjustments and the addition of the final 1.65 percent OPD fee schedule update factor. It also includes the impact of the additional adjustment of 1.0004 for laboratory services with “L1” modifiers packaged into the OPPS.

Column (5) shows the additional adjustments to the conversion factor resulting from the frontier adjustment, a change in the pass-through payment estimate, and adding estimated outlier payments.

* These 3,906 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.

(3) Estimated Effects of OPSS Changes on CMHCs

The last line of Table U1 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPSS. In CY 2016, CMHCs are paid under two APCs for these services: APC 5851 (Level 1 Partial Hospitalization (3 services) for CMHCs) and APC 5852 (Level 2 Partial Hospitalization (4 or more services) for CMHCs). For CY 2017, we are to combining APCs 5851 and 5852 into new 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 2015 claims data used for this final rule with comment period. We excluded days with 1 or 2 services because our policy only pays a per diem rate for partial hospitalization when 3 or more qualifying services are provided to the beneficiary. We estimate that CMHCs will experience an overall 13.7 percent decrease in payments from CY 2016 (shown in Column 5). We note that this includes the trimming methodology described in section VIII.B. of this final rule with comment period.

Column 3 shows that the estimated impact of adopting the FY 2017 wage index values will result in a small decrease of 0.4 percent to CMHCs. Column 4 shows that combining this OPD fee schedule increase factor, along with changes in APC policy for CY 2017 and the FY 2017 wage index updates, will result in an estimated decrease of 13.9 percent. Column 5 shows that adding the changes in outlier and pass-through payments will result in a total 13.7 percent decrease in payment for CMHCs. This reflects all changes to CMHCs for CY 2017.

(4) Estimated Effect of OPSS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary's payment will increase for services for which the OPSS payments will rise and will decrease for services for which the OPSS payments will fall. For further discussion on the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.I. of this final rule with comment period. In all cases, section 1833(t)(8)(C)(i) of the Act limits beneficiary liability for copayment for a procedure performed in a year to the hospital inpatient deductible for the applicable year.

We estimate that the aggregate beneficiary coinsurance percentage will be 18.5 percent for all services paid under the OPSS in CY 2017. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the CY 2017 comprehensive APC payment policy discussed in section II.A.2.e. of this final rule with comment period.

(5) Estimated Effects of OPSS Changes on Other Providers

The relative payment weights and payment amounts established under the OPSS affect the payments made to ASCs as discussed in section XII. of this final rule with comment period. No types of providers or suppliers other than hospitals, CMHCs, and ASCs will be affected by the changes in this final rule with comment period.

(6) Estimated Effects of OPSS Changes on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be an increase of \$773 million in program payments for OPSS services furnished in CY 2017. 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 XXIII.A.4.a.(4) of this final rule with comment period.

(7) Alternative OPSS Policies Considered

Alternatives to the OPSS changes we are making and the reasons for our selected alternatives are discussed throughout this final rule with comment period.

b. Estimated Effects of CY 2017 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 final rule with comment period, we are setting the CY 2017 ASC relative payment weights by scaling the CY 2017 OPSS relative payment weights by the ASC scalar of 0.9000. The estimated effects of the updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 53 and 54 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 2017 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 CY 2017 ASC conversion factor by adjusting the CY 2016 ASC conversion factor by 0.9997 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2016 and CY 2017 and by applying the CY 2017 MFP-adjusted CPI-U update factor of 1.9 percent (projected CPI-U update of 2.2 percent minus a projected productivity adjustment of 0.3 percentage point). The CY 2017 ASC conversion factor is \$45.016.

(1) Limitations of Our Analysis

Presented here are the projected effects of the changes for CY 2017 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2015 and CY 2017 with precision. We believe that the net effect on Medicare expenditures resulting from the CY 2017 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 ASC Payment System Policies on ASCs

Some ASCs are multispecialty facilities that perform the gamut of surgical procedures from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as eye, digestive system, or orthopedic procedures. The combined effect on an individual ASC of the update to the CY 2017 payments will depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare

beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion presents tables that display estimates of the impact of the CY 2017 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services as reflected in our CY 2015 claims data. Table 53 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2016 payments to estimated CY 2017 payments, and Table 54 shows a comparison of estimated CY 2016 payments to estimated CY 2017 payments for procedures that we estimate will receive the most Medicare payment in CY 2016.

Table 53 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 53.

- 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 2016 ASC Payments were calculated using CY 2015 ASC utilization (the most recent full year of ASC utilization) and CY 2016 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2016 ASC payments.
- Column 3—Estimated CY 2017 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 updates to ASC payment rates for CY 2017 compared to CY 2016.

As seen in Table 53, 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 1-percent increase in aggregate payment amounts for digestive system procedures, no change in aggregate payment amounts for nervous system procedures, a 8-percent increase in aggregate payment amounts for musculoskeletal system procedures, a 1-percent decrease in aggregate payment amounts for genitourinary system procedures, and a 3-percent decrease in aggregate payment amounts for integumentary system procedures.

Also displayed in Table 53 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 will be \$31 million for CY 2017.

TABLE 53—ESTIMATED IMPACT OF THE CY 2017 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2017 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical specialty group (1)	Estimated CY 2016 ASC payments (in millions) (2)	Estimated CY 2017 percent change (3)
Total	\$3,993	2
Eye and ocular adnexa	1,556	2
Digestive system	813	1
Nervous system	687	0
Musculoskeletal system	466	8
Genitourinary system	178	-1
Integumentary system	132	-3

Table 54 below shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2017. The table displays 30 of the procedures receiving the greatest estimated CY 2016 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending

order by estimated CY 2016 program payment.

- Column 1—CPT/HCPCS code.
- Column 2—Short Descriptor of the HCPCS code.
- Column 3—Estimated CY 2016 ASC Payments were calculated using CY 2015 ASC utilization (the most recent full year of ASC utilization) and the CY

2016 ASC payment rates. The estimated CY 2016 payments are expressed in millions of dollars.

- Column 4—Estimated CY 2017 Percent Change reflects the percent differences between the estimated ASC payment for CY 2016 and the estimated payment for CY 2017 based on the update.

TABLE 54—ESTIMATED IMPACT OF THE CY 2017 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS code	Short descriptor	Estimated CY 2016 ASC payment (in millions)	Estimated CY 2017 percent change
(1)	(2)	(3)	(4)
66984	Cataract surg w/iol 1 stage	\$1,108	1
43239	Egd biopsy single/multiple	185	-9
45380	Colonoscopy and biopsy	180	13
45385	Colonoscopy w/lesion removal	118	13
66982	Cataract surgery complex	96	1
64483	Inj foramen epidural l/s	87	6
63685	Insrt/redo spine n generator	82	10
64493	Inj paravert f jnt l/s 1 lev	71	-24
63650	Implant neuroelectrodes	66	12
66821	After cataract laser surgery	65	4
64635	Destroy lumb/sac facet jnt	55	2
29827	Arthroscop rotator cuff repr	54	7
G0105	Colorectal scrn; hi risk ind	53	-14
45378	Diagnostic colonoscopy	52	-14
G0121	Colon ca scrn not hi rsk ind	50	-14
0191T	Insert ant segment drain int	41	43
64590	Insrt/redo pn/gastr stimul	38	10
64721	Carpal tunnel surgery	32	2
29881	Knee arthroscopy/surgery	32	-8
15823	Revision of upper eyelid	32	-2
29880	Knee arthroscopy/surgery	27	-8
26055	Incise finger tendon sheath	24	-14
43235	Egd diagnostic brush wash	24	-9
64490	Inj paravert f jnt c/t 1 lev	24	-24
67042	Vit for macular hole	23	-2
52000	Cystoscopy	21	2
G0260	Inj for sacroiliac jt anesth	21	-16
50590	Fragmenting of kidney stone	21	1
64555	Implant neuroelectrodes	19	14
67904	Repair eyelid defect	18	2

(3) Estimated Effects of ASC Payment System Policies on Beneficiaries

We estimate that the CY 2017 update to the ASC payment system will be generally positive for beneficiaries with respect to the new procedures that we are adding to the ASC list of covered surgical procedures and for those that we are designating as office-based for CY 2017. 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 designating as office-based in CY 2017, 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 making and the reasons for our selected alternatives are discussed throughout this final rule with comment period.

c. Accounting Statements and Tables

As required by OMB Circular A-4 (available on the Office of Management and Budget Web site at: https://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf), we have prepared two accounting statements to illustrate the impacts of this final rule with comment period. The first accounting statement, Table 55 below, illustrates the classification of expenditures for the CY 2017 estimated hospital OPSS incurred benefit impacts associated with the CY 2017 OPD fee schedule increase, based on the 2016 Trustee's Report. The second accounting statement, Table 56 below, illustrates the classification of expenditures associated with the 1.9 percent CY 2017 update to the ASC payment system, based on the provisions of this final rule with comment period and the baseline spending estimates for ASCs in the 2016 Trustee's Report. Lastly, the tables classify most estimated impacts as transfers.

TABLE 55—ACCOUNTING STATEMENT: CY 2017 ESTIMATED HOSPITAL OPPTS TRANSFERS FROM CY 2016 TO CY 2017 ASSOCIATED WITH THE CY 2017 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers From Whom to Whom	\$773 million. Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPTS.
Total	\$773 million.

TABLE 56—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2016 TO CY 2017 AS A RESULT OF THE CY 2017 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers From Whom to Whom	\$63 million. Federal Government to Medicare Providers and Suppliers.
Total	\$63 million

d. Effects of Requirements for the Hospital OQR Program

We refer readers to the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70593 through 70594), for the estimated effects of changes to the Hospital OQR Program for the CY 2018 payment determination. In section XIII. of this final rule with comment period, we are finalizing changes to policies affecting the Hospital OQR Program. Of the 3,266 hospitals that met eligibility requirements for the CY 2016 payment determination, we determined that 113 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor. Most of these hospitals (71 of the 113), chose not to participate in the Hospital OQR Program for the CY 2016 payment determination.²⁶⁴ We estimate that approximately 108 to 121 hospitals will not receive the full OPD fee schedule increase factor for the CY 2018 payment determination and subsequent years.

In section XIII. of this final rule with comment period, we are finalizing several changes to the Hospital OQR Program for the CY 2018 payment determination and subsequent years, CY 2019 payment determination and subsequent years, and the CY 2020 payment determination and subsequent years. We do not believe that any of the other changes we are making will increase burden, as further discussed below.

For the CY 2018 payment determination and subsequent years, we are finalizing, as proposed, that we will publicly display data on the *Hospital*

Compare Web site, or other CMS Web site, as soon as possible after measure data have been submitted to CMS. In addition, we are finalizing, as proposed, that hospitals will generally have approximately 30 days to preview their data. Both of these policies are consistent with current practice. Lastly, we are finalizing, as proposed, that we will announce the timeframes for the preview period starting with the CY 2018 payment determination on a CMS Web site and/or on our applicable listservs. We do not anticipate additional burden to hospitals as a result of these changes to the public display policies because hospitals will not be required to submit additional data or forms to CMS.

For the CY 2019 payment determination and subsequent years, we are finalizing our proposal to extend the time for filing an extraordinary circumstance extension or exemption request from 45 days to 90 days. We do not anticipate additional burden to hospitals as a result of this policy because the requirements for filing a request have not otherwise changed.

For the CY 2020 payment determination and subsequent years, we are finalizing, as proposed, two new claims-based measures for the Hospital OQR Program: OP-35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy; and OP-36: Hospital Visits after Hospital Outpatient Surgery (NQF #2687). For the CY 2020 payment determination and subsequent years, we also are adopting, as proposed, five new OAS CAHPS Survey-based measures: (1) OP-37a: OAS CAHPS—About Facilities and Staff; (2) OP-37b: OAS CAHPS—Communication About Procedure; (3) OP-37c: OAS CAHPS—Preparation for Discharge and Recovery; (4) OP-37d: OAS CAHPS—Overall Rating of

Facility; and (5) OP-37e: OAS CAHPS—Recommendation of Facility. As discussed in section XXI.B.4. of this final rule with comment period, we do not believe that the OP-35 and OP-36 measures will create any additional burden across all participating hospitals because these measures use Medicare FFS claims data and do not require additional hospital data submissions. In addition, as discussed in the same section, the burden associated with the OAS CAHPS Survey-based measures (OP-37a, OP-37b, OP-37c, OP-37d, and OP-37e) is already accounted for in previously approved OMB Control Number 0938-1240.

We refer readers to section XXI.B. of this final rule with comment period (information collection requirements) for a detailed discussion of the burden of the additional requirements for submitting data to the Hospital OQR Program.

e. Effects of Requirements for the ASCQR Program

In section XIV. of this final rule with comment period, we discuss our finalized policies affecting the ASCQR Program. For the CY 2016 payment determination, of the 5,260 ASCs that met eligibility requirements for the ASCQR Program, 261 ASCs did not meet the requirements to receive the full annual payment update. We note that, in the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70594), we used the CY 2015 payment determination numbers as a baseline, and estimated that approximately 115 ASCs will not receive the full annual payment update in CY 2018 due to failure to meet the ASCQR Program requirements (CY 2016 and CY 2017 payment determination information were not yet available).

²⁶⁴ We note in the CY 2017 OPPTS/ASC proposed rule (81 FR 45769), we stated that the hospitals chose not to participate in the Hospital OQR Program for the CY 2015 payment determination instead of the CY 2016 payment determination. This was a typographical error, and the correct payment determination year is CY 2016.

For the CY 2018 payment determination and subsequent years, we are making a few changes in policies. In section XIV.B.7. of this final rule with comment period, we are finalizing, as proposed, that we will publicly display data on the *Hospital Compare* Web site, or other CMS Web site, as soon as possible after measure data have been submitted to CMS. In addition, we are finalizing, as proposed, that ASCs will generally have approximately 30 days to preview their data. Both of these policies are consistent with current practice. Lastly, we are finalizing, as proposed, that we will announce the timeframes for the preview period starting with the CY 2018 payment determination on a CMS Web site and/or on our applicable listservs. We believe that these changes to the ASCQR Program public reporting policies will have no effect on burden for ASCs because these changes would not require participating ASCs to submit additional data to CMS.

For the CY 2019 payment determination and subsequent years, we are finalizing, as proposed, two new policy changes. In section XIV.D.3. of this final rule with comment period, we are finalizing our proposal to implement a submission deadline with an end date of May 15 for all data submitted via a CMS Web-based tool beginning with the CY 2019 payment determination, as proposed. (For all data submitted via a non CMS Web-based tool, ASCs are already required to submit by May 15 of the year prior to the affected payment determination year (79 FR 66985 through 66986).) We do not anticipate additional burden as the data collection and submission requirements have not changed; only the deadline will be moved to a slightly earlier date that we anticipate will alleviate burden by aligning data submission deadlines. In section XIV.D.6. of this final rule with comment period, we are finalizing our proposal to extend the time for filing an extraordinary circumstance extension or exemption request from 45 days to 90 days. We do not believe this policy will result in additional burden to ASCs because the requirements for filing a request have not otherwise changed. We are not adding any quality measures to the ASCQR Program measure set for the CY 2019 payment determination, nor do we believe that the other measures we previously adopted will cause any additional ASCs to fail to meet the ASCQR Program requirements. (We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66978 through 66979) for a list of these measures.) Therefore, we do not believe

that these changes will increase the number of ASCs that do not receive a full annual payment update for the CY 2019 payment determination.

In section XIV.B.4. of this final rule with comment period, we are finalizing, as proposed, two new measures collected via a CMS online data submission tool to the ASCQR Program measure set beginning with the CY 2020 payment determination—ASC-13: Normothermia Outcome and ASC-14: Unplanned Anterior Vitrectomy—and five new OAS CAHPS Survey-based measures beginning with the CY 2020 payment determination: (1) ASC-15a: OAS CAHPS—About Facilities and Staff; (2) ASC-15b: OAS CAHPS—Communication About Procedure; (3) ASC-15c: OAS CAHPS—Preparation for Discharge and Recovery; (4) ASC-15d: OAS CAHPS—Overall Rating of Facility; and (5) ASC-15e: OAS CAHPS—Recommendation of Facility. As discussed in section XXI.C.2. of this final rule with comment period, we estimate a data collection and submission burden of approximately 15.75 hours and \$517 (15.75 hours x \$32.84 per hour) each per ASC for the ASC-13 and ASC-14 measures based on an average sample of 63 cases. This results in a total estimated burden of approximately 82,845 hours and \$2,720,630 each for the ASC-13 and ASC-14 measures across all ASCs based on an average sample of 63 cases per ASC. In addition, and as discussed in the same section, the burden associated with the OAS CAHPS Survey-based measures is already accounted for in a previously approved OMB Control Number 0938-1240.

In the CY 2017 OPPS/ASC proposed rule (81 FR 45770 through 45771), we invited public comment on the burden associated with our proposals in the proposed rule. We did not receive any comments on the burden associated with our proposals in the proposed rule, and therefore, are finalizing our burden estimates as discussed. We refer readers to the information collection requirements in sections XXI.C.2. through XXI.C.5. of this final rule with comment period for a detailed discussion of the financial and hourly burden of the ASCQR Program's current and new requirements.

f. Effects of the Changes to Transplant Performance Thresholds

In section XV. of this final rule with comment period, we discuss our proposed and finalized changes to the transplant centers performance thresholds to restore the tolerance range for patient and graft survival with respect to organ transplants to those we

established in our 2007 regulations. We considered the option of leaving the current regulation unchanged. However, given the recent upward trend in the percent of unused adult kidneys, combined with an increase in the number of recovered organs, we do not believe that inaction is advisable. In addition, in the original 2007 organ transplant rule, CMS committed to review the outcomes thresholds if it considered them to be set at a level that was too high or too low. We are following through on that commitment.

We considered the option of leaving the regulation unchanged and instead reclassifying a larger range of outcomes as a “standard-level” rather than the more serious “condition-level” deficiency. We have already taken this approach to a considerable extent in survey and certification guidance (<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html>). However, standard-level deficiencies must be remedied at some point; therefore, reclassification may not yield the change necessary to address an increasingly stringent outcomes requirement.

We considered the option of creating a “balancing measure” that would directly measure a transplant program's effectiveness in using organs, including tracking organs that are declined to see if other programs were able to make use of the organs successfully for long term graft survival. Such a balancing measure could “unflag” a program that had been flagged for substandard outcomes under the existing outcome measures. The OPTN developed a concept paper to obtain public comment for a similar idea, in which highest risk organs might be removed from the data when calculating outcomes (<https://optn.transplant.hrsa.gov/governance/public-comment/performance-metrics-concept-paper/>). This concept is slightly different than use of a balancing measure, but both approaches would require a multiyear effort to construct, test, and study the effects, including potential undesirable side effects. It is not an option readily available.

We considered the argument that the regulation should be unchanged because CMS should expect health care providers to improve outcomes over time, and, if the outcomes standard is becoming more difficult to meet, providers should rise to the challenge. We agree that we should expect health care providers to improve outcomes over time. However, once programs are at a very high level of performance, there is little room to improve.

Therefore, there is no persuasive reason to leave the regulations unchanged. First, in addition to patient and graft survival, we are interested in optimizing the use of organs so that individuals on the waiting list can gain the benefits of a transplant. To the extent that there are unintended and undesirable effects on this access goal that outweigh the value gained from an increasingly stringent outcomes requirement, we believe we should respond. Second, the transplant community has demonstrated a track record of consistent improvement efforts and innovation. Third, we commissioned a study that found that the overall risk levels of both available organs and transplant candidates have been increasing every year.²⁶⁵ To the extent these population trends continue (for example, increasing age, higher rates of diabetes, obesity, hypertension), transplant programs will continue to be challenged to improve their care and processes just to sustain the patient and graft survival rates already achieved. We will continue to monitor these trends.

Finally, we considered the option to adopt the Bayesian methodology that the OPTN recently adopted. We are not doing so at this time because the OPTN continues to study its implementation of that methodology and to evaluate its own thresholds for flagging programs in relation to the Bayesian model.

We believe that the finalized changes in this final rule with comment period will result in costs savings to hospitals. The savings results from: (1) Fewer programs that would need to file a request for approval on the basis of mitigating factors; and (2) fewer programs that would need to fulfill the terms of an SIA. Both a mitigating factors review and completion of an SIA are voluntary acts on the part of a hospital that maintains a transplant program. Since the 2007 effective date of the CMS regulation, only one hospital has not filed a request for mitigating factors review after being cited by CMS for a condition-level deficiency for patient outcomes or clinical experience, and few hospitals have declined a CMS offer to complete an SIA. Therefore, we have concluded that the costs involved in these activities are much lower for the hospital compared with other alternatives, such as filing an appeal and incurring the legal costs of that appeal.

In the two SRTR reports from 2015, a total of 54 programs were flagged once (24 of which were adult kidney

programs). If the performance threshold were set at 1.85 instead of the existing 1.5, this number would have been reduced to 48 programs (21 of which would have been adult kidney programs). However, the cost savings would occur mainly for programs that were multiple-flagged and met the criteria for citation at the condition-level. These are the programs that are cited at the condition level and risk termination of Medicare approval unless they are approved under the mitigating factors provision, and some of those programs would not be approved without successful completion of an SIA. Historically, of the programs that voluntarily withdrew from Medicare participation pending termination or were terminated based on outcomes deficiencies for which data are available, all had O/E ratios above the performance threshold of 1.85. For CY 2015, a total of 30 programs met the criteria for condition-level deficiency (15 of which were adult kidney programs). If the threshold had been at the 1.85 instead of 1.5 level, these numbers would have been reduced to 27 and 13 respectively.

We estimate the cost associated with the application for mitigating factors at \$10,000. This is based on the salary for the transplant administrator to prepare the documents for the application during the 30-day timeframe allotted. Based on the CY 2015 SRTR reports described earlier, we estimate that three fewer programs each year will need to file a mitigating factors request, yielding a small savings of \$30,000 per year.

We also estimate that four fewer programs each year will be required to complete an SIA. For transplant programs that enter into an SIA, the estimated cost to the transplant program is \$250,000 based on reports from programs that have completed such agreements in the past. Therefore, we estimate the annual cost savings to hospitals from fewer SIAs to be \$1 million.

We estimate that the total costs savings will be \$1 million per year (\$1 million plus \$30,000), and conclude that our finalized policies will not have a significant impact on a substantial number of small businesses or other small entities, given both the small number of programs affected and the large size of many entities with transplant programs. Nor will they have a significant impact on small rural hospitals.

g. Effects of the Changes Relating to Organ Procurement Organizations (OPOs)

In section XVI. of this final rule with comment period, we discuss our proposed and finalized policies to expand and clarify the current OPO regulation as it relates to revising the definition of eligible death, adjusting the outcome performance yield measure and changing the documentation requirements of donor information to the transplant center to align CMS policy with OPTN policy and the SRTR yield metric.

All 58 OPOs will be affected by the changed requirements to a greater or lesser degree. Many OPOs have already put into practice many of these requirements. Thus, while we do not believe these changed requirements will have a substantial economic impact on a significant number of OPOs, we believe it is desirable to inform the public of our projections of the likely effects of these changed requirements on OPOs. It is important to note that because OPOs are paid by the Medicare program on a cost basis, any additional costs that exceed an OPO's annual revenues will be fully paid under the Medicare program. In addition, these changed requirements will have no identifiable economic impact on transplant hospitals. It is expected that improved OPO performance will result from the proposals and increase organ donation and the number of organs available for transplantation.

The definition and yield metric changes will result in no additional burden. OPOs already report a large amount of data to the OPTN which, in turn, provides the data to the SRTR for analysis. OPOs will not be asked to report additional data as a result of the changes.

The change in the documentation requirements of donor information sent to the transplant center with the organs will reduce burden for the OPOs. This change will reduce the amount of hard copy documentation that is packaged and shipped with each organ and will free up the OPO transplant coordinator's time to focus on the critical donor management and organ preparation tasks. We estimate that this change will save OPOs a total of approximately \$259,000 a year for all 58 certified OPOs. There were approximately 7,000 deceased eligible donors in 2014 (according to the CMS data report), which will require hard copy documentation packaged and shipped with the organ(s) procured by the OPO transplant coordinator. According to <http://www.payscale.com/>, the average

²⁶⁵ White, Zinsser et al., "Patient Selection and Volume in the Era Surrounding Implementation of Medicare Conditions of Participation for Transplant Programs," *Health Services Research*, DOI: 10.1111/1465-6773.12188.

salary for an OPO transplant coordinator is \$70,693 per year, which is approximately \$37 an hour. We estimate that it takes an OPO transplant coordinator approximately 1 hour to print, package, and ship the hard copy documentation with the organ(s) at \$37 an hour for approximately 7,000 deceased donors. Thirty-seven dollars an hour multiplied by 7,000 deceased donors which require hard copy documentation equals \$259,000 and 7,000 hours saved for OPOs nationwide. The primary economic impact of these changes will lie with their potential to increase organ donation. However, it is difficult to predict precisely what that impact will be, but we estimate that, by increasing OPOs' efficiency and adherence to continuous quality improvement measures, these changes could increase the number of organ donors in the regulation's first year.

With regard to the impact of the transplant enforcement technical corrections and other revisions to § 488.61 discussed in section XVII. of this final rule with comment period, there is no economic impact.

h. Effects of the Changes to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs

In section XVIII. of this final rule with comment period, we discuss changed requirements for the Medicare and Medicaid EHR Incentive Programs. Specifically, in this final rule with comment period, for eligible hospitals and CAHs attesting to CMS, we are eliminating the Clinical Decision Support (CDS) and Computerized Provider Order Entry (CPOE) objectives and measures for Modified Stage 2 and Stage 3 as well as reducing the reporting thresholds on a subset of the remaining objectives and measures to the Modified Stage 2 thresholds. We do not believe that the changes will increase burden on eligible hospitals and CAHs as the objectives and measures remain the same; only a subset of thresholds will be reduced. In addition, the changes to eliminate the CDS and CPOE objectives and measures are based on high performance and the statistical evidence demonstrates that the expected result of any provider attesting to the EHR Incentive Programs will be a score near the maximum. While the functions of measures and the processes behind them will continue even without a requirement to report the results, the provisions will result in a reduction in reporting requirements. Based on the public comments we received, we are finalizing a policy that these changes to the objectives and measures apply for all eligible hospitals and CAHs that

attest to CMS, including eligible hospitals and CAHs that are eligible to participate in both the Medicare and Medicaid EHR Incentive Programs.

We also are modifying the EHR reporting period in 2016 and 2017 for all returning EPs, eligible hospitals and CAHs that have previously demonstrated meaningful use to any continuous 90-day period within the calendar year. We do not believe that the modification of the EHR reporting period in 2016 and 2017 to any continuous 90-day period will increase the reporting burden of providers in the Medicare and Medicaid EHR Incentive Programs as all providers attested to a 90-day EHR reporting period in 2015. We are modifying the options for reporting on Modified Stage 2 or Stage 3 objectives finalized in the 2015 EHR Incentive Programs Final Rule by requiring new participants in 2017 who are seeking to avoid the 2018 payment adjustment to attest to the Modified Stage 2 objectives and measures. We do not believe that requiring new participants in 2017 to attest to Modified Stage 2 objectives and measures will increase the reporting burden because new participants using 2014 Edition, 2015 Edition, or any combination of 2014 and 2015 Edition certified EHR technology in 2017 will have the necessary technical capabilities to attest to the Modified Stage 2 objectives and measures.

We are providing that for all meaningful use measures, unless otherwise specified, actions included in the numerator must occur within the EHR reporting period if that period is a full calendar year, or if it is less than a full calendar year, within the calendar year in which the EHR reporting period occurs. Because this change only affect the time period within which certain actions must occur, but not the underlying actions to be reported, we do not believe that this change will affect the burden on meaningful users. Finally, we are providing a one-time significant hardship exception from the 2018 payment adjustment for certain EPs who are new participants in the EHR Incentive Program in 2017 and are transitioning to MIPS in 2017. We do not believe the change to allow a one-time significant hardship exception from the 2018 payment adjustment for certain EPs will increase their burden. Rather, we believe this will reduce the reporting burden for 2017 because this change will reduce confusion on the different reporting requirements for the EHR Incentive Program and MIPS as well as the different systems to which participants will need to register and attest.

i. Effects of Requirements for the Hospital VBP Program

In section XIX. of this final rule with comment period, we discuss finalizing our proposal to change the scoring methodology for the Patient- and Caregiver-Centered Experience of Care/ Care Coordination domain in the Hospital VBP Program by removing the HCAHPS Pain Management dimension from the Patient- and Caregiver-Centered Experience of Care/ Care Coordination domain beginning with the FY 2018 program year.

As noted in section XXI.G. of this final rule with comment period, as required under section 1886(o)(2)(A) of the Act, the HCAHPS Survey is included the Hospital IQR Program. Therefore, we believe that removing the HCAHPS Pain Management dimension from the Hospital VBP Program beginning with the FY 2018 program year will have no effect on burden for participating hospitals because this change does not change the data that are submitted to CMS; it only affects how the scoring is computed under the domain in the Hospital VBP Program.

j. Effects of Implementation of Section 603 of the Bipartisan Budget Act of 2015 Relating to Payment for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Departments of a Provider

In section X.A. of this final rule with comment period, we discuss the implementation of section 603 of the Bipartisan Budget Act of 2015 relating to payments for nonexcepted items and services furnished by nonexcepted off-campus departments of a provider. Section 603 does not impact OPPS payment rates or payments to OPPS-eligible providers. The impact tables displayed in section XXIII.A.3. of this final rule with comment period do not factor in changes in volume or service-mix in OPPS payments. As a result, the impact tables displayed in section XXIII.A.3. of this final rule with comment period do not reflect changes in the volume of OPPS services due to the implementation of section 603.

We estimate that implementation of section 603 will reduce net OPPS payments by \$500 million in CY 2017, relative to a baseline where section 603 was not implemented in CY 2017. These estimates reflect that the reduced spending from implementation of section 603 results in a lower Part B premium; the reduced Part B spending is slightly offset by lower aggregate Part B premium collections. Additional information on the impact of implementing section 603 of Public Law

114–74 is provided in the interim final rule with comment period under section X.B. of this document.

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 final rule with comment period will increase payments to small rural hospitals by less than 3 percent; therefore, it should not have a significant impact on approximately 639 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 \$146 million. This final rule with comment period does not mandate any requirements for State, local, or tribal governments, or for the private sector.

D. Conclusion

The changes we are making in this final rule with comment period will affect all classes of hospitals paid under the OPSS and will affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPSS will experience a modest increase or a minimal decrease in payment for services furnished under the OPSS in CY 2017. Table 52 demonstrates the estimated distributional impact of the OPSS budget neutrality requirements that will result in a 1.7 percent increase in payments for all services paid under the OPSS in CY 2017, after considering all of the changes to APC reconfiguration and recalibration, as well as the OPD fee schedule increase factor, wage index changes, including the frontier State wage index adjustment, estimated payment for outliers, and changes to the pass-through payment estimate. However, some classes of providers that are paid under the OPSS will experience more significant gains or losses in OPSS payments in CY 2017.

The updates to the ASC payment system for CY 2017 will affect each of the approximately 5,300 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 53 demonstrates the estimated distributional impact among ASC surgical specialties of the MFP-adjusted CPI-U update factor of 1.9 percent for CY 2017.

XXV. 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 OPSS and ASC provisions included in this final rule with comment period in accordance with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on State, local or tribal governments, preempt State law, or otherwise have a Federalism implication. As reflected in Table 52 of this final rule with comment period, we estimate that OPSS payments to governmental hospitals (including State

and local governmental hospitals) will increase by 1.6 percent under this final rule with comment period. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that it is small. The analyses we have provided in this section of this final rule with comment period, in conjunction with the remainder of this document, demonstrate that this final rule with comment period is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act. This final rule with comment period will affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant.

List of Subjects

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney disease, Medicare, Reporting and recordkeeping

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 486

Grant programs—health, Health facilities, Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Electronic health records, Health facilities, Health professions, Health maintenance organizations (HMO), Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For reasons stated in the preamble of this document, the Centers for Medicare & Medicaid Services is amending 42 CFR chapter IV as set forth below:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 1. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(2) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

§ 414.22 [Amended]

■ 2. Section 414.22 is amended by removing and reserving paragraph (b)(5)(ii).

PART 416—AMBULATORY SURGICAL SERVICES

■ 3. 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).

■ 4. Section 416.171 is amended by revising paragraph (b)(2) to read as follows:

§ 416.171 Determination of payment rates for ASC services.

* * * * *

(b) * * *

(2) The device portion of device-intensive procedures, which are procedures with a HCPCS code-level device offset of greater than 40 percent when calculated according to the standard OPPI APC ratesetting methodology.

* * * * *

■ 5. Section 416.310 is amended by revising paragraphs (c)(1)(ii) and (d)(1) and adding paragraph (e) to read as follows:

§ 416.310. Data collection and submission requirements under the ASCQR Program.

* * * * *

(c) * * *

(1) * * *

(ii) *Data collection requirements.* The data collection time period for quality measures for which data are submitted via a CMS online data submission tool is for services furnished during the calendar year 2 years prior to the payment determination year. Beginning with the CY 2017 payment determination year, data collected must be submitted during the time period of January 1 to May 15 in the year prior to the payment determination year.

* * * * *

(d) * * *

(1) Upon request of the ASC, ASCs may request an extension or exemption within 90 days of the date that the extraordinary circumstance occurred. Specific requirements for submission of

a request for an extension or exemption are available on the QualityNet Web site; or

* * * * *

(e) *Requirements for Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey.* OAS CAHPS is the Outpatient and Ambulatory Surgical Center Consumer Assessment of Healthcare Providers and Systems survey that measures patient experience of care after a recent surgery or procedure at either a hospital outpatient department or an ambulatory surgical center. Ambulatory surgical centers must use an approved OAS CAHPS survey vendor to administer and submit OAS CAHPS data to CMS.

(1) [Reserved]

(2) CMS approves an application for an entity to administer the OAS CAHPS survey as a vendor on behalf of one or more ambulatory surgical centers when the applicant has met the Minimum Survey Requirements and Rules of Participation that can be found on the official OAS CAHPS Web site, and agrees to comply with the current survey administration protocols that can be found on the official OAS CAHPS Web site. An entity must be an approved OAS CAHPS Survey vendor in order to administer the OAS CAHPS Survey and submit data to CMS on behalf of one or more ambulatory surgical centers.

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 6. The authority citation for part 419 continues to read as follows:

Authority: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395l(t), and 1395hh).

■ 7. Section 419.22 is amended by adding paragraph (v) to read as follows:

§ 419.22 Hospital services excluded from payment under the hospital outpatient prospective payment system.

* * * * *

(v) Effective January 1, 2017, for cost reporting periods beginning on or after January 1, 2017, items and services that do not meet the definition of excepted items and services under § 419.48(a).

■ 8. Section 419.32 is amended by adding paragraph (b)(1)(iv)(B)(8) to read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(8) For calendar year 2017, a multiproductivity adjustment (as determined by CMS) and 0.75 percentage point.

* * * * *

■ 9. Section 419.43 is amended by adding paragraph (d)(7) to read as follows:

§ 419.43 Adjustments to national program payment and beneficiary copayment amounts.

* * * * *

(d) * * *

(7) *Community mental health center (CMHC) outlier payment cap.* Outlier payments made to CMHCs for services provided on or after January 1, 2017 are subject to a cap, applied at the individual CMHC level, so that each CMHC's total outlier payments for the calendar year do not exceed 8 percent of that CMHC's total per diem payments for the calendar year. Total per diem payments are total Medicare per diem payments plus the total beneficiary share of those per diem payments.

* * * * *

■ 10. Section 419.44 is amended by revising paragraph (b)(2) to read as follows:

§ 419.44 Payment reductions for procedures.

* * * * *

(b) * * *

(2) For all device-intensive procedures (defined as having a device offset of greater than 40 percent), the device offset portion of the device-intensive procedure payment is subtracted prior to determining the program payment and beneficiary copayment amounts identified in paragraph (b)(1)(ii) of this section.

■ 11. Section 419.46 is amended by adding paragraph (g) to read as follows:

§ 419.46 Participation, data submission, and validation requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

* * * * *

(g) *Requirements for Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey.* OAS CAHPS is the Outpatient and Ambulatory Surgical Center Consumer Assessment of Healthcare Providers and Systems Survey that measures patient experience of care after a recent surgery or procedure at either a hospital outpatient department or an ambulatory surgical center. Hospital outpatient departments must use an approved OAS

CAHPS survey vendor to administer and submit OAS CAHPS data to CMS.

(1) [Reserved]

(2) CMS approves an application for an entity to administer the OAS CAHPS Survey as a vendor on behalf of one or more hospital outpatient departments when the applicant has met the Minimum Survey Requirements and Rules of Participation that can be found on the official OAS CAHPS Web site, and agrees to comply with the current survey administration protocols that can be found on the official OAS CAHPS Survey Web site. An entity must be an approved OAS CAHPS Survey vendor in order to administer and submit OAS CAHPS Survey data to CMS on behalf of one or more hospital outpatient departments.

■ 12. Section 419.48 is added to subpart D to read as follows:

§ 419.48 Definition of excepted items and services.

(a) Excepted items and services are items or services that are furnished on or after January 1, 2017—

(1) By a dedicated emergency department (as defined at § 489.24(b) of this chapter); or

(2) By an excepted off-campus provider-based department defined in paragraph (b) of this section that has not impermissibly relocated or changed ownership.

(b) For the purpose of this section, “excepted off-campus provider-based department” means a “department of a provider” (as defined at § 413.65(a)(2) of this chapter) that as of November 2, 2015 was located on the campus (as defined in § 413.65(a)(2) of this chapter) or within the distance described in such definition from a “remote location of a hospital” (as defined in § 413.65(a)(2) of this chapter) that meets the requirements for provider-based status under § 413.65 of this chapter. This definition also includes a department of a provider that was billing under the OPDS with respect to covered OPD services furnished prior to November 2, 2015.

(c) Payment for items and services that do not meet the definition in paragraph (a) of this section will generally be made under the Medicare Physician Fee Schedule on or after January 1, 2017.

■ 13. Section 419.66 is amended by revising paragraph (g) to read as follows:

§ 419.66 Transitional pass-through payments: Medical devices.

* * * * *

(g) *Limited period of payment for devices.* CMS limits the eligibility of a pass-through payment established under

this section to a period of at least 2 years, but not more than 3 years, beginning on the first date on which pass-through payment is made.

* * * * *

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 14. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

■ 15. Section 482.80 is amended by revising paragraph (c)(2)(ii)(C) to read as follows:

§ 482.80 Condition of participation: Data submission, clinical experience, and outcome requirements for initial approval of transplant centers.

* * * * *

(c) * * *

(2) * * *

(ii) * * *

(C) The number of observed events divided by the number of expected events is greater than 1.85.

* * * * *

■ 16. Section 482.82 is amended by revising paragraph (c)(2)(ii)(C) to read as follows:

§ 482.82 Condition of participation: Data submission, clinical experience, and outcome requirements for re-approval of transplant centers.

* * * * *

(c) * * *

(2) * * *

(ii) * * *

(C) The number of observed events divided by the number of expected events is greater than 1.85.

* * * * *

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

■ 17. The authority citation for part 486 continues to read as follows:

Authority: 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b–8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C. 273).

■ 18. Section 486.302 is amended by revising the definition of “Eligible death” to read as follows:

§ 486.302 Definitions.

* * * * *

Eligible death. An eligible death for organ donation means the death of a person—

(1) Who is 75 years old or younger;

(2) Who is legally declared dead by neurologic criteria in accordance with State or local law;

(3) Whose body weight is 5 kg or greater;

(4) Whose body mass Index (BMI) is 50 kg/m² or less;

(5) Who had at least one kidney, liver, heart, or lung that is deemed to meet the eligible data definition as follows:

(i) The kidney would be initially deemed to meet the eligible data definition unless the donor meets one of the following:

- (A) Is more than 70 years of age;
- (B) Is age 50–69 years with history of Type 1 diabetes for more than 20 years;
- (C) Has polycystic kidney disease;
- (D) Has glomerulosclerosis equal to or more than 20 percent by kidney biopsy;
- (E) Has terminal serum creatinine greater than 4/0 mg/dl;
- (F) Has chronic renal failure; or
- (G) Has no urine output for at least or more than 24 hours;

(ii) The liver would be initially deemed to meet the eligible data definition unless the donor has one of the following:

- (A) Cirrhosis;
- (B) Terminal total bilirubin equal to or more than 4 mg/dl;
- (C) Portal hypertension;
- (D) Macrosteatosis equal to or more than 50 percent of fibrosis equal to or more than stage II;
- (E) Fulminant hepatic failure; or
- (F) Terminal AST/ALT of more than 700 U/L.

(iii) The heart would be initially deemed to meet the eligible data definition unless the donor meets one of the following:

- (A) Is more than 60 years of age;
- (B) Is at least or more than 45 years of age with a history of at least or more than 10 years of HTN or at least or more than 10 years of type 1 diabetes;
- (C) Has a history of Coronary Artery Bypass Graft (CABG);

(D) Has a history of coronary stent/intervention;

(E) Has a current or past medical history of myocardial infarction (MI);

(F) Has a severe vessel diagnosis as supported by cardiac catheterization (that is more than 50 percent occlusion or 2+ vessel disease);

(G) Has acute myocarditis and/or endocarditis;

(H) Has heart failure due to cardiomyopathy;

(I) Has an internal defibrillator or pacemaker;

(J) Has moderate to severe single valve or 2-valve disease documented by echo or cardiac catheterization, or previous valve repair;

(K) Has serial echo results showing severe global hypokinesia;

(L) Has myxoma; or
(M) Has congenital defects (whether surgically corrected or not).

(iv) The lung would be initially deemed to meet the eligible data definition unless the donor meets one of the following:

(A) Is more than 65 years of age;
(B) Is diagnosed with coronary obstructive pulmonary disease (COPD) (for example, emphysema);
(C) Has terminal PaO₂/FiO₂ less than 250 mmHg;

(D) Has asthma (with daily prescription);

(E) Asthma is the cause of death;

(F) Has pulmonary fibrosis;

(G) Has previous lobectomy;

(H) Has multiple blebs documented on Computed Axial Tomography (CAT) Scan;

(I) Has pneumonia as indicated on Computed Tomography (CT), X-ray, bronchoscopy, or cultures;

(J) Has bilateral severe pulmonary contusions as per CT.

(6) If a deceased person meets the criteria specified in paragraphs (1) through (5) of this definition, the death of the person would be classified as an eligible death, unless the donor meets any of the following criteria:

(i) The donor was taken to the operating room with the intent for the OPO to recover organs for transplant and all organs were deemed not medically suitable for transplantation; or

(ii) The donor exhibits any of the following active infections (specific diagnoses) of—

(A) Bacterial: Tuberculosis, Gangrenous bowel or perforated bowel or intra-abdominal sepsis;

(B) Viral: HIV infection by serologic or molecular detection, Rabies, Reactive Hepatitis B Surface Antigen, Retroviral infections including Viral Encephalitis or Meningitis, Active Herpes simplex, varicella zoster, or cytomegalovirus viremia or pneumonia, Acute Epstein Barr Virus (mononucleosis), West Nile
(c) Virus infection, SARS, except as provided in paragraph (8) of this definition.

(C) Fungal: Active infection with *Cryptococcus*, *Aspergillus*, *Histoplasma*, *Coccidioides*, Active candidemia or invasive yeast infection;

(D) Parasites: Active infection with *Trypanosoma cruzi* (Chagas'), *Leishmania*, *Strongyloides*, or *Malaria* (*Plasmodium* sp.); or

(E) Prion: Creutzfeldt-Jacob Disease.

(7) The following are general exclusions:

(i) Aplastic anemia, Agranulocytosis;
(ii) Current malignant neoplasms except non-melanoma skin cancers such

as basal cell and squamous cell cancer and primary CNS tumors without evident metastatic disease;

(iii) Previous malignant neoplasms with current evident metastatic disease;

(iv) A history of melanoma;

(v) Hematologic malignancies:

Leukemia, Hodgkin's Disease,

Lymphoma, Multiple Myeloma;

(vi) Active Fungal, Parasitic, Viral, or Bacterial Meningitis or Encephalitis; and

(vii) No discernable cause of death.

(8) Notwithstanding paragraph (6)(ii)(B) of this definition, an HIV positive organ procured for the purpose of transplantation into an HIV positive recipient would be an exception to an active infection rule out, consistent with the HIV Organ Policy Equity Act (the Hope Act).

* * * * *

■ 19. Section 486.318 is amended by revising paragraphs (a)(3) and (b)(3) to read as follows:

§ 486.318 Condition: Outcome measures.

(a) * * *

(3) The OPO data reports, averaged over the 4 years of the recertification cycle, must meet the rules and requirements of the most current OPTN aggregate donor yield measure.

(i) The initial criteria used to identify OPOs with lower than expected organ yield, for all organs as well as for each organ type, will include all of the following:

(A) More than 10 fewer observed organs per 100 donors than expected yield (Observed per 100 donors—Expected per 100 donors < -10);

(B) A ratio of observed to expected yield less than 0.90; and

(C) A two-sided p-value is less than 0.05.

(ii) The number of organs used for research per donor, including pancreata used for islet cell research.

(b) * * *

(3) The OPO data reports, averaged over the 4 years of the recertification cycle, must meet the rules and requirements of the most current OPTN aggregate donor yield measure.

(i) The initial criteria used to identify OPOs with lower than expected organ yield, for all organs as well as for each organ type, will include all of the following:

(A) More than 10 fewer observed organs per 100 donors than expected yield (Observed per 100 donors—Expected per 100 donors < -10);

(B) A ratio of observed to expected yield less than 0.90; and

(C) A two-sided p-value is less than 0.05.

(ii) The number of organs used for research per donor, including pancreata used for islet cell research.

* * * * *

■ 20. Section 486.346 is amended by revising paragraph (b) to read as follows:

§ 486.346 Condition: Organ preparation and transport.

* * * * *

(b)(1) The OPO must send complete documentation of donor information to the transplant center with the organ, including donor evaluation, the complete record of the donor's management, documentation of consent, documentation of the pronouncement of death, and documentation for determining organ quality. This information is available to the transplant center electronically.

(2) The OPO must physically send a paper copy of the following documentation with each organ:

(i) Blood type;

(ii) Blood subtype, if used for allocation; and

(iii) Infectious disease testing results available at the time of organ packaging.

(3) The source documentation must be placed in a watertight container in either of the following:

(i) A location specifically designed for documentation; or

(ii) Between the inner and external transport materials.

(4) Two individuals, one of whom must be an OPO employee, must verify that the documentation that accompanies an organ to a transplant center is correct.

* * * * *

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 21. The authority citation for part 488 continues to read as follows:

Authority: Secs. 1102, 1128l, 1864, 1865, 1871 and 1875 of the Social Security Act, unless otherwise noted (42 U.S.C. 1302, 1320a-7j, 1395aa, 1395bb, 1395hh) and 1395ll.

■ 22. Section 488.61 is amended by revising paragraphs (f)(1) introductory text, (f)(3), and (h)(2) to read as follows:

§ 488.61 Special procedures for approval and re-approval of organ transplant centers.

* * * * *

(f) * * *

(1) *Factors.* Except for situations of immediate jeopardy or deficiencies other than failure to meet requirements of § 482.80 or § 482.82 of this chapter, CMS will consider such mitigating factors as may be appropriate in light of the nature of the deficiency and circumstances, including (but not

limited to) the following, in making a decision of initial and re-approval of a transplant center that does not meet the data submission, clinical experience, or outcome requirements:

* * * * *

(3) *Timing.* Within 14 calendar days after CMS has issued formal written notice of a condition-level deficiency to the program, CMS must receive notification of the program's intent to seek mitigating factors approval or re-approval, and receive all information for consideration of mitigating factors within 120 calendar days of the CMS written notification for a deficiency due to data submission, clinical experience or outcomes at § 482.80 or § 482.82 of this chapter. Failure to meet these timeframes may be the basis for denial of mitigating factors. However, CMS may permit an extension of the timeline for good cause, such as a declared public health emergency.

* * * * *

(h) * * *

(2) *Timeframe.* A Systems Improvement Agreement will be established for up to a 12-month period, subject to CMS' discretion to determine if a shorter timeframe may suffice. At the hospital's request, CMS may extend the agreement for up to an additional 6-month period. A signed Systems Improvement Agreement remains in force even if a subsequent SRTR report indicates that the program has restored compliance with the CMS conditions of participation, except that CMS in its sole discretion may shorten the timeframe or allow modification to any portion of the elements of the Agreement in such a case.

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 23. The authority citation for part 495 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 24. Section 495.4 is amended—

■ a. In the definition of "EHR reporting period", by revising paragraphs (1)(ii)(B)(2), (1)(ii)(C)(2), (2)(ii)(B)(2), and (2)(ii)(C)(2).

■ b. In the definition of "EHR reporting period for a payment adjustment year", by revising paragraphs (1)(ii)(B)(2), (2)(ii)(B)(2), (2)(ii)(C)(3), and (3)(ii)(B)(2), and (3)(ii)(C)(3).

The revisions read as follows:

§ 495.4 Definitions.

* * * * *

EHR reporting period. * * *

(1) * * *

(ii) * * *

(B) * * *

(2) For the EP who has successfully demonstrated he or she is a meaningful EHR user in any prior year, any continuous 90-day period within CY 2016.

(C) * * *

(2) For the EP who has successfully demonstrated he or she is a meaningful EHR user in any prior year, any continuous 90-day period within CY 2017.

* * * * *

(2) * * *

(ii) * * *

(B) * * *

(2) For the eligible hospital or CAH that has successfully demonstrated it is a meaningful EHR user in any prior year, any continuous 90-day period within CY 2016.

(C) * * *

(2) For the eligible hospital or CAH that has successfully demonstrated it is a meaningful EHR user in any prior year, any continuous 90-day period within CY 2017.

* * * * *

EHR reporting period for a payment adjustment year. * * *

(1) * * *

(ii) * * *

(B) * * *

(2) If in a prior year an EP has successfully demonstrated he or she is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2016 and applies for the CY 2018 payment adjustment year.

* * * * *

(2) * * *

(ii) * * *

(B) * * *

(2) If in a prior year an eligible hospital has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2016 and applies for the FY 2018 payment adjustment year.

(C) * * *

(3) If in a prior year an eligible hospital has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2017 and applies for the FY 2019 payment adjustment year.

* * * * *

(3) * * *

(ii) * * *

(B) * * *

(2) If in a prior year a CAH has successfully demonstrated it is a meaningful EHR user, the EHR reporting

period is any continuous 90-day period within CY 2016 and applies for the FY 2016 payment adjustment year.

(C) * * *

(3) If in a prior year a CAH has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2017 and applies for the FY 2017 payment adjustment year.

* * * * *

■ 25. Section 495.22 is amended by revising paragraphs (a), (c)(1), (d)(1), and the paragraph (e) heading, and adding paragraph (f) to read as follows:

§ 495.22 Meaningful use objectives and measures for EPs, eligible hospitals, and CAHs for 2015 through 2017.

(a) *General rules.* (1) Subject to the provisions of paragraph (a)(2) of this section, the criteria specified in this section are applicable for EPs, eligible hospitals, and CAHs for 2015 through 2017.

(2) For 2017 only, EPs, eligible hospitals, and CAHs that have successfully demonstrated meaningful use in a prior year have the option to use the criteria specified for 2018 in § 495.24 instead of the criteria specified for 2017 under paragraphs (e) and (f) of this section.

* * * * *

(c) * * *

(1) *General rule regarding criteria for meaningful use for 2015 through 2017 for eligible hospitals and CAHs.* Except as specified in paragraph (c)(2) of this section, eligible hospitals and CAHs attesting to CMS must meet all objectives and associated measures of the meaningful use criteria specified under paragraph (e) of this section to meet the definition of a meaningful EHR user in 2015 and 2016 and must meet all objectives and associated measures of the meaningful use criteria specified under paragraph (f) of this section to meet the definition of a meaningful EHR user in 2017. Except as specified in paragraph (c)(2) of this section, eligible hospitals and CAHs attesting to a State for the Medicaid EHR Incentive Program must meet all objectives and associated measures of the meaningful use criteria specified under paragraph (e) of this section to meet the definition of a meaningful EHR user in 2015 through 2017.

* * * * *

(d) * * *

(1) If a measure (or associated objective) in paragraph (e) or (f) of this section references this paragraph (d), the measure may be calculated by reviewing only the actions for patients whose records are maintained using CEHRT. A

patient's record is maintained using CEHRT if sufficient data were entered in the CEHRT to allow the record to be saved, and not rejected due to incomplete data.

* * * * *

(e) *Meaningful use objectives and measures for EPs for 2015 through 2017, for eligible hospitals and CAHs attesting to CMS for 2015 and 2016, and for eligible hospitals and CAHs attesting to a State for the Medicaid EHR Incentive Program for 2015 through 2017.*

* * * * *

(f) *Meaningful use objectives and measures for eligible hospitals and CAHs attesting to CMS for 2017.*—(1) *Protect patient health information*—(i) *Objective.* Protect electronic protected health information created or maintained by the CEHRT through the implementation of appropriate technical capabilities.

(ii) *Security risk analysis measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI created or maintained in CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary, and correct identified security deficiencies as part of the eligible hospital's or CAH's risk management process.

(2) [Reserved]

(3) [Reserved]

(4) *Electronic Prescribing*—(i) *Objective.* Generate and transmit permissible discharge prescriptions electronically (eRx).

(ii) *e-Prescribing measure.* Subject to the provisions of paragraph (d) of this section, more than 10 percent of hospital discharge medication orders for permissible prescriptions are queried for a drug formulary and transmitted electronically using CEHRT.

(iii) *Exclusion for nonapplicable objectives.* Subject to the provisions of paragraph (c)(2) of this section, any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and is not located within 10 miles of any pharmacy that accepts electronic prescriptions at the start of their EHR reporting period.

(5) *Health Information Exchange*—(i) *Objective.* The eligible hospital or CAH who transitions a patient to another setting of care or provider of care or refers a patient to another provider of care provides a summary care record for each transition of care or referral.

(ii) *Health information exchange measure.* Subject to the provisions of

paragraph (d) of this section, the eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care must do the following:

(A) Use CEHRT to create a summary of care record; and

(B) Electronically transmit such summary to a receiving provider for more than 10 percent of transitions of care and referrals.

(6) *Patient specific education*—(i) *Objective.* Use clinically relevant information from CEHRT to identify patient-specific education resources and provide those resources to the patient.

(ii) *Patient-specific education measure.* More than 10 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) are provided patient specific education resources identified by CEHRT.

(7) *Medication reconciliation*—(i) *Objective.* The eligible hospital or CAH that receives a patient from another setting of care or provider of care or believes an encounter is relevant performs medication reconciliation.

(ii) *Medication reconciliation measure.* Subject to the provisions of paragraph (d) of this section, the eligible hospital or CAH performs medication reconciliation for more than 50 percent of transitions of care in which the patient is admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23).

(8) *Patient electronic access*—(i) *Objective.* Provide patients the ability to view online, download, and transmit information within 36 hours of hospital discharge.

(ii) *Measures.* An eligible hospital or CAH must meet the following two measures:

(A) *Provide patient access measure.* More than 50 percent of all unique patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have timely access to view online, download, and transmit to a third party their health information.

(B) *View, download or transmit (VDT) measure.* At least 1 patient (or patient-authorized representative) who is discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH during the EHR reporting period views, downloads, or transmits to a third party his or her information during the EHR reporting period.

(iii) *Exclusion for nonapplicable objectives.* Subject to the provisions of paragraph (c)(2) of this section, any eligible hospital or CAH that is located in a county that does not have 50

percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period is excluded from paragraph (f)(8)(ii)(B) of this section.

(9) *Public health reporting*—(i) *Objective.* The eligible hospital or CAH is in active engagement with a public health agency to submit electronic public health data from CEHRT, except where prohibited, and in accordance with applicable law and practice.

(ii) *Measures.* In order to meet the objective under paragraph (f)(9)(i) of this section, an eligible hospital or CAH must choose from measures 1 through 4 (as described in paragraphs (f)(9)(ii)(A) through (D) of this section).

(A) *Immunization registry reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit immunization data.

(B) *Syndromic surveillance reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data.

(C) *Specialized registry reporting measure.* The eligible hospital or CAH is in active engagement to submit data to a specialized registry.

(D) *Electronic reportable laboratory result reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results.

(iii) *Exclusions for non-applicable objectives.* Subject to the provisions of paragraph (c)(2) of this section—

(A) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the immunization measure specified in paragraph (f)(9)(ii)(A) of this section if the eligible hospital or CAH—

(1) Does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the EHR reporting period.

(2) Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(3) Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data from the eligible hospital or CAH at the start of the EHR reporting period.

(B) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance measure specified in paragraph (f)(9)(ii)(B) of this section if the eligible hospital or CAH—

(1) Does not have an emergency or urgent care department.

(2) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from eligible hospitals or CAHs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(3) Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs at the start of the EHR reporting period.

(C) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the specialized registry measure specified in paragraph (f)(9)(ii)(C) of this section if the eligible hospital or CAH—

(1) Does not diagnose or directly treat any disease associated with or collect relevant data is required by a specialized registry for which the eligible hospital or CAH is eligible in their jurisdiction.

(2) Operates in a jurisdiction for which no specialized registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or

(3) Operates in a jurisdiction where no specialized registry for which the eligible hospital or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

(D) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the electronic reportable laboratory result reporting measure specified in paragraph (f)(9)(ii)(D) of this section if the eligible hospital or CAH—

(1) Does not perform or order laboratory tests that are reportable in the eligible hospital's or CAH's jurisdiction during the EHR reporting period.

(2) Operates in a jurisdiction for which no public health agency that is capable of accepting the specific ELR standards required to meet the CEHRT definition at the start of the EHR reporting period.

(3) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic reportable laboratory results from

eligible hospitals or CAHs at the start of the EHR reporting period.

■ 26. Section 495.24 is revised to read as follows:

§ 495.24 Stage 3 meaningful use objectives and measures for EPs, eligible hospitals and CAHs for 2018 and subsequent years.

The criteria specified in paragraphs (c) and (d) of this section are optional for 2017 for EPs, eligible hospitals, and CAHs that have successfully demonstrated meaningful use in a prior year. The criteria specified in paragraph (c) of this section are applicable for eligible hospitals and CAHs attesting to CMS for 2018. The criteria specified in paragraph (d) of this section are applicable for all EPs for 2018 and subsequent years, and for eligible hospitals and CAHs attesting to a State for the Medicaid EHR Incentive Program for 2018.

(a) *Stage 3 criteria for EPs—(1) General rule regarding Stage 3 criteria for meaningful use for EPs.* Except as specified in paragraphs (a)(2) and (3) of this section, EPs must meet all objectives and associated measures of the Stage 3 criteria specified in paragraph (d) of this section to meet the definition of a meaningful EHR user.

(2) *Selection of measures for specified objectives in paragraph (d) of this section.* An EP may meet the criteria for 2 out of the 3 measures associated with an objective, rather than meeting the criteria for all 3 of the measures, if the EP meets all of the following requirements:

(i) Must ensure that the objective in paragraph (d) of this section includes an option to meet 2 out of the 3 associated measures.

(ii) Meets the threshold for 2 out of the 3 measures for that objective.

(iii) Attests to all 3 of the measures for that objective.

(3) *Exclusion for non-applicable objectives and measures.* (i) An EP may exclude a particular objective that includes an option for exclusion contained in paragraph (d) of this section, if the EP meets all of the following requirements:

(A) Meets the criteria in the applicable objective that would permit the exclusion.

(B) Attests to the exclusion.

(ii) An EP may exclude a measure within an objective which allows for a provider to meet the threshold for 2 of the 3 measures, as outlined in paragraph (a)(2) of this section, in the following manner:

(A)(1) Meets the criteria in the applicable measure or measures that would permit the exclusion; and

(2) Attests to the exclusion or exclusions.

(B)(1) Meets the threshold; and
(2) Attests to any remaining measure or measures.

(4) *Exception for Medicaid EPs who adopt, implement or upgrade in their first payment year.* For Medicaid EPs who adopt, implement, or upgrade its CEHRT in their first payment year, the meaningful use objectives and associated measures of the Stage 3 criteria specified in paragraph (d) of this section apply beginning with the second payment year, and do not apply to the first payment year.

(5) *Objectives and associated measures in paragraph (d) of this section that rely on measures that count unique patients or actions.* (i) If a measure (or associated objective) in paragraph (d) of this section references paragraph (a)(5) of this section, the measure may be calculated by reviewing only the actions for patients whose records are maintained using CEHRT. A patient's record is maintained using CEHRT if sufficient data were entered in the CEHRT to allow the record to be saved, and not rejected due to incomplete data.

(ii) If the objective and associated measure does not reference paragraph (a)(5) of this section, the measure must be calculated by reviewing all patient records, not just those maintained using CEHRT.

(b) *Stage 3 criteria for meaningful use for eligible hospitals and CAHs—(1) General rule.* Except as specified in paragraphs (b)(2) and (3) of this section, eligible hospitals and CAHs must meet all objectives and associated measures of the Stage 3 criteria specified in paragraphs (c) and (d) of this section, as applicable, to meet the definition of a meaningful EHR user.

(2) *Selection of measures for specified objectives in paragraphs (c) and (d) of this section.* An eligible hospital or CAH may meet the criteria for 2 out of the 3 measures associated with an objective, rather than meeting the criteria for all 3 of the measures, if the eligible hospital or CAH meets all of the following requirements:

(i) Must ensure that the objective in paragraph (c) or (d) of this section, as applicable, includes an option to meet 2 out of the 3 associated measures.

(ii) Meets the threshold for 2 out of the 3 measures for that objective.

(iii) Attests to all 3 of the measures for that objective.

(3) *Exclusion for nonapplicable objectives and measures.* (i) An eligible hospital or CAH may exclude a particular objective that includes an option for exclusion contained in

paragraph (c) or (d) of this section, as applicable, if the eligible hospital or CAH meets all of the following requirements:

(A) Meets the criteria in the applicable objective that would permit the exclusion.

(B) Attests to the exclusion.

(ii) An eligible hospital or CAH may exclude a measure within an objective which allows for a provider to meet the threshold for 2 of the 3 measures, as outlined in paragraph (b)(2) of this section, in the following manner:

(A)(1) Meets the criteria in the applicable measure or measures that would permit the exclusion; and

(2) Attests to the exclusion or exclusions.

(B)(1) Meets the threshold; and

(2) Attests to any remaining measure or measures.

(4) *Exception for Medicaid eligible hospitals or CAHs that adopt, implement or upgrade in their first payment year.* For Medicaid eligible hospitals or CAHs that adopt, implement or upgrade CEHRT in their first payment year, the meaningful use objectives and associated measures of the Stage 3 criteria specified in paragraph (c) or (d) of this section apply beginning with the second payment year, and do not apply to the first payment year.

(5) *Objectives and associated measures in paragraph (c) or (d) of this section that rely on measures that count unique patients or actions.* (i) If a measure (or associated objective) in paragraph (c) or (d) of this section, as applicable, references paragraph (b)(5) of this section, the measure may be calculated by reviewing only the actions for patients whose records are maintained using CEHRT. A patient's record is maintained using CEHRT if sufficient data were entered in the CEHRT to allow the record to be saved, and not rejected due to incomplete data.

(ii) If the objective and associated measure does not reference this paragraph (b)(5) of this section, the measure must be calculated by reviewing all patient records, not just those maintained using CEHRT.

(c) *Stage 3 objectives and measures for eligible hospitals and CAHs attesting to CMS for 2018.—(1) Protect patient health information.* (i) *Objective.* Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.

(ii) *Security risk analysis measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR

164.308(a)(1), including addressing the security (including encryption) of data created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.

(2) *Electronic prescribing.—(i) Objective.* Generate and transmit permissible discharge prescriptions electronically (eRx).

(ii) *e-Prescribing measure.* Subject to paragraph (b)(5) of this section, more than 25 percent of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.

(iii) *Exclusions in accordance with paragraph (b)(3) of this section.* Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of the eligible hospital or CAH's EHR reporting period.

(3) [Reserved]

(4) [Reserved]

(5) *Patient electronic access to health information.—(i) Objective.* The eligible hospital or CAH provides patients (or patient-authorized representative) with timely electronic access to their health information and patient-specific education.

(ii) *Measures.* Eligible hospitals and CAHs must meet the following two measures:

(A) *Provide patient access measure.* For more than 50 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):

(1) The patient (or patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and

(2) The provider ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider's CEHRT.

(B) *Patient-specific education measure.* The eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 10 percent of unique patients discharged from the eligible hospital or

CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

(iii) *Exclusion in accordance with paragraph (b)(3) of this section.* Any eligible hospital or CAH that is located in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period is excluded from the measures specified in paragraphs (c)(5)(ii)(A) and (B) of this section.

(6) *Coordination of care through patient engagement.—(i) Objective.* Use CEHRT to engage with patients or their authorized representatives about the patient's care.

(ii) *Measures.* In accordance with paragraph (b)(2) of this section, an eligible hospital or CAH must satisfy 2 of the 3 following measures in paragraphs (c)(6)(ii)(A), (B), and (C) of this section, except those measures for which an eligible hospital or CAH qualifies for an exclusion under paragraph (b)(3) of this section.

(A) *View, download or transmit (VDT) measure.* During the EHR reporting period, at least one unique patient (or their authorized representatives) discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engage with the electronic health record made accessible by the provider and one of the following:

(1) View, download or transmit to a third party their health information.

(2) Access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT; or

(3) A combination of paragraphs (c)(6)(ii)(A)(1) and (2) of this section.

(B) *Secure messaging measure.* During the EHR reporting period, more than 5 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient authorized representative), or in response to a secure message sent by the patient (or the patient authorized representative).

(C) *Patient generated health data.* Patient generated health data or data from a non-clinical setting is incorporated into the CEHRT for more than 5 percent of unique patients discharged from the eligible hospital or CAH inpatient or emergency department

(POS 21 or 23) during the EHR reporting period.

(iii) *Exclusions under paragraph (b)(3) of this section.* Any eligible hospital or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in paragraphs (c)(6)(ii)(A) through (C) of this section.

(7) *Health information exchange—(i) Objective.* The eligible hospital or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of CEHRT.

(ii) *Measures.* In accordance with paragraph (b)(2) of this section, a eligible hospital or CAH must attest to all 3 measures, but must meet the threshold for 2 of the 3 measures in paragraphs (e)(7)(ii)(A) through (C) of this section. Subject to paragraph (b)(5) of this section—

(A) *Send a summary of care measure.* For more than 10 percent of transitions of care and referrals, the eligible hospital or CAH that transitions or refers its patient to another setting of care or provider of care—

(1) Creates a summary of care record using CEHRT; and

(2) Electronically exchanges the summary of care record.

(B) *Request/accept summary of care measure.* For more than 10 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH incorporates into the patient's EHR an electronic summary of care document.

(C) *Clinical information reconciliation measure.* For more than 50 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH performs a clinical information reconciliation. The provider must implement clinical information reconciliation for the following three clinical information sets:

(1) *Medication.* Review of the patient's medication, including the name, dosage, frequency, and route of each medication.

(2) *Medication allergy.* Review of the patient's known allergic medications.

(3) *Current problem list.* Review of the patient's current and active diagnoses.

(iii) *Exclusions in accordance with paragraph (b)(3) of this section.* (A) Any eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period may be excluded from paragraphs (c)(7)(ii)(B) and (C) of this section.

(B) Any eligible hospital or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may be excluded from the measures specified in paragraphs (e)(7)(ii)(A) and (B) of this section.

(8) *Public health and clinical data registry reporting—(i) Objective.* The eligible hospital or CAH is in active engagement with a public health agency (PHA) or clinical data registry (CDR) to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.

(ii) *Measures.* In order to meet the objective under paragraph (c)(8)(i) of this section, an eligible hospital or CAH must choose from measures 1 through 6 (as described in paragraphs (c)(8)(ii)(A) through (F) of this section) and must successfully attest to any combination of three measures. These measures may be met by any combination, including meeting the measure specified in paragraphs (c)(8)(ii)(D) and (E) of this section multiple times, in accordance with applicable law and practice:

(A) *Immunization registry reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

(B) *Syndromic surveillance reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting.

(C) *Electronic case reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.

(D) *Public health registry reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit data to public health registries.

(E) *Clinical data registry reporting measure.* The eligible hospital or CAH is in active engagement to submit data to a clinical data registry.

(F) *Electronic reportable laboratory result reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results.

(iii) *Exclusions in accordance with paragraph (b)(3) of this section.* (A) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting measure specified in paragraph (c)(8)(ii)(A) of this section if the eligible hospital or CAH—

(1) Does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the EHR reporting period.

(2) Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(3) Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the EHR reporting period.

(B) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure specified in paragraph (c)(8)(ii)(B) of this section if the eligible hospital or CAH—

(1) Does not have an emergency or urgent care department.

(2) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(3) Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs as of 6 months prior to the start of the EHR reporting period.

(C) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the case reporting measure specified in paragraph (e)(8)(ii)(C) of this section if the eligible hospital or CAH—

(1) Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the EHR reporting period.

(2) Operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of their EHR reporting period.

(3) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the EHR reporting period.

(D) Any eligible hospital or CAH meeting at least one of the following criteria may be excluded from the public health registry reporting measure specified in paragraph (c)(8)(ii)(D) of this section if the eligible hospital or CAH—

(1) Does not diagnose or directly treat any disease or condition associated with a public health registry in its jurisdiction during the EHR reporting period.

(2) Operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(3) Operates in a jurisdiction where no public health registry for which the eligible hospital or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

(E) Any eligible hospital or CAH meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure specified in paragraph (c)(8)(ii)(E) of this section if the eligible hospital or CAH—

(1) Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period.

(2) Operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(3) Operates in a jurisdiction where no clinical data registry for which the eligible hospital or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

(F) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the electronic reportable laboratory result reporting measure specified in paragraph (c)(8)(ii)(F) of this section if the eligible hospital or CAH—

(1) Does not perform or order laboratory tests that are reportable in its jurisdiction during the EHR reporting period.

(2) Operates in a jurisdiction for which no public health agency that is capable of accepting the specific ELR standards required to meet the CEHRT definition at the start of the EHR reporting period.

(3) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic reportable laboratory results from an eligible hospital or CAH as of 6 months prior to the start of the EHR reporting period.

(d) *Stage 3 objectives and measures for all EPs for 2018 and subsequent years, and for eligible hospitals and CAHs attesting to a State for the Medicaid EHR Incentive Program for 2018—*(1) *Protect patient health information—*(i) *EP protect patient health information—*(A) *Objective.* Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.

(B) *Measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including encryption) of data created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.

(ii) *Eligible hospital/CAH protect patient health information—*(A) *Objective.* Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.

(B) *Measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including encryption) of data created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.

(2) *Electronic Prescribing—*(i) *EP Electronic Prescribing—*(A) *Objective.* Generate and transmit permissible prescriptions electronically (eRx).

(B) *Measure.* Subject to paragraph (a)(5) of this section, more than 60 percent of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.

(C) *Exclusions in accordance with paragraph (a)(3) of this section.* (1) Any EP who writes fewer than 100 permissible prescriptions during the EHR reporting period; or

(2) Any EP who does not have a pharmacy within its organization and there are no pharmacies that accept electronic prescriptions within 10 miles of the EP's practice location at the start of his/her EHR reporting period.

(ii) *Eligible hospital/CAH electronic prescribing—*(A) *Objective.* Generate and transmit permissible discharge prescriptions electronically (eRx).

(B) *Measure.* Subject to paragraph (b)(5) of this section, more than 25 percent of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.

(C) *Exclusions in accordance with paragraph (b)(3) of this section.* Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of the eligible hospital or CAH's EHR reporting period.

(3) *Clinical decision support—*(i) *EP clinical decision support—*(A) *Objective.* Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.

(B) *Measures.* (1) Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an EP's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions; and

(2) The EP has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

(C) *Exclusion in accordance with paragraph (a)(3) of this section for paragraph (d)(3)(i)(B)(2) of this section.* An EP who writes fewer than 100 medication orders during the EHR reporting period.

(ii) *Eligible hospital/CAH clinical decision support—*(A) *Objective.* Implement clinical decision support (CDS) interventions focused on

improving performance on high-priority health conditions.

(B) *Measures*—(1) Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an eligible hospital or CAH's patient population, the clinical decision support interventions must be related to high-priority health conditions; and

(2) The eligible hospital or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

(4) *Computerized provider order entry (CPOE)*—(i) *EP CPOE*—(A) *Objective*. Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant, who can enter orders into the medical record per state, local, and professional guidelines.

(B) *Measures*. Subject to paragraph (a)(5) of this section—

(1) More than 60 percent of medication orders created by the EP during the EHR reporting period are recorded using computerized provider order entry;

(2) More than 60 percent of laboratory orders created by the EP during the EHR reporting period are recorded using computerized provider order entry; and

(3) More than 60 percent of diagnostic imaging orders created by the EP during the EHR reporting period are recorded using computerized provider order entry.

(C) *Exclusions in accordance with paragraph (a)(3) of this section*. (1) For the measure specified in paragraph (d)(4)(i)(B)(1) of this section, any EP who writes fewer than 100 medication orders during the EHR reporting period.

(2) For the measure specified in paragraph (d)(4)(i)(B)(2) of this section, any EP who writes fewer than 100 laboratory orders during the EHR reporting period.

(3) For the measure specified in paragraph (d)(4)(i)(B)(3) of this section, any EP who writes fewer than 100 diagnostic imaging orders during the EHR reporting period.

(ii) *Eligible hospital and CAH CPOE*—(A) *Objective*. Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a

medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per State, local, and professional guidelines.

(B) *Measures*. Subject to paragraph (b)(5) of this section—

(1) More than 60 percent of medication orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry;

(2) More than 60 percent of laboratory orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry; and

(3) More than 60 percent of diagnostic imaging orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

(5) *Patient electronic access to health information*—(i) *EP patient electronic access to health information*—(A) *Objective*. The EP provides patients (or patient-authorized representative) with timely electronic access to their health information and patient-specific education.

(B) *Measures*. EPs must meet the following two measures:

(1) For more than 80 percent of all unique patients seen by the EP—

(i) The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and

(ii) The provider ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider's CEHRT.

(2) The EP must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients seen by the EP during the EHR reporting period.

(C) *Exclusions in accordance with paragraph (a)(3) of this section*. (1) Any EP who has no office visits during the reporting period may exclude from the measures specified in paragraphs (d)(5)(i)(B)(1) and (2) of this section.

(2) Any EP that conducts 50 percent or more of his or her patient encounters

in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in paragraphs (d)(5)(i)(B)(1) and (2) of this section.

(ii) *Eligible hospital and CAH patient electronic access to health information*—(A) *Objective*. The eligible hospital or CAH provides patients (or patient-authorized representative) with timely electronic access to their health information and patient-specific education.

(B) *Measures*. Eligible hospitals and CAHs must meet the following two measures:

(1) For more than 80 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):

(i) The patient (or patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and

(ii) The provider ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider's CEHRT.

(2) The eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

(C) *Exclusion in accordance with paragraph (b)(3) of this section*. Any eligible hospital or CAH that is located in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period is excluded from the measures specified in paragraphs (d)(5)(ii)(B)(1) and (2) of this section.

(6) *Coordination of care through patient engagement*—(i) *EP coordination of care through patient engagement*—(A) *Objective*. Use CEHRT to engage with patients or their authorized representatives about the patient's care.

(B) *Measures*. In accordance with paragraph (a)(2) of this section, an EP must satisfy 2 out of the 3 following

measures in paragraphs (d)(6)(i)(B)(1) through (3) of this section except those measures for which an EP qualifies for an exclusion under paragraph (a)(3) of this section.

(1) During the EHR reporting period, more than 10 percent of all unique patients (or their authorized representatives) seen by the EP actively engage with the electronic health record made accessible by the provider and either of the following:

(i) View, download or transmit to a third party their health information;

(ii) their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT; or

(iii) A combination of paragraphs (d)(6)(i)(B)(1)(i) and (ii) of this section.

(iv) For an EHR reporting period in 2017 only, an EP may meet a threshold of 5 percent instead of 10 percent for the measure at paragraph (d)(6)(i)(B)(1) of this section.

(2) During the EHR reporting period—

(i) For an EHR reporting period in 2017 only, for more than 5 percent of all unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient; or

(ii) For an EHR reporting period other than 2017, for more than 25 percent of all unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient.

(3) Patient generated health data or data from a nonclinical setting is incorporated into the CEHRT for more than 5 percent of all unique patients seen by the EP during the EHR reporting period.

(C) *Exclusions in accordance with paragraph (a)(3) of this section.* (1) Any EP who has no office visits during the reporting period may exclude from the measures specified in paragraphs (d)(6)(i)(B)(1) through (3) of this section.

(2) Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in paragraphs (d)(6)(i)(B)(1) through (3) of this section.

(ii) *Eligible hospital and CAH coordination of care through patient engagement—(A) Objective.* Use CEHRT to engage with patients or their authorized representatives about the patient's care.

(B) *Measures.* In accordance with paragraph (b)(2) of this section, an eligible hospital or CAH must satisfy 2 of the 3 following measures in paragraphs (d)(6)(ii)(B)(1) through (3) of this section, except those measures for which an eligible hospital or CAH qualifies for an exclusion under paragraph (b)(3) of this section.

(1) During the EHR reporting period, more than 10 percent of all unique patients (or their authorized representatives) discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engage with the electronic health record made accessible by the provider and one of the following:

(i) View, download or transmit to a third party their health information.

(ii) Access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT.

(iii) A combination of paragraphs (d)(6)(ii)(B)(1)(i) and (ii) of this section.

(iv) For an EHR reporting period in 2017, an eligible hospital or CAH may meet a threshold of 5 percent instead of 10 percent for the measure at paragraph (d)(6)(ii)(B)(1) of this section.

(2) During the EHR reporting period—

(i) For an EHR reporting period in 2017 only, for more than 5 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient (or their authorized representatives).

(ii) For an EHR reporting period other than 2017, for more than 25 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient (or their authorized representatives).

(3) Patient generated health data or data from a non-clinical setting is incorporated into the CEHRT for more than 5 percent of unique patients discharged from the eligible hospital or CAH inpatient or emergency department

(POS 21 or 23) during the EHR reporting period.

(C) *Exclusions under paragraph (b)(3) of this section.* Any eligible hospital or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in paragraphs (d)(6)(ii)(B)(1) through (3) of this section.

(7) *Health information exchange—(i) EP health information exchange—(A) Objective.* The EP provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of CEHRT.

(B) *Measures.* In accordance with paragraph (a)(2) of this section, an EP must attest to all 3 measures, but must meet the threshold for 2 of the 3 measures in paragraphs (d)(7)(i)(B)(1) through (3) of this section, in order to meet the objective. Subject to paragraph (c) of this section—

(1) *Measure 1.* For more than 50 percent of transitions of care and referrals, the EP that transitions or refers their patient to another setting of care or provider of care—

(i) Creates a summary of care record using CEHRT; and

(ii) Electronically exchanges the summary of care record.

(2) *Measure 2.* For more than 40 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP incorporates into the patient's EHR an electronic summary of care document.

(3) *Measure 3.* For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP performs clinical information reconciliation. The EP must implement clinical information reconciliation for the following three clinical information sets:

(i) *Medication.* Review of the patient's medication, including the name, dosage, frequency, and route of each medication.

(ii) *Medication allergy.* Review of the patient's known allergic medications.

(iii) *Current problem list.* Review of the patient's current and active diagnoses.

(C) *Exclusions in accordance with paragraph (a)(3) of this section.* An EP must be excluded when any of the following occur:

(1) Any EP who transfers a patient to another setting or refers a patient to another provider less than 100 times during the EHR reporting period must be excluded from paragraph (d)(7)(i)(B)(1) of this section.

(2) Any EP for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period may be excluded from paragraphs (d)(7)(i)(B)(2) and (3) of this section.

(3) Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in paragraphs (d)(7)(i)(B)(1) and (2) of this section.

(ii) *Eligible hospitals and CAHs health information exchange—(A) Objective.* The eligible hospital or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of CEHRT.

(B) *Measures.* In accordance with paragraph (b)(2) of this section, an eligible hospital or CAH must attest to all three measures, but must meet the threshold for 2 of the 3 measures in paragraphs (d)(7)(ii)(B)(1) through (3) of this section. Subject to paragraph (b)(5) of this section—

(1) *Measure 1.* For more than 50 percent of transitions of care and referrals, the eligible hospital or CAH that transitions or refers its patient to another setting of care or provider of care—

(i) Creates a summary of care record using CEHRT; and

(ii) Electronically exchanges the summary of care record.

(2) *Measure 2.* For more than 40 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH incorporates into the patient's EHR an electronic summary of care document from a source other than the provider's EHR system.

(3) *Measure 3.* For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH performs a clinical information reconciliation. The provider must implement clinical information reconciliation for the following three clinical information sets:

(i) *Medication.* Review of the patient's medication, including the name, dosage, frequency, and route of each medication.

(ii) *Medication allergy.* Review of the patient's known allergic medications.

(iii) *Current problem list.* Review of the patient's current and active diagnoses.

(C) *Exclusions in accordance with paragraph (b)(3) of this section.* (1) Any eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period may be excluded from paragraphs (d)(7)(i)(B)(2) and (3) of this section.

(2) Any eligible hospital or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in paragraphs (d)(7)(ii)(B)(1) and (2) of this section.

(8) *Public Health and Clinical Data Registry Reporting—(i) EP Public Health and Clinical Data Registry: Reporting objective—(A) Objective.* The EP is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.

(B) *Measures.* In order to meet the objective under paragraph (d)(8)(i)(A) of this section, an EP must choose from measures 1 through 5 (paragraphs (d)(8)(i)(B)(1) through (5) of this section) and must successfully attest to any combination of two measures. These measures may be met by any combination, including meeting measure specified in paragraph (d)(8)(i)(B)(4) or (5) of this section multiple times, in accordance with applicable law and practice:

(1) *Immunization registry reporting.* The EP is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization

registry/immunization information system (IIS).

(2) *Syndromic surveillance reporting.* The EP is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting.

(3) *Electronic case reporting.* The EP is in active engagement with a public health agency to submit case reporting of reportable conditions.

(4) *Public health registry reporting.* The EP is in active engagement with a public health agency to submit data to public health registries.

(5) *Clinical data registry reporting.* The EP is in active engagement to submit data to a clinical data registry.

(C) *Exclusions in accordance with paragraph (a)(3) of this section.* (1) Any EP meeting one or more of the following criteria may be excluded from the immunization registry reporting measure in paragraph (d)(8)(i)(B)(1) of this section if the EP—

(i) Does not administer any immunizations to any of the populations for which data is collected by their jurisdiction's immunization registry or immunization information system during the EHR reporting period.

(ii) Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of its EHR reporting period.

(iii) Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the EHR reporting period.

(2) Any EP meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure described in paragraph (d)(8)(i)(B)(2) of the section if the EP—

(i) Is not in a category of providers from which ambulatory syndromic surveillance data is collected by their jurisdiction's syndromic surveillance system.

(ii) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from EPs as of 6 months prior to the start of the EHR reporting period.

(3) Any EP meeting one or more of the following criteria may be excluded from

the case reporting measure at paragraph (d)(8)(i)(B)(3) of this section if the EP:

(i) Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the EHR reporting period.

(ii) Operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the EHR reporting period.

(4) Any EP meeting at least one of the following criteria may be excluded from the public health registry reporting measure specified in paragraph (d)(8)(i)(B)(4) of this section if the EP—

(i) Does not diagnose or directly treat any disease or condition associated with a public health registry in the EP's jurisdiction during the EHR reporting period.

(ii) Operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

(5) Any EP meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure specified in paragraph (d)(8)(i)(B)(5) of this section if the EP—

(i) Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period.

(ii) Operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no clinical data registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

(ii) *Eligible hospital and CAH Public Health and Clinical Data Registry: Reporting objective—(A) Objective.* The eligible hospital or CAH is in active engagement with a public health agency

(PHA) or clinical data registry (CDR) to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.

(B) *Measures.* In order to meet the objective under paragraph (d)(8)(ii)(A) of this section, an eligible hospital or CAH must choose from measures 1 through 6 (as described in paragraphs (d)(8)(ii)(B)(1) through (6) of this section) and must successfully attest to any combination of four measures.

These measures may be met by any combination, including meeting the measure specified in paragraph (d)(8)(ii)(B)(4) or (5) of this section multiple times, in accordance with applicable law and practice:

(1) *Immunization registry reporting.* The eligible hospital or CAH is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

(2) *Syndromic surveillance reporting.* The eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting.

(3) *Case reporting.* The eligible hospital or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.

(4) *Public health registry reporting.* The eligible hospital or CAH is in active engagement with a public health agency to submit data to public health registries.

(5) *Clinical data registry reporting.* The eligible hospital or CAH is in active engagement to submit data to a clinical data registry.

(6) *Electronic reportable laboratory result reporting.* The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results.

(C) *Exclusions in accordance with paragraph (b)(3) of this section.* (1) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from to the immunization registry reporting measure specified in paragraph (d)(8)(ii)(B)(1) of this section if the eligible hospital or CAH—

(i) Does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the EHR reporting period.

(ii) Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific CEHRT

definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the EHR reporting period.

(2) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure specified in paragraph (d)(8)(ii)(B)(2) of this section if the eligible hospital or CAH—

(i) Does not have an emergency or urgent care department.

(ii) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs as of 6 months prior to the start of the EHR reporting period.

(3) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the case reporting measure specified in paragraph (d)(8)(ii)(B)(3) of this section if the eligible hospital or CAH—

(i) Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the EHR reporting period.

(ii) Operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of their EHR reporting period.

(iii) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the EHR reporting period.

(4) Any eligible hospital or CAH meeting at least one of the following criteria may be excluded from the public health registry reporting measure specified in paragraph (d)(8)(ii)(B)(4) of this section if the eligible hospital or CAH—

(i) Does not diagnose or directly treat any disease or condition associated with a public health registry in its jurisdiction during the EHR reporting period.

(ii) Operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards

required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health registry for which the eligible hospital or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

(5) Any eligible hospital or CAH meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure specified in paragraph (d)(8)(ii)(B)(5) of this section if the eligible hospital or CAH—

(i) Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period.

(ii) Operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no clinical data registry for which the eligible hospital or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

(6) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the electronic reportable laboratory result reporting measure specified in paragraph (d)(8)(ii)(B)(6) of this section if the eligible hospital or CAH—

(i) Does not perform or order laboratory tests that are reportable in its jurisdiction during the EHR reporting period.

(ii) Operates in a jurisdiction for which no public health agency that is capable of accepting the specific ELR standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic reportable laboratory results from an eligible hospital or CAH as of 6 months prior to the start of the EHR reporting period.

■ 27. Section 495.40 is amended by—

■ a. Revising paragraph (a) introductory text.

■ b. Revising paragraphs (a)(2)(i)(E) and (F).

■ c. Adding paragraph (a)(2)(i)(G).

■ d. Revising paragraphs (b) introductory text and (b)(2)(i)(E) and (F).

■ e. Redesignating paragraph (b)(2)(i)(G) as paragraph (b)(2)(i)(H).

■ f. Adding a new paragraph (b)(2)(i)(G). The revisions and additions read as follows:

§ 495.40 Demonstration of meaningful use criteria.

(a) *Demonstration by EPs.* An EP must demonstrate that he or she satisfies each of the applicable objectives and associated measures under § 495.20 or § 495.24, as follows:

* * * * *

(2) * * *

(i) * * *

(E) For CYs 2015 through 2016, satisfied the required objectives and associated measures under § 495.22(e) for meaningful use.

(F) For CY 2017: An EP that has successfully demonstrated it is a meaningful EHR user in any prior year may satisfy either the objectives and measures specified in § 495.22(e) for meaningful use or the objectives and measures specified in § 495.24(d) for meaningful use; an EP that has never successfully demonstrated it is a meaningful EHR user in any prior year must satisfy the objectives and measures specified in § 495.22(e) for meaningful use.

(G) For CY 2018 and subsequent years, satisfied the required objectives and associated measures under § 495.24(d) for meaningful use.

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(b) *Demonstration by eligible hospitals and CAHs.* To successfully demonstrate that it is a meaningful EHR user, an eligible hospital or CAH must satisfy the following requirements:

* * * * *

(2) * * *

(i) * * *

(E) For CYs 2015 through 2016, satisfied the required objectives and associated measures under § 495.22(e) for meaningful use.

(F) For CY 2017:

(1) For an eligible hospital or CAH attesting to CMS: An eligible hospital or CAH that has successfully demonstrated it is a meaningful EHR user in any prior year may satisfy either the objectives and measures specified in § 495.22(f) for meaningful use or the objectives and measures specified in § 495.24(c) for meaningful use; an eligible hospital or CAH that has never successfully demonstrated it is a meaningful EHR user in any prior year must satisfy the objectives and measures specified in § 495.22(f) for meaningful use.

(2) For an eligible hospital or CAH attesting to a State for the Medicaid EHR

Incentive Program: An eligible hospital or CAH that has successfully demonstrated it is a meaningful EHR user in any prior year may satisfy either the objectives and measures specified in § 495.22(e) for meaningful use or the objectives and measures specified in § 495.24(d) for meaningful use; an eligible hospital or CAH that has never successfully demonstrated it is a meaningful EHR user in any prior year must satisfy the objectives and measures specified in § 495.22(e) for meaningful use.

(G) For CY 2018:

(1) For an eligible hospital or CAH attesting to CMS, satisfied the required objectives and associated measures under § 495.24(c) for meaningful use.

(2) For an eligible hospital or CAH attesting to a State for the Medicaid EHR Incentive Program, satisfied the required objectives and associated measures under § 495.24(d) for meaningful use.

* * * * *

■ 28. Section 495.102 is amended by adding paragraph (d)(4)(v) to read as follows:

§ 495.102 Incentive payments to EPs.

* * * * *

(d) * * *

(4) * * *

(v) For the 2018 payment adjustment only, an EP who has not successfully demonstrated meaningful use in a prior year, intends to attest to meaningful use for an EHR reporting period in 2017 by October 1, 2017 to avoid the 2018 payment adjustment, and intends to transition to the Merit-Based Incentive Payment System (MIPS) and report on measures specified for the advancing care information performance category under the MIPS in 2017. The EP must explain in the application why demonstrating meaningful use for an EHR reporting period in 2017 would result in a significant hardship. Applications requesting this exception must be submitted no later than October 1, 2017, or a later date specified by CMS.

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Dated: October 25, 2016.

Andrew M. Slavitt,
Acting Administrator, Centers for Medicare and Medicaid Services.

Dated: October 26, 2016.

Sylvia M. Burwell,
Secretary, Department of Health and Human Services.

[FR Doc. 2016-26515 Filed 11-1-16; 4:15 pm]

BILLING CODE 4120-01-P