This document is scheduled to be published in the
Federal Register on 07/14/2016 and available online at
http://federalregister.gov/a/2016-16098, and on **FDsys.gov**

CMS-1656-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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

[CMS-1656-P]

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 Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program

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

ACTION: Proposed rule.

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

Further, in this proposed rule, we are proposing to make 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 proposing to remove the HCAHPS Pain Management dimension from the Hospital Value-Based Purchasing (VBP) Program. In addition, we are proposing to implement section 603 of the Bipartisan Budget Act of 2015 relating to payment for certain items and services furnished by certain off-campus outpatient departments of a provider.

DATES: Comment period: To be assured consideration, comments on all sections of this proposed rule must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on September 6, 2016**.**

ADDRESSES: In commenting, please refer to file code CMS-1656-P. 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,

CMS-1656-P

Attention: CMS-1656-P,

P.O. Box 8013,

Baltimore, MD 21244-1850.

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

3. By express or overnight mail. You may send written comments via express or overnight mail to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1656-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

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

a. For delivery in Washington, DC—

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, S.W.,

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 Carol Schwartz at (410) 786-0576.

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 OPPS and ASC Payment Files, contact Chuck Braver at (410) 786-9379.

Composite APCs (Extended Assessment and Management, Low Dose Brachytherapy, 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.

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

OPPS 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 or Erick Chuang at (410) 786-1816.

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

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

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

OPPS Pass-Through Devices and New Technology Procedures/Services, contact Carol Schwartz at (410) 786-0576.

OPPS 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 (Off-Campus Departments of a Provider), contact David Rice at (410) 786-6004 or Elisabeth Daniel at (410) 786-0237.

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 Marjorie Baldo at (410) 786-4617.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following 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.

Electronic Access

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

Addenda Available Only Through the Internet on the CMS Web Site

In the past, a majority of the Addenda referred to in our OPPS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with the CY 2012 OPPS/ASC proposed rule, all of the Addenda no longer appear in the **Federal Register** as part of the annual OPPS/ASC proposed and final rules to decrease administrative burden and reduce costs associated with publishing lengthy tables. Instead, these Addenda are published and available only on the CMS Web site. The Addenda relating to the OPPS are available at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html. The Addenda relating to the ASC payment

system are available at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/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
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, Pub. L. 105-33
BBRA	Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Pub. L. 106-113
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. 106-554
BLS	Bureau of Labor Statistics
CAH	Critical access hospital
CAHPS	Consumer Assessment of Healthcare Providers and Systems

CAP	Competitive Acquisition Program
C-APC	Comprehensive Ambulatory Payment Classification
CASPER	Certification and Survey Provider Enhanced Reporting
CAUTI	Catheter-associated urinary tract infection
CBSA	Core-Based Statistical Area
CCM	Chronic care management
CCN	CMS Certification Number
CCR	Cost-to-charge ratio
CDC	Centers for Disease Control and Prevention
CED	Coverage with Evidence Development
CERT	Comprehensive Error Rate Testing
CfC	Conditions of coverage
CFR	Code of Federal Regulations
CI	Comment indicator
CLABSI	Central Line [Catheter] Associated Blood Stream Infection
CLFS	Clinical Laboratory Fee Schedule
CMHC	Community mental health center
CMS	Centers for Medicare & Medicaid Services
CoP	Condition of participation
CPI-U	Consumer Price Index for All Urban Consumers
CPT	Current Procedural Terminology (copyrighted by the American Medical Association)

CR	Change request
CRC	Colorectal cancer
CSAC	Consensus Standards Approval Committee
CT	Computed tomography
CV	Coefficient of variation
CY	Calendar year
DFO	Designated Federal Official
DIR	Direct or indirect remuneration
DME	Durable medical equipment
DMEPOS	Durable Medical Equipment, Prosthetic, Orthotics, and Supplies
DRA	Deficit Reduction Act of 2005, Pub. L. 109-171
DSH	Disproportionate share hospital
EACH	Essential access community hospital
EAM	Extended assessment and management
ECD	Expanded criteria donor
EBRT	External beam radiotherapy
ECG	Electrocardiogram
ED	Emergency department
EDTC	Emergency department transfer communication
EHR	Electronic health record
E/M	Evaluation and management
ESRD	End-stage renal disease

ESRD QIP	End-Stage Renal Disease Quality Improvement Program
FACA	Federal Advisory Committee Act, Pub. L. 92-463
FDA	Food and Drug Administration
FFS	[Medicare] Fee-for-service
FTE	Full-time equivalent
FY	Fiscal year
GAO	Government Accountability Office
GI	Gastrointestinal
GME	Graduate medical education
HAI	Healthcare-associated infection
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems
HCERA	Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152
HCP	Health care personnel
HCPCS	Healthcare Common Procedure Coding System
HCRIS	Healthcare Cost Report Information System
HCUP	Healthcare Cost and Utilization Project
HEU	Highly enriched uranium
HH QRP	Home Health Quality Reporting Program
HHS	Department of Health and Human Services
HIE	Health information exchange
HIPAA	Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191

HOP	Hospital Outpatient Payment [Panel]
HOPD	Hospital outpatient department
HOP QDRP	Hospital Outpatient Quality Data Reporting Program
HPMS	Health Plan Management System
IBD	Inflammatory bowel disease
ICC	Interclass correlation coefficient
ICD	Implantable cardioverter defibrillator
ICD-9-CM	International Classification of Diseases, Ninth Revision, Clinical Modification
ICD-10	International Classification of Diseases, Tenth Revision
ICH	In-center hemodialysis
ICR	Information collection requirement
IME	Indirect medical education
IDTF	Independent diagnostic testing facility
IGI	IHS Global Insight, Inc.
IHS	Indian Health Service
I/OCE	Integrated Outpatient Code Editor
IOL	Intraocular lens
IORT	Intraoperative radiation treatment
IPFQR	Inpatient Psychiatric Facility Quality Reporting
IPPS	[Hospital] Inpatient Prospective Payment System
IQR	[Hospital] Inpatient Quality Reporting

IRF	Inpatient rehabilitation facility
IRF QRP	Inpatient Rehabilitation Facility Quality Reporting Program
IT	Information technology
LCD	Local coverage determination
LDR	Low dose rate
LTCH	Long-term care hospital
LTCHQR	Long-Term Care Hospital Quality Reporting
MAC	Medicare Administrative Contractor
MACRA	Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. 114-10
MAP	Measure Application Partnership
MDH	Medicare-dependent, small rural hospital
MedPAC	Medicare Payment Advisory Commission
MEG	Magnetoencephalography
MFP	Multifactor productivity
MGCRB	Medicare Geographic Classification Review Board
MIEA-TRHCA	Medicare Improvements and Extension Act under Division B, Title I of the Tax Relief Health Care Act of 2006, Pub. L. 109-432
MIPPA	Medicare Improvements for Patients and Providers Act of 2008, Pub. L. 110-275
MLR	Medical loss ratio
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173

MMEA	Medicare and Medicaid Extenders Act of 2010, Pub. L. 111-309
MMSEA	Medicare, Medicaid, and SCHIP Extension Act of 2007, Pub. L. 110-173
MPFS	Medicare Physician Fee Schedule
MR	Medical review
MRA	Magnetic resonance angiography
MRgFUS	Magnetic Resonance Image Guided Focused Ultrasound
MRI	Magnetic resonance imaging
MRSA	Methicillin-Resistant Staphylococcus Aures
MS-DRG	Medicare severity diagnosis-related group
MSIS	Medicaid Statistical Information System
MUC	Measure under consideration
NCCI	National Correct Coding Initiative
NEMA	National Electrical Manufacturers Association
NHSN	National Healthcare Safety Network
NOTA	National Organ and Transplantation Act
NOS	Not otherwise specified
NPI	National Provider Identifier
NPWT	Negative Pressure Wound Therapy
NQF	National Quality Forum
NQS	National Quality Strategy
NTIOL	New technology intraocular lens
NUBC	National Uniform Billing Committee

OACT	[CMS] Office of the Actuary
OBRA	Omnibus Budget Reconciliation Act of 1996, Pub. L. 99-509
O/E	Observed to expected event
OIG	[HHS] Office of the Inspector General
OMB	Office of Management and Budget
ONC	Office of the National Coordinator for Health Information Technology
OPD	[Hospital] Outpatient Department
OPO	Organ Procurement Organization
OPPS	[Hospital] Outpatient Prospective Payment System
OPSF	Outpatient Provider-Specific File
OPTN	Organ Procurement and Transplantation Network
OQR	[Hospital] Outpatient Quality Reporting
OT	Occupational therapy
PAMA	Protecting Access to Medicare Act of 2014, Pub. L. 113-93
PCHQR	PPS-Exempt Cancer Hospital Quality Reporting
PCR	Payment-to-cost ratio
PDC	Per day cost
PDE	Prescription Drug Event
PE	Practice expense
PEPPER	Program Evaluation Payment Patterns Electronic Report
PHP	Partial hospitalization program
PHSA	Public Health Service Act, Pub. L. 96-88

PN	Pneumonia
POS	Place of service
PPI	Producer Price Index
PPS	Prospective payment system
PQRI	Physician Quality Reporting Initiative
PQRS	Physician Quality Reporting System
QDC	Quality data code
QIO	Quality Improvement Organization
RFA	Regulatory Flexibility Act
RHQDAPU	Reporting Hospital Quality Data for Annual Payment Update
RTI	Research Triangle Institute, International
RVU	Relative value unit
SAD	Self-administered drug
SAMS	Secure Access Management Services
SCH	Sole community hospital
SCOD	Specified covered outpatient drugs
SES	Socioeconomic status
SI	Status indicator
SIA	Systems Improvement Agreement
SIR	Standardized infection ratio
SNF	Skilled nursing facility
SRS	Stereotactic radiosurgery

SRTR	Scientific Registry of Transplant Recipients
SSA	Social Security Administration
SSI	Surgical site infection
TEP	Technical Expert Panel
TIP	Transprostatic implant procedure
TOPs	Transitional Outpatient Payments
USPSTF	United States Preventive Services Task Force
VBP	Value-based purchasing
WAC	Wholesale acquisition cost

Table of Contents

I. Summary and Background

A. Executive Summary of This Document

1. Purpose

2. Summary of the Major Provisions

3. Summary of Costs and Benefits

B. Legislative and Regulatory Authority for the Hospital OPPS

C. Excluded OPPS Services and Hospitals

D. Prior Rulemaking

E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)

1. Authority of the Panel

2. Establishment of the Panel

3. Panel Meetings and Organizational Structure

F. Public Comments Received in Response to CY 2016 OPPS/ASC Final Rule with Comment Period

II. Proposed Updates Affecting OPPS Payments

A. Proposed Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

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

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

a. Recommendations of the Panel Regarding Data Development

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

(1) Blood and Blood Products

(2) Brachytherapy Sources

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

(1) Background

(2) Proposed C-APCs for CY 2017

(a) Proposed Additional CY 2017 C-APCs

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

d. Proposed Calculation of Composite APC Criteria-Based Costs

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

(2) Mental Health Services Composite APC

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

3. Proposed Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPS

b. Proposed Clinical Diagnostic Laboratory Test Packaging Policy

(1) Background

(2) Proposed "Unrelated" Laboratory Test Exception

(3) Proposed Molecular Pathology Test Exception

c. Conditional Packaging Status Indicators "Q1" and "Q2"

(1) Background

(2) Proposed Change in Conditional Packaging Status Indicators Logic

4. Proposed Calculation of OPPS Scaled Payment Weights

B. Proposed Conversion Factor Update

C. Proposed Wage Index Changes

D. Proposed Statewide Average Default CCRs

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

F. Proposed OPPS Payment to Certain Cancer Hospitals Described by Section 1886(d)(1)(B)(v) of the Act

1. Background

2. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2017

G. Proposed Hospital Outpatient Outlier Payments

1. Background

2. Proposed Outlier Calculation

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

I. Proposed Beneficiary Copayments

1. Background

2. Proposed OPPS Copayment Policy

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

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

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

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

2. Proposed Process for New Level II HCPCS Codes That Will Be Effective October 1, 2016 and January 1, 2017 for Which We Will Be Soliciting Public Comments in the CY 2017 OPPS/ASC Final Rule With Comment Period

3. Proposed Treatment of New and Revised CY 2017 Category I and III CPT Codes That Will Be Effective January 1, 2017 for Which We Are Soliciting Public Comments in This CY 2017 OPPS/ASC Proposed Rule

B. Proposed OPPS Changes--Variations within APCs

1. Background

2. Application of the 2 Times Rule

3. Proposed APC Exceptions to the 2 Times Rule

C. Proposed New Technology APCs

1. Background

2. Proposed Additional New Technology APC Groups

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

a. Overall Proposal

b. Retinal Prosthesis Implant Procedures

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

1. Imaging

2. Strapping and Cast Application (APCs 5101 and 5102)

3. Transprostatic Urethral Implant Procedure

IV. Proposed OPPS Payment for Devices

A. Proposed Pass-Through Payments for Devices

1. Expiration Dates for Current Transitional Pass-Through Devices

a. Background

b. Proposed CY 2017 Pass-Through Device Policy

2. New Device Pass-Through Applications

a. Background

b. Applications Received for Device Pass-Through Payment for CY 2017

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

(2) ENCORE™ Suspension System

(3) Endophys Pressure Sensing System (Endophys PSS) or Endophys Pressure Sensing Kit

3. Proposal to Change the Beginning Eligibility Date for Device Pass-Through Payment Status

4. Proposal 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

(b) Proposed CY 2017 Policy

5. Proposed Changes to Cost-to-Charge Ratios (CCRs) That Are Used to Determine Device Pass-Through Payment

a. Background

b. Proposed CY 2017 Policy

6. Proposed Provisions for Reducing Transitional Pass-Through Payments to Offset Costs Packaged into APC Groups

a. Background

b. Proposed CY 2017 Policy

B. Proposed Device-Intensive Procedures

1. Background

2. Proposed HCPCS Code-Level Device-Intensive Determination

3. Proposed Changes to Device Edit Policy

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

a. Background

b. Proposed Policy for CY 2017

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

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

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

1. Background

2. Proposal 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

3. Proposed Drugs and Biologicals with Expiring Pass-Through Payment Status in CY 2016

4. Proposed Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Status in CY 2017

5. Proposed Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs and Biologicals to Offset Costs Packaged into APC Groups

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

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

a. Proposed Packaging Threshold

b. Proposed Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Therapeutic Radiopharmaceuticals under the Cost Threshold (Threshold Packaging Policy)

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

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

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

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

b. Proposed CY 2017 Payment Policy

c. Biosimilar Biological Products

3. Proposed Payment Policy for Therapeutic Radiopharmaceuticals

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

5. Proposed Payment for Blood Clotting Factors

6. Proposed Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes but without OPPS Hospital Claims Data

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

A. Background

B. Proposed Estimate of Pass-Through Spending

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

VIII. Proposed Payment for Partial Hospitalization Services

A. Background

B. Proposed PHP APC Update for CY 2017

1. Proposed PHP APC Changes and Effect on Geometric Mean Per Diem Costs

a. Proposed Changes to PHP APCs

b. Rationale for Proposed Changes in PHP APCs

c. Alternatives Considered

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

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

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

3. PHP Ratesetting Process

C. Proposed Outlier Policy for CMHCs

1. Estimated Outlier Thresholds

2. Proposed CMHC Outlier Cap

3. Implementation Strategy for a Proposed 8-Percent Cap on CMHS Outlier Payments

4. Summary of Proposals

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

A. Background

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

C. Solicitation of Public Comments on Possible Removal of Total Knee Arthroplasty (TKA) Procedures from the IPO List

1. Background

2. Discussion of TKA and the IPO List

3. Topics and Questions for Public Comment

X. Proposed 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 Certain Off-Campus Departments of a Provider

1. Background

2. Defining Applicable Items and Services and 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

b. Proposed Exemption of Items and Services Furnished in a Dedicated Emergency Department or an On-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)

(2) On-Campus Locations

(3) Within the Distance from Remote Locations

c. Applicability of Exception at Section 1833(t)(21)(B)(ii) of the Act

(1) Relocation of Off-Campus PBDs Excepted under Section 1833(t)(21)(B)(ii) of the Act

(2) Expansion of Clinical Family of Services at an Off-Campus PBD Excepted under Section 1833(t)(21)(B)(ii) of the Act

d. Change of Ownership and Excepted Status

e. Comment Solicitation for Data Collection under Section 1833(t)(21)(D) of the Act

3. Payment for Services Furnished in Off-Campus PBDs to Which Sections 1833(t)(1)(B)(v) and 1833(t)(21) of the Act Apply (Nonexcepted Off-Campus PBDs)

a. Background on Medicare Payment for Services Furnished in an Off-Campus PBD

b. Proposed Payment for Items and Services Furnished in Off-Campus PBD That Are Subject to Sections 1833(t)(1)(B)(v) and (t)(21)(C) of the Act

(1) Definition of "Applicable Payment System" for Nonexcepted Items and Services

(2) Definition of Applicable Items and Services and Section 603 Amendments to Section 1833(t)(1)(B) of the Act and Proposed Payment for Nonexcepted Items and Services for CY 2017

(3) Comment Solicitation on Allowing Direct Billing and Payment for Nonexcepted Items and Services in CY 2018

4. Beneficiary Cost-Sharing

5. Summary of Proposals

6. Proposed Changes to Regulations

B. Changes for Payment for Film X-Ray

C. Changes to Certain Scope of Services Elements for Chronic Care Management (CCM) Services

D. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

XI. Proposed CY 2017 OPPS Payment Status and Comment Indicators

A. Proposed CY 2017 OPPS Payment Status Indicator Definitions

B. Proposed CY 2017 Comment Indicator Definitions

XII. Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background

1. Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System

2. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

B. Proposed Treatment of New and Revised Codes

1. Background on Current Process for Recognizing New and Revised Category I and Category III CPT Codes and Level II HCPCS Codes

2. Proposed Treatment of New and Revised Level II HCPCS Codes and Category III CPT Codes Implemented in April 2016 and July 2016 for Which We Are Soliciting Public Comments in this Proposed Rule

3. Proposed Process for Recognizing New and Revised Category I and Category III CPT Codes That Will Be Effective January 1, 2017 for Which We Will Be Soliciting Public Comments in the CY 2017 OPPS/ASC Final Rule with Comment Period

4. Proposed Process for New and Revised Level II HCPCS Codes That Will Be Effective October 1, 2016 and January 1, 2017 for Which We Will be Soliciting Public Comments in the CY 2017 OPPS/ASC Final Rule with Comment Period

C. Proposed Update to the Lists of ASC Covered Surgical Procedures and Covered Ancillary Services

1. Covered Surgical Procedures

a. Proposed Covered Surgical Procedures Designated as Office-Based

b. ASC Covered Surgical Procedures Designated as Device-Intensive—Finalized Policy for CY 2016 and Proposed Policy for CY 2017

c. Proposed Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

d. Proposed Additions to the List of ASC Covered Surgical Procedures

2. Covered Ancillary Services

D. Proposed ASC Payment for Covered Surgical Procedures and Covered Ancillary Services

1. Proposed ASC Payment for Covered Surgical Procedures

a. Background

b. Proposed Update to ASC Covered Surgical Procedure Payment Rates for CY 2017

2. Proposed Payment for Covered Ancillary Services

a. Background

b. Proposed Payment for Covered Ancillary Services for CY 2017

E. New Technology Intraocular Lenses (NTIOLs)

1. NTIOL Application Cycle

2. Requests to Establish New NTIOL Classes for CY 2017

3. Payment Adjustment

F. Proposed ASC Payment and Comment Indicators

1. Background

2. Proposed ASC Payment and Comment Indicators

G. Calculation of the Proposed ASC Conversion Factor and the Proposed ASC Payment Rates

1. Background

2. Proposed Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2017 and Future Years

b. Updating the ASC Conversion Factor

3. Display of Proposed CY 2017 ASC Payment Rates

XIII. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

A. Background

1. Overview

2. Statutory History of the Hospital OQR Program

3. Regulatory History of the Hospital OQR Program

B. Hospital OQR Program Quality Measures

1. Considerations in the Selection of Hospital OQR Program Quality Measures

2. Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

3. Removal of Quality Measures from the Hospital OQR Program Measure Set

a. Considerations in Removing Quality Measures from the Hospital OQR Program

b. Criteria for Removal of "Topped-Out" Measures

4. Hospital OQR Program Quality Measures Adopted in Previous Rulemaking

5. Proposed New Hospital OQR Program Quality Measures for the CY 2020 Payment Determination and Subsequent Years

a. OP-35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy Measure

b. OP-36: Hospital Visits after Hospital Outpatient Surgery Measure (NQF #2687)

c. OP-37a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey Measures

d. Summary of Previously Adopted and Newly Proposed Hospital OQR Program Measures for the CY 2020 Payment Determinations and Subsequent Years

6. Hospital OQR Program Measures and Topics for Future Consideration

a. Future Measure Topics

b. Electronic Clinical Quality Measures

c. Possible Future eCQM: Safe Use of Opioids-Concurrent Prescribing

7. Maintenance of Technical Specifications for Quality Measures

8. Public Display of Quality Measures

C. Administrative Requirements

1. QualityNet Account and Security Administrator

2. Requirements Regarding Participation Status

D. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

1. Hospital OQR Program Annual Payment Determinations

2. Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS for the CY 2019 Payment Determination and Subsequent Years

3. Claims-Based Measure Data Requirements for the CY 2019 Payment Determination and Subsequent Years and CY 2020 Payment Determination and Subsequent Years

4. Proposed Data Submission Requirements for the Proposed 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

a. Survey Requirements

b. Vendor Requirements

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

6. Population and Sampling Data Requirements for the CY 2019 Payment Determination and Subsequent Years

7. Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS for the CY 2019 Payment Determination and Subsequent Years

8. Proposed Extension or Exemption Process for the CY 2019 Payment Determination and Subsequent Years

9. Hospital OQR Program Reconsideration and Appeals Procedures for the CY 2019 Payment Determination and Subsequent Years--Clarification

E. Proposed Payment Reduction for Hospitals That Fail to Meet the Hospital Outpatient Quality Reporting (OQR) Program Requirements for the CY 2017 Payment Determination

1. Background

2. Proposed Reporting Ratio Application and Associated Adjustment Policy for CY 2017

XIV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

2. Statutory History of the ASCQR Program

3. Regulatory History of the ASCQR Program

B. ASCQR Program Quality Measures

1. Considerations in the Selection of ASCQR Program Quality Measures

2. Policies for Retention and Removal of Quality Measures from the ASCQR Program

3. ASCQR Program Quality Measures Adopted in Previous Rulemaking

4. Proposed ASCQR Program Quality Measures for the CY 2020 Payment Determination and Subsequent Years

a. ASC-13: Normothermia Outcome

b. ASC-14: Unplanned Anterior Vitrectomy

c. ASC-15a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey Measures

5. ASCQR Program Measure for Future Consideration

6. Maintenance of Technical Specifications for Quality Measures

7. Public Reporting of ASCQR Program Data

C. Administrative Requirements

1. Requirements Regarding QualityNet Account and Security Administrator

2. Requirements Regarding Participation Status

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)

2. Minimum Threshold, Minimum Case Volume, and Data Completeness for Claims‑Based Measures Using QDCs

3. Requirements for Data Submitted Via a CMS Online Data Submission Tool

a. Requirements for Data Submitted via a non-CMS Online Data Submission Tool

b. Requirements for Data Submitted via a CMS Online Data Submission Tool

4. Claims-Based Measure Data Requirements for the CY 2019 Payment Determination and Subsequent Years

5. Proposed Data Submission Requirements for the Proposed 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

a. Survey Requirements

b. Vendor Requirements

6. Extraordinary Circumstances Extensions or Exemptions for the CY 2019 Payment Determination and Subsequent Years

7. ASCQR Program Reconsideration Procedures

E. Payment Reduction for ASCs That Fail to Meet the ASCQR Program Requirements

XV. Transplant Outcomes: Restoring the Tolerance Range for Patient and Graft Survival

A. Background

B. Proposed Revisions to Performance Thresholds

XVI. Organ Procurement Organizations (OPOs): Changes to Definitions, Outcome Measures, and Documentation Requirements

A. Background

1. Organ Procurement Organizations (OPOs)

2. Statutory Provisions

3. HHS Initiatives Related to OPO Services

4. Requirements for OPOs

B. Proposed Provisions

1. Definition of "Eligible Death"

2. Aggregate Donor Yield for OPO Outcome Performance Measures

3. Organ Preparation and Transport-Documentation with the Organ

XVII. Transplant Enforcement Technical Corrections and Proposals

A. Technical Corrections to Transplant Enforcement Regulatory References

B. Other Proposed Revisions to § 488.61

XVIII. Proposed Changes to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs

A. Background

B. Summary of Proposals Included in this Proposed Rule

C. Proposed Revisions to Objectives and Measures for Eligible Hospitals and CAHs

1. Removal of the Clinical Decision Support (CDS) and Computerized Provider Order Entry (CPOE) Objectives and Measures for Eligible Hospitals and CAHs

2. Reduction of Measure Thresholds for Eligible Hospitals and CAHs for 2017 and 2018

a. Proposed Changes to the Objectives and Measures for Modified Stage 2 (42 CFR 495.22) in 2017

b. Proposed Changes to the Objectives and Measures for Stage 3 (42 CFR 495.24) in 2017 and 2018

D. Proposed Revisions 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"

2. Clinical Quality Measurement

E. Proposal to Require Modified Stage 2 for New Participants in 2017

F. Proposed Significant Hardship Exception for New Participants Transitioning to MIPS in 2017

G. Proposed Modifications to Measure Calculations for Actions Outside the EHR Reporting Period

XIX. Proposed Additional Hospital Value-Based Purchasing (VBP) Program Policies

A. Background

B. Proposed Removal of the HCAHPS Pain Management Dimension from the Hospital VBP Program

1. Background of the HCAHPS Survey in the Hospital VBP Program

2. Background of the Patient- and Caregiver-Centered Experience of Care/Care Coordination Domain Performance Scoring Methodology

3. Proposed Removal of the HCAHPS Pain Management Dimension from the Hospital VBP Program Beginning with the FY 2018 Program Year

XX. Files Available to the Public Via the Internet

XXI. Collection of Information Requirements

A. Legislative Requirements for Solicitation of Comments

B. ICRs for the Hospital OQR Program

C. ICRs for the ASCQR Program

D. ICRs Relating to Proposed Changes in Transplant Enforcement Performance Thresholds

E. ICRs for Proposed Changes to Organ Procurement Organizations (OPOs)

F. ICRs Relating to Proposed Changes to Medicare Electronic Health Record (EHR) Incentive Program

G. ICRs Relating to Proposed Additional Hospital VBP Program Policies

H. ICRs for Site Neutral OPPS Payments for Off-Campus Provider-Based Departments Proposals for CY 2017

XXII. Response to Comments

XXIII. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

2. Statement of Need

3. Overall Impacts for the OPPS and ASC Payment Provisions

4. Detailed Economic Analyses

a. Estimated Effects of Proposed OPPS Changes in this Proposed Rule

(1) Limitations of Our Analysis

(2) Estimated Effects of Proposed OPPS Changes on Hospitals

(3) Estimated Effects of Proposed OPPS Changes on CMHCs

(4) Estimated Effect of Proposed OPPS Changes on Beneficiaries

(5) Estimated Effects of Proposed OPPS Changes on Other Providers

(6) Estimated Effects of Proposed OPPS Changes on the Medicare and Medicaid Programs

(7) Alternative OPPS Policies Considered

b. Estimated Effects of Proposed CY 2017 ASC Payment System Policies

(1) Limitations of Our Analysis

(2) Estimated Effects of Proposed CY 2017 ASC Payment System Policies on ASCs

(3) Estimated Effects of Proposed ASC Payment System Policies on Beneficiaries

(4) Alternative ASC Payment Policies Considered

c. Accounting Statements and Tables

d. Effects of Proposed Requirements for the Hospital OQR Program

e. Effects of Proposed Policies for the ASCQR Program

f. Effects of Proposed Changes to Transplant Performance Thresholds

g. Effects of Proposed Changes Relating to Organ Procurement Organizations (OPOs)

h. Effects of Proposed Changes Relating to Medicare Electronic Health Record (EHR) Incentive Program

i. Effects of Proposed Requirements for the Hospital VBP Program

j. Effects of Proposed Implementation of Section 603 of the Bipartisan Budget Act of 2015 Relating to Payment for Certain Items and Services Furnished by Certain Off-Campus Departments of a Provider

B. Regulatory Flexibility Act (RFA) Analysis

C. Unfunded Mandates Reform Act Analysis

D. Conclusion

XXIV. Federalism Analysis

Regulation Text

I. Summary and Background

A. Executive Summary of This Document

1. Purpose

In this proposed rule, we are proposing to update the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs) beginning January 1, 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 proposed rule. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

In addition, we are proposing 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 proposing policies to implement section 603 of the Bipartisan Budget Act of 2015 relating to payment for certain items and services furnished by certain off-campus outpatient departments of a provider.

2. Summary of the Major Provisions

- *OPPS Update:* For CY 2017, we are proposing to increase the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 1.55 percent. This proposed increase factor is based on the proposed hospital inpatient market basket percentage increase of 2.8 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the proposed multifactor productivity (MFP) adjustment of 0.5 percentage point, and minus a 0.75 percentage point adjustment required by the Affordable Care Act. Based on this proposed update, we estimate that proposed total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix), for CY 2017 would be approximately $63 billion, an increase of approximately $5.1 billion compared to estimated CY 2016 OPPS payments.

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

- *Rural Adjustment:* We are proposing to continue the adjustment of 7.1 percent to the OPPS payments to certain rural sole community hospitals (SCHs), including essential access community hospitals (EACHs). This proposed adjustment would apply to all services paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to cost.

- *Cancer Hospital Payment Adjustment:* For CY 2017, we are proposing to continue to provide additional payments to cancer hospitals so that the cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data. Based on those data, a proposed target PCR of 0.92 would be used to determine the CY 2017 cancer hospital payment adjustment to be paid at cost report settlement. That is, the proposed payment adjustments would be the additional payments needed to result in a PCR equal to 0.92 for each cancer hospital.

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

- *Chronic Care Management (CCM)*: For CY 2017, we are proposing some minor changes to certain CCM scope of service elements. Refer to the CY 2017 MPFS proposed rule for a detailed discussion of these changes to the scope of service elements for CCM. We are proposing that these changes will also apply to CCM furnished to hospital outpatients.

- *Device-Intensive Procedures:* For CY 2017, we are proposing that 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 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 proposing to revise the device intensive calculation methodology and calculate 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 proposing to discontinue the use of the "L1" modifier to identify unrelated laboratory tests on claims. In addition, we are proposing to expand 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 proposing to align 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 proposing that, effective for services furnished on or after January 1, 2017, hospitals would be required to use a modifier on claims for X-rays that are taken using film. The use of this proposed modifier would 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 Certain Items and Services Furnished by Certain Off-Campus Departments of a Provider:* We are proposing to implement 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 provider-based departments (PBDs) (collectively referenced as nonexcepted items and services) shall not be considered covered OPD services for purposes of OPPS payment and those items and services will instead be paid "under the applicable payment system" beginning January 1, 2017. We are making several proposals relating to which off-campus PBDs and which items and services

furnished by such off-campus PBDs may be exempt from application of payment changes under this provision.

In addition, we are proposing that the Medicare Physician Fee Schedule (MPFS) will be the "applicable payment system" for the majority of the items and services furnished by nonexcepted off-campus PBDs. We are proposing that physicians furnishing services in these departments would be paid based on the professional claim and would be paid at the nonfacility rate for services which they are permitted to bill. We are proposing to pay physicians at the nonfacility rate because we are not able to operationalize a mechanism to provide payment to the off-campus PBD for nonexcepted items and services under a payment system other than the OPPS at this time. We are clarifying that, for CY 2017, provided an off-campus PBD can meet all Federal and other requirements, a hospital also has the option of enrolling the off-campus PBD as the provider/supplier it wishes to bill as in order to meet the requirements of that payment system (such as an ASC or a group practice to be paid under the MPFS, in which case the physician would be paid at the facility rate). We intend that this payment proposal would be a transitional policy, applicable in CY 2017 only, while we continue to explore operational changes that would allow a nonexcepted off-campus PBD to bill Medicare under an applicable payment system, which, in the majority of cases, we expect will be the MPFS.

- *Ambulatory Surgical Center Payment Update:* For CY 2017, we are proposing to increase payment rates under the ASC payment system by 1.2 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This proposed

increase is based on a projected CPI–U update of 1.7 percent minus a multifactor productivity adjustment required by the Affordable Care Act of 0.5 percentage point. Based on this proposed update, we estimate that proposed total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix), for CY 2017 would be approximately $4.42 billion, an increase of approximately $214 million compared to estimated CY 2016 Medicare payments.

- *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program, we are making 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 proposing 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 proposing that hospitals will generally have approximately 30 days to preview their data. We are also proposing to 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 proposing to change the timeframe for extraordinary circumstances exemptions (ECE) 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 proposing to adopt 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 proposed 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 proposed 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 making proposals for the CY 2018 payment determination, 2019 payment determination and CY 2020 payment determination and subsequent years. For the CY 2018 payment determination and subsequent years, we are proposing 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 proposing that ASCs will generally have approximately 30 days to preview their data. We are also proposing to 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 proposing to change the submission deadline from August 15 in the year prior to the affected payment determination year to May 15 for all data submitted via a CMS Web-based tool. We also are proposing to extend the submission deadline for Extraordinary Circumstance Extensions and Exemptions requests. For the CY 2020 payment determination and subsequent years, we are proposing to adopt 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 proposed 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 proposed 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 proposed rule, we are proposing to remove the HCAHPS Pain Management dimension of the Hospital VBP Program, beginning with the FY 2018 program year.

- *Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs:* In this proposed rule, we are proposing changes to the objectives and measures of meaningful use for Modified Stage 2 and Stage 3 starting with the EHR reporting periods in calendar year 2017. Under both Modified Stage 2 in 2017 and Stage 3 in 2017 and 2018, for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program, we are proposing to eliminate the Clinical Decision Support (CDS) and Computerized Provider Order Entry (CPOE) objectives and measures, and lower the reporting thresholds for a subset of the remaining objectives and measures, generally to the Modified Stage 2 thresholds. The proposal to reduce 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 proposed requirements focus on reducing hospital administrative 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 are proposing changes to the EHR reporting period in calendar year 2016 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 proposing 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 proposals are responsive to additional stakeholder feedback received through both correspondence and in-person meetings and would 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 proposing to restore the effective tolerance range for clinical outcomes that was allowed in our original 2007 rule. These outcomes 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.

- *Organ Procurement Organizations (OPOs) Changes.* In this proposed rule, we are proposing to: change the current "eligible death" definition to be consistent with the OPTN definition; modify CMS current outcome measures to be consistent with yield calculations currently utilized by the SRTR; and modify 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 proposed rule, we set forth a detailed analysis of the regulatory and Federalism impacts that the proposed changes would have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of the Proposed OPPS Update

(1) Impacts of All OPPS Proposed Changes

Table 30 in section XXIII. of this proposed rule displays the distributional impact of all the proposed OPPS changes on various groups of hospitals and CMHCs for CY 2017 compared to all estimated OPPS payments in CY 2016. We estimate that the

proposed policies in this proposed rule would result in a 1.6 percent overall increase in OPPS payments to providers. We estimate that proposed total OPPS payments for CY 2017, including beneficiary cost-sharing, to the approximate 3,900 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) would increase by approximately $671 million compared to CY 2016 payments, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our proposed OPPS policies on CMHCs because CMHCs are only paid for partial hospitalization services under the OPPS. Continuing the provider-specific structure that we adopted beginning in CY 2011 and basing payment fully on the type of provider furnishing the service, we estimate an 8.4 percent decrease in CY 2017 payments to CMHCs relative to their CY 2016 payments.

(2) Impacts of the Proposed Updated Wage Indexes

We estimate that our proposed update of the wage indexes based on the FY 2017 IPPS proposed rule wage indexes results in no change for urban hospitals and a 0.3 percent increase for rural hospitals under the OPPS. These wage indexes include the continued implementation of the OMB labor market area delineations based on 2010 Decennial Census data.

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

There are no significant impacts of our proposed CY 2017 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not proposing to make any change in policies for determining the rural 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 proposed OPD fee schedule increase factor of 1.6 percent to the conversion factor for CY 2017 would mitigate the impacts of the budget neutrality adjustments. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that rural and urban hospitals would experience increases of approximately 1.6 percent for urban hospitals and 2.3 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 Proposed ASC Payment Update

For impact purposes, the surgical procedures on the ASC list of covered procedures are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The proposed percentage change in estimated total payments by specialty groups under the proposed CY 2017 payment rates compared to estimated CY 2016 payment rates ranges between 6 percent for musculoskeletal system procedures and -2 percent for integumentary system procedures.

c. Impacts of the Hospital OQR Program

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

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

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. We estimate that section 603 would increase payments to physicians under the MPFS by $170 million in CY 2017, resulting in a net Medicare Part B impact from the provision of reducing CY 2017 Part B expenditures by $330 million. These estimates include both the FFS impact of the provision and the Medicare Advantage impact of the provision. These estimates also 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.

B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the Social Security Act was enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the reasonable

cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33) added section 1833(t) to the Act authorizing implementation of a PPS for hospital outpatient services. The OPPS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPPS are located at 42 CFR Parts 410 and 419.

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

December 23, 2011; the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA, Pub. L. 112-96), enacted on February 22, 2012; the American Taxpayer Relief Act of 2012 (Pub. L. 112-240), enacted January 2, 2013; the Pathway for SGR Reform Act of 2013 (Pub. L. 113-67) enacted on December 26, 2013; the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113-93), enacted on March 27, 2014; the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 114-10), enacted April 16, 2015; the Bipartisan Budget Act of 2015 (Pub. L. 114-74), enacted November 2, 2015; and the Consolidated Appropriations Act, 2016 (Pub. L. 114-113), enacted on December 18, 2015.

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

The OPPS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is

adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

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

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

pass-through payments, an assignment to a New Technology APC is temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

C. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercises the authority granted under the statute to also exclude from the OPPS certain services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule (MPFS); certain laboratory services paid under the Clinical Laboratory Fee Schedule (CLFS); services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD prospective payment system; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. We set forth the services that are excluded from payment under the OPPS in regulations at 42 CFR 419.22.

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

access hospitals (CAHs); hospitals located in Maryland and paid under the Maryland All-Payer Model; hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico; and Indian Health Service (IHS) hospitals.

D. Prior Rulemaking

On April 7, 2000, we published in the **Federal Register** a final rule with comment period (65 FR 18434) to implement a prospective payment system for hospital outpatient services. The hospital OPPS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS, not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors.

Since initially implementing the OPPS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS Web site at: http://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 Pub. L. 106-113, and redesignated by section 202(a)(2) of Pub. L. 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 and section 222 of the Public Health Service (PHS) 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: http://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 March 14, 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 OPPS (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 March 14, 2016 meeting that the subcommittees continue. We accepted this recommendation.

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

F. Public Comments Received on the CY 2016 OPPS/ASC Final Rule with Comment Period

We received 25 timely pieces of correspondence on the CY 2016 OPPS/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 OPPS Addendum B, ASC Addendum AA, and ASC Addendum BB to that final rule). Summaries of the public comments on new or replacement Level II HCPCS codes will be set forth in the CY 2017 final rule with comment period under the appropriate subject matter headings.

II. Proposed Updates Affecting OPPS Payments

A. Proposed Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review not less often than annually and revise the relative payment weights for APCs. In the April 7, 2000 OPPS final rule with comment period (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000 for each APC group.

For CY 2017, we are proposing 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 OPPS/ASC final

rule with comment period (80 FR 70309 through 70321). That is, we are proposing to recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services, using the most recent available data to construct a database for calculating APC group weights. For this proposed rule, 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. 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 OPPS/ASC proposed rule on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

Addendum N to this proposed rule includes the proposed list of bypass codes for CY 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 are retaining 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 are identified by asterisks (*) in the third column of Addendum N to this proposed rule. HCPCS codes that we are proposing to add for CY 2017 are identified by asterisks (*) in the fourth column of Addendum N.

We are proposing a CY 2017 bypass list of 194 HCPCS codes, as displayed in Addendum N to this proposed rule (which is available via the Internet on the CMS Web site). Table 1 below contains the list of codes that we are proposing to remove from the CY 2017 bypass list.

TABLE 1.—HCPCS CODES PROPOSED TO BE 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. Proposed Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2017, we are proposing to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. To calculate the APC costs on which the proposed CY 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 this proposed rule.

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

In this section of this proposed rule, we discuss the use of claims to calculate the proposed OPPS payment rates for CY 2017. The Hospital OPPS page on the CMS Web site on which this proposed rule is posted (http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html) provides an accounting of claims used in the development of the proposed payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, below in this section we discuss the file of claims that comprises the data set that is available 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 proposed 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, we are proposing to continue to use geometric mean costs to calculate the relative weights on which the proposed CY 2017 OPPS payment rates are based.

We used the methodology described in sections II.A.2.a. through II.A.2.d. of this proposed rule to calculate the costs we used to establish the proposed relative payment weights used in calculating the proposed OPPS payment rates for CY 2017 shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). We refer readers to section II.A.4. of this proposed rule for a discussion of the conversion of APC costs to scaled payment weights.

For details of the claims process used in this proposed rule, we refer readers to the claims accounting narrative under supporting documentation for this CY 2017 OPPS/ASC proposed rule 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

At the March 14, 2016 meeting of the Panel, we discussed 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 OPPS/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 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 subcommittee Chair for the August 2016 HOP Panel.

CMS Response: We are accepting this recommendation.

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

(1) Blood and Blood Products

(a) Methodology

Since the implementation of the OPPS in August 2000, we have made separate payments for blood and blood products through APCs rather than packaging payment for them into payments for the procedures with which they are administered. Hospital payments for the costs of blood and blood products, as well as for the costs of collecting, processing, and storing blood and blood products, are made through the OPPS payments for specific blood product APCs.

For CY 2017, we are proposing to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology, which utilizes actual or

simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers, and past public comments indicating that the former OPPS policy of defaulting to the overall hospital CCR for hospitals not reporting a blood-specific cost center often resulted in an underestimation of the true hospital costs for blood and blood products. Specifically, in order to address the differences in CCRs and to better reflect hospitals' costs, we are proposing to continue to simulate blood CCRs for each hospital that does not report a blood cost center by calculating the ratio of the blood-specific CCRs to hospitals' overall CCRs for those hospitals that do report costs and charges for blood cost centers. We also are proposing to apply this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports in order to simulate blood-specific CCRs for those hospitals. We are proposing to calculate the costs upon which the proposed CY 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 OPPS/ASC final rule with comment period (78 FR 74861 through 74910), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66798 through 66810), and the CY 2016 OPPS/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 are proposing to continue to apply the blood-specific CCR methodology described in this section when calculating the costs of the blood and blood products that appear on claims with services assigned to the C-APCs. Because the costs of blood and blood products will be reflected in the overall costs of the C-APCs (and, as a result, in the proposed payment rates of the C-APCs), we are proposing to not make separate payments for blood and blood products when they appear on the same claims as services assigned to the C-APCs (we refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66796)).

We are inviting public comments on these proposals. We refer readers to Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) for the proposed CY 2017 payment rates for blood and blood products (which are identified with status indicator "R"). For a more detailed discussion of the blood-specific CCR methodology, we refer readers to the CY 2005 OPPS proposed rule (69 FR 50524 through 50525). For a full history of OPPS payment for blood and blood products, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810).

(b) 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. We are requesting 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," "leukocyte reduced + irradiated + CMV-negative," among others. We are asking 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 are inviting 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 this proposed rule (which is available via the Internet on the CMS Web site).

(2) Brachytherapy Sources

Section 1833(t)(2)(H) of the Act mandates the creation of additional groups of covered OPD services that classify devices of brachytherapy consisting of a seed or seeds (or radioactive source) ("brachytherapy sources") separately from other services or groups of services. The statute provides certain criteria for the additional groups. For the history of OPPS payment for brachytherapy sources, we refer readers to prior OPPS final rules, such as the CY 2012 OPPS/ASC final rule with comment period (77 FR 68240 through 68241). As we have stated in prior OPPS updates, we believe that adopting the

general OPPS prospective payment methodology for brachytherapy sources is appropriate for a number of reasons (77 FR 68240). The general OPPS methodology uses costs based on claims data to set the relative payment weights for hospital outpatient services. This payment methodology results in more consistent, predictable, and equitable payment amounts per source across hospitals by averaging the extremely high and low values, in contrast to payment based on hospitals' charges adjusted to costs. We believe that the OPPS methodology, as opposed to payment based on hospitals' charges adjusted to cost, also would provide hospitals with incentives for efficiency in the provision of brachytherapy services to Medicare beneficiaries. Moreover, this approach is consistent with our payment methodology for the vast majority of items and services paid under the OPPS. We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70323 through 70325) for further discussion of the history of OPPS payment for brachytherapy sources.

In this proposed rule, for CY 2017, we are proposing to use the costs derived from CY 2015 claims data to set the proposed CY 2017 payment rates for brachytherapy sources because CY 2015 is the same year of data we are proposing to use to set the proposed payment rates for most other items and services that would be paid under the CY 2017 OPPS. We are proposing to base the proposed payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we are proposing for other items and services paid under the OPPS, as discussed in section II.A.2. of this proposed rule. We also are proposing to continue the other payment policies for brachytherapy sources that we finalized and first implemented

in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537). We are proposing to pay for the stranded and nonstranded not otherwise specified (NOS) codes, HCPCS codes C2698 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 OPPS/ASC final rule with comment period (72 FR 66785). For CY 2017 and subsequent years, we also are proposing to continue the policy we first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537) regarding payment for new brachytherapy sources for which we have no claims data, based on the same reasons we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was delayed until January 1, 2010 by section 142 of Pub. L. 110-275). Specifically, this policy is intended to enable us to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals.

The proposed CY 2017 payment rates for brachytherapy sources are included in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) and are identified with status indicator "U". We note that, for CY 2017, we are proposing 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 proposed payment rate based on the

general OPPS 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 are proposing to assign new proposed status indicator "E2" to HCPCS code C2644.

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

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

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910), we finalized a comprehensive payment policy that packages payment for

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

A C-APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. We established C-APCs as a category broadly for OPPS payment and implemented 25 C-APCs beginning in CY 2015 (79 FR 66809 through 66810). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70332), we finalized 10 additional C-APCs to be paid under the existing C-APC payment policy.

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 OPPS status indicator "J1". When such a primary service is reported on a hospital outpatient claim, taking into consideration the few exceptions that are discussed below, we make payment for all other items and services reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service (hereinafter collectively referred to as "adjunctive services") and representing components of a complete comprehensive service (78 FR 74865 and 79 FR 66799). Payments for adjunctive services are packaged into the payments for the primary services. This results in a single

prospective payment for each of the primary, comprehensive services based on the costs of all reported services at the claim level.

Services excluded from the C-APC policy include services that are not covered OPD services, services that cannot by statute be paid for under the OPPS, and services that are required by statute to be separately paid. This includes certain mammography and ambulance services that are not covered OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act; brachytherapy seeds, which also are required by statute to receive separate payment under section 1833(t)(2)(H) of the Act; pass-through drugs and devices, which also require separate payment under section 1833(t)(6) of the Act; self-administered drugs (SADs) that are not otherwise packaged as supplies because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act; and certain preventive services (78 FR 74865 and 79 FR 66800 through 66801). A list of services excluded from the C-APC policy is included in Addendum J to this proposed rule (which is available via the Internet on the CMS Web site).

The C-APC policy payment methodology set forth in the CY 2014 OPPS/ASC final rule with comment period for the C-APCs and modified and implemented beginning in CY 2015 is summarized as follows (78 FR 74887 and 79 FR 66800):

Basic Methodology. As stated in the CY 2015 OPPS/ASC final rule with comment period, we define the C-APC payment policy as including all covered OPD services on a hospital outpatient claim reporting a primary service that is assigned to status indicator "J1," excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS. Services and procedures described by HCPCS

codes assigned to status indicator "J1" are assigned to C-APCs based on our usual APC assignment methodology by evaluating the geometric mean costs of the primary service claims to establish resource similarity and the clinical characteristics of each procedure to establish clinical similarity within each APC. In the CY 2016 OPPS/ASC final rule with comment period, we expanded the C-APC payment methodology 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 OPPS payable services and items reported on the claim (excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS) to be deemed adjunctive services representing components of a comprehensive service and resulting in a single prospective payment for the comprehensive service based on the costs of all reported services on the claim (80 FR 70333 through 70336).

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

In addition, payment for outpatient department services that are similar to therapy services and delivered either by therapists or nontherapists is included as part of the payment for the packaged complete comprehensive service. These services that are provided during the perioperative period are adjunctive services and are deemed to be not therapy services as described in section 1834(k) of the Act, regardless of whether the services are delivered by therapists or other nontherapist health care workers. We have previously noted that therapy services are those provided by therapists under a plan of care in accordance with section 1835(a)(2)(C) and section 1835(a)(2)(D) of the Act and are paid for under section 1834(k) of the Act, subject to annual therapy caps as applicable (78 FR 74867 and 79 FR 66800). However, certain other services similar to therapy services are considered and paid for as outpatient department services. Payment for these nontherapy outpatient department services that are reported with therapy codes and provided with a comprehensive service is included in the payment for the packaged complete comprehensive service. We note that these services, even though they are reported with therapy codes, are 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, we are proposing to apply the frequency and cost criteria thresholds discussed above, testing claims reporting one unit of a single primary service assigned to status indicator "J1" and any number of units of a single add-on code. 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 list 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 this proposed rule (which is available via the Internet on the CMS Web site). For CY 2017, we are proposing 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 proposed rule. Therefore, because the 2 times rule would not typically apply to complexity-adjusted code combinations, we are proposing to discontinue this requirement.

We are providing in Addendum J to this 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 this proposed rule also contains 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 this proposed rule allows stakeholders the opportunity to better assess the impact associated with the proposed reassignment of each of the code combinations eligible for a complexity adjustment.

(2) Proposed C-APCs for CY 2017

(a) Proposed Additional C-APCs for CY 2017

For CY 2017 and subsequent years, we are proposing to continue to apply the C-APC payment policy methodology made effective in CY 2015, as described in detail below. We are proposing 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 are proposing 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 are proposing 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 OPPS.

As a result of our annual review of the services and APC assignments under the OPPS, we are proposing 25 additional C-APCs to be paid under the existing C-APC payment policy beginning in CY 2017. The proposed CY 2017 C-APCs are listed in Table 2 below. All C-APCs, including those effective in CY 2016 and those being proposed for CY 2017, also are displayed in Addendum J to this proposed rule. Addendum J to this proposed rule (which is available via the Internet on the CMS Web site) also contains all of the data related to the C-APC payment policy methodology, including the list of proposed complexity adjustments and other information.

TABLE 2.—PROPOSED CY 2017 C-APCs

C-APC	CY 2017 APC Title	Clinical Family	Proposed New C-APC
5072	Level 2 Excision/ Biopsy/ Incision and Drainage	EBIDX	*
5073	Level 3 Excision/ Biopsy/ Incision and Drainage	EBIDX	*
5091	Level 1 Breast/Lymphatic Surgery and Related Procedures	BREAS	*
5092	Level 2 Breast/Lymphatic Surgery and Related Procedures	BREAS	*
5093	Level 3 Breast/Lymphatic Surgery & Related Procedures	BREAS	
5094	Level 4 Breast/Lymphatic Surgery & Related Procedures	BREAS	
5112	Level 2 Musculoskeletal Procedures	ORTHO	*
5113	Level 3 Musculoskeletal Procedures	ORTHO	*
5114	Level 4 Musculoskeletal Procedures	ORTHO	
5115	Level 5 Musculoskeletal Procedures	ORTHO	
5116	Level 6 Musculoskeletal Procedures	ORTHO	
5153	Level 3 Airway Endoscopy	AENDO	*
5154	Level 4 Airway Endoscopy	AENDO	*
5155	Level 5 Airway Endoscopy	AENDO	*
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	*

C-APC	CY 2017 APC Title	Clinical Family	Proposed New C-APC
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	

*Proposed 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) Proposed 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 OPPS 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 OPPS, 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 OPPS/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, for CY 2017, we are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing to no longer use revenue code 0819 for the identification of stem cell acquisition charges for allogeneic bone marrow/stem cell transplants. We are inviting public comments on these proposals.

d. Proposed Calculation of Composite APC Criteria-Based Costs

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide necessary, high quality care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite policies for low dose rate (LDR) prostate brachytherapy, mental health services, and multiple imaging services. We refer readers to the CY 2008 OPPS/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 OPPS/ASC final rule with comment period (76 FR 74163) for more recent background.

In this proposed rule, for CY 2017 and subsequent years, we are proposing to continue our composite APC payment policies for LDR prostate brachytherapy services, mental health services, and multiple imaging services, as discussed below.

(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 OPPS 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 OPPS/ASC final rule with comment period (72 FR 66652 through 66655) for a full history of OPPS payment for LDR prostate brachytherapy services and a detailed description of how we developed the LDR prostate brachytherapy composite APC.

In this proposed rule, for CY 2017, we are proposing 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 are proposing 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 this proposed rule, we are proposing 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 are proposing 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 this CY 2017 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 is based.

(2) Mental Health Services Composite APC

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

Specifically, we are proposing 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 are proposing to continue to set the payment rate for composite APC 8010 at the same payment rate that we are proposing 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 OPPS than the highest partial hospitalization per diem payment rate for hospitals.

(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 OPPS/ASC final rule with comment period (78 FR 74920 through 74924).

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under section 1833(t)(2)(G) of the Act that we differentiate payment for OPPS imaging services provided with and without contrast.

While the ultrasound procedures included under the policy do not involve contrast, both CT/CTA and MRI/MRA scans can be provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

We define the single imaging session for the "with contrast" composite APCs as having at least one or more imaging procedures from the same family performed with contrast on the same date of service. For example, if the hospital performs an MRI without contrast during the same session as at least one other MRI with contrast, the hospital will receive payment based on the payment rate for APC 8008, the "with contrast" composite APC.

We make a single payment for those imaging procedures that qualify for payment based on the composite APC payment rate, which includes any packaged services furnished on the same date of service. The standard (noncomposite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. For a full discussion of the development of the multiple imaging composite APC methodology, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569).

In this proposed rule, for CY 2017 and subsequent years, we are proposing 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) are based on proposed geometric mean costs calculated from a partial year of CY 2015 claims data available for this 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 CY 2014 and CY 2015 geometric mean costs for these composite APCs, as described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918). The imaging HCPCS codes referred to as "overlap bypass codes" that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC geometric mean costs, in accordance with our established methodology as stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918), are identified by asterisks in Addendum N to this CY 2017 proposed rule (which is available via the Internet on the CMS Web site) and are discussed in more detail in section II.A.1.b. of this proposed rule.

For this CY 2017 OPPS/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 3 below 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.

TABLE 3.—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCs	
Family 1 – Ultrasound	
CY 2017 APC 8004 (Ultrasound Composite)	**CY 2017 Approximate APC Geometric Mean Cost = $303**
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 = $292**
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 = $515**
70487	Ct maxillofacial w/dye
70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye

70481	Ct orbit/ear/fossa w/dye
70482	Ct orbit/ear/fossa w/o & w/dye
70488	Ct maxillofacial w/o & w/dye
70491	Ct soft tissue neck w/dye
70492	Ct sft tsue nck w/o & w/dye
70496	Ct angiography, head
70498	Ct angiography, neck
71260	Ct thorax w/dye
71270	Ct thorax w/o & w/dye
71275	Ct angiography, chest
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72129	Ct chest spine w/dye
72130	Ct chest spine w/o & w/dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72191	Ct angiograph pelv w/o & w/dye
72193	Ct pelvis w/dye
72194	Ct pelvis w/o & w/dye
73201	Ct upper extremity w/dye
73202	Ct uppr extremity w/o & w/dye
73206	Ct angio upr extrm w/o & w/dye
73701	Ct lower extremity w/dye
73702	Ct lwr extremity w/o & w/dye
73706	Ct angio lwr extr w/o & w/dye
74160	Ct abdomen w/dye
74170	Ct abdomen w/o & w/dye
74175	Ct angio abdom w/o & w/dye
74262	Ct colonography, w/dye
75635	Ct angio abdominal arteries
74177	Ct angio abd & pelv w/contrast
74178	Ct angio abd & pelv 1+ regns
***** If a “without contrast” CT or CTA procedure is performed during the same session as a “with contrast” CT or CTA procedure, the I/OCE assigns the procedure to APC 8006 rather than APC 8005.	
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 = $587**
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 = $900**
70549	Mr angiograph neck w/o & w/dye
70542	Mri orbit/face/neck w/dye
70543	Mri orbt/fac/nck w/o & w/dye
70545	Mr angiography head w/dye
70546	Mr angiograph head w/o & w/dye
70547	Mr angiography neck w/o dye
70548	Mr angiography neck w/dye

70552	Mri brain w/dye
70553	Mri brain w/o & w/dye
71551	Mri chest w/dye
71552	Mri chest w/o & w/dye
72142	Mri neck spine w/dye
72147	Mri chest spine w/dye
72149	Mri lumbar spine w/dye
72156	Mri neck spine w/o & w/dye
72157	Mri chest spine w/o & w/dye
72158	Mri lumbar spine w/o & w/dye
72196	Mri pelvis w/dye
72197	Mri pelvis w/o & w/dye
73219	Mri upper extremity w/dye
73220	Mri uppr extremity w/o & w/dye
73222	Mri joint upr extrem w/dye
73223	Mri joint upr extr w/o & w/dye
73719	Mri lower extremity w/dye
73720	Mri lwr extremity w/o & w/dye
73722	Mri joint of lwr extr w/dye
73723	Mri joint lwr extr w/o & w/dye
74182	Mri abdomen w/dye
74183	Mri abdomen w/o & w/dye
75561	Cardiac mri for morph w/dye
75563	Card mri w/stress img & dye
C8900	MRA w/cont, abd
C8902	MRA w/o fol w/cont, abd
C8903	MRI w/cont, breast, uni
C8905	MRI w/o fol w/cont, brst, un
C8906	MRI w/cont, breast, bi
C8908	MRI w/o fol w/cont, breast,
C8909	MRA w/cont, chest
C8911	MRA w/o fol w/cont, chest
C8912	MRA w/cont, lwr ext
C8914	MRA w/o fol w/cont, lwr ext
C8918	MRA w/cont, pelvis
C8920	MRA w/o fol w/cont, pelvis
C8931	MRA, w/dye, spinal canal

C8933	MRA, w/o&w/dye, spinal canal
C8934	MRA, w/dye, upper extremity
C8936	MRA, w/o&w/dye, upper extr
* If a "without contrast" MRI or MRA procedure is performed during the same session as a "with contrast" MRI or MRA procedure, the I/OCE assigns the procedure to APC 8008 rather than APC 8007.	

3. Proposed Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPS

Like other prospective payment systems, the OPPS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular patient. The OPPS packages 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 this CY 2017 proposed rule, we are proposing some modifications to our packaging policies and to package the costs of two drugs that function as supplies in a surgical procedure.

b. Proposed 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 OPPS (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 OPPS 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) Proposed "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, we are proposing 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 give the granularity of ICD-10 diagnosis coding. Packaging of other ancillary services in the OPPS 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 integral, ancillary, supportive, dependent, or adjunctive to other hospital outpatient services provided to the beneficiary during the hospital stay, we are proposing 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 are proposing to package any and all

laboratory tests if they appear on a claim with other hospital outpatient services. We are inviting public comments on this proposal.

(3) Proposed 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 OPPS/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, we are proposing 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 would assign status indicator "A" (Separate payment under the CLFS) to ADLTs once a laboratory test is designated an ADLT under the CLFS. We are inviting public comments on this proposal.

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 package 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) Proposed 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 are proposing 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. We point 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 are inviting public comments on this proposal.

4. Proposed Calculation of OPPS Scaled Payment Weights

We established a policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68283) of using geometric mean-based APC costs to calculate relative payment weights under the OPPS. In the CY 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 are proposing to continue to apply the policy established in CY 2016 and calculate relative payment weights for each APC for CY 2017 using geometric mean-based APC costs.

For CY 2012 and CY 2013, outpatient clinic visits were assigned to one of five levels of clinic visit APCs, with APC 0606 representing a mid-level clinic visit. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75036 through 75043), we finalized a new policy that created alphanumeric HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), representing any and all clinic visits under the OPPS. HCPCS code G0463 was assigned to APC 0634 (Hospital Clinic Visits). We also finalized a policy to use CY 2012 claims data to develop the CY 2014 OPPS payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT E/M codes for clinic visits previously recognized under the OPPS (CPT codes 99201 through 99205 and 99211

through 99215). In addition, we finalized a policy to no longer recognize a distinction between new and established patient clinic visits.

For CY 2016, we deleted APC 0634 and moved the outpatient clinic visit HCPCS code G0463 to APC 5012 (Level 2 Examinations and Related Services) (80 FR 70351). For CY 2017, we are proposing to continue to standardize all of the relative payment weights to APC 5012. We believe that standardizing relative payment weights to the geometric mean of the APC to which HCPCS code G0463 is assigned maintains consistency in calculating unscaled weights that represent the cost of some of the most frequently provided OPPS services. For CY 2017, we are proposing to assign APC 5012 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the proposed geometric mean cost for APC 5012 to derive the proposed unscaled relative payment weight for each APC. The choice of the APC on which to standardize the proposed relative payment weights does not affect payments made under the OPPS 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 OPPS 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 are proposing 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.

For CY 2016, we multiplied the CY 2016 scaled APC relative payment weight applicable to a service paid under the OPPS 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, we are proposing to apply the same process using the estimated CY 2017 unscaled relative payment weights rather than scaled relative payment weights. We are proposing 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 OPPS 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 OPPS proposed rule link and open the claims accounting document link at the bottom of the page.

In this CY 2017 proposed rule, we are proposing 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 are proposing to adjust the calculated CY 2017 unscaled relative payment weights for purposes of budget neutrality. We are proposing 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 this proposed rule (which are available via the Internet on the CMS Web site) are scaled and incorporate the recalibration adjustments discussed in sections II.A.1. and II.A.2. of this proposed rule.

Section 1833(t)(14) of the Act provides the payment rates for certain SCODs. Section 1833(t)(14)(H) of the Act provides that additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years. Therefore, the cost of those SCODs (as discussed in section V.B.3. of this proposed rule) is included in the budget neutrality calculations for the CY 2017 OPPS.

B. Proposed Conversion Factor Update

Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor used to determine the payment rates under the OPPS on an annual basis by applying the OPD fee schedule increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD fee schedule increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25077), consistent with current law, based on IHS Global Insight, Inc.'s first quarter 2016 forecast of the FY 2017 market basket increase, the proposed FY 2017 IPPS market basket update is 2.8 percent. However, sections 1833(t)(3)(F) and 1833(t)(3)(G)(v) of the Act, as added

by section 3401(i) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148) and as amended by section 10319(g) of that law and further amended by section 1105(e) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), provide adjustments to the OPD fee schedule increase factor for CY 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. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25077), we discussed the calculation of the proposed MFP adjustment for FY 2017, which is -0.5 percentage point.

We are proposing that if more recent data become subsequently available after the publication of this CY 2017 OPPS/ASC 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, components in calculating the OPD fee schedule increase factor under

sections 1833(t)(3)(C)(iv) and 1833(t)(3)(F) of the Act, in the CY 2017 OPPS/ASC final rule with comment period.

In addition, section 1833(t)(3)(F)(ii) of the Act requires that, for each of years 2010 through 2019, the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act be reduced by the adjustment described in section 1833(t)(3)(G) of the Act. For CY 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, we are proposing 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 proposing to apply an OPD fee schedule increase factor of 1.55 percent for the CY 2017 OPPS (which is 2.8 percent, the proposed estimate of the hospital inpatient market basket percentage increase, less the proposed 0.5 percentage point MFP adjustment, and less the 0.75 percentage point additional adjustment).

Hospitals that fail to meet the Hospital OQR Program reporting requirements are subject to an additional reduction of 2.0 percentage points from the OPD fee schedule increase factor adjustment to the conversion factor that would be used to calculate the OPPS payment rates for their services, as required by section 1833(t)(17) of the Act. For

further discussion of the Hospital OQR Program, we refer readers to section XIII. of this proposed rule.

In this CY 2017 OPPS/ASC proposed rule, we are proposing 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 2016, 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.

To set the OPPS conversion factor for CY 2017, we are proposing 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 are proposing to further adjust the conversion factor for CY 2017 to ensure that any revisions made to the wage index and rural adjustment are made on a budget neutral basis. We are proposing to calculate an overall proposed budget neutrality factor of 1.0000 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 CY 2017, we are proposing to maintain the current rural adjustment policy, as discussed in section II.E. of this proposed rule. Therefore, the proposed budget neutrality factor for the rural adjustment would be 1.0000.

For CY 2017, we are proposing to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act, as discussed in section II.F. of this proposed rule. We are proposing to calculate a CY 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 are identical to estimated payments applying the CY 2016 final cancer hospital payment adjustment. Therefore, we are proposing to apply a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment.

For CY 2017, we are proposing 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 this proposed rule, we estimate that proposed pass-through spending for drugs, biologicals, and devices for CY 2017 would equal approximately $148.3 million, which represents 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 be 1.0 percent of total

OPPS payments for CY 2017. We currently estimated that outlier payments will 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.

For this proposed rule, we also are proposing that hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor. For hospitals that fail to meet the requirements of the Hospital OQR Program, we are proposing to make all other adjustments discussed above, but use a reduced OPD fee schedule update factor of -0.45 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 are proposing 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 are proposing 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).

For CY 2017, we are proposing to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act, as discussed in section II.F. of this proposed rule.

As a result of these proposed policies, the proposed OPD fee schedule increase factor for the CY 2017 OPPS is 1.55 percent (which is 2.8 percent, the estimate of the hospital inpatient market basket percentage increase, less the 0.5 percentage point MFP adjustment, and less the 0.75 percentage point additional adjustment). For CY 2017, we are proposing to use a conversion factor of $74.909 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 1.55 percent for CY 2017, the required wage index budget neutrality adjustment of approximately 1.0000, the cancer hospital payment adjustment of 1.0000, the packaging of unrelated laboratory tests adjustment factor of 1.0003, and the adjustment of -0.06 percentage point of projected OPPS spending for the difference in the pass-through spending and outlier payments that result in a proposed conversion factor for CY 2017 of $74.909.

C. Proposed Wage Index Changes

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

portion of the OPPS payment rate is called the OPPS labor-related share. Budget neutrality is discussed in section II.B. of this proposed rule.

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). We are proposing to continue this policy for the CY 2017 OPPS. We refer readers to section II.H. of this proposed rule for a description and an example of how the wage index for a particular hospital is used to determine payment for the hospital.

As discussed in section II.A.2.c. of this proposed rule, for estimating APC costs, we standardize 60 percent of estimated claims costs for geographic area wage variation using the same proposed 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 OPPS payment rate and copayment amount.

Under 42 CFR 419.41(c)(1) and 419.43(c) (published in the OPPS April 7, 2000 final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS post-reclassified wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Therefore, the wage index that applies to a particular acute care, short-stay hospital under the IPPS

also applies to that hospital under the OPPS. As initially explained in the September 8, 1998 OPPS proposed rule (63 FR 47576), we believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained several provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). Section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines a frontier State and amended section 1833(t) of the Act to add 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 are proposing to implement this provision in the same manner as we have since CY 2011. Under this policy, the frontier State hospitals would receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, 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 2016 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; and for FY 2016, 80 FR 49498.

In addition to the changes required by the Affordable Care Act, we note that the proposed 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 proposed rule (81 FR 25062 through 25076) for a detailed discussion of all proposed 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) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49488 through 49489 and 49494 through 49496), 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. 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, we are proposing to implement these revisions to the OMB statistical area delineations, effective

January 1, 2017, beginning with the CY 2017 OPPS wage indexes. Tables 2 and 3 for the FY 2017 IPPS/LTCH PPS proposed rule and the County to CBSA Crosswalk File and Urban CBSAs and Constituent Counties for Acute Care Hospitals File posted on the CMS Web site reflect these CBSA changes. We are inviting public comments on these proposals for the CY 2017 OPPS wage indexes.

For this CY 2017 OPPS/ASC proposed rule, we are proposing to use the proposed FY 2017 hospital IPPS post-reclassified wage index for urban and rural areas as the proposed wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment standardized amount for CY 2017. Thus, 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 the proposed FY 2017 hospital wage index files posted on the CMS Web site.)

Hospitals that are paid under the OPPS, but not under the IPPS, do not have an assigned hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPPS, it is our longstanding policy to assign the wage index that would be applicable if the hospital were paid under the IPPS, based on its geographic location and any applicable wage index adjustments. We are proposing to continue this policy for CY 2017. The following is a brief summary of the major proposed FY 2017 IPPS wage index policies and adjustments that we are proposing to apply to these hospitals under the

OPPS for CY 2017. We further refer readers to the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25062 through 25076) for a detailed discussion of the proposed changes to the FY 2017 IPPS wage indexes.

It has been our longstanding policy to allow non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)). Applying this adjustment is consistent with our policy of adopting IPPS wage index policies for hospitals paid under the OPPS. We note that, because non-IPPS hospitals cannot reclassify, they 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 are proposing to continue our policy of allowing non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the MMA).

As stated earlier, in the FY 2015 IPPS/LTCH PPS final rule, we adopted the OMB labor market area delineations issued by OMB in OMB Bulletin No. 13-01 on February 28, 2013, based on standards published on June 28, 2010 (75 FR 37246 through 37252) and the 2010 Census data to delineate labor market areas for purposes of the IPPS wage index. For IPPS wage index purposes, for hospitals that were located in urban CBSAs in FY 2014 but were designated as rural under these revised OMB labor market area delineations, we generally assigned them the urban wage index value of the CBSA in which they were physically located for FY 2014 for a period of 3 fiscal years

(79 FR 49957 through 49960). To be consistent, we applied the same policy to hospitals paid under the OPPS but not under the IPPS so that such hospitals 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). Thus, for the CY 2017 OPPS, consistent with the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25066 through 25067), this 3-year transition will continue for the third year in CY 2017.

In addition, for the FY 2017 IPPS, we proposed to extend the imputed floor policy (both the original methodology and alternative methodology) for another year, through September 30, 2017 (81 FR 25067 through 25068). For purposes of the CY 2017 OPPS, we also are proposing to apply the imputed floor policy to hospitals paid under the OPPS but not under the IPPS so long as the IPPS continues an imputed floor policy.

For CMHCs, for CY 2017, we are proposing to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. As with OPPS hospitals and for the same reasons, for CMHCs previously located in urban CBSAs that were designated as rural under the revised OMB labor market area delineations in OMB Bulletin No. 13-01, we finalized a policy to maintain the urban wage index value of the CBSA in which they were physically located for CY 2014 for 3 calendar years (until December 31, 2017). 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.

Table 2 associated with the FY 2017 IPPS/LTCH PPS proposed rule (available via the Internet on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html) identifies counties eligible for the out-migration adjustment and IPPS hospitals that would receive the adjustment for FY 2017. We are including the out-migration adjustment information from Table 2 associated with the FY 2017 IPPS/LTCH PPS proposed rule as Addendum L to this proposed rule with the addition of non-IPPS hospitals that would receive the section 505 out-migration adjustment under the CY 2017 OPPS. Addendum L is available via the Internet on the CMS Web site. With the exception of the proposed out-migration wage adjustment table (Addendum L to this proposed rule, which is available via the Internet on the CMS Web site), which includes non-IPPS hospitals paid under the OPPS, we are not reprinting the proposed FY 2017 IPPS wage indexes referenced in this discussion of the wage index. We refer readers to the CMS Web site for the OPPS at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html. At this link, readers will find a link to the proposed FY 2017 IPPS wage index tables and Addendum L.

D. Proposed Statewide Average Default CCRs

In addition to using CCRs to estimate costs from charges on claims for ratesetting, CMS uses overall hospital-specific CCRs calculated from the hospital's most recent cost report to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS during the PPS year. MACs cannot calculate a CCR for some hospitals because there is no cost report available. For

these hospitals, CMS uses the statewide average default CCRs to determine the payments mentioned 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 this proposed rule, we are proposing to update the default ratios for CY 2017 using the most recent cost report data. We discuss our policy for using default CCRs, including setting the ceiling threshold for a valid CCR, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009.

For detail on our process for calculating the statewide average CCRs, we refer readers to the CY 2017 OPPS NPRM Claims Accounting Narrative that is posted on the CMS Web site. Table 4 below lists the proposed statewide average default CCRs for OPPS services furnished on or after January 1, 2017.

TABLE 4.—PROPOSED CY 2017 STATEWIDE AVERAGE CCRs

State	Urban/Rural	Proposed CY 2017 Default CCR	Previous Default CCR (CY 2016 OPPS Final Rule)
ALASKA	RURAL	0.472	0.588
ALASKA	URBAN	0.261	0.269
ALABAMA	RURAL	0.207	0.224
ALABAMA	URBAN	0.162	0.168
ARKANSAS	RURAL	0.215	0.223
ARKANSAS	URBAN	0.208	0.218
ARIZONA	RURAL	0.251	0.246
ARIZONA	URBAN	0.171	0.170
CALIFORNIA	RURAL	0.188	0.179
CALIFORNIA	URBAN	0.187	0.190
COLORADO	RURAL	0.356	0.366
COLORADO	URBAN	0.210	0.208
CONNECTICUT	RURAL	0.445	0.366
CONNECTICUT	URBAN	0.256	0.257
DISTRICT OF COLUMBIA	URBAN	0.293	0.298
DELAWARE	URBAN	0.303	0.308
FLORIDA	RURAL	0.170	0.170
FLORIDA	URBAN	0.145	0.150
GEORGIA	RURAL	0.242	0.251
GEORGIA	URBAN	0.192	0.199
HAWAII	RURAL	0.340	0.339
HAWAII	URBAN	0.323	0.313
IOWA	RURAL	0.295	0.305
IOWA	URBAN	0.247	0.256
IDAHO	RURAL	0.338	0.337
IDAHO	URBAN	0.452	0.459
ILLINOIS	RURAL	0.240	0.234
ILLINOIS	URBAN	0.207	0.208
INDIANA	RURAL	0.277	0.314
INDIANA	URBAN	0.233	0.237
KANSAS	RURAL	0.281	0.287
KANSAS	URBAN	0.199	0.209
KENTUCKY	RURAL	0.193	0.202
KENTUCKY	URBAN	0.190	0.203

State	Urban/Rural	Proposed CY 2017 Default CCR	Previous Default CCR (CY 2016 OPPS Final Rule)
LOUISIANA	RURAL	0.225	0.256
LOUISIANA	URBAN	0.200	0.202
MASSACHUSETTS	RURAL	0.324	0.324
MASSACHUSETTS	URBAN	0.326	0.330
MAINE	RURAL	0.452	0.470
MAINE	URBAN	0.418	0.395
MARYLAND	RURAL	0.269	0.277
MARYLAND	URBAN	0.230	0.234
MICHIGAN	RURAL	0.293	0.317
MICHIGAN	URBAN	0.319	0.319
MINNESOTA	RURAL	0.414	0.449
MINNESOTA	URBAN	0.326	0.377
MISSOURI	RURAL	0.227	0.238
MISSOURI	URBAN	0.263	0.253
MISSISSIPPI	RURAL	0.235	0.235
MISSISSIPPI	URBAN	0.168	0.169
MONTANA	RURAL	0.470	0.480
MONTANA	URBAN	0.365	0.403
NORTH CAROLINA	RURAL	0.232	0.229
NORTH CAROLINA	URBAN	0.228	0.235
NORTH DAKOTA	RURAL	0.411	0.443
NORTH DAKOTA	URBAN	0.333	0.355
NEBRASKA	RURAL	0.284	0.283
NEBRASKA	URBAN	0.239	0.238
NEW HAMPSHIRE	RURAL	0.309	0.306
NEW HAMPSHIRE	URBAN	0.279	0.306
NEW JERSEY	URBAN	0.193	0.194
NEW MEXICO	RURAL	0.240	0.280
NEW MEXICO	URBAN	0.286	0.290
NEVADA	RURAL	0.199	0.219
NEVADA	URBAN	0.129	0.146
NEW YORK	RURAL	0.303	0.311
NEW YORK	URBAN	0.304	0.298
OHIO	RURAL	0.296	0.295
OHIO	URBAN	0.207	0.212
OKLAHOMA	RURAL	0.229	0.255
OKLAHOMA	URBAN	0.185	0.192

State	Urban/Rural	Proposed CY 2017 Default CCR	Previous Default CCR (CY 2016 OPPS Final Rule)
OREGON	RURAL	0.264	0.265
OREGON	URBAN	0.332	0.341
PENNSYLVANIA	RURAL	0.283	0.277
PENNSYLVANIA	URBAN	0.186	0.195
PUERTO RICO	URBAN	0.585	0.590
RHODE ISLAND	URBAN	0.292	0.290
SOUTH CAROLINA	RURAL	0.189	0.188
SOUTH CAROLINA	URBAN	0.194	0.197
SOUTH DAKOTA	RURAL	0.376	0.367
SOUTH DAKOTA	URBAN	0.228	0.224
TENNESSEE	RURAL	0.182	0.198
TENNESSEE	URBAN	0.179	0.177
TEXAS	RURAL	0.223	0.238
TEXAS	URBAN	0.175	0.179
UTAH	RURAL	0.368	0.493
UTAH	URBAN	0.310	0.325
VIRGINIA	RURAL	0.188	0.195
VIRGINIA	URBAN	0.231	0.233
VERMONT	RURAL	0.435	0.434
VERMONT	URBAN	0.336	0.336
WASHINGTON	RURAL	0.279	0.349
WASHINGTON	URBAN	0.301	0.308
WISCONSIN	RURAL	0.367	0.317
WISCONSIN	URBAN	0.291	0.296
WEST VIRGINIA	RURAL	0.272	0.276
WEST VIRGINIA	URBAN	0.285	0.294
WYOMING	RURAL	0.445	0.433
WYOMING	URBAN	0.320	0.311

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

In the CY 2006 OPPS 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 OPPS, excluding drugs, biologicals, brachytherapy sources, and devices paid under the pass-through payment policy in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173). Section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised § 419.43(g) of the regulations to clarify that 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 Pub. L. 105-33, a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating outlier payments and copayments. We stated in the CY 2006 OPPS final rule with comment period (70 FR 68560) that we would not reestablish the adjustment amount on an annual basis, but we may review the adjustment in the future and, if appropriate,

would revise the adjustment. We provided the same 7.1 percent adjustment to rural SCHs, including EACHs, again in CYs 2008 through 2016. Further, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68590), we updated the regulations at § 419.43(g)(4) to specify, in general terms, that items paid at charges adjusted to costs by application of a hospital-specific CCR are excluded from the 7.1 percent payment adjustment.

For the CY 2017 OPPS, we are proposing to continue our policy of a 7.1 percent payment adjustment that is done in a budget neutral manner for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, 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).

F. Proposed OPPS Payment to Certain Cancer Hospitals Described by Section 1886(d)(1)(B)(v) of the Act

1. Background

Since the inception of the OPPS, which was authorized by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33), Medicare has paid the 11 hospitals that meet the criteria for cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act under the OPPS for covered outpatient hospital services. These cancer hospitals are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106-113), Congress established section 1833(t)(7) of the Act, "Transitional Adjustment to Limit Decline in Payment," to determine OPPS

payments to cancer and children's hospitals based on their pre-BBA payment amount (often referred to as "held harmless").

As required under section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient services under the OPPS and a "pre-BBA amount." That is, cancer hospitals are permanently held harmless to their "pre-BBA amount," and they receive transitional outpatient payments (TOPs) or hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS, as set forth in section 1833(t)(7)(F) of the Act. The "pre-BBA amount" is the product of the hospital's reasonable costs for covered outpatient services occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital defined in section 1833(t)(7)(F)(ii) of the Act. The "pre-BBA amount" and the determination of the base PCR are defined at 42 CFR 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital Cost Report or the Hospital Health Care Complex Cost Report (Form CMS-2552-96 or Form CMS-2552-10, respectively) as applicable each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

Section 3138 of the Affordable Care Act amended section 1833(t) of the Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the OPPS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed outpatient costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as

determined appropriate by the Secretary. Section 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by cancer hospitals and other hospitals. Section 1833(t)(18)(B) of the Act provides that, if the Secretary determines that cancer hospitals' costs are greater than other 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 OPPS hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74200 through 74201).

Based on these findings, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects their higher outpatient costs as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74202 through 74206). Specifically, we adopted a policy to provide additional payments to the cancer hospitals so that each cancer hospital's final PCR for services provided in a given calendar year is equal to the weighted average PCR (which we refer to as the "target PCR") for other hospitals paid under the OPPS. The target PCR is set in advance of the calendar year and is calculated using the most 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 OPPS/ASC final rule with comment period (80 FR 70362 through 70363).

2. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2017

For CY 2017, we are proposing 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 OPPS hospitals using the most recent submitted or settled cost report data that are available at the time of the development of this proposed rule. 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 this proposed rule, used to estimate costs for the CY 2017 OPPS. Using these cost report data, we included data from Worksheet E, Part B, for each hospital, using data from each hospital's most recent cost report, whether as submitted or settled.

We then limited the dataset to the hospitals with CY 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 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2014 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 OPPS and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed the cost report data of 14 hospitals because these hospitals had cost report data that were not complete (missing aggregate OPPS payments, missing aggregate cost data, or missing both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to a proposed analytic file of 3,652 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated that, on average, the OPPS payments to other hospitals furnishing services under the OPPS are approximately 92 percent of reasonable cost (weighted average PCR of 0.92). Therefore, we are proposing that the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement would be the additional payment needed to result in a proposed target PCR equal to 0.92 for each cancer hospital. Table 5 below indicates the proposed estimated percentage increase in OPPS payments to each cancer hospital for CY 2017 due to the 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.—PROPOSED ESTIMATED CY 2017 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider Number	Hospital Name	Proposed Estimated Percentage Increase in OPPS Payments for CY 2017
050146	City of Hope Comprehensive Cancer Center	27.2%
050660	USC Norris Cancer Hospital	15.3%
100079	Sylvester Comprehensive Cancer Center	33.8%
100271	H. Lee Moffitt Cancer Center & Research Institute	28.7%
220162	Dana-Farber Cancer Institute	51.4%
330154	Memorial Sloan-Kettering Cancer Center	46.9%
330354	Roswell Park Cancer Institute	31.4%
360242	James Cancer Hospital & Solove Research Institute	39.4%
390196	Fox Chase Cancer Center	17.9%
450076	M.D. Anderson Cancer Center	54.0%
500138	Seattle Cancer Care Alliance	60.4%

G. Proposed Hospital Outpatient Outlier Payments

1. Background

The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. As explained in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66832 through 66834), we set our

projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for the prospective year. Outlier payments are provided on a service-by-service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by a certain amount) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain amount of dollars). In CY 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 proposed OPPS. Our estimate of total outlier payments as a percent of total CY 2015 OPPS payment, using CY 2015 claims available for this proposed rule and the revised OPPS expenditure estimate for the FY 2016 President's Budget, is approximately 1.0 percent of the total aggregated OPPS payments. Therefore, for CY 2015, we estimate that we paid the outlier target of 1.0 percent of total aggregated OPPS payments.

Using CY 2015 claims data and CY 2016 payment rates, we currently estimate that the aggregate outlier payments for CY 2016 will be approximately 1.0 percent of the total CY 2016 OPPS payments. We provide 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 Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

2. Proposed Outlier Calculation

For CY 2017, we are proposing to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We are proposing that a portion of that 1.0 percent, an amount equal to less than 0.01 percent of outlier payments (or 0.0001 percent of total OPPS payments) would be allocated to CMHCs for PHP outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated OPPS outlier payments. As discussed in section VIII.D. of this proposed rule, we are proposing 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 this proposed rule.

To ensure that the estimated CY 2017 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we are proposing that the hospital outlier threshold be set so that outlier payments would be triggered when a hospital's cost of furnishing a service exceeds 1.75 times the APC payment amount and exceeds the APC payment amount plus $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 this 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 this 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 proposed rule (81 FR 25271). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65845), we believe that the use of these charge inflation factors are appropriate for the OPPS because, with the

exception of the inpatient routine service cost centers, hospitals use the same ancillary and outpatient cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we are proposing to apply the same CCR inflation adjustment factor that we are proposing to apply for the FY 2017 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2017 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2017, we are proposing 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 is 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 multiple 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 OPPS payments. We estimated that a proposed fixed-dollar threshold of $3,825, combined with the proposed multiple threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments. For CMHCs, we are proposing that, if a CMHC's cost for partial hospitalization services, paid under APC 5853, exceeds 3.40 times the payment rate for APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 5853 payment rate.

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

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

The basic methodology for determining prospective payment rates for HOPD services under the OPPS is set forth in existing regulations at 42 CFR Part 419, Subparts C and D. For this CY 2017 OPPS/ASC proposed rule, the proposed payment rate for most services and procedures for which payment is made under the OPPS is the product of the proposed conversion factor calculated in accordance with section II.B. of this proposed rule and the proposed relative payment weight determined under section II.A. of this proposed rule. Therefore, the proposed national unadjusted payment rate for most APCs contained in Addendum A to this proposed rule (which is available via the Internet on the CMS Web site) and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) was calculated by multiplying the proposed CY 2017 scaled weight for the APC by the proposed 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 proposed rule.

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

Individual providers interested in calculating the payment amount that they would receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the proposed national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the "full"

national unadjusted payment rate. We refer to the proposed national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the "reduced" national unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.980 times the "full" national unadjusted payment rate. The proposed national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements in order to receive the proposed full CY 2017 OPPS fee schedule increase factor.

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

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

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

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

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. We note that, under the proposed CY 2017 OPPS policy for continuing to use the OMB labor market area delineations based on the 2010 Decennial Census data for the wage indexes used under the IPPS, a hold harmless policy for the wage index may apply, as discussed in section II.C. of this proposed rule. The proposed wage index values assigned to each area reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are proposed to be 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 Pub. L. 98-21. (For further discussion of the proposed changes to the FY 2017 IPPS wage indexes, as applied to the CY 2017 OPPS, we refer readers to section II.C. of this proposed rule. We are proposing to continue to apply a wage index floor of 1.00 to frontier States, in accordance with section 10324 of the Affordable Care Act of 2010.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of Pub. L. 108-173. Addendum L to this proposed rule (which is available via the Internet on the CMS Web site) contains the qualifying counties and the proposed associated wage index increase developed for the FY 2017 IPPS, which are listed in Table 2 in the FY 2017 IPPS/LTCH PPS proposed rule 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 * (national unadjusted payment rate) * applicable wage index.

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

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

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

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

Adjusted Medicare Payment = $Y + X_a$.

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

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

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

We are providing examples below of the calculation of both the proposed full and reduced national unadjusted payment rates that will apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined above. For purposes of this example, we used a provider that is located in Brooklyn, New York that is assigned to CBSA 35614. This provider bills one service that is assigned to APC 5071 (Level 1 Excision/Biopsy/Incision and Drainage). The proposed CY 2017 full national unadjusted payment rate for APC 5071 is approximately $531.31. The proposed reduced national unadjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is approximately $520.68. This proposed reduced rate is calculated by multiplying the proposed reporting ratio of 0.980 by the proposed full unadjusted payment rate for APC 5071.

The proposed FY 2017 wage index for a provider located in CBSA 35614 in New York is 1.2775. The labor-related portion of the proposed full national unadjusted

payment is approximately $407.25 (.60 * $531.31 * 1.2775). The labor-related portion of the proposed reduced national unadjusted payment is approximately $399.10 (.60 * $520.68 * 1.2775). The nonlabor-related portion of the proposed full national unadjusted payment is approximately $212.52 (.40 * $531.31). The nonlabor-related portion of the proposed reduced national unadjusted payment is approximately $208.27 (.40 * $520.68). The sum of the labor-related and nonlabor-related portions of the proposed full national adjusted payment is approximately $619.77 ($407.25 + $212.52). The sum of the portions of the proposed reduced national adjusted payment is approximately $607.37 ($399.10 + $208.27).

I. Proposed Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services. Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the Act, the effective copayment rate for a covered OPD service paid under the OPPS in CY 2006, and in calendar years thereafter, shall not exceed 40 percent of the APC payment rate.

Section 1833(t)(3)(B)(ii) of the Act provides that, for a covered OPD service (or group of such services) furnished in a year, the national unadjusted copayment amount

cannot be less than 20 percent of the OPD fee schedule amount. However, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

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

2. Proposed OPPS Copayment Policy

For CY 2017, we are proposing to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. (We refer readers to the November 7, 2003 OPPS final rule with comment period (68 FR 63458).) In addition, we are proposing to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. (We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles.)

The proposed national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2017, are shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). As discussed in section XIII.E. of this proposed rule, for CY 2017, the proposed Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

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

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

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

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

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

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

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

- If HCPCS codes are added to an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in an increase in the coinsurance percentage for the reconfigured APC, the copayment amount would be calculated as the product of the payment rate of the reconfigured APC and the lowest coinsurance percentage of the codes being added to the reconfigured APC.

We noted in that CY 2004 OPPS final rule with comment period that we would seek to lower the copayment percentage for a service in an APC from the prior year if the copayment percentage was greater than 20 percent. We noted that this principle was consistent with section 1833(t)(8)(C)(ii) of the Act, which accelerates the reduction in the national unadjusted coinsurance rate so that beneficiary liability will eventually equal 20 percent of the OPPS payment rate for all OPPS services to which a copayment applies, and with section 1833(t)(3)(B) of the Act, which 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).

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

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

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its payment rate. For example, using APC 5071, $106.26 is approximately 20 percent of the proposed full national unadjusted payment rate of $531.31. For APCs with only a minimum unadjusted copayment in

Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site), the beneficiary payment percentage is 20 percent.

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

B is the beneficiary payment percentage.

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

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

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

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

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

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

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

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

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

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

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

CPT and Level II HCPCS codes are used to report procedures, services, items, and supplies under the hospital OPPS. Specifically, CMS recognizes the following codes on OPPS claims:

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

CPT codes are established by the American Medical Association (AMA) and the Level II HCPCS codes are established by the CMS HCPCS Workgroup. These codes are

updated and changed throughout the year. CPT and HCPCS code changes that affect the OPPS are published both through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). CMS releases new Level II HCPCS codes to the public or recognizes the release of new CPT codes by the AMA and makes these codes effective (that is, the codes can be reported on Medicare claims) outside of the formal rulemaking process via OPPS quarterly update CRs. Based on our review, we assign the new CPT and Level II HCPCS codes to interim status indicator (SI) and APC assignments. These interim assignments are finalized in the OPPS/ASC final rules. This quarterly process offers hospitals access to codes that may more accurately describe items or services furnished and provides payment or more accurate payment for these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit public comments on these new codes and finalize our proposals related to these codes through our annual rulemaking process.

We note that, under the OPPS, the APC assignment determines the payment rate for an item, procedure, or service. For those items, procedures, or services not paid separately under the hospital OPPS, they are assigned to appropriate status indicators. Section XI. of this proposed rule provides a discussion of the various status indicators used under the OPPS. 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 OPPS quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the OPPS.

TABLE 6.—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April l, 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

*****In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that would be effective January 1. We refer readers to section III.A.3. of this CY 2017 OPPS/ASC proposed rule for further discussion of this issue.

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

Through the April 2016 OPPS quarterly update CR (Transmittal 3471, Change Request 9549, dated February 26, 2016), and the July 2016 OPPS quarterly update CR (Transmittal 3523, Change Request 9658, dated May 13, 2016), we recognized several new HCPCS codes for separate payment under the OPPS.

Effective April 1, 2016, we made effective 10 new Level II HCPCS codes and also assigned them to appropriate interim OPPS status indicators and APCs. Through the April 2016 OPPS quarterly update CR, we allowed separate payment for 10 new Level II HCPCS codes. Table 7 below lists the 10 Level II HCPCS codes that were allowed for separate payment effective April 1, 2016.

In this CY 2017 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for the Level II HCPCS codes implemented on April 1, 2016 and listed in Table 7 of this proposed rule. The proposed payment rates for these codes, where applicable, can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

TABLE 7.—NEW LEVEL II HCPCS CODES IMPLEMENTED IN APRIL 2016

CY 2016 HCPCS Code	CY 2016 Long Descriptor	Proposed CY 2017 Status Indicator	Proposed CY 2017 APC
C9137	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U.	G	1844
C9138	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), 1 I.U.	G	1846
C9461	Choline C 11, diagnostic, per study dose	G	9461
C9470	Injection, aripiprazole lauroxil, 1 mg	G	9470
C9471	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg	G	9471
C9472	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)	G	9472
C9473	Injection, mepolizumab, 1 mg	G	9473
C9474	Injection, irinotecan liposome, 1 mg	G	9474
C9475	Injection, necitumumab, 1 mg	G	9475
J7503	Tacrolimus, extended release, (Envarsus XR), oral, 0.25 mg	G	1845

Effective July 1, 2016, we made effective several new CPT and Level II HCPCS codes and also assigned them to appropriate interim OPPS status indicators and APCs. Through the July 2016 OPPS quarterly update CR (Transmittal 3523, Change Request 9658, dated May 13, 2016), we assigned interim OPPS status indicators and APCs for nine new Category III CPT codes and nine Level II HCPCS codes that were made effective July 1, 2016. Specifically, as displayed in Table 8 below, we made interim OPPS status indicators 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 note 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.

In addition, we note that HCPCS code Q9982 replaced HCPCS code C9459 (Flutemetamol f18, diagnostic, per study dose, up to 5 millicuries), effective July 1, 2016. Similarly, HCPCS code Q9983 replaced HCPCS code C9458 (Florbetaben f18, diagnostic, per study dose, up to 8.1 millicuries), effective July 1, 2016. Because HCPCS code Q9982 and Q9983 describe the same drugs as HCPCS code C9459 and C9458, respectively, we are proposing to continue their pass-through payment status, and assign the HCPCS Q-codes to the same APC and status indicators as their predecessor HCPCS C-codes, as shown in Table 8.

In addition, the CPT Editorial Panel established CPT code 0438T, effective July 1, 2016. We note that CPT code 0438T replaced HCPCS code C9743 (Injection/implantation of bulking or spacer material (any type)), effective July 1, 2016. Because CPT code 0438T describes the same procedure as HCPCS code C9743, we are proposing to assign the CPT code to the same APC and status indicator as its predecessor HCPCS C-code, as shown in Table 8.

In this CY 2017 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for the CPT and Level II HCPCS codes implemented on July 1, 2016. Table 8 below lists the CPT and Level II HCPCS

codes that were implemented on July 1, 2016, along with the proposed status indicators and proposed APC assignments for CY 2017.

TABLE 8.—NEW CATEGORY III CPT AND LEVEL II HCPCS CODES IMPLEMENTED IN JULY 2016

CY 2016 CPT/ HCPCS Code	CY 2016 Long Descriptor	Proposed CY 2017 Status Indicator	Proposed CY 2017 APC
C9476	Injection, daratumumab, 10 mg	G	9476
C9477	Injection, elotuzumab, 1 mg	G	9477
C9478	Injection, sebelipase alfa, 1 mg	G	9478
C9479	Injection, ciprofloxacin otic suspension, per vial	G	9479
C9480	Injection, trabectedin, 0.1 mg	G	9480
Q5102	Injection, Infliximab, Biosimilar, 10 mg	K	1847
Q9981	Rolapitant, oral, 1 mg	K	1761
Q9982*	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	G	9459
Q9983**	Florbetaben f18, diagnostic, per study dose, up to 8.1 millicuries	G	9458
0437T	Implantation of non-biologic or synthetic implant (eg, polypropylene) for fascial reinforcement of the abdominal wall (List separately in addition to primary procedure)	N	N/A
0438T***	Transperineal placement of biodegradable material, peri-prostatic (via needle), single or multiple, includes image guidance	T	5374
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
0440T	Ablation, percutaneous, cryoablation, includes imaging guidance; upper extremity distal/peripheral nerve	J1	5361

CY 2016 CPT/ HCPCS Code	CY 2016 Long Descriptor	Proposed CY 2017 Status Indicator	Proposed CY 2017 APC
0441T	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve	J1	5361
0442T	Ablation, percutaneous, cryoablation, includes imaging guidance; nerve plexus or other truncal nerve (eg, brachial plexus, pudendal nerve)	J1	5361
0443T	Real time spectral analysis of prostate tissue by fluorescence spectroscopy	T	5373
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	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.

In summary, we are soliciting public comments on the proposed CY 2017 status indicators and APC assignments for the Level II HCPCS codes and the Category III CPT codes that were made effective April 1, 2016, and July 1, 2016. These codes are listed in Tables 7 and 8 of this proposed rule. We also are proposing to finalize the status indicator and APC assignments and payment rates for these codes in the CY 2017 OPPS/ASC final rule with comment period. The proposed payment rates for these codes can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

2. Proposed Process for New Level II HCPCS Codes That Will Be Effective October 1, 2016 and January 1, 2017 for Which We Will Be Soliciting Public Comments in the CY 2017 OPPS/ASC Final Rule with Comment Period

As has been our practice in the past, we incorporate those new Level II HCPCS codes that are effective January 1 in the final rule with comment period, thereby updating the OPPS for the following calendar year. These codes are released to the public via the CMS HCPCS Web site, and also through the January OPPS quarterly update CRs. In the past, we also released new Level II HCPCS codes that are effective October 1 through the October OPPS quarterly update CRs and incorporated these new codes in the final rule with comment period, thereby updating the OPPS for the following calendar year.

For CY 2017, we are proposing to continue our established policy of assigning comment indicator "NI" in Addendum B to the OPPS/ASC final rule with comment period to those new Level II HCPCS codes that are effective October 1 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 the CY 2017 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2017. We will be inviting public comments in the CY 2017 OPPS/ASC final rule with comment period on the status indicator, APC assignments, and payment rates for these codes that would be finalized in the CY 2018 OPPS/ASC final rule with comment period.

3. Proposed Treatment of New and Revised CY 2017 Category I and III CPT Codes That Will Be Effective January 1, 2017, for Which We Are Soliciting Public Comments in This CY 2017 OPPS/ASC Proposed Rule

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

interim APC and status indicator assignments for CPT codes that are not available in time for the proposed rule and that describe wholly new services (such as new technologies or new surgical procedures), solicit public comments, and finalize the specific APC and status indicator assignments for those codes in the following year's final rule.

For the CY 2017 OPPS update, we received the CY 2017 CPT codes from AMA in time for inclusion in this CY 2017 OPPS/ASC proposed rule. The new and revised CY 2017 Category I and III CPT codes can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) and are assigned to new comment indicator "NP" to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year with a proposed APC assignment and that comments will be accepted on the proposed APC assignment and status indicator.

Further, we remind readers that the CPT code descriptors that appear in Addendum B are short descriptors and do not accurately describe the complete procedure, service, or item described by the CPT code. Therefore, we are including the 5-digit placeholder codes and their long descriptors for the new and revised CY 2017 CPT codes in Addendum O to this proposed rule (which is available via the Internet on the CMS Web site) so that the public can adequately comment on our proposed APCs and status indicator assignments. The 5-digit placeholder codes can be found in Addendum O, specifically under the column labeled "CY 2017 OPPS/ASC Proposed Rule 5-Digit Placeholder Code," to this proposed rule. The final CPT code numbers will be included in the CY 2017 OPPS/ASC final rule with comment period. We note that not

every code listed in Addendum O is subject to comment. For the new/revised Category I and III CPT codes, we are requesting comments on only those codes that are assigned to comment indicator "NP."

In summary, we are soliciting public comments on the proposed CY 2017 status indicators and APC assignments for the new and revised Category I and III CPT codes that will be effective January 1, 2017. The CPT codes are listed in Addendum B to this proposed rule with short descriptors only. We list them again in Addendum O to this proposed rule with long descriptors. We also are proposing to finalize the status indicator and APC assignments for these codes (with their final CPT code numbers) in the CY 2017 OPPS/ASC final rule with comment period. The proposed status indicator and APC assignment for these codes can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

B. Proposed OPPS Changes—Variations within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. Section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this classification system, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in § 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 proposed rule.

Under the OPPS, we generally pay for covered hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. For CY 2017, we are proposing that each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in APC 5012 (Clinic Visits and Related Services). The APC relative payment weights are scaled to APC 5012 because it is the hospital clinic visit APC and clinic visits are among the most frequently furnished services in the hospital outpatient setting.

2. Application of the 2 Times Rule

In accordance with section 1833(t)(2) of the Act and § 419.31 of the regulations, we annually review the items and services within an APC group to determine, with respect to comparability of the use of resources, if the highest cost for an item or service in the APC group is more than 2 times greater than the lowest cost for an item or service within the same APC group (referred to as the "2 times rule"). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act). In determining the APCs with a 2 times rule violation, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant procedure codes for examination under the 2 times rule, we consider procedure codes that have more than 1,000 single major claims or procedure codes that 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 this section of this proposed rule, for

CY 2017, we are proposing 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, we have identified the APCs with violations of the 2 times rule. Therefore, we are proposing changes to the procedure codes assigned to these APCs in Addendum B to this proposed rule. We note that Addendum B does not appear in the printed version of the **Federal Register** as part of this CY 2017 OPPS/ASC proposed rule. Rather, it is 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, we are proposing to reassign these procedure codes to new APCs that contain services that are similar with regard to both their clinical and resource characteristics. In many cases, the proposed procedure code reassignments and associated APC reconfigurations for CY 2017 included in this 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 are proposing changes to the status indicators for some procedure codes that are not specifically and separately discussed in this proposed rule. In these cases, we are proposing 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 are proposing for CY 2017. Addendum B to this CY 2017 OPPS/ASC proposed rule identifies with a comment indicator "CH" those procedure codes for which we are proposing a change to the APC

assignment or status indicator, or both, that were initially assigned in the 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).

3. Proposed APC Exceptions to the 2 Times Rule

Taking into account the APC changes that we are proposing 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 this 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 are proposing 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 this proposed rule. We did not include in that determination those APCs where a 2 times rule violation was not a relevant concept, such as APC 5401 (Dialysis), which has a proposed APC geometric mean cost of approximately $585. Therefore, we have only identified those APCs,

including those with criteria-based costs, such as device-dependent CPT/HCPCS codes, with 2 times rule violations.

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).

We note 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 this proposed rule lists the 4 APCs that we are proposing 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. 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.

The geometric mean costs for covered hospital outpatient services for these and all other APCs that were used in the development of this proposed rule can be found on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.

TABLE 9.—PROPOSED APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2017

Proposed CY 2017 APC	Proposed CY 2017 APC Title
5521	Level 1 Diagnostic Radiology without Contrast
5735	Level 5 Minor Procedures
5771	Cardiac Rehabilitation
5841	Psychotherapy

C. Proposed 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 OPPS final rule with comment period (68 FR 63416), we restructured the New Technology APCs to make the cost intervals more consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of

New Technology APCs, one set with a status indicator of "S" (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment) and the other set with a status indicator of "T" (Significant Procedure, Multiple Reduction Applies. Paid under OPPS; separate APC payment). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently.

We note that the cost bands for the New Technology APCs, specifically, APCs 1491 through 1599, vary with increments ranging from $10 to $10,000. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. For example, payment for New Technology APC 1507 (New Technology Level 7 ($500 - $600)) is made at approximately $550.

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 during 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 that Medicare should make full payment. However, we believe that it is most appropriate to set payment rates based on costs that are associated with providing care to Medicare beneficiaries. As claims data for new

services become available, we use these data to establish payment rates for new technology APCs.

2. Proposed Additional New Technology APC Groups

As stated above, for the CY 2016 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, we are proposing to expand the New Technology APC groups by adding 3 more levels, specifically, adding New Technology Levels 49 through 51. We are proposing 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 proposed rule. Therefore, for the CY 2017 OPPS update, we are proposing to establish six new groups of New Technology APCs--APCs 1901 through 1906 (for New Technology APC Levels 49 through 51) with procedures assigned to both OPPS 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 below includes the complete list of the proposed additional six New Technology APC groups for CY 2017.

TABLE 10.—PROPOSED ADDITIONAL NEW TECHNOLOGY APC GROUPS FOR CY 2017

Proposed New CY 2017 APC	Proposed CY 2017 APC Group Title	Proposed Status Indicator
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

The proposed payment rates for New Technology APC 1901 through 1906 can be found in Addendum A to this proposed rule (which is available via the Internet on the CMS Web site).

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

a. Overall Proposal

As we explained in the CY 2002 OPPS final rule with comment period (66 FR 59902), we generally retain a procedure in the New Technology APC to which it is initially assigned until we have obtained sufficient claims data to justify reassignment of the procedure to a clinically appropriate APC. 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 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, we are proposing to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to a clinically appropriate APC. The flexibility associated with this policy allows us to reassign a service from a New Technology APC in less than 2 years if sufficient claims data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient claims data upon which to base a decision for reassignment have not been obtained (66 FR 59902).

b. Retinal Prosthesis Implant Procedure

CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy) describes the implantation of a retinal prosthesis, specifically, a procedure involving 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 procedure described by HCPCS code C1841 was assigned to OPPS status indicator "N" to indicate that payment for the procedure 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 (New Technology - Level 48 ($90,001-$100,000)), which has a CY 2016 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 procedures 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 OPPS claims data used for this CY 2017 proposed rule shows 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. We note that the final payment rate in the CY 2017 OPPS/ASC final rule with comment period will be based on claims submitted between January 1, 2015, through December 31, 2015, and processed through June 30, 2016. Based on the latest OPPS claims data available for this proposed rule and our further understanding of the Argus® II procedure, we are proposing to reassign the procedure described by CPT code 0100T from APC 1599 to APC 1906 (New Technology - Level 51 ($140,001-$160,000)), which has a proposed payment rate of approximately $150,000 for CY 2017. We believe that APC 1906 is the most appropriate APC assignment for the Argus® II procedure described by CPT code 0100T. We note that this payment rate includes the cost of both the surgical procedure, including the cost of the retinal

prosthesis (noted above) (CPT code 0100T), and the cost of the Argus® II device (HCPCS code C1841). We are inviting public comments on this proposal.

D. Proposed OPPS APC-Specific Policies

1. Imaging

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 OPPS 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 OPPS 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 agree that further improvements can be achieved by making further changes to the structure of the APC groupings of the imaging procedures classified within the imaging APCs. Therefore, for CY 2017, we are proposing to make further changes to the structure of the imaging APCs. Below in Table 11 we list the CY 2016 imaging APCs, and in Table 12 we list 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 are listed in Addendum B to this proposed rule, which is available via the Internet on the CMS Web site. We note that some of the imaging procedures are assigned to APCs that are not listed in the tables below (for example, the vascular procedures APCs). Also, the nuclear

medicine services APCs are not included in this proposal. We are inviting public comments on our proposal to consolidate the imaging APCs from 17 APCs in CY 2016 to 8 in CY 2017.

TABLE 11.—CY 2016 IMAGING APCs

CY 2016 APC	CY 2016 APC Group Title	CY 2016 Status Indicator
5521	Level 1 X-Ray and Related Services	S
5522	Level 2 X-Ray and Related Services	S
5523	Level 3 X-Ray and Related Services	S
5524	Level 4 X-Ray and Related Services	S
5525	Level 5 X-Ray and Related Services	S
5526	Level 6 X-Ray and Related Services	S
5531	Level 1 Ultrasound and Related Services	S
5532	Level 2 Ultrasound and Related Services	S
5533	Level 3 Ultrasound and Related Services	S
5534	Level 4 Ultrasound and Related Services	S
5561	Level 1 Echocardiogram with Contrast	S
5562	Level 1 Echocardiogram with Contrast	S
5570	Computed Tomography without Contrast	S
5571	Level 1 Computed Tomography with Contrast and Computed Tomography Angiography	S
5572	Level 2 Computed Tomography with Contrast and Computed Tomography Angiography	S
5581	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast	S

CY 2016 APC	CY 2016 APC Group Title	CY 2016 Status Indicator
5582	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast	S

TABLE 12.—PROPOSED CY 2017 IMAGING APCs

Proposed CY 2017 APC	Proposed CY 2017 APC Group Title	Proposed CY 2017 Status Indicator
5521	Level 1 Diagnostic Radiology without Contrast	S
5522	Level 2 Diagnostic Radiology without Contrast	S
5523	Level 3 Diagnostic Radiology without Contrast	S
5524	Level 4 Diagnostic Radiology without Contrast	S
5525	Level 5 Diagnostic Radiology without Contrast	S
5571	Level 1 Diagnostic Radiology with Contrast	S
5572	Level 2 Diagnostic Radiology with Contrast	S
5573	Level 3 Diagnostic Radiology with Contrast	S

2. Strapping and Cast Application (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 OPPS status indicator "S" (Procedure or Service, Not Discounted When Multiple; Paid under OPPS; 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 review of the procedures assigned to APCs 5101 and 5102, we are proposing 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 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 primarily associated with surgical treatments, 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. Consequently, we also are proposing 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.

3. Transprostatic Urethral Implant Procedure

The procedure described by HCPCS code C9740 (Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants) is one of two procedure codes

associated with the UroLift System, which is used to treat patients diagnosed with benign prostatic hyperplasia (BPH). This procedure code was assigned to New Technology APC 1564 (New Technology - Level 27 ($4500-$5000) with a payment rate of $4,750 on April 1, 2014, when the HCPCS C-code was established. We continued this APC assignment for CY 2015. For the CY 2016 update, we revised the APC assignment for the procedure described by HCPCS code C9740 from APC 1564 to APC 1565 (New Technology - Level 28 ($5000-$5500), with a payment rate of $5,250 based on the OPPS claims data used for the CY 2016 OPPS ratesetting. We further discussed the APC reassignment for the procedure described by HCPCS code C9740 in the CY 2016 OPPS/ASC final rule (80 FR 70376 through 70377).

For the CY 2017 update, review of our claims data for the procedure described by HCPCS code C9740 shows a geometric mean cost of approximately $6,312 based on 585 single claims (out of 606 total claims), which is based on claims submitted between January 1, 2015 through December 31, 2015 and processed through December 31, 2015. We note that the final CY 2017 payment rates that will be included in the CY 2017 OPPS/ASC final rule with comment period will be based on claims submitted between January 1, 2015, through December 31, 2015, and processed through June 30, 2016. Based on the latest OPPS claims data available for this proposed rule, we are proposing to reassign the procedure described by HCPCS code C9740 from APC 1565 to APC 5376 (Level 6 Urology and Related Services), which has a geometric mean cost of approximately $7,723. We believe that the proposed reassignment is appropriate because the geometric mean cost of approximately $6,312 for the procedure described by HCPCS

code C9740 is similar to the geometric mean cost of $7,723 for APC 5376. Therefore, we are proposing to reassign the procedure described by HCPCS code C9740 from APC 1565 to APC 5376 for the CY 2017 update. The proposed CY 2017 payment rate for the procedure described by HCPCS code C9740 is included in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

IV. Proposed OPPS Payment for Devices

A. Proposed 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 OPPS 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 propose and finalize the dates for expiration of pass-through status for device categories as part of the OPPS 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. Proposed CY 2017 Pass-Through Devices

As stated earlier, section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2 years, but not more than 3 years. There currently are 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, we are proposing, 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. The other three codes listed will continue with pass-through status in CY 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 meets 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).

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, so that the criterion of substantial clinical improvement is fully understood and can be met.

b. Applications Received for Device Pass-Through Payment for CY 2017

We received three applications by the March 1, 2016 quarterly deadline, which is the last quarterly deadline in time for this CY 2017 OPPS/ASC proposed rule. None of these three applications was 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) 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 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.

(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 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). We are inviting public comment on whether BioBag® should be eligible under § 419.66(b) to be considered for device pass-through payment.

With respect to the existence of a previous pass-through device category that describes the BioBag®, the applicant proposed a category descriptor of "Larval therapy for the debridement of necrotic non-healing skin and soft tissue wounds." We have not identified an existing pass-through category that describes the BioBag®, but we welcome public comments on this issue.

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 x 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 x 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 x 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

[1] Dumville, et al.: Larval therapy for leg ulcers (VenUS II): randomized controlled trial).

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 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

---

[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.

[3] Tian et al.: Maggot debridement therapy for the treatment of diabetic foot ulcers: a meta-analysis. *Journal of Wound Care*. Vol. 22, No. 9, 2013.

to existing treatments. Based on the evidence submitted with the application, we are not yet convinced that the BioBag® provides a substantial clinical improvement over other treatments for wound debridement. We are inviting public comments on whether the BioBag® meets the substantial clinical improvement criterion.

(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)). We are inviting 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.

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 $1616.90, 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 x 100 percent = 136 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 x 100 percent = 13880 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 x 100 percent = 135 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, 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).

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 was lacking.

The application included information on a case series of 17 obstructive apnea patients who received an Encore hyo-mandibular 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 one 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 is 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. We are inviting public comments on whether the Encore™ System meets the substantial clinical improvement criterion.

(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 proposed a category descriptor within either the HCPCS code C18XX series or the HCPCS code C26XX series and 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. We are inviting public comment on whether Endophys PSS is described by a previously existing category.

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 x 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 x 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 x 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. We are inviting public comments on this issue.

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 have not been persuaded that the threshold for substantial clinical improvement has been met. We are inviting public comments on whether the Endophys PSS meets the substantial clinical improvement criterion.

3. Proposal to Change the 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. We are proposing 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 are inviting public comments on our proposal.

4. Proposal 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 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 status effective on April 1 would receive 2 years and 3 quarters of pass-through status while a pass-through device with pass-through status effective on October 1 would receive 2 years and 1 quarter of pass-through status.

b. Proposed CY 2017 Policy

We are proposing, beginning with pass-through devices newly approved in CY 2017 and subsequent calendar years, to allow for a quarterly expiration of pass-through status for devices to afford a pass-through 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 status would expire on September 30, 2020. We believe that the payment adjustment for transitional pass-through payments for devices under the OPPS 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 period for all pass-through devices will better insure robust data collection and more representative procedure payments once the pass-through devices are packaged. We are inviting public comments on this proposal.

5. Proposed 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 device pass-through 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 OPPS 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 IPPS 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 IPPS final rule and which determined that there was charge compression in both the IPPS and the OPPS 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 OPPS 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 OPPS 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 this proposed rule indicates that about two-thirds of providers have an "Implantable Devices Charged to Patients" CCR. For the hospitals that have an "Implantable Devices Charged to Patients" CCR, the median is 0.3911, compared with a median hospital-wide CCR of 0.2035.

b. Proposed CY 2017 Policy

We are proposing 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 are inviting public comments on this proposal.

6. Proposed 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. Proposed CY 2017 Policy

For CY 2017, we are proposing 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 this proposed rule for a discussion of this proposal. 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. Proposed Device-Intensive Procedures

1. Background

Under the OPPS, 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 proposed rule. 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 OPPS/ASC final rule with comment period (80 FR 70421 through 70426).

2. Proposed 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. For CY 2017, we are proposing to modify the methodology for assigning device-intensive status. Specifically, for CY 2017, we are proposing 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 2016 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 this proposed rule, respectively. We are proposing 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.

In addition, for new HCPCS codes describing procedures requiring the implantation of medical devices that do not yet have associated claims data, we are proposing 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, 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 is included in a new Addendum P to this proposed rule (which is available via the Internet on the CMS Web site).

3. Proposed Changes to the Device Edit Policy

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795), we finalized a policy and implemented claims processing edits that require any of the device codes used in the previous device-to-procedure edits to be present on the claim whenever a procedure code assigned to any of the APCs listed in Table 5 of the CY 2015 OPPS/ASC final rule with comment period (the CY 2015 device-dependent APCs) is reported on the claim. In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422), we modified our previously existing policy and applied the device coding requirements exclusively to procedures that require the implantation of a device that are assigned to a device-intensive APC. In the CY 2016 OPPS/ASC final rule with comment period, we also finalized our policy that the claims processing edits are such that any device code, when reported on a claim with a procedure assigned to a device-intensive APC (listed in Table 42 of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422)) will satisfy the edit.

As part of our proposal described in section IV.B.2. of this 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 are proposing to modify our existing device edit policy.

Specifically, for CY 2017 and subsequent years, we are proposing 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 are proposing that any device code, when reported on a claim with a device-intensive procedure, would satisfy the edit.

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

a. Background

To ensure equitable OPPS payment when a hospital receives a device without cost or with full credit, in CY 2007, we implemented a policy to reduce the payment for specified device-dependent APCs by the estimated portion of the APC payment attributable to device costs (that is, the device offset) when the hospital receives a specified device at no cost or with full credit (71 FR 68071 through 68077). Hospitals were instructed to report no cost/full credit device cases on the claim using the "FB" modifier on the line with the procedure code in which the no cost/full credit device is used. In cases in which the device is furnished without cost or with full credit, hospitals were instructed to report a token device charge of less than $1.01. In cases in which the device being inserted is an upgrade (either of the same type of device or to a different type of device) with a full credit for the device being replaced, hospitals were instructed to report as the device charge the difference between the hospital's usual charge for the device being implanted and the hospital's usual charge for the device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include

cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals were instructed to append the "FC" modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more background information on the "FB" and "FC" modifiers payment adjustment policies (72 FR 66743 through 66749).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), beginning in CY 2014, we modified our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our policy had been to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we reduced OPPS payment, for the applicable APCs, by the full or partial credit a hospital receives for a replaced device. Specifically, under this modified policy, hospitals are required to report on the claim the amount of the credit in the amount portion for value code "FD" (Credit Received from the Manufacturer for a Replaced Medical Device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. For CY 2014, we also limited the OPPS payment deduction for the applicable APCs to the total amount of the device offset when the "FD" value code appears on a claim. For CY 2015, we continued our existing

policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit and to use the three criteria established in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68072 through 68077) for determining the APCs to which our CY 2015 policy will apply (79 FR 66872 through 66873). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), we finalized our policy to no longer specify a list of devices to which the OPPS payment adjustment for no cost/full credit and partial credit devices would apply and instead apply this APC payment adjustment to all replaced devices furnished in conjunction with a procedure assigned to a device-intensive APC when the hospital receives a credit for a replaced specified device that is 50 percent or greater than the cost of the device.

b. Proposed Policy for CY 2017

For CY 2017, we are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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.

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

For CY 2016, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act and used the median cost (instead of the geometric mean cost per our standard methodology) to calculate the payment rate for the implantable miniature telescope procedure described by CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis), which is the only code assigned to APC 5494 (Level 4 Intraocular Procedures) (80 FR 70388). We note that we are proposing 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 are proposing 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 are proposing 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 geometric mean cost for the procedure described by CPT code 0308T (based on 30 claims) is approximately $7,762, and the median cost is approximately $15,567. The proposed CY 2017 payment rate (calculated using the median cost) is approximately $17,188.90. We are inviting public comments on this proposal.

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

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

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or "transitional pass-through payments" for certain drugs and biologicals. Throughout this

proposed rule, the term "biological" is used because this is the term that appears in section 1861(t) of the Act. "Biological" as used in this proposed rule 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 outpatient hospital services under Medicare Part B for which payment was made on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain "new" drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996 and whose cost is "not insignificant" in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as "drugs." As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the product as a hospital outpatient service under Medicare Part B. Proposed CY 2017 pass-through drugs and biologicals and their designated APCs are assigned status indicator "G" in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site).

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. The methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64. These regulations specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the APC payment that CMS determines is associated with the drug or biological. Section 1847A of the Act establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In this proposed rule, the term "ASP methodology" and "ASP-based" are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on the CMS 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. Proposal 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 OPPS 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 1/2 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.

We are proposing, 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 are inviting public comments on this proposal.

3. Proposed Drugs and Biologicals with Expiring Pass-Through Payment Status in CY 2016

We are proposing that the pass-through status of 15 drugs and biologicals would expire on December 31, 2016, as listed in Table 13 below. All of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2016. These drugs and biologicals were approved for pass-through 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 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 status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year (which is proposed at $110 for CY 2017), as discussed further in section V.B.2. of this proposed rule. If the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we are proposing 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 OPPS drug packaging threshold, we are proposing to provide separate payment at the applicable relative ASP-based payment amount (which is proposed at ASP+6 percent for CY 2017, as discussed further in section V.B.3. of this proposed rule).

TABLE 13.—PROPOSED DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS EXPIRES DECEMBER 31, 2016

CY 2016 HCPCS Code	CY 2016 Long Descriptor	CY 2016 Status Indicator	CY 2016 APC
C9497	Loxapine, inhalation powder, 10 mg	G	9497
J1322	Injection, elosulfase alfa, 1mg	G	1480
J1439	Injection, ferric carboxymaltose, 1 mg	G	9441
J1447	Injection, TBO-Filgrastim, 1 microgram	G	1748
J3145	Injection, testosterone undecanoate, 1 mg	G	1487
J3380	Injection, vedolizumab, 1 mg	G	1489
J7181	Injection, factor xiii a-subunit, (recombinant), per iu	G	1746
J7200	Factor ix (antihemophilic factor, recombinant), Rixubus, per i.u.	G	1467
J7201	Injection, factor ix, fc fusion protein (recombinant), per iu	G	1486
J7205	Injection, factor viii fc fusion (recombinant), per iu	G	1656
J7508	Tacrolimus, extended release, (astagraf xl), oral, 0.1 mg	G	1465
J9301	Injection, obinutuzumab, 10 mg	G	1476
J9308	Injection, ramucirumab, 5 mg	G	1488
J9371	Injection, Vincristine Sulfate Liposome, 1 mg	G	1466
Q4121	Theraskin, per square centimeter	G	1479

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

4. Proposed Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Payment Status in CY 2017

We are proposing to continue pass-through payment status in CY 2017 for 38 drugs and biologicals. None of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2016. These drugs and biologicals, which were approved for pass-through status between January 1, 2014, and July 1, 2016, are listed in Table 14 below. The APCs and HCPCS codes for these drugs and biologicals approved for pass-through status through July 1, 2016 are assigned status indicator "G" in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site).

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For CY 2017, we are proposing to continue to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the rate these drugs and biologicals would receive in the physician's office setting in CY 2017. We are proposing that a $0 pass-through payment amount would be paid for pass-through drugs

and biologicals under the CY 2017 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is proposed at ASP+6 percent, is $0.

In the case of policy-packaged drugs (which include the following: contrast agents; diagnostic radiopharmaceuticals; 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), we are proposing 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 are proposing 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 OPPS/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 are proposing to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a

diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2017, we are proposing to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is proposed at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we are proposing to provide pass-through payment at WAC+6 percent, the equivalent payment provided to pass-through drugs and biologicals without ASP information. If WAC information also is not available, we are proposing to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

The 38 drugs and biologicals that we are proposing to continue to have pass-through payment status for CY 2017 or have been granted pass-through payment status as of July 2016 are shown in Table 14 below.

TABLE 14.—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS IN CY 2017

CY 2016 HCPCS Code	CY 2017 HCPCS Code	CY 2017 Long Descriptor	Proposed CY 2017 Status Indicator	Proposed CY 2017 APC
A9586	A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	1664
C9137	C9137	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U.	G	1844
C9138	C9138	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), 1 I.U.	G	1846
C9349	C9349	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	C9461	Choline C 11, diagnostic, per study dose	G	9461
C9470	C9470	Injection, aripiprazole lauroxil, 1 mg	G	9470
C9471	C9471	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg	G	9471

CY 2016 HCPCS Code	CY 2017 HCPCS Code	CY 2017 Long Descriptor	Proposed CY 2017 Status Indicator	Proposed CY 2017 APC
C9472	C9472	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)	G	9472
C9473	C9473	Injection, mepolizumab, 1 mg	G	9473
C9474	C9474	Injection, irinotecan liposome, 1 mg	G	9474
C9475	C9475	Injection, necitumumab, 1 mg	G	9475
C9476	C9476	Injection, daratumumab, 10 mg	G	9476
C9477	C9477	Injection, elotuzumab, 1 mg	G	9477
C9478	C9478	Injection, sebelipase alfa, 1 mg	G	9478
C9479	C9479	Instillation, ciprofloxacin otic suspension, 6 mg	G	9479
C9480	C9480	Injection, trabectedin, 0.1 mg	G	9480
J0596	J0596	Injection, c1 esterase inhibitor (recombinant), 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
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 microgram	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
Q9982	Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	G	9459

CY 2016 HCPCS Code	CY 2017 HCPCS Code	CY 2017 Long Descriptor	Proposed CY 2017 Status Indicator	Proposed CY 2017 APC
Q9983	Q9983	Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries	G	9458

5. Proposed 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 OPPS/ASC final rule with comment period (80 FR 70430 through 70432). For CY 2017, as we did in CY 2016, we are proposing to continue to apply the same policy packaged offset policy to payment for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes. The proposed APCs to which a diagnostic radiopharmaceutical payment offset may be applicable are the same as for CY 2016 (80 FR 70430). Also, the proposed APCs to which a contrast agent payment offset may be applicable, a stress agent payment offset, or a skin substitute payment offset are also the same as for CY 2016 (80 FR 70431 through 70432).

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

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

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

a. Proposed Packaging Threshold

In accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to $50 per administration during CYs 2005 and 2006. In CY 2007, we used the four quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the $50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108-173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest $5 increment in order to determine the CY 2007 threshold amount of $55. Using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086)), we set the packaging threshold for establishing separate APCs for drugs and biologicals at $100 for CY 2016 (80 FR 70433).

Following the CY 2007 methodology, for this CY 2017 OPPS/ASC proposed rule, we used the most recently available four quarter moving average PPI levels to trend the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 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 are proposing a packaging threshold for CY 2017 of $110.

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

To determine the proposed CY 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 OPPS. 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 this proposed rule, or for the following policy-packaged items that we are proposing 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 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 68638). For each drug and biological HCPCS code, we used an estimated payment rate of ASP+6 percent (which is the payment rate we are proposing for separately payable drugs and biologicals for CY 2017, as discussed in more detail in section V.B.2.b. of this 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 are proposing 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 this proposed rule (which are available via the Internet on the CMS Web site) because these are the most recent data available for use at the time of development of this proposed rule. These data also were the basis for drug payments in the physician's office setting, effective April 1, 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 are proposing 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 OPPS claims data from the CY 2015 HCPCS codes that were reported to the CY 2016 HCPCS codes that we display in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) for proposed payment in CY 2017.

Our policy during previous cycles of the OPPS has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule with comment period. We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year. Only HCPCS codes that are identified as separately payable in the final rule with comment period are subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs and biologicals in this CY 2017 OPPS/ASC proposed rule, we are proposing to use 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 are proposing to use these data for budget neutrality estimates and impact analyses for this CY 2017 OPPS/ASC proposed rule.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B for the final rule will be based on ASP data from the second quarter of CY 2016. These data will be the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology,

effective October 1, 2016. These payment rates would then be updated in the January 2017 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2017. For items that do not currently have an ASP-based payment rate, we are proposing to recalculate their mean unit cost from all of the CY 2015 claims data and updated cost report information available for the CY 2017 final rule with comment period to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in this CY 2017 OPPS/ASC proposed rule may be different from the same drug HCPCS code's packaging status determined based on the data used for the CY 2017 OPPS/ASC final rule with comment period. Under such circumstances, we are proposing to continue to follow the established policies initially adopted for the CY 2005 OPPS (69 FR 65780) in order to more equitably pay for those drugs whose cost fluctuates relative to the proposed CY 2017 OPPS 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 OPPS/ASC final rule with comment period (80 FR 70434).

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

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74938), we unconditionally packaged skin substitute products into their associated surgical procedures as part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure. As part of the policy to finalize the packaging of skin substitutes, we also finalized a methodology that divides the skin

substitutes into a high cost group and a low cost group, in order to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures (78 FR 74933). We continued the high cost/low cost categories policy in CY 2015 and CY 2016, and are proposing 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 are proposing 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 are proposing to assign skin substitutes that exceed either the MUC or PDC threshold to the high cost group. We are proposing to assign skin substitutes with an MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group. For CY 2017, we analyzed CY 2015 claims data to calculate the MUC threshold (a weighted average of all

skin substitutes' MUCs) and PDC threshold (a weighted average of all skin substitutes' PDCs). The proposed CY 2017 MUC threshold is $25 per cm^2 (rounded to the nearest $1) and the proposed CY 2017 PDC threshold is $729 (rounded to the nearest $1).

For CY 2017, as in CY 2016, we are proposing 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 would use WAC+6 percent or 95 percent of AWP to assign a product to either the high cost or low cost category. New skin substitutes without pricing information would be assigned to the low cost category until pricing information is available to compare to the CY 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 are proposing 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 this 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 the CY 2017 final rule with comment period. Table 15 below displays the proposed CY 2017 high cost or low cost category assignment for each skin substitute product.

TABLE 15.—PROPOSED SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2017

CY 2017 HCPCS Code	CY 2017 Short Descriptor	Proposed CY 2017 High/Low Assignment
C9349*	PuraPly, PuraPly antimic	High
C9363	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

CY 2017 HCPCS Code	CY 2017 Short Descriptor	Proposed CY 2017 High/Low Assignment
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	Amnion bio and woundex sq cm	Low
Q4164	Helicoll, per square cm	High
Q4165	Keramatrix, per square cm	Low

*Pass-through payment status in CY 2017.

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

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

flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, we are proposing to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 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 this 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 is displayed in Table 16 below.

TABLE 16.—PROPOSED HCPCS CODES TO WHICH THE CY 2017 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2017 HCPCS Code	CY 2017 Long Descriptor	Proposed CY 2017 SI
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular, over 10 cc	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J1850	Injection, kanamycin sulfate, up to 75 mg	N
J1840	Injection, kanamycin sulfate, up to 500 mg	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	N
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	N
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N

CY 2017 HCPCS Code	CY 2017 Long Descriptor	Proposed CY 2017 SI
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
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N
J8520	Capecitabine, oral, 150 mg	N
J8521	Capecitabine, oral, 500 mg	N
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N

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

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

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i) of the Act, a "specified covered outpatient drug" (known as a SCOD) is defined as a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or is a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not included in the definition of SCODs. These exceptions are—

- A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.
- A drug or biological for which a temporary HCPCS code has not been assigned.
- During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs in CY 2006 and subsequent years be equal to the average acquisition cost for the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the Government Accountability Office (GAO) in CYs 2004 and 2005, and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, the law requires that payment be equal to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary. We refer to this alternative methodology as the "statutory default." Most physician Part B drugs are paid at ASP+6 percent in accordance with section 1842(o) and section 1847A of the Act.

Section 1833(t)(14)(E)(ii) of the Act provides for an adjustment in 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 this CY 2017 OPPS/ASC proposed rule, we are proposing to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. Although we do not distinguish SCODs in this discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs, but we also are applying this provision to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

For a detailed discussion of our OPPS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68383 through 68385). In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386 through 68389), we first adopted the statutory default policy to pay for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act. We continued this policy of paying for

separately payable drugs and biologicals at the statutory default for CY 2014, CY 2015, and CY 2016 (80 FR 70440).

b. Proposed CY 2017 Payment Policy

For CY 2017 and subsequent years, we are proposing to continue our payment policy that has been in effect from CY 2013 to present and pay for separately payable drugs and biologicals at ASP+6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). We are proposing that the ASP+6 percent payment amount for separately payable drugs and biologicals requires no further adjustment and represents the combined acquisition and pharmacy overhead payment for drugs and biologicals. We also are proposing that payments for separately payable drugs and biologicals are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act, and that the budget neutral weight scaler is not applied in determining payments for these separately paid drugs and biologicals.

We note that separately payable drug and biological payment rates listed in Addenda A and B to this proposed rule (available via the Internet on the CMS Web site), which illustrate the proposed 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 April 1, 2016, or WAC, AWP, or mean unit cost from CY 2015 claims data and updated cost report information available for this proposed rule. In general, these published payment rates are not the same as the actual January 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 proposed rule for which there was no ASP information available for April 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 proposed rule (reflecting April 2016 ASP data) that do not have ASP information available for the quarter beginning in January 2017. These drugs and biologicals would then be paid based on mean unit cost data derived from CY 2015 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to this proposed rule are not for January 2017 payment purposes and are only illustrative of the proposed CY 2017 OPPS payment methodology using the most recently available information at the time of issuance of this proposed rule.

c. Biosimilar Biological Products

For CY 2016, we finalized a policy to pay for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act and to subject nonpass-through biosimilar biological products to our annual

threshold-packaged policy (80 FR 70445 through 70446). For CY 2017, we are proposing to continue this same payment policy for biosimilar biological products.

3. Proposed Payment Policy for Therapeutic Radiopharmaceuticals

For CY 2017, we are proposing to continue the payment policy for therapeutic radiopharmaceuticals that began in CY 2010. We pay for separately paid therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. If ASP information is unavailable for a therapeutic radiopharmaceutical, we base therapeutic radiopharmaceutical payment on mean unit cost data derived 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 are proposing 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 are proposing 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 are in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site).

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

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

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

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

We stated in the CY 2013 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, for CY 2017, we are proposing to continue to provide an additional $10 payment for radioisotopes produced by non-HEU sources.

5. Proposed Payment for Blood Clotting Factors

For CY 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.

For CY 2017, we are proposing to pay for blood clotting factors at ASP+6 percent, consistent with our proposed payment policy for other nonpass-through, separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount. Our policy to pay for a furnishing fee for blood clotting factors under the OPPS is consistent with the methodology applied in the physician's office and in the inpatient hospital setting. These methodologies were first articulated in the CY 2006 OPPS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update is based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the MPFS and OPPS/ASC proposed rules are published, we are not able to include the actual updated furnishing fee in the proposed rules. Therefore, in accordance with our policy, as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we are proposing to announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.

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

For CY 2017, we are proposing to continue to use the same payment policy as in CY 2016 for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS 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 OPPS hospital claims data is listed in Addendum B to this proposed rule, which is available via the Internet on the CMS Web site.

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

A. Background

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for drugs, biologicals, radiopharmaceuticals, and categories of devices for a given year to an "applicable percentage," currently not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year. If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate

prorata reduction to the conversion factor for the projected level of pass-through spending in the following year to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing 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 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of items that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 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 OPPS/ASC final rule with comment period (78 FR 75034 through 75036). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision or a

natural orifice) use the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), in this proposed rule for CY 2017, we are proposing to include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. Similarly, we finalized a policy in CY 2015 that applications for pass-through payment for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology (76 FR 66885 through 66888). Therefore, as we did beginning in CY 2015, for CY 2017, we also are proposing to include an estimate of any skin substitutes and similar products in our estimate of pass-through spending for devices.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. Because we are proposing to pay for most nonpass-through separately payable drugs and biologicals under the CY 2017 OPPS at ASP+6 percent, and because we are proposing to pay for CY 2017 pass-through drugs and biologicals at ASP+6 percent, as we discussed in section V.A. of this proposed rule, our estimate of

drug and biological pass-through payment for CY 2017 for this group of items is $0, as discussed below.

Furthermore, payment for certain drugs, specifically diagnostic radiopharmaceuticals and contrast agents without pass-through status, is packaged into payment for the associated procedures, and these products will not be separately paid. In addition, we policy-package all nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies when used in a surgical procedure, as discussed in section II.A.3. of this proposed rule. We are proposing that all of these policy-packaged drugs and biologicals with pass-through payment status would be paid at ASP+6 percent, like other pass-through drugs and biologicals, for CY 2017. Therefore, our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2017 is not $0, as discussed below. In section V.A.4. of this proposed rule, we discuss our policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving pass-through payment, we are proposing to offset the amount of pass-through payment for the policy-packaged drug or biological. For these drugs or biologicals, the APC offset amount is the portion of the APC payment for the specific procedure performed with the pass-through drug or biological, which we refer to as the policy-packaged drug APC

offset amount. If we determine that an offset is appropriate for a specific policy-packaged drug or biological receiving pass-through payment, we are proposing to reduce our estimate of pass-through payments for these drugs or biologicals by this amount.

Similar to pass-through estimates for devices, the first group of drugs and biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 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. Proposed Estimate of Pass-Through Spending

We are proposing to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 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 estimate 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 estimate 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 estimate 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 are proposing an estimate for the first group of devices of $102.7 million.

In estimating our proposed CY 2017 pass-through spending for device categories in the second group, we include: device categories that we knew at the time of the development of this proposed rule will be newly eligible for pass-through payment in CY 2017; additional device categories that we estimate 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. We are proposing to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new

pass-through device categories. For this proposed rule, the estimate of CY 2017 pass-through spending for this second group of device categories is $10 million.

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 estimate the pass-through payment amount as the difference between ASP+6 percent and the payment rate for nonpass-through drugs and biologicals that will be separately paid at ASP+6 percent, which is zero for this group of drugs. Because payment for policy-packaged drugs and biologicals is packaged if the product was not paid separately due to its pass-through payment status, we are proposing to include in the CY 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 this 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.

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 are proposing to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2017 pass-through payment estimate. We also are proposing to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 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.

In summary, in accordance with the methodology described earlier in this section, for this proposed rule, we estimate that proposed 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 would be approximately $148.3 million (approximately $112.7 million for device categories and approximately $35.6 million for drugs and biologicals), which represents 0.24 percent of total projected OPPS payments for CY 2017. Therefore, we estimate that proposed pass-through spending in CY 2017 would not amount to 2.0 percent of total projected OPPS CY 2017 program spending.

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

For CY 2017, we are proposing to continue with and are not proposing any changes to our current clinic and emergency department (ED) hospital outpatient visits payment policies. For a description of the current clinic and ED hospital outpatient visits policies, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70448). We also are proposing to continue with and are not proposing 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). We are seeking public comments on any

changes to these codes that we should consider for future rulemaking cycles. We encourage those parties who comment to provide the data and analysis necessary to justify any proposed changes.

VIII. Proposed Payment for Partial Hospitalization Services

A. Background

A partial hospitalization program (PHP) is an intensive outpatient program of psychiatric services provided as an alternative to inpatient psychiatric care for individuals who have an acute mental illness. 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 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). In that final rule, we made two refinements to the methodology for computing the PHP median: the first remapped 10 revenue codes that are common among hospital-based PHP claims to the most appropriate cost centers; and the second refined our methodology for computing the PHP median per diem cost by computing a separate per diem cost for each day rather than for each bill.

In CY 2009, we implemented several regulatory, policy, and payment changes, including a two-tiered payment approach for partial hospitalization services under which we paid one amount for days with 3 services under PHP APC 0172 (Level 1 Partial Hospitalization) and a higher amount for days with 4 or more services under PHP APC 0173 (Level 2 Partial Hospitalization) (73 FR 68688 through 68693). We also finalized our policy to deny payment for any PHP claims submitted for days when fewer than 3 units of therapeutic services are provided (73 FR 68694). Furthermore, for CY 2009, we revised the regulations at 42 CFR 410.43 to codify existing basic PHP patient eligibility criteria and to add a reference to current physician certification requirements under 42 CFR 424.24 to conform our regulations to our longstanding policy (73 FR 68694 through 68695). We also revised the partial hospitalization benefit to include several coding updates (73 FR 68695 through 68697). For CY 2010, we retained the two-tiered payment

approach for partial hospitalization services and used only hospital-based PHP data in computing the PHP APC per diem costs, upon which PHP APC per diem payment rates are based. We used only hospital-based PHP data because we were concerned about further reducing both PHP APC per diem payment rates without knowing the impact of the policy and payment changes we made in CY 2009. Because of the 2-year lag between data collection and rulemaking, the changes we made in CY 2009 were reflected for the first time in the claims data that we used to determine payment rates for the CY 2011 rulemaking (74 FR 60556 through 60559).

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71994), we established four separate PHP APC per diem payment rates: two for CMHCs (APC 0172 (for Level 1 services) and APC 0173 (for Level 2 services)) and two for hospital-based PHPs (APC 0175 (for Level 1 services) and 0176 (for Level 2 services)), based on each provider type's own unique data. 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 PHP APCs Level 1 and Level 2

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

For CY 2012, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74348 through 74352), we determined the relative payment weights for partial hospitalization services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for partial hospitalization services provided by hospital-based PHPs based exclusively on hospital data.

In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal to base the relative payment weights that underpin the OPPS APCs, including the four PHP APCs (APCs 0172, 0173, 0175, and 0176), on geometric mean costs rather than on the median costs. We established these four PHP APC per diem payment rates based on geometric mean cost levels calculated using the most recent claims and cost

data for each provider type. For a detailed discussion on this policy, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68406 through 68412).

In the CY 2014 OPPS/ASC proposed rule (78 FR 43621 through 43622), we solicited comments on possible future initiatives that may help to ensure the long-term stability of PHPs and further improve the accuracy of payment for PHP services, but proposed no changes. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75050 through 75053), we summarized the comments received on those possible future initiatives. We also continued to apply our established policies to calculate the four PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims data for each provider type. For a detailed discussion on this policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75050 through 75053).

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66902 through 66908), we continued to apply our established policies to calculate the four PHP APC per diem payment rates based on PHP APC geometric mean per diem costs, using the most recent claims and cost data for each provider type.

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70455 through 70465), we 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 OPPS/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 OPPS/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 OPPS/ASC final rule with comment period (80 FR 70456) that, without using a trimming process, the data from these providers would inappropriately skew the geometric mean per diem cost for Level 2 CMHC PHP 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 OPPS ±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 OPPS ±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 CY 2016 OPPS/ASC proposed rule (80 FR 39242 and 39293) and reiterated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70456), OPPS 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 OPPS/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 OPPS/ASC final rule with comment period (80 FR 70453 through 70455).

B. Proposed PHP APC Update for CY 2017

1. Proposed PHP APC Changes and Effects on Geometric Mean Per Diem Costs

For CY 2017, we are proposing to continue to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims and cost data for each provider type. However, as explained in greater detail below, we are proposing 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 OPPS/ASC final rule with comment period (80 FR 70459).

a. Proposed Changes to PHP APCs

In this CY 2017 OPPS/ASC proposed rule, we are proposing 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 are proposing to replace existing CMHC PHP 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 PHP 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 are proposing 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, 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, for CY 2017 and subsequent years. Further, we are proposing to compute the proposed new CMHC PHP APC 5853 proposed geometric mean per diem costs for partial hospitalization services provided by

CMHCs using only CY 2015 CMHC claims data and the most recent cost data, and to compute the proposed hospital-based PHP APC 5863 proposed geometric mean per diem costs for partial hospitalization services provided by hospital-based PHPs using only CY 2015 hospital-based PHP claims data and the most recent cost data. We discuss these computations under section VIII.B.2 of this preamble. The proposed geometric mean per diem costs are shown in Table 19 in section VIII.B.2. of this proposed rule.

b. Rationale for Proposed Changes in PHP APCs

One of the primary reasons for our proposal to replace the existing Level 1 and Level 2 PHP APCs with a single PHP APC, by provider type, is because the proposed new PHP APCs would 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 would be 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 OPPS/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 would be $241.08 and the CY 2017 Level 2 hospital-based PHP APC geometric mean per diem cost would be $187.06, which again demonstrates an inversion.

We analyzed the CY 2015 hospital-based PHP claims data used for this 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. 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 proposal to collapse 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 OPPS/ASC final rule with comment period (73 FR 68688 through 68693), to determine whether the rationales continued to be applicable. In the CY 2009 OPPS/ASC final rule with comment period, we referenced the CY 2008 OPPS/ASC final rule with comment period (72 FR 66672), which noted that a significant portion of PHP service days actually provided fewer than three services to Medicare beneficiaries. In our CY 2009 OPPS/ASC final rule with comment period, we noted that PHP service days that provide exactly three 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 below to determine if a significant portion of PHP service days only provided exactly 3 services. Table 17 shows that the frequency of claims reporting PHP service days providing exactly 3 services (Level 1 services) has decreased greatly from 73 percent of CMHC PHP service days in the CY 2009 rulemaking to 4 percent of CMHC PHP service days in this CY 2017 proposed rulemaking, 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 this CY 2017 proposed rulemaking. Level 1 PHP service days now represent a small portion of PHP service days, particularly for CMHCs, as shown in Table 17 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 17 indicate that for the CY 2017 rulemaking year, the Level 2 CMHC PHP service days and the hospital-based PHP Level 2 service days are 96 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 higher rate when 4 or more services are provided compared to when only 3 services are provided. Our proposed 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 proposed new PHP APCs 5853 and 5863 result in appropriate per diems based on costs for providing 3 or more services per day.

TABLE 17.—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 CY 2015 CLAIMS

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	4%	96%	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 proposal to replace the existing two-tiered PHP APCs with proposed new PHP APCs 5853 and 5863 would provide payment for providing 3 or more services per day by CMHCs and hospital-based PHPs, respectively. Therefore, this flexibility in scheduling remains.

Another primary reason for proposing 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 should reduce these cost fluctuations and provide more stability in the PHP APC geometric mean per diem costs.

We also note that our proposal 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 services 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 proposal 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 would expect that the resource use (that is, the geometric mean per diem cost) for providing partial hospitalization services under Level 1 would represent approximately 75 percent or less of the resource use for providing partial hospitalization services under Level 2, by provider type. Table 18 shows 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 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 and welcome public comments that can help explain the difference.

TABLE 18.—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%	85.5%
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%*	128.9%*

*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. We found that individual therapy was provided in roughly the same proportion under the two payment tiers for hospital-based PHPs (in 1.3

percent of PHP APC Level 1 service days and in 1.5 percent of PHP APC Level 2 service days). However, we found that individual therapy was provided less frequently under the Level 1 CMHC PHP service days than under the Level 2 CMHC PHP service days (2.1 percent versus 5.1 percent). The greater frequency of CMHCs' providing more costly individual therapy under Level 2 PHP service days should increase resource use for the more costly partial hospitalization services provided under Level 2 CMHC PHP service days, widening the cost difference between Level 1 and Level 2 CMHC PHP service days. However, as noted previously, that is not what the data show.

As we have 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 because of the policy concerns noted above, we are proposing to replace the Level 1 and Level 2 PHP APCs, by provider type, with a single PHP APC for each provider type for CY 2017 and subsequent years.

Our proposal 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 proposal 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 proposal to combine the PHP APCs two-tiered payment structure by provider type would more appropriately pay providers for partial hospitalization services provided to Medicare beneficiaries and avoid cost inversions in the future. Our proposal to combine the PHP APC payment tiers by provider type also would provide more predictable 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 proposal 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 proposal 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 proposing to create proposed new CMHC PHP 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 PHP APCs 5851 and 5852 for CY 2017 and subsequent years. We also are proposing to create proposed 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 proposed geometric mean per

diem cost for proposed new CMHC APC 5853 and the proposed geometric mean per diem cost for proposed new hospital-based PHP APC 5863 in section VIII.B.2. of this proposed rule.

If our CY 2017 proposals are implemented, we would 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 PHP services are intensive outpatient services, our regulations at § 410.43(c)(1) require that PHPs provide each beneficiary at least 20 hours of services each week. 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 program 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 assure that they meet the 20 hours of services per week requirement, and we will communicate how we intend to undertake such enhanced monitoring in subregulatory guidance in the future.

Finally, we are concerned by the low frequency of providing individual therapy, which we noted earlier in this section, and we will be monitoring its provision. We believe that appropriate treatment for PHP patients includes some 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.

c. Alternatives Considered

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 propose 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 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 this CY 2017 proposed rule. This suggested that adjusting data trims may not be an effective method for resolving the inversion. Nevertheless, we reconsidered our analysis of the 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 are not proposing to change the existing CCR>5 trim on hospital-based PHP service days for our CY 2017 ratesetting.

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

For CY 2017 and subsequent years, generally, we are proposing to follow the detailed PHP ratesetting methodology described in section VIII.B.2.e. of the CY 2016

OPPS/ASC final rule with comment period (80 FR 70462 through 70466) to determine the proposed PHP APCs' geometric mean per diem costs and to calculate the proposed payment rates for the two proposed single hospital-based PHP APC and CMHC APC. However, as discussed in section VIII.B.1. of this preamble, in support of our CY 2017 proposals to establish single PHP APCs for hospital-based PHPs and CMHCs, we are proposing to combine the geometric mean per diem costs for the two existing hospital-based PHP APCs to calculate a proposed geometric mean per diem cost for proposed new 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 among these two APCs, we are proposing 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 proposed new PHP APC 5863. We then are proposing to continue to follow the existing methodology to its end to calculate the proposed geometric mean per diem cost for proposed new PHP APC 5863. Therefore, the proposed geometric mean per diem cost for proposed new 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 are proposing to combine the geometric mean per diem costs for the two existing CMHC PHP APCs to calculate a proposed geometric mean per diem cost for proposed new CMHC PHP APC 5853. Currently, CMHC PHP service days with exactly

3 service units (based on allowable PHP HCPCS codes) are assigned to Level 1 CMHC PHP APC 5851, and CMHC PHP service days with 4 or more service units (based on allowable PHP HCPCS codes) are assigned to Level 2 CMHC PHP APC 5852. Under our CY 2017 proposal, instead of separating the service days among these two APCs, we are proposing to combine the service days so that CMHC PHP service days that provide 3 or more service units (based on allowable PHP HCPCS codes) are assigned to proposed new PHP APC 5853. We then are proposing to continue to follow the existing PHP ratesetting methodology described in section VIII.B.2.e. of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 through 70466) to its end to calculate the proposed geometric mean per diem cost for proposed new PHP APC 5853. Therefore, the proposed geometric mean per diem cost for proposed new PHP APC 5853 would be based upon actual CMHC claims and costs for CMHC PHP service days providing 3 or more services.

To prevent confusion, we refer to the per diem costs listed in Table 17 of this proposed rule as the proposed PHP APC per diem costs or the proposed PHP APC geometric mean per diem costs, and the per diem payment rates listed in Addendum A to this proposed rule (which is available via the Internet on the CMS Web site) as the proposed PHP APC per diem payment rates or the proposed PHP APC geometric mean per diem payment rates. The PHP APC per diem costs are the provider-specific costs derived from the most recent claims and cost data. The PHP APC per diem payment rates are the national unadjusted payment rates calculated from the PHP APC per diem

costs, after applying the OPPS budget neutrality adjustments described in section II.A.4. of this proposed rule.

We are proposing to apply our established methodologies in developing the 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 OPPS/ASC final rule with comment period (80 FR 70456 through 70459) for CY 2016 and subsequent years.

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

Prior to calculating the proposed geometric mean per diem cost for proposed new CMHC PHP APC 5853, we prepared the data by first applying trims and data exclusions, and assessing CCRs as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465), so that our ratesetting is not skewed by providers with extreme data. Under the ±2 standard deviation trim policy, we exclude any data from a CMHC for ratesetting purposes when the CMHC's geometric mean cost per day is more than ±2 standard deviations from the geometric mean cost per day for all CMHCs. By applying this trim for CY 2017 ratesetting, 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. We also apply the OPPS ±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 a number of providers from ratesetting whose

data would have skewed the calculated proposed geometric mean per diem cost downward.

In accordance with our PHP ratesetting methodology, we also remove service days with no wage index values because we use the wage index data to remove the effects of geographic variation in costs prior to APC geometric mean per diem cost calculation (80 FR 70465). In our proposed CY 2017 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 OPPS ratesetting methodology defaults any CMHC CCR>1 to the statewide hospital ancillary CCR (80 FR 70457). In our proposed CY 2017 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 proposed 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 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 proposed CMHC PHP APC geometric mean per diem cost. Moreover, we believe that these trims, exclusions, and adjustments help prevent inappropriate fluctuations in the PHP APC geometric mean per diem payment rates.

After applying all of the above trims, exclusions, or adjustments, the proposed geometric mean per diem cost for all CMHCs for providing 3 or more services per day (proposed new CMHC PHP APC 5853) is $135.30.

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

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 to 70465) so that our ratesetting is not skewed by providers with extreme data. Before any trimming or exclusions, there were 404 hospital-based PHP providers in the claims data. For hospital-based PHP providers, we apply a trim on hospital service days when the CCR is greater than 5 at the cost center level. The CCR>5 hospital service day trim removes 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 excludes CMHC providers that fail the trim, the CCR>5 trim excludes 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. 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 ratesetting. In addition, the OPPS ±3 standard deviation trim on costs per day removed four providers from ratesetting.

Finally, we excluded 13 hospital-based PHP providers that reported zero daily costs on their claims, in accordance with our 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 ratesetting. After completing these data preparation steps, we calculated the proposed 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 (proposed hospital-based PHP APC 5863) is $192.57.

Currently, the Level 2 hospital-based PHP per diem costs serve as the cap for all outpatient mental health services provided in a single service day. If our proposal to replace the existing two-tiered PHP APCs structure with a single APC grouping for these services by specific provider type is finalized, the proposed outpatient mental health cap would be the geometric mean per diem costs for proposed new hospital-based PHP APC 5863.

The proposed CY 2017 PHP APC geometric mean per diem costs for the proposed new CMHC and hospital-based PHP APCs are shown in Table 19 below. The proposed PHP APC payment rates are included in Addendum A to this proposed rule (which is available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html).

TABLE 19.—PROPOSED CY 2017 PHP APC GEOMETRIC MEAN PER DIEM COSTS

Proposed CY 2017 APC	Group Title	Proposed PHP APC Geometric Mean Per Diem Costs
5853	Partial Hospitalization (3 or more services per day) for CMHCs	$135.30
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	$192.57

We are inviting public comments on these proposals.

3. PHP Ratesetting Process

While PHP services are part of the OPPS, 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 OPPS/ASC final rule with comment period (80 FR 70462 through 70467). The OPPS 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 proposed rule and encourage readers to review these discussions to increase their overall understanding of the entire OPPS ratesetting process. We also refer readers to the OPPS Claims Accounting narrative, which is a supporting document to this proposed rule, available on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html; click on the link to this proposed rule 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. Proposed Outlier Policy for CMHCs

1. Estimated Outlier Threshold

As discussed in the CY 2004 OPPS final rule with comment period (68 FR 63469 through 63470), after examining the costs, charges, and outlier payments for CMHCs, we believed that establishing a separate OPPS outlier policy for CMHCs would be appropriate. A CMHC-specific outlier policy would direct OPPS 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 OPPS payments provided to CMHCs. Beginning in CY 2004, we designated a portion of the estimated OPPS outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS each year, excluding outlier payments, and established a separate outlier threshold for CMHCs.

The separate outlier threshold for CMHCs resulted in $1.8 million in outlier payments to CMHCs in CY 2004, and $0.5 million in outlier payments to CMHCs in CY 2005. In contrast, in CY 2003, more than $30 million was paid to CMHCs in outlier payments. We note that, in the CY 2009 OPPS/ASC final rule with comment period, we also established an outlier reconciliation policy to address charging aberrations related to OPPS outlier payments (73 FR 68594 through 68599).

In this CY 2017 proposed rule, we are proposing 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 OPPS in CY 2017, excluding outlier payments. CMHCs are projected to receive 0.03 percent of total OPPS payments in CY 2017, excluding outlier payments. As we do for each rulemaking cycle, we have updated the CMHC CCRs and claims data used to model the PHP payments rates. This 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 are proposing to designate less than 0.01 percent of the estimated 1.0 percent outlier threshold for CMHCs.

Based on our simulations of CMHC payments for CY 2017, in this proposed rule, we are proposing to continue to set the cutoff point for CY 2017 at 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year, which for CY 2017 is the proposed payment rate for proposed new CMHC PHP APC 5853. In addition, we are proposing to continue to apply the same outlier payment percentage that applies to hospitals. Therefore, for CY 2017, we are proposing to continue to pay 50 percent of CMHC PHP 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 proposed new CMHC PHP APC 5853 exceeds 3.4 times the proposed payment rate for proposed new CMHC PHP APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.4 times the payment rate for proposed new CMHC PHP APC 5853.

In section II.G. of this proposed rule, for the hospital outpatient outlier payment policy, we are proposing to set a dollar threshold in addition to an APC multiplier threshold. Because the PHP APCs are the only APCs for which CMHCs may receive payment under the OPPS, we would not expect to redirect outlier payments by imposing a dollar threshold. Therefore, we are not proposing to set a dollar threshold for CMHC outlier payments.

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

2. Proposed CMHC Outlier Cap

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 little 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. Contrast that 36 percent with the OPPS outlier threshold of 1 percent of total OPPS payments (with the CMHC threshold being a fraction of that 1 percent, based on the percentage of projected per diem payments to CMHCs under the OPPS). 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 for exceptional high cost patients, but instead as a routine supplement to the per diem payment because outlier payments are being made for nearly all patients. The OPPS outlier policy is intended to compensate providers for treating exceptionally resource-intensive patients. As we noted in our CY 2004 OPPS/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 CMHC APC 0173 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 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 rate includes payment for fewer items and services than the inpatient psychiatric facility daily rate, we believe that the cost of a day of outpatient PHP care 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 cost-to-charge ratio. The cost-to-charge ratio used for calculating outlier payments has established upper limits for hospitals and for CMHCs (we refer readers to the CY 2016 OPPS/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). Inflated costs, therefore, usually result from inflated charges, and lead to excessive outlier payments. 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 paying CMHCs that are participating in Medicare accurately. Therefore, outlier payments resulting from inflated costs need to be addressed. We also are concerned that if these CMHCs continue this pattern of inflated charges for partial

hospitalization services, CMHCs will continue to receive a disproportionate share of outlier payments compared to other OPPS providers that do not artificially inflate their charges, thereby limiting outlier payments for truly deserving cases.

At this point in time, and 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 ≥ 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 < 30 percent of their total per diem payments. In our review of CY 2015 claims data for this CY 2017 rulemaking, the average charge per day for the CMHCs that received outlier payments ≥ 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 < 30 percent of their total per diem payments.

In our review of CY 2015 claims data for this CY 2017 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 ≥ 30 percent of their total payments, which suggests a 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 patients. 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 are proposing 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 are proposing 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 proposed 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 patients that merit an outlier payment, while also protecting the benefit from making payments for outlier cases that exceed the marginal cost of care. We used CY 2015 preliminary claims data to perform a detailed impact analysis of CMHC outlier payments. We will not have final CY 2015 claims data until after this proposed rule is published, but we will update this analysis using final claims data for our CY 2017 OPPS/ASC final rule with comment period. 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 ≥30 percent of their total CMHC payments in CY 2015, and 5 CMHCs that received had outlier payments <30 percent of their total CMHC payments in CY 2015.

The 5 CMHCs that received outlier payments that were <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 below.

TABLE 20.—EFFECT OF CMHC OUTLIER CAP SIMULATION ON OUTLIER PAYMENTS

	Simulated Outlier Payments						
	Total Per Diem Payments	**Actual Outlier Payments**	**3% Cap**	**5% Cap**	**6% Cap**	**8% Cap**	**10% Cap**
All 51 CMHCs	12,316,182	3,222,896					
5 CMHCs with Outlier Payments < 30 Percent of Total Per Diem Payments	9,471,380	11,496	4,196	6,465	7,599	9,868	12,136
Reduction in Outlier Payments			7,299	5,031	3,896	1,628	0
Percent Reduction							
Number of CMHCs Affected			1	1	1	1	0
	Simulated Outlier Payments						
	Total Per Diem Payments	**Actual Outlier Payments**	**3% Cap**	**5% Cap**	**6% Cap**	**8% Cap**	**10% Cap**
All 51 CMHCs	12,316,182	3,222,896					
4 CMHCs with Outlier Payments ≥ 30 Percent	2,844,802	3,211,401	85,344	142,240	170,688	227,584	284,480
Reduction in Outlier Payments			3,137,552	3,080,656	3,052,208	2,995,312	2,938,416
Percent Reduction			97.7%	95.9%	95.0%	93.3%	91.5%

Based on CY 2015 preliminary claims data.

Note: Of 51 CMHCs in CY 2015 claims data, 9 received outlier payments; 4 CMHCs of those 9 CMHCs received outlier payments ≥30 percent of their total per diem payments. Two of these 4 CMHCs received outlier payments that were >100 percent of their total per diem payments.

The table above shows that 4 out of the 5 CMHCs that received outlier payments < 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 5th 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 is 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 (about $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 < 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 3 CMHCs that received outlier payments ≥ 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 are proposing 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 are inviting public comment on the CMHC provider-level outlier cap percentage.

Our existing outlier reconciliation policy would continue to remain in effect with the proposed CMHC outlier payment cap serving as a complement. We are proposing 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 will continue to monitor the trends in outlier payments and if our proposed CMHC outlier payment cap is implemented, we would also monitor these policy effects. We also would analyze CMHC outlier payments at the provider level, relative to the proposed 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 a Proposed 8-Percent Cap on CMHC Outlier Payments

CMS envisions that the proposed 8-percent CMHC cap on outlier payments would be managed by the claims processing system. If the proposed CMHC outlier payment cap is finalized, we would provide detailed information on our implementation strategy through sub-regulatory channels. However, to foster a clearer understanding of the proposed 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 would 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 could determine whether or not a given outlier payment exceeds the 8-percent cap on a "rolling" basis. Under such an implementation approach, for each CMHC, the claims processing system would maintain a running tally of the YTD total CMHC per diem payments. The claims processing system would ensure that each time an outlier claim for a CMHC is processed, actual outlier payments would never exceed 8 percent of the CMHC's YTD total payments. While a CMHC would receive its per diem payment timely, the outlier portion of the claim would be paid as the CMHC's YTD payments support payment of the outlier. As part of our routine claims processing, we would utilize a periodic review process under which outlier payments that were withheld would subsequently be paid if the CMHC's total payments have increased to the point that its outlier payments can be made. This process would result in additional cash flow to

CMHCs. As noted previously, we also would 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 would 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 Proposals

In summary, for CY 2017, we are proposing 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 OPPS 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;
- Continue to set the cutoff point for CMHC outlier payments in CY 2017 at 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year, which for CY 2017 is proposed new CMHC PHP 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 proposals would minimize the impact of inflated CMHC charges on outlier payments, would 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. We are inviting public comments on these proposals.

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

A. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352 through 74353) for a full historical discussion of our longstanding policies on how we identify procedures that are typically provided only in an inpatient setting (referred to as the inpatient only (IPO) list) and, therefore, will not be paid by Medicare under the OPPS, and on the criteria that we use to review the IPO list each year to determine whether or not any procedures should be removed from the list. The complete list of codes (IPO list) that we are proposing to be paid by Medicare in CY 2017 as inpatient only procedures is included as Addendum E to this proposed rule (which is available via the Internet on the CMS Web site).

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

For CY 2017, we are proposing to use the same methodology (described in the November 15, 2004 final rule with comment period (69 FR 65834)) of reviewing the current list of procedures on the IPO list to identify any procedures that may be removed from the list. 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 are proposing 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 (eg, 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 osteophytectomy 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 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 are proposing 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: 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 are proposing that the two laryngoplasty procedure codes would be assigned to APC 5165 (Level 5 ENT Procedures) with status indicator "J1."

C. 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; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)), has traditionally been considered an inpatient surgical procedure. The procedure was placed on the original IPO list in the 2000 OPPS 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 post-acute 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 OPPS/ASC proposed rule, we proposed to remove the procedure described by CPT code 27447 from the IPO list (77 FR 45153). 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 providing TKA 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 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. Then we are asking the public to comment 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

We are seeking 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 are seeking 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 are seeking 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 are seeking 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 are seeking 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.

X. Proposed 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 Certain Off-Campus Departments of a Provider

1. Background

In recent years, the research literature and popular press have documented the increased trend toward hospital acquisition of physician practices, integration of those practices as a department of the hospital, and the resultant increase in the delivery of

physicians' services in a hospital setting. 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 physicians' office. Medicare pays a higher amount because it generally pays two separate claims for these services—one under the OPPS 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 significantly higher total beneficiary cost-sharing than if the service had been furnished in a physician's office.

Section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114-74), enacted on November 2, 2015, amended section 1833(t) of the Act. Specifically, this provision amended the OPPS statute at section 1833(t) by amending paragraph (1)(B) and adding a new paragraph (21). As a general matter, under section 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) for purposes of payment under the OPPS and will instead be paid "under the applicable payment system" under Medicare Part B if the requirements for such payment are otherwise met. We 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 this proposed rule, 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 Pub. L. 114-74 made two amendments to section 1833 of the Act—one amending paragraph (t)(1)(B) and the other adding new paragraph (t)(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 (t)(21)(A)) that are furnished on or after January 1, 2017 by an off-campus PBD, as defined in paragraph (t)(21)(B). The second amendment added a new paragraph (t)(21), which defines the terms "applicable items and services" and "off-campus outpatient department of a provider," requires the Secretary to establish a new payment policy for such applicable items and services furnished by an off-campus PBD on or after January 1, 2017, 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 and information.

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), an off-campus PBD that was billing under subsection (t) with respect to covered OPD

services furnished prior to the date of enactment of paragraph (t)(21), that is, November 2, 2015. We are proposing 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 OPPS. Moreover, as noted earlier, 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 OPPS.

In this proposed rule, we are making a number of proposals to implement section 603 of Pub. L. 114-74. Broadly, we are proposing 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, in this rule, we are proposing policies that define whether certain items and services furnished by a given off-campus PBD may be considered excepted and, thus, continue to be paid under the

OPPS; 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 are soliciting 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 Pub. L. 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 Pub. L. 114-74 in the CY 2017 OPPS/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 these proposals. We have considered this stakeholder feedback in developing this proposed rule.

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 OPPS for services provided at the provider-based facility and may also increase the coinsurance liability of Medicare beneficiaries receiving those services. 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 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 would be 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 OPPS/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 would help identify the type and costs of services typically furnished in off-campus PBDs. Based on the provision in the CY 2015 OPPS/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 PBD in which services were furnished, nor does it distinguish between multiple PBDs of the same hospital. As discussed later in this section, we are

soliciting public comments on the type of information that would be needed to identify nonexcepted PBDs for purposes of section 603, although we are not proposing to collect such information for CY 2017.

b. Proposed 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 [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), we are proposing 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 are proposing 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 a dedicated ED as described in the regulations at 42 CFR 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 (t)(1)(B)(v) and (t)(21) as a department of a provider (as defined at 42 CFR 413.65(a)(2) *as that term is in effect as of November 2, 2015*), 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 believe that the statutory language refers to such departments as defined by the regulations at § 413.65 as they existed at the time of enactment of Pub. L. 114-74. The existing regulatory definition 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 Pub. L. 114-74.

We are not proposing to change the existing definition of "campus" located at § 413.65(a)(2) of our regulations and 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. As we gain experience under section 603 of Pub. L. 114-74, we may consider issuing further guidance regarding provider-based attestations if needed.

In accordance with section 1833(t)(21)(B)(i)(I) of the Act, we are proposing 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.

(3) Within the Distance from Remote Locations

In addition to the statutory exception for off-campus PBDs located on the campus of a provider, section 1833(t)(21)(B)(i)(II) of the Act excepts from the definition of

off-campus PBDs those 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 "multicampus" hospitals, as discussed previously, under current provider-based rules, a hospital is only allowed to have a single "main" campus for each hospital. Therefore, when determining whether an off-campus PBD meets the exception set forth at section 1833(t)(21)(B)(i)(II) of the Act, we are proposing that the off-campus PBD must be located at or within the distance of 250 yards from a remote location of a hospital facility. 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.

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 OPPS, with respect to covered OPD services furnished prior to November 2, 2015. We are proposing 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 (to be

discussed in greater detail below) that were being billed under the OPPS 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.

We have 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.

Providers also have 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. 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.

We believe that section 1833(t)(21)(B)(ii) of the Act excepted off-campus PBDs as they existed at the time that Pub. L. 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 have 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 are making a number of proposals 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. These proposals are made in accordance with our belief that section 603 of Pub. L. 114-74 is intended to curb the practice of hospital acquisition of physician practices that then result in receiving additional Medicare payment for similar services.

(1) Relocation of Off-Campus PBDs Excepted under Section 1833(t)(21)(B)(ii) of the Act

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 are concerned that if we propose 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 Pub. L. 114-74 intended to preclude.

As previously stated, we believe that section 603 of Pub. L. 114-74 applies to off-campus PBDs as they existed at the time of enactment and only 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 are proposing that, for purposes of paragraphs (t)(1)(B)(v) and (t)(21) of section 1833 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. Once an excepted off-campus PBD has relocated, we are proposing that both the off-campus PBD itself and the items and services provided at that off-campus PBD would no longer be excepted, that is considered to be an excepted off-campus PBD for which the items and services furnished are covered OPD services payable under the OPPS, and instead, would be subject to paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act.

Hospitals have 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. We are soliciting 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 (under which CMS allows a hospital to request a Hospital VBP Program exception within 90 days of the natural disaster or other extraordinary circumstance) that would allow off-campus PBDs to relocate in very limited situations, and that 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 are seeking 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 circumstance would be.

(2) Expansion of Clinical Family of Services at an Off-Campus PBD Excepted under Section 1833(t)(21)(B)(ii) of the Act

We have 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*, pointing out that the statute is not written with any limiting language 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 Pub. L. 114-74.

We believe that 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 Pub. L. 114-74, as guided by our regulatory definition of department of a provider. Thus, we are proposing that the excepted off-campus PBD would be limited to seeking payment under the OPPS for the provision of items and services it was furnishing prior to the date of enactment of section 603 of Pub. L. 114-74 only. Moreover, we are proposing 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 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 physicians' offices purchased *after* the date of enactment of section 603. We are 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 are proposing, 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 below) such department was billing for under the OPPS and were furnished prior to November 2, 2015. We are proposing 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 this proposed rule. We note that we are proposing 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 are proposing that service types be defined by the 19 clinical families of hospital outpatient service types described in Table 21 below. Moreover, we are proposing 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 are proposing 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 refer readers to Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) for which HCPCS codes map to each clinical family of services. If we add a new HCPCS code or APC in future years, we will provide mapping to these clinical families of services, where relevant.

In addition, we considered, but are not proposing in this proposed rule, 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 are seeking 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.

TABLE 21.—PROPOSED CLINICAL FAMILIES OF SERVICES FOR PURPOSES OF SECTION 603 IMPLEMENTATION

Clinical Families	APCs
Advanced Imaging	5523-25, 5571-73, 5593-4
Airway Endoscopy	5151-55
Blood Product Exchange	5241-44
Cardiac/Pulmonary Rehabilitation	5771, 5791
Clinical Oncology	5691-94
Diagnostic tests	5721-24, 5731-35, 5741-43
Ear, Nose, Throat (ENT)	5161-66
General Surgery	5051-55, 5061, 5071-73, 5091-94, 5361-62
Gastrointestinal (GI)	5301-03, 5311-13, 5331, 5341
Gynecology	5411-16
Minor Imaging	5521-22, 5591-2
Musculoskeletal Surgery	5111-16, 5101-02
Nervous System Procedures	5431-32, 5441-43, 5461-64, 5471
Ophthalmology	5481, 5491-95, 5501-04
Pathology	5671-74
Radiation Oncology	5611-13, 5621-27, 5661
Urology	5371-77
Vascular/Endovascular/Cardiovascular	5181-83, 5191-94, 5211-13, 5221-24, 5231-32
Visits and Related Services	5012, 5021-25, 5031-35, 5041, 5045, 5821-22, 5841

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 are proposing to pay for expanded items and services that are furnished at excepted off-campus PBDs, that is, are nonexcepted items and services.

We are seeking public comments on these proposals. In addition, we are seeking 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.

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 would not result in any material change of provider-based status. A provider-based approval letter for such a department would 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.

We are proposing 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. 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 are proposing that individual excepted off-campus PBDs cannot be transferred from one hospital to another and maintain excepted status. We are soliciting public comments on these proposals.

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.

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 this time, we are 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 are seeking 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 are seeking 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 earlier in Table 21) that were provided by the excepted off-campus PBD prior to the November 2, 2015 date of enactment. 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.

3. Payment for Services Furnished in Off-Campus PBDs to Which Sections 1833(t)(1)(B)(v) and 1833(t)(21) of the Act Apply (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 OPPS. Items and services furnished in an off-campus PBD are billed using HCPCS codes and paid under the OPPS according to the APC group to which the item or service is assigned. The OPPS includes payment for most hospital outpatient services, except those identified in section I.C. of this proposed rule. Section 1833(t)(1)(B) of the Act generally outlines what are covered OPD services eligible for payment under the OPPS. Sections 1833(t)(1)(B)(i) through (iii) of the Act provide for Medicare payment under the OPPS 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) list those items and services that are not covered OPD services and, therefore, not eligible for Medicare payment under the OPPS.

The second type of payment for 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 (the facility rate); and another that assumes the professional furnishes and incurs the full costs associated with furnishing the service (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 OPPS. 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 OPPS hospital payment amount and the MPFS allowed amount. Because the sum of the OPPS payment and the MPFS facility payment for most services 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 paid through both an institutional payment system like the OPPS and the MPFS.

The incentives for hospital acquisition of physician practices and the resultant higher payments for the same types of services have been the topic of several reports in the popular media and by governmental agencies. For example, the Medicare Payment Advisory Commission (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 financial arrangement that occurs when a hospital acquires a physician practice and/or hires physicians to work as salaried employees. 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 in the physician office setting. These types of reports highlight the types of concerns we believe Congress may have been trying to address when it legislated section 603 of Pub. L. 114-74. As we developed our proposal to implement section 603, we took into consideration the concerns described above, the specific statutory language, and the available discretion found in that statutory language.

As described in detail above and below, section 603 of Pub. L. 114-74, through amendments to section 1833(t) at paragraphs (1)(B)(v) and (21), provides that items and services furnished by nonexcepted off-campus PBDs and certain items and services furnished by excepted off-campus PBDs are not covered OPD services under the OPPS, 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 items and services furnished by nonexcepted off-campus PBDs and for certain items and services furnished by excepted off-campus PBDs that are not covered OPD services under the OPPS (for example, expanded clinical families of services). We refer to these items and services collectively as "nonexcepted items and services." Section 1833(t)(21)(C) of the Act provides that payments for these nonexcepted items and services furnished by an off-campus outpatient department of a provider shall be made under the applicable payment system under Medicare Part B (other than under this subsection, that is OPPS), if the requirements for such payment are otherwise met.

While we intend to provide a mechanism for an off-campus PBD to bill and receive payment for furnishing nonexcepted items and services under an applicable payment system that is not the OPPS, at this time, there is no straightforward way to do that before January 1, 2017. 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 OPPS 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 OPPS claims. Rather, OPPS 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 OPPS would require significant changes to these complex systems as well as other systems involved in the processing of Medicare Part B claims. We are not suggesting these operational issues are insurmountable, but they are multifaceted and will require time and care to resolve. As such, we are not able to propose at this time 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 OPPS.

As described in greater detail below, in order to begin implementing the requirements of section 603 of Pub. L. 114-74, we are proposing to specify that the applicable payment system for purposes of section 1833(t)(21)(C) of the Act is the MPFS. While we do 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 are actively exploring options that would allow off-campus PBDs to bill for these services under another payment system, such as the MPFS, and be paid at the applicable rate under such system beginning in CY 2018. We are soliciting 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 OPPS in a way that provides accurate payments under such payment system and minimizes burden on both providers and Medicare beneficiaries. Accordingly, we intend the policy we are proposing in this proposed rule to be a temporary, 1-year solution until we can 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 OPPS.

b. Proposed 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 this section, 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 only. 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 OPPS) 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 subsection (t) of section 1833 (that is, the OPPS), 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.[4] 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 OPPS 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, we are proposing to designate the applicable payment system for the payment of the majority of nonexcepted items and services to be the MPFS. Specifically, we are proposing that, because we currently do not have a

[44] 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)

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. 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 OPPS.

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 OPPS 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 OPPS 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 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 this time, we are not proposing new mechanisms to allow an off-campus PBD to bill and receive payment from Medicare for nonexcepted items and services as currently enrollment as a hospital based department. However, as described in detail later in this section, we are soliciting comment 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 OPPS.

Accordingly, for CY 2017, we are proposing 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 OPPS; 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 note that the hospital may continue to bill for services that are not paid under the OPPS, such as laboratory services.

(2) Definition of Applicable Items and Services and Section 603 Amendment to Section 1833(t)(1)(B) of the Act and Proposed 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 (t)(1)(B)(v) and paragraph (t)(21) to mean items and services (other than those furnished by a dedicated emergency department). Paragraph (1)(B)(v) 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 (t)(21)(B). Thus, such applicable items and services are not eligible for payment under the OPPS because they are not covered OPD services. Under our proposals, 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, instead of being eligible for payment under the OPPS as covered OPD services, paragraph (t)(21)(C) requires that, for nonexcepted items and services, payment shall be made under the applicable payment system, other than OPPS, if the requirements for such payment are otherwise met. In other words, the payment requirement under paragraph (t)(21)(C) 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).

(b) Proposed Payment Policy for CY 2017

In accordance with sections 1833(t)(1)(B)(v) and 1833(t)(21)(C) of the Act, payment for nonexcepted items and services as defined in section X.A.2. of this proposed rule will no longer be made under the OPPS, effective January 1, 2017. Instead, we are proposing 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 earlier in this section, we do not believe that, under current systems, an off-campus PBD could be paid for its facility services under the MPFS, but are actively exploring options that would allow for this beginning in CY 2018. Alternatively, an off-campus PBD would 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 this time, we are not proposing a change in payment policy under the MPFS regarding these nonexcepted items and services. However, in the CY 2017 MPFS proposed rule, we are proposing 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. 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 would be paid to the facility under the applicable institutional payment system.

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 OPPS 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 to pay under the MPFS for all nonexcepted items and services furnished to beneficiaries may result in hospitals establishing business arrangements with the physicians or nonphysician practitioners who bill under the MPFS. We are interested in 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 are interested in 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 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.

We note that there are some services that off-campus departments may furnish that are not billed or paid under the OPPS. For example, although laboratory tests are generally packaged under the OPPS, 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 is being proposed for deletion for CY 2017. We refer readers to section II.B.3.b.(2) of this proposed rule for a discussion of this policy.

- Molecular pathology laboratory tests and advanced diagnostic laboratory tests (ADLTs) (proposed for CY 2017 in section II.B.3.b.(3) of this proposed rule).

- 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 Medicare Program 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 note that a nonexcepted off-campus PBD is eligible for PHP payment if the entity enrolls and bills as a CMHC for payment under the OPPS. A hospital may choose to enroll a nonexcepted off-campus PBD as a CMHC, provided it meets all Medicare requirements and conditions of participation.

(3) Comment Solicitation on Allowing Direct Billing and Payment for Nonexcepted Items and Services in CY 2018

For nonexcepted items and services furnished in an off-campus PBD, we are soliciting public comments which we intend to consider in developing a new billing and payment policy proposal for CY 2018. Specifically, we are interested in 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 PBD meets all the applicable MPFS requirements. Under this proposal, we envision 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 participations 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 note 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 are seeking public comments on whether or not there are administrative impediments for hospitals billing for such services. We are seeking 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 are seeking 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.

4. Beneficiary Cost-Sharing

Under our proposed policy, 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, we expect that 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.

5. Summary of Proposals

Under our proposed policy, all excepted off-campus PBDs would be permitted to continue to bill for excepted items and services under the OPPS. 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 for all services within a clinical family of services, provided that those services continue to be furnished at the same physical address of the PBD as of November 2, 2015. Items and services furnished in a new off-campus PBD (that is, not billing under the OPPS for covered OPD services furnished prior to November 2, 2015) or new lines of service furnished in an excepted off-campus PBD would not be excepted items and services. An excepted off-campus PBD would lose its status as excepted (that is, the off-campus PBD would be considered a new nonexcepted off-campus PBD) if the excepted off-campus PBD changes location or changes ownership; if the new owners also acquire the main hospital and adopt the existing Medicare provider agreement, the excepted off-campus PBD may maintain its excepted status under the other rules outlined in this proposed rule.

For CY 2017, we are proposing that 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 departments would be paid based on the professional claim and would be paid at the nonfacility rate for services for which they are permitted to bill. 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 group practice).

For CY 2018, we are soliciting public comments on regulatory and operational changes that we could make to allow an off-campus PBD to bill and be paid for its services under an applicable payment system. We will take these comments into consideration in developing a new payment policy proposal for CY 2018

As we and our contractors conduct audits of hospital billing, we and our contractors will examine whether off-campus PBDs are billing under the proper billing system. We expect hospitals to maintain proper documentation showing what lines of service were provided at each off-campus PBD prior to November 2, 2015, and to make this documentation available to us and our contractors upon request.

6. Proposed Changes to Regulations

To implement the provisions of section 1833(t) of the Act, as amended by section 603 of Pub. L. 114-74, we are proposing 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 OPPS are items and services that are provided by an off-campus provider-based department of a hospital 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.

B. 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 proposed 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 this proposed rule, we are proposing 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 can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site). We are proposing that, beginning January 1, 2017, hospitals would be required to use this modifier on claims imaging services that are X-rays taken using film. The use of this proposed modifier would result in a 20-percent payment reduction for an imaging service that is an X-ray service taken using film, 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). For further discussion regarding the budget neutrality of the payment reductions under section 1833(t)(16)(F) of the Act, we refer readers to section XX.A.3. of this proposed rule.

C. 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 MPFS proposed rule, we are proposing some minor changes to certain CCM scope of service elements. We are proposing 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 week basis, as is currently required. We refer readers to the CY 2017 MPFS proposed rule for a detailed discussion of the proposed changes to the scope of service elements for CCM.

D. 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 OPPS, and the ASC payment system. The CY 2017 MPFS proposed rule includes 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 proposes specific clinical priority areas and exceptions to the AUC consultation and reporting requirements. We refer readers to the CY 2017 MPFS proposed rule for further information.

XI. Proposed CY 2017 OPPS Payment Status and Comment Indicators

A. Proposed CY 2017 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs serve an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system and also whether particular OPPS policies apply to the code. The complete list of the payment status indicators and their definitions that we are proposing for CY 2017 is displayed in Addendum D1 to this proposed rule, which is available on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html. The proposed CY 2017 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this proposed rule, which are available on the CMS Web

site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

For CY 2017, we are proposing to revise the current definition of status indicator "E" by creating two status indicators, "E1" and "E2," to replace status indicator "E." 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.

B. Proposed CY 2017 Comment Indicator Definitions

For CY 2017 OPPS, we are proposing to use four comment indicators. Three of these comment indicators, "CH", "NI," and "NP," are in effect for CY 2016 and we are proposing to continue their use in CY 2017. In this proposed rule, we are proposing 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 believe that this new comment indicator "NC" will help hospitals easily identify new HCPCS codes that will have a final payment assignment effective January 1, 2017. The proposed CY 2017 OPPS comment indicators are as follows:

- "CH"—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.

- "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.

The definitions of the OPPS comment indicators for CY 2017 are listed in Addendum D2 to this proposed rule, which is available on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

XII. Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background

1. Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System

For a detailed discussion of the legislative history and statutory authority related to payments to ASCs under Medicare, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74377 through 74378) and the June 12, 1998 proposed rule (63 FR 32291 through 32292). For a discussion of prior rulemaking on the ASC

payment system, we refer readers to the 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. Proposed Treatment of New and Revised Codes

1. Background on Current Process for Recognizing New and Revised Category I and Category III CPT Codes and Level II HCPCS Codes

Category I CPT, Category III CPT, and Level II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims:

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

We finalized a policy in the August 2, 2007 final rule (72 FR 42533 through 42535) to evaluate each year all new and revised Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures. In addition, we identify new

and revised codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. In prior rulemakings, we refer to this process as recognizing new codes; however, this process has always involved the recognition of new and revised codes. We consider revised codes to be new when they have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator. To clarify, we refer to these codes as new and revised in this CY 2017 OPPS/ASC proposed rule.

We have separated our discussion below based on when the codes are released and whether we are proposing to solicit public comments in this proposed rule (and respond to those comments in the CY 2017 OPPS/ASC final rule with comment period) or whether we will be soliciting public comments in the 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 will respond to public comments and finalize the treatment of these codes under the ASC payment system in the CY 2017 OPPS/ASC final rule with comment period.

In Table 22 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 22.—COMMENT AND FINALIZATION TIMEFRAMES FOR CY 2017 FOR NEW AND REVISED CATEGORY I AND III CPT CODES AND LEVEL II HCPCS CODES

ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April l, 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

ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
	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 proposed rule for further discussion of this issue.

2. Proposed Treatment of New and Revised Level II HCPCS Codes and Category III CPT Codes Implemented in April 2016 and July 2016 for Which We Are Soliciting Public Comments in This 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 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 below lists 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 below lists 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 this 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 are listed in Table 25 below, along with their proposed payment indicators. The proposed payment rates for these new Category III CPT codes can be found in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

We are inviting public comments on these 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 below. We are proposing to finalize their payment indicators and their payment rates in the CY 2017 OPPS/ASC final rule with comment period.

TABLE 23.—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES OR COVERED ANCILLARY SERVICES IMPLEMENTED IN APRIL 2016

CY 2016 HCPCS Code	CY 2016 Long Descriptor	Proposed CY 2017 Payment Indicator
C9137	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U.	K2
C9138	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), 1 I.U.	K2
C9461	Choline C 11, diagnostic, per study dose	K2
C9470	Injection, aripiprazole lauroxil, 1 mg	K2
C9471	Hyaluronan or derivative, Hymovis, for intra-articular	K2

CY 2016 HCPCS Code	CY 2016 Long Descriptor	Proposed CY 2017 Payment Indicator
	injection, 1 mg	
C9472	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)	K2
C9473	Injection, mepolizumab, 1 mg	K2
C9474	Injection, irinotecan liposome, 1 mg	K2
C9475	Injection, necitumumab, 1 mg	K2
J7503	Tacrolimus, extended release, (Envarsus XR), oral, 0.25 mg	K2

TABLE 24.—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2016

CY 2016 HCPCS Code	CY 2016 Long Descriptor	Proposed CY 2017 Payment Indicator
C9476	Injection, daratumumab, 10 mg	K2
C9477	Injection, elotuzumab, 1 mg	K2
C9478	Injection, sebelipase alfa, 1 mg	K2
C9479	Instillation, ciprofloxacin otic suspension, 6 mg	K2
C9480	Injection, trabectedin, 0.1 mg	K2
Q9981	Rolapitant, oral, 1 mg	K2
Q5102	Injection, infliximab, biosimilar, 10 mg	K2
Q9982*	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	K2
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 25.—NEW CATEGORY III CPT CODES FOR COVERED SURGICAL PROCEDURES OR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2016

CY 2016 CPT Code	CY 2016 Long Descriptor	Proposed CY 2017 Payment Indicator
0437T	Implantation of non-biologic or synthetic implant (eg, polypropylene) for fascial reinforcement of the abdominal wall (List separately in addition to primary procedure)	N1
0438T*	Transperineal placement of biodegradable material, peri-prostatic (via needle), single or multiple, includes image guidance	G2
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	Ablation, percutaneous, cryoablation, includes imaging guidance; upper extremity distal/peripheral nerve	G2
0441T	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve	G2
0442T	Ablation, percutaneous, cryoablation, includes imaging guidance; nerve plexus or other truncal nerve (eg, brachial plexus, pudendal nerve)	G2
0443T	Real time spectral analysis of prostate tissue by fluorescence spectroscopy	G2
0444T	Initial placement of a drug-eluting ocular insert under one or more eyelids, including fitting, training, and insertion, unilateral or bilateral	N1
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 Accepting Comments in This CY 2017 Proposed Rule

For new and revised CPT codes effective January 1 that are received in time to be included in the proposed rule, we are proposing APC and status indicator assignments. We will accept comments and finalize the APC and status indicator assignments in the OPPS/ASC final rule with comment period. For those new/revised CPT codes that are received too late for inclusion in the OPPS/ASC proposed rule, we may either make interim final assignments in the final rule with comment period or possibly use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year's rulemaking cycle.

For the CY 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 proposed rule (which are available via the Internet on the CMS Web site). The new and revised CY 2017 Category I and III CPT codes are assigned to new comment indicator "NP" to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year and that comments will be accepted on the proposed payment indicator. Further, we remind readers that the CPT code descriptors that appear in Addendum AA and Addendum BB are short descriptors and do not accurately describe the complete procedure, service, or item described by the CPT

code. Therefore, we are including the 5-digit placeholder codes and their long descriptors for the new and revised CY 2017 CPT codes in Addendum O to this proposed rule (which is available via the Internet on the CMS Web site) so that the public can adequately comment on our proposed payment indicator assignments. The 5-digit placeholder codes can be found in Addendum O, specifically under the column labeled "CY 2017 OPPS/ASC Proposed Rule 5-Digit Placeholder Code," to this proposed rule. The final CPT code numbers will be included in the CY 2017 OPPS/ASC final rule with comment period. We note that not every code listed in Addendum O is subject to comment. For the new/revised Category I and III CPT codes, we are requesting comments on only those codes that are assigned to comment indicator "NP."

In summary, we are soliciting public comments on the proposed CY 2017 payment indicators for the new and revised Category I and III CPT codes that will be effective January 1, 2017. The CPT codes are listed in Addendum AA and Addendum BB to this proposed rule with short descriptors only. We list them again in Addendum O to this proposed rule with long descriptors. We also are proposing to finalize the payment indicator for these codes (with their final CPT code numbers) in the CY 2017 OPPS/ASC final rule with comment period. The proposed payment indicator for these codes can be found in Addendum AA and Addendum BB to this proposed rule (which are available via the Internet on the CMS Web site).

4. Proposed Process for New and Revised Level II HCPCS Codes That Will Be Effective October 1, 2016 and January 1, 2017 for Which We Will Be Soliciting Public Comments in the CY 2017 OPPS/ASC Final Rule with Comment Period

As has been our practice in the past, we incorporate those new and revised Level II HCPCS codes that are effective January 1 in the final rule with comment period, thereby updating the OPPS and the ASC payment system for the following calendar year. These codes are released to the public via the CMS HCPCS Web site, and also through the January OPPS quarterly update CRs. In the past, we also released new and revised Level II HCPCS codes that are effective October 1 through the October OPPS quarterly update CRs and incorporated these new codes in the final rule with comment period, thereby updating the OPPS and the ASC payment system for the following calendar year.

For CY 2017, we are proposing to continue our established policy of assigning comment indicator "NI" in Addendum B to the OPPS/ASC final rule with comment period to those new 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 the CY 2017 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2017. We will invite public comments in the CY 2017 OPPS/ASC final rule with comment period on the status indicator, APC assignments, and payment rates for these codes that will be finalized in the CY 2018 OPPS/ASC final rule with comment period.

C. Proposed Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services

1. Covered Surgical Procedures

a. Proposed Covered Surgical Procedures Designated as Office-Based

(1) Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as "office-based" those procedures that are added to the ASC list of covered surgical procedures in CY 2008 or later years that we determine are performed predominantly (more than 50 percent of the time) in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that rule, we also finalized our policy to exempt all procedures on the CY 2007 ASC list from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC list of covered surgical procedures beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that rule by payment indicator "P2" (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight); "P3" (Office-based surgical procedures added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs); or "R2" (Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated the procedure would be paid according to the

standard ASC payment methodology based on its OPPS relative payment weight or at the MPFS nonfacility PE RVU-based amount.

Consistent with our final policy to annually review and update the list of covered surgical procedures eligible for payment in ASCs, each year we identify covered surgical procedures as either temporarily office-based (these are new procedure codes with little or no utilization data that we have determined are clinically similar to other procedures that are permanently office-based), permanently office-based, or nonoffice-based, after taking into account updated volume and utilization data.

(2) Proposed Changes for CY 2017 to Covered Surgical Procedures Designated as Office-Based

In developing this proposed rule, we followed our policy to annually review and update the covered surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment, including their potential designation as office-based. We reviewed CY 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 OPPS relative payment weight) in CY 2016, as well as for those procedures assigned one of the temporary office-based payment indicators, specifically "P2," "P3," or "R2" in the CY 2016 OPPS/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 the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. The CPT code that we are proposing to permanently designate as office-based for CY 2017 is listed in Table 26 below.

TABLE 26.—ASC COVERED SURGICAL PROCEDURE PROPOSED TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2017

CY 2017 CPT Code	CY 2017 Long Descriptor	CY 2016 ASC Payment Indicator	Proposed 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

*Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. Current law specifies a 0.5 percent update to the MPFS payment rates for CY 2017. For a discussion of the MPFS rates, we refer readers to the CY 2017 MPFS proposed rule.

We also reviewed CY 2015 volume and utilization data and other information for eight procedures finalized for temporary office-based status in Tables 64 and 65 in the CY 2016 OPPS/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). Consequently, we are proposing to maintain the temporary office-based designations for these eight codes for CY 2017. We list all of these codes for which we are proposing to maintain the temporary office-based designations for CY 2017 in Table 27 below. The procedures for which the proposed office-based designations for CY 2017 are temporary also are indicated by asterisks in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

TABLE 27.—PROPOSED CY 2017 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2016 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2017 CPT Code	CY 2017 Long Descriptor	CY 2016 ASC Payment Indicator*	CY 2017 ASC Proposed 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**
C9800	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.

** Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. Current law specifies a 0.5 percent update to the MPFS payment rates for CY 2017. For a discussion of the MPFS rates, we refer readers to the CY 2017 MPFS proposed rule.

For CY 2017, we are proposing to designate certain new CY 2017 codes for ASC covered surgical procedures as temporary office-based, displayed in Table 28 below. After reviewing the clinical characteristics, utilization, and volume of related 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 are proposing 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 are indicated by asterisks in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

We are inviting public comment on these proposals.

TABLE 28.—PROPOSED CY 2017 PAYMENT INDICATORS FOR NEW CY 2017 CPT CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED

Proposed CY 2017 OPPS/ASC Proposed Rule 5-Digit CMS Placeholder Code***	CY 2017 Long Descriptor	Proposed CY 2017 ASC Payment Indicator**
369X1***	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***	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated	P2*

* If designation is temporary.
** Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. Current law specifies a 0.5 percent update to the MPFS payment rates for CY 2017. For a discussion of the MPFS rates, we refer readers to the CY 2017 MPFS proposed rule.
*** New CPT codes (with CMS 5-digit placeholder codes) that will be effective January 1, 2017. The proposed ASC payment rate for this code can be found in ASC Addendum AA, which is available via the Internet on the CMS Web site.

b. ASC Covered Surgical Procedures Designated as Device-Intensive--Finalized Policy for CY 2016 and Proposed 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 OPPS device-dependent APCs with a device offset percentage greater than 50 percent of the APC cost under the OPPS, 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 OPPS APC ratesetting methodology to the OPPS national unadjusted payment to determine the device cost included in the OPPS payment rate for a device-intensive ASC covered surgical procedure, which we then set as equal to the device portion of the national unadjusted ASC payment rate for the procedure. We 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 OPPS relative payment weight for the device-intensive procedure. Finally, we sum the ASC device portion and ASC service portion to establish the full payment for the device-intensive procedure under the revised ASC payment system. For CY 2015, we implemented a comprehensive APC policy under the OPPS under which we created C-APCs to replace most of the then-current device-dependent APCs and a few nondevice-dependent APCs under the OPPS, 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 OPPS/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 OPPS. To avoid duplicating payment, we provided that the CY 2015 ASC payment rates for these C-APCs were based on the CY 2015 OPPS 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 OPPS 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 OPPS 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 OPPS 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 OPPS claims and cost report data available for the CY 2015 OPPS/ASC proposed rule and final rule with comment period.

(2) Proposed ASC Device-Intensive Designation by HCPCS Code

In CY 2016, we restructured many of the APCs under the OPPS, which resulted in some procedures with significant device costs not being designated device-intensive. In the CY 2016 OPPS/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 OPPS 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 OPPS/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 OPPS/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 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 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 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.

Therefore, for CY 2017, we are proposing 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 are proposing to revise the regulations at 42 CFR 416.171(b)(2) to redefine device-intensive procedures in accordance with this proposal.

In addition, for new HCPCS codes describing procedures requiring the implantation of medical devices that do not yet have associated claims data, we are proposing 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, 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 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 ASC device-intensive procedures can be found in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

(3) Proposed Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2017

For CY 2017, we are proposing to revise our methodology for designating ASC covered surgical procedures as device-intensive. Specifically, for CY 2017, we are proposing to update the ASC list of covered surgical procedures that are eligible for payment according to our device-intensive procedure payment methodology, consistent with our proposed revised definition of device-intensive procedures, reflecting the proposed individual HCPCS code device offset percentages based on CY 2015 OPPS claims and cost report data available for this proposed rule.

The ASC covered surgical procedures we are proposing to designate as device-intensive and would be subject to the device-intensive procedure payment methodology for CY 2017 can be found in Addendum AA to this 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 if the full credit/partial credit (FB/FC) device adjustment policy would apply can also be found in Addendum AA. All of these procedures are included in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

We are inviting public comments on the proposed list of ASC device-intensive procedures.

c. Proposed Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC payment policy for costly devices implanted in ASCs at no cost/full credit or partial credit, as set forth in § 416.179 of our regulations, is consistent with the OPPS 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 OPPS to which this policy applies. We refer readers to the CY 2009 OPPS/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 OPPS/ASC final rule with comment period (78 FR 75005 through 75006), we finalized our proposal to modify our former policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. Formerly, under the OPPS, our policy was to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnished a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital received partial credit in the amount of 50 percent or more (but less than 100 percent) of the cost for the specified device. For CY 2014, we finalized our proposal to reduce OPPS payment for applicable APCs by the full or partial credit a provider receives for a replaced device, capped at the device offset amount.

Although we finalized our proposal to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPPS, in that final rule with comment period (78 FR 75076 through 75080), we finalized our proposal to maintain our ASC policy for reducing payments to ASCs for specified device-intensive procedures when the ASC furnishes a device without cost or with full or partial credit. Unlike the OPPS, there is currently no mechanism within the ASC claims processing system for ASCs to submit to CMS the actual amount received when furnishing a specified device at full or partial credit. Therefore, under the ASC payment system, we finalized our proposal for CY 2014 to continue to reduce ASC payments by 100 percent or 50 percent of the device offset amount when an ASC furnishes a device without cost or with full or partial credit, respectively.

We are proposing to update the list of ASC covered device-intensive procedures, 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 are proposing to reduce the payment for implantation procedures that are subject to the no cost/full credit or partial credit device adjustment policy by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the new device. The ASC would append the HCPCS "FC" modifier to the HCPCS code for a device-intensive surgical procedure that is subject to the no cost/full credit or partial credit device adjustment policy, when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a new device, ASCs would have the option of either: (1) submitting the claim for the device replacement procedure to their Medicare contractor after the procedure's performance but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment once the credit determination is made; or (2) holding the claim for the device implantation procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the "FC" modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the replacement device. Beneficiary coinsurance would be based on the reduced payment amount. As finalized in the CY 2015 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 are inviting public comments on our proposals to adjust ASC payments for no cost/full credit and partial credit devices.

d. Proposed Additions to the List of ASC Covered Surgical Procedures

We conducted a review of HCPCS codes that currently are paid under the 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, we are proposing 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 are proposing to include them on the list of ASC covered surgical procedures for CY 2017.

The eight procedures that we are proposing to add to the ASC list of covered surgical procedures, including their HCPCS code long descriptors and proposed CY 2017 payment indicators, are displayed in Table 29 below.

TABLE 29.—PROPOSED ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2017

CY 2017 HCPCS Code	CY 2017 Long Descriptor	Proposed CY 2017 ASC Payment Indicator
20936	Autograft for spine surgery only (includes harvesting the graft); local (eg, 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, osteophytectomy 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 (eg, 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 (eg, 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
22851	Application of intervertebral biomechanical device(s) (eg, synthetic cage(s), methlmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure)	N1

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 list for possible inclusion on the ASC list of covered surgical procedures. After reviewing the procedures proposed to be removed from the OPPS IPO list for CY 2017, we also are proposing to add CPT codes 22840, 22842, and 22845 listed in Table 29 above to the ASC list of covered surgical procedures for CY 2017. We are proposing to add these three procedure codes to the ASC list of covered surgical procedures (as well as proposing to remove them from the IPO list) for CY 2017 because 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 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 codes that we are proposing to remove from the OPPS IPO list, we believe that CPT codes 22858 (Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy 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), which also are proposed to be removed from the OPPS IPO list for CY 2017, should continue to be excluded from the ASC list of covered surgical procedures because the procedures described by these codes would generally be expected to require at least an overnight stay.

2. Covered Ancillary Services

a. Proposed List of Covered Ancillary Services

Consistent with the established ASC payment system policy, we are proposing to update the ASC list of covered ancillary services to reflect the proposed 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 2015 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 are proposing that these services also would be packaged under the ASC payment system for CY 2017. We are proposing to continue this reconciliation of packaged status for subsequent calendar years. Comment indicator "CH," discussed in section XII.F. of this proposed rule, is used in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site) to indicate covered ancillary services for which we are proposing a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2017.

All ASC covered ancillary services and their proposed payment indicators for CY 2017 are included in Addendum BB to this proposed rule. We are inviting public comments on this proposal.

D. Proposed ASC Payment for Covered Surgical Procedures and Covered Ancillary Services

1. Proposed ASC Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are fully described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy 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 OPPS, and only the service portion of the rate is subject to the ASC standard ratesetting methodology. In the CY 2016 OPPS/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 OPPS update. We also updated payment rates for device-intensive procedures to incorporate the CY 2016 OPPS device offset percentages calculated under the standard APC ratesetting methodology as discussed earlier in this section.

Payment rates for office-based procedures (payment indicators "P2," "P3," and "R2") are the lower of the MPFS nonfacility PE RVU-based amount (we refer readers to the CY 2017 MPFS proposed rule) or the amount calculated using the ASC standard ratesetting methodology for the procedure. In the CY 2016 OPPS/ASC final rule with comment period, we updated the payment amounts for office-based procedures (payment indicators "P2," "P3," and "R2") using the most recent available MPFS and OPPS data. We compared the estimated CY 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 OPPS/ASC final rule with comment period (78 FR 75081), we finalized our proposal to calculate the CY 2014 payment rates for ASC covered surgical procedures according to our established methodologies, with the exception of device removal procedures. For CY 2014, we finalized a policy to conditionally package payment for device removal codes under the OPPS. Under the OPPS, a conditionally packaged code (status indicators "Q1" and "Q2") describes a HCPCS code where the

payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a covered surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indicator "N1") under the ASC payment system. Under the OPPS, device removal procedures are conditionally packaged and, therefore, would be packaged under the ASC payment system. There would be no Medicare payment made when a device removal procedure is performed in an ASC without another surgical procedure included on the claim; therefore, no Medicare payment would be made if a device was removed but not replaced. To address this concern, for the device removal procedures that are conditionally packaged in the OPPS (status indicator "Q2"), we assigned the current ASC payment indicators associated with these procedures and continued to provide separate payment in CYs 2014, 2015, and 2016.

b. Proposed Update to ASC Covered Surgical Procedure Payment Rates for CY 2017

We are proposing 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 this proposed rule. Because the proposed OPPS relative payment weights are based on geometric mean costs for CY 2017 and subsequent years, the ASC system will use geometric means to determine proposed relative payment weights under the ASC standard methodology. We are proposing to continue to use the amount calculated under

the ASC standard ratesetting methodology for procedures assigned payment indicators "A2" and "G2."

We are proposing 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 this proposed rule. Therefore, we are proposing to update the payment amount for the service portion of the device-intensive procedures using the ASC standard ratesetting methodology and the payment amount for the device portion based on the proposed CY 2017 OPPS device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. Payment for office-based procedures would be at the lesser of the proposed CY 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 are proposing to continue our policy for device removal procedures such that device removal procedures that are conditionally packaged in the OPPS (status indicators "Q1" and "Q2") would be assigned the current ASC payment indicators associated with these procedures and would continue to be paid separately under the ASC payment system.

We are inviting public comments on these proposals.

2. Proposed Payment for Covered Ancillary Services

a. Background

Our 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 OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators "N," "Q1," and "Q2") under the OPPS. In the CY 2013 OPPS/ASC rulemaking (77 FR 45169 and 77 FR 68457 through 68458), we further clarified our policy regarding the payment indicator assignment of codes that are conditionally packaged in the OPPS (status indicators "Q1" and "Q2"). Under the OPPS, a conditionally packaged code describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indictor "N1") under the ASC payment system (except for device removal codes as discussed in section IV. of this proposed rule). Thus, our final policy generally aligns ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for those ancillary services also to be paid, ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates. We generally pay for separately payable radiology services at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to "Z2" so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount, regardless of which is lower.

Similarly, we also finalized our policy to set the payment indicator to "Z2" for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight using the ASC standard ratesetting methodology and, therefore, will include the cost for the contrast agent (42 CFR 416.171(d)(2)).

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at contractor-priced rates (72 FR 42499). Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS.

Our ASC policies also provide separate payment for: (1) certain items and services that CMS designates as contractor-priced, including, but not limited to, the procurement of corneal tissue; and (2) certain implantable items that have pass-through payment status under the OPPS. These categories do not have prospectively established ASC payment rates according to 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 OPPS are separately paid under the ASC payment system and are contractor-priced. Under the revised ASC payment system (72 FR 42502), payment for the surgical procedure associated with the pass-through device is made according to our standard methodology for the ASC payment system, based on only the service (nondevice) portion of the procedure's OPPS relative payment weight if the APC weight for the procedure includes other packaged device costs. We also refer to this methodology as applying a "device offset" to the ASC payment for the associated surgical procedure. This ensures that duplicate payment is not provided for any portion of an implanted device with OPPS pass-through payment status.

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized that, beginning in CY 2015, certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS are

covered ancillary services when they are integral to an ASC covered surgical procedure. We finalized that diagnostic tests within the medicine range of CPT codes include all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT. In the CY 2015 OPPS/ASC final rule with comment period, we also finalized our policy to pay for these tests at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (79 FR 66933 through 66934). We finalized that the diagnostic tests for which the payment is based on the ASC standard ratesetting methodology be assigned to payment indicator "Z2" and revised the definition of payment indicator "Z2" to include reference to diagnostic services and those for which the payment is based on the MPFS nonfacility PE RVU-based amount be assigned payment indicator "Z3," and revised the definition of payment indicator "Z3" to include reference to diagnostic services.

b. Proposed Payment for Covered Ancillary Services for CY 2017

For CY 2017 and subsequent years, we are proposing to update the ASC payment rates and to make changes to ASC payment indicators as necessary to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2017 OPPS and ASC payment rates and subsequent year payment rates. We also are proposing 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 are proposing 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 are proposing 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 this proposed rule (which is available via the Internet on the CMS Web site) indicate 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 are proposing 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 are proposing to continue this modification to the payment methodology for CY 2017 and subsequent years and, therefore, are proposing 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 set 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 are proposing to continue this modification to the payment methodology for CY 2017 and subsequent years and, therefore, are proposing 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 are proposing to continue in CY 2017 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. We also are proposing 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 are proposing 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 are proposing 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 are proposing 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, we are proposing 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 are listed in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site).

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 OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of Pub. L. 103-432 and our regulations at 42 CFR 416.185(b), the deadline for receipt of public comments is 30 days following publication of the list of requests in the proposed rule.

- In the final rule updating the ASC and OPPS payment rates for the following calendar year, we—

++ Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments;

++ When a new NTIOL class is created, identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome.

++ Set the date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

++ Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

2. Requests to Establish New NTIOL Classes for CY 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 OPPS/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 are not proposing to revise the payment adjustment amount for CY 2017.

F. Proposed ASC Payment and Comment Indicators

1. Background

In addition to the payment indicators that we introduced in the August 2, 2007 final rule, we created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs,

such as whether they were on the ASC list of covered services prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services, including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, or NTIOLs.

We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators used in Addenda AA and BB to the proposed rules and final rules with comment period serve to identify, for the revised ASC payment system, the status of a specific HCPCS code and its payment indicator with respect to the timeframe when comments will be accepted. The comment indicator "NP" is used in the OPPS/ASC proposed rule to indicate new codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator "NP" also is assigned to existing codes with substantial revisions to their descriptors such that we consider them to be describing new services, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622). In the CY 2017 OPPS/ASC final rule with comment period, we will 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 OPPS/ASC final rule with comment period.

The "CH" comment indicator is used in Addenda AA and BB to this 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. Proposed ASC Payment and Comment Indicators

For CY 2017 and subsequent years, we are proposing 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 are proposing 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 this CY 2017 OPPS/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 this CY 2017 OPPS/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 will respond to public comments on ASC payment and comment indicators and finalize their ASC assignment in the CY 2017 OPPS/ASC final rule with comment period. We refer readers to Addenda DD1 and DD2 to this proposed rule (which are

available via the Internet on the CMS Web site) for the complete list of ASC payment and comment indicators proposed for the CY 2017 update.

G. Calculation of the Proposed ASC Conversion Factor and the Proposed ASC Payment Rates

1. Background

In the August 2, 2007 final rule (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and the OPPS relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 being equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007 as required under section 1833(i)(2)(E) of the Act (72 FR 42522). We adopted a policy to make the system budget neutral in subsequent calendar years (72 FR 42532 through 42533; 42 CFR 416.171(e)).

We note that we consider the term "expenditures" in the context of the budget neutrality requirement under section 1833(i)(2)(D)(ii) of the Act to mean expenditures from the Medicare Part B Trust Fund. We do not consider expenditures to include beneficiary coinsurance and copayments. This distinction was important for the CY 2008 ASC budget neutrality model that considered payments across the OPPS, ASC, and MPFS payment systems. However, because coinsurance is almost always 20 percent for ASC services, this interpretation of expenditures has minimal impact for subsequent budget neutrality adjustments calculated within the revised ASC payment system.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66857 through 66858), we set out a step-by-step illustration of the final budget neutrality adjustment calculation based on the methodology finalized in the August 2, 2007 final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of $41.401. For covered office-based surgical procedures, covered ancillary radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XII.D.2. of this proposed rule), and certain diagnostic tests

within the medicine range that are covered ancillary services, the established policy is to set the payment rate at the lower of the MPFS unadjusted nonfacility PE RVU-based amount or the amount calculated using the ASC standard ratesetting methodology. Further, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive procedures).

As discussed in the August 2, 2007 final rule (72 FR 42517 through 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified IPPS hospital wage indexes to the labor-related share, which is 50 percent of the ASC payment amount based on a GAO report of ASC costs using 2004 survey data. Beginning in CY 2008, CMS accounted for geographic wage variation in labor cost when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment under the IPPS, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003.

The reclassification provision in section 1886(d)(10) of the Act is specific to hospitals. We believe that using the most recently available pre-floor and pre-reclassified IPPS hospital wage indexes results in the most appropriate adjustment to the labor portion of ASC costs. We continue to believe that the unadjusted hospital wage indexes, which are updated yearly and are used by many other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs. Therefore, the

wage index for an ASC is the pre-floor and pre-reclassified hospital wage index under the IPPS of the CBSA that maps to the CBSA where the ASC is located.

On February 28, 2013, OMB issued OMB Bulletin No. 13-01, which provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252) and 2010 Census Bureau data. (A copy of this bulletin may be obtained at: 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 OPPS/ASC final rule with comment period (79 FR 66937), we finalized a 1-year transition policy that we applied in CY 2015 for all ASCs that experienced any decrease in their actual wage index exclusively due to the implementation of the new OMB delineations. This transition does not apply in CY 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 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, we are proposing to implement these revisions to the OMB statistical area delineations effective January 1, 2017, beginning with the CY 2017 ASC wage indexes. We are inviting public comments on these proposals.

For CY 2017, the proposed 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 will continue our current policy of calculating an urban or rural area's wage index by calculating the average of the wage indexes for CBSAs (or metropolitan divisions where applicable) that are contiguous to the area with no wage index.)

2. Proposed Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2017 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and MPFS nonfacility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42533). Consistent with our established policy, we are proposing to scale the CY 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 are proposing 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 OPPS relative payment weights between CY 2016 and CY 2017. We are proposing to

use the ratio of CY 2016 to CY 2017 total payment (the weight scalar) to scale the ASC relative payment weights for CY 2017. The proposed CY 2017 ASC scalar is 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 OPPS relative payment weights.

Scaling would not apply in the case of ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC payment amounts are not based on OPPS relative payment weights), such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services. The ASC payment weights for those services without predetermined national payment amounts (that is, those services with national payment amounts that would be based on OPPS relative payment weights) would be scaled to eliminate any difference in the total payment between the current year and the update year.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. At the time of this proposed rule, we have available 98 percent of CY 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 this proposed rule, is posted on the CMS Web site at: http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/ASCPaymentSystem.html.

b. Updating the ASC Conversion Factor

Under the OPPS, we typically apply a budget neutrality adjustment for provider level changes, most notably a change in the wage index values for the upcoming year, to the conversion factor. Consistent with our final ASC payment policy, for the CY 2017 ASC payment system and subsequent years, we are proposing to calculate and apply a budget neutrality adjustment to the ASC conversion factor for supplier level changes in wage index values for the upcoming year, just as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor. For CY 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 OPPS/ASC final rule with comment period (76 FR 74516), we finalized a policy that ASCs begin submitting data on quality measures for services beginning on October 1, 2012 for the CY 2014 payment determination under the ASC Quality Reporting (ASCQR) Program. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), we finalized a methodology to calculate reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for the CY 2014 payment determination and subsequent years. The application of the 2.0 percentage point reduction to the annual update factor, which 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 OPPS/ASC final rule with comment period (75 FR 72062 through 72064) for examples of how the MFP adjustment is applied to the ASC payment system.

For this proposed rule, 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 is 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 is 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 OPPS/ASC final rule with comment period (80 FR 70500 through 70501).

As we discussed in the CY 2011 MPFS final rule with comment period, section 1833(i)(2)(D)(v) of the Act, as added by section 3401(k) of the Affordable Care Act, requires that any annual update to the ASC payment system after application of the quality adjustment 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 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 Bureau of Labor Statistics (BLS) publishes the official measure of private nonfarm business MFP. We refer readers to the BLS Web site at: http://www.bls.gov/mfp for the BLS historical published MFP data.

MFP is derived by subtracting the contribution of labor and capital input growth from output growth. The projections of the components of MFP are currently produced by IHS Global Insight, Inc. (IGI), a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of MFP. As we discussed in the

CY 2016 OPPS/ASC final rule with comment period (80 FR 70500 through 70501), beginning with the CY 2016 rulemaking cycle, the MFP adjustment is calculated using a revised series developed by IGI to proxy the aggregate capital inputs. Specifically, in order to generate a forecast of MFP, IGI forecasts BLS aggregate capital inputs using a regression model. A complete description of the MFP projection methodology is available on the CMS Web site at: http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html. As discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70500 through 70501), if IGI makes changes to the MFP methodology, we will announce them on our Web site rather than in the annual rulemaking.

For CY 2017, we are proposing 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 are proposing 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 are proposing 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 reduction. Therefore, we are proposing to apply a -0.8 percent quality reporting/MFP-adjusted CPI-U update factor to

the CY 2016 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also are proposing that if more recent data are subsequently available (for example, a more recent estimate of the CY 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 are proposing 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 results 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 are proposing 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 quality reporting/MFP-adjusted CPI-U update factor of -0.8 percent discussed above, which results in a proposed CY 2017 ASC conversion factor of $43.801.

We are inviting public comments on these proposals.

3. Display of Proposed CY 2017 ASC Payment Rates

Addenda AA and BB to this proposed rule (which are available via the Internet on the CMS Web site) display the proposed 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 proposed rates under the ASC standard ratesetting methodology and the MPFS proposed rates, the proposed payment indicators and rates set forth in this

proposed rule are based on a comparison using the proposed MPFS rates that would be effective January 1, 2017. For a discussion of the MPFS rates, we refer readers to the CY 2017 MPFS proposed rule.

The proposed payment rates included in these addenda reflect the full ASC payment update and not the reduced payment update used to calculate payment rates for ASCs not meeting the quality reporting requirements under the ASCQR Program. These addenda contain several types of information related to the proposed CY 2017 payment rates. Specifically, in Addendum AA, a "Y" in the column titled "Proposed 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 proposed ASC payment indicator assignments for the new code.

The values displayed in the column titled "Proposed CY 2017 Payment Weight" are the proposed relative payment weights for each of the listed services for CY 2017. The proposed relative payment weights for all covered surgical procedures and covered ancillary services where the ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Therefore, scaling was not applied to the device portion of the device-intensive procedures, services that are paid at the MPFS nonfacility PE RVU-based amount, separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy sources that are separately paid under the OPPS, or services that are contractor-priced or paid at reasonable cost in ASCs.

To derive the proposed CY 2017 payment rate displayed in the "Proposed CY 2017 Payment Rate" column, each ASC payment weight in the "Proposed CY 2017 Payment Weight" column was multiplied by the proposed CY 2017 conversion factor of $44.684. The proposed conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update factor as reduced by the productivity adjustment (as discussed in section XII.G.2.b. of this proposed rule).

In Addendum BB, there are no relative payment weights displayed in the "Proposed CY 2017 Payment Weight" column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The "Proposed CY 2017 Payment" column displays the proposed CY 2017 national

unadjusted ASC payment rates for all items and services. The proposed 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 April 2016.

Addendum EE provides the HCPCS codes and short descriptors for surgical procedures that are proposed to be excluded from payment in ASCs for CY 2017. We are inviting public comment on these proposals.

XIII. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

A. Background

1. Overview

CMS seeks to promote higher quality and more efficient healthcare for Medicare beneficiaries. 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. We are not proposing 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. We are not proposing 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. We are not proposing 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.

We are not proposing 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). We are not proposing 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)
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: ED- 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***

Hospital OQR Program Measure Set Previously Adopted for the CY 2019 Payment Determination and Subsequent Years	
NQF #	**Measure Name**
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 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).

5. Proposed New Hospital OQR Program Quality Measures for the CY 2020 Payment Determinations and Subsequent Years

In this proposed rule, for the CY 2020 payment determination and subsequent years, we are proposing 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.

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.[5] Each year, about 22 percent of cancer patients receive chemotherapy,[6] with Medicare payments for cancer treatment totaling $34.4 billion in 2011, almost 10 percent of Medicare fee-for-service (FFS) dollars.[7] With an increasing number of cancer patients receiving chemotherapy in a hospital outpatient department,[8] 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.[9] As a result, cancer patients who receive chemotherapy in a hospital outpatient department

[5] American Cancer Society. "Cancer Facts & Figures 2015." Available at: http://www.cancer.org/acs/groups/content/@editorial/documents/document/acspc-044552.pdf.
[6] 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. Beveridgel. "Benchmarks for Value in Cancer Care: An Analysis of a Large Commercial Population." *Journal of Oncology Practice*, Vol. 7, 2011, pp. 301–306.
[7] 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.
[8] 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.
[9] 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.

require more frequent acute care in the hospital setting and experience more adverse events than cancer patients who are not receiving chemotherapy.[10,11,12]

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.[13] 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

[10] 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*, Vol. 5, No. 2, 2014, pp. 85–90. Available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4129880/#ref4.
[11] 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.
[12] Foltran, L., G. Aprile, F.E. Pisa, P. Ermacora, N. Pella, E. Iaiza, E. Poletto, S.E. 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.
[13] 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.

common side effects and complications of chemotherapy.[14] Appropriate outpatient care should curb potentially avoidable hospital admissions and ED 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, we are proposing 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

[14] 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 Infections Diseases Society of America." *Clinical Infectious Diseases*, vol. 52, no. 4: 2011, pp. e56–e93.

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. We routinely monitor the impact of SDS on hospitals' results on our measures.

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. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of SDS 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 related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

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 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 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.[15,16,17] 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.

---

[15] 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.

[16] Foltran, L., G. Aprile, F.E. Pisa, P. Ermacora, N. Pella, E. Iaiza, E. Poletto, S.E. 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.

[17] 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.

(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 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 are inviting 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.

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.[18] Same-day surgery offers significant patient benefits as compared with inpatient surgery, including shorter waiting times,

[18] Cullen KA, Hall MJ, Golosinskiy A. Ambulatory surgery in the United States, 2006. National health statistics reports. Jan 28 2009(11):1-25.

avoidance of hospitalizations, and rapid return home.[19] Furthermore, same-day surgery costs significantly less than an equivalent inpatient surgery, and therefore, presents a significant cost saving opportunity to the health system.[20] 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 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.[21,22,23,24,25,26,27,28] Furthermore, hospital

---

[19] 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.

[20] 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.

[21] Ibid.

[22] Linares-Gil MJ, Pelegri-Isanta MD, Pi-Siqués F, Amat-Rafols S, Esteva-Ollé MT, Gomar C. Unanticipated admissions following ambulatory surgery. *Ambulatory Surgery*. 1997;5(4):183-188.

[23] 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.

[24] 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.

visit rates vary among hospitals,[29] 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.[30] 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, we are proposing to include OP-36: Hospital Visits after Hospital Outpatient Surgery in the Hospital OQR Program 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

---

[25] Hollingsworth JM, Saigal CS, Lai JC, Dunn RL, Strope SA, Hollenbeck BK. Surgical quality among Medicare beneficiaries undergoing outpatient urological surgery. *The Journal of Urology*. Oct 2012;188(4):1274-1278.

[26] 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.

[27] Fortier J, Chung F, Su J. Unanticipated admission after ambulatory surgery--a prospective study. Canadian journal of anaesthesia = *Journal Canadien d'Anesthesie*. Jul 1998;45(7):612-619.

[28] 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.

[29] 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.

[30] Mezei G, Chung F. Return hospital visits and hospital readmissions after ambulatory surgery. Annals of surgery. Nov 1999;230(5):721-727.

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.[31] In addition, the MAP supported the measure for program use citing the vital importance of measures that help facilities reduce unnecessary hospital visits.[32] 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.[33]

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.[34] 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. We routinely monitor the impact of SDS on hospitals' results on our measures.

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. For 2 years, NQF will

---

[31] 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.

[32] Spreadsheet of MAP 2016 Final Recommendations. February 1, 2016. Available at: http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593.

[33] Ibid.

[34] 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.

conduct a trial of 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 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 related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

(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 (refer to Addendum AA 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).[35] 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

[35] 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.

Classification System (CCS),[36] to account for organ-specific differences in risk and complications, which are not adequately captured by the Work RVU alone.

We are inviting 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.

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 hospital outpatient departments 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 hospital outpatient departments that would allow valid comparisons across hospital outpatient departments.

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.[37] In addition, information on patient experience with care at a provider/facility is an important quality

[36] HCUP Clinical Classifications Software for Services and Procedures. Healthcare Cost and Utilization Project (HCUP). 2008. Agency for Healthcare Research and Quality, Rockville, MD http://www.hcup-us.ahrq.gov/toolssoftware/ccs_svcsproc/ccssvcproc.jsp, 2014.

[37] CMS National Quality Strategy 2016. Available at: https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/qualityinitiativesgeninfo/downloads/cms-quality-strategy.pdf.

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.[38] 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 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

[38] 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.

26510), the ESRD QIP (76 FR 70269 through 70270), the HH QRP (80 FR 68709 through 68710), and the HQRP (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."

We are proposing 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 hospital outpatient departments. We note that we are making similar proposals in the ASCQR Program in section XIV.B.4.c. of this 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 are proposing were included on the CY 2014 MUC list,[39] and reviewed by the MAP.[40] 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.[41] The MAP stated that these are high impact measures that will improve both quality and efficiency of care and be meaningful to consumers.[42] Further, the MAP stated that given that these measures are also under consideration for

[39] 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.
[40] 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.
[41] Ibid.
[42] Ibid.

the ASCQR Program, they help to promote alignment across care settings.[43] 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.[44] 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.[45]

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 AHRQ[46] and its CAHPS Consortium[47] 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 on January 25, 2013 (78 FR 5460) requesting information regarding

---

[43] Ibid.
[44] Ibid.
[45] Ibid.
[46] Agency for Healthcare Research and Quality. "Principles Underlying CAHPS Surveys". Available at: https://cahps.ahrq.gov/about-cahps/principles/index.html.
[47] Agency for Healthcare Research and Quality. "The CAHPS Program." Available at: https://cahps.ahrq.gov/about-cahps/cahps-program/index.html.

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 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.[48]

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 proposed rule, the Hospital VBP Program is proposing to remove the HCAHPS Pain Management dimension (which consists of three questions) in the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain due to confusion about the intent of these questions and the public health concern about the ongoing prescription opioid overdose epidemic. For more information about the pain

[48] Outpatient and Ambulatory Surgery CAHPS Survey: "National Implementation." Available at: https://oascahps.org/General-Information/National-Implementation.

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 proposed rule.

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 proposed rule 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. 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?[49]

- A1: Yes.
- A2: No.

[49] 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.

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 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. In addition, we note that, unlike in the Hospital VBP Program, there is no link between scoring well on the questions and higher hospital payments. However, we also recognize that questions remain about the ongoing prescription opioid epidemic. For these reasons, we are proposing 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 welcome 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 proposed rule 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 are proposing 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 (Q1-Q24). The list of approved vendors is available at: https://oascahps.org. We also are proposing 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 proposed rule 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 are proposing 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 are further proposing 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 are also proposing 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 are proposing 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) 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 proposed rule below, we also are proposing 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 (https://oascahps.org/Survey-Materials).

Furthermore, we are proposing 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 are proposing 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 proposed rule. 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 proposed rule, 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 are proposing 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) 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 measures 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 are proposing 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 provides hospitals with 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 are not proposing a format or timing for public reporting of OAS CAHPS Survey data at this time.

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 are inviting 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.

d. Summary of Previously Adopted and Newly Proposed Hospital OQR Program Measures for the CY 2020 Payment Determinations and Subsequent Years

The table below outlines the proposed Hospital OQR Program measure set for the CY 2020 payment determination and subsequent years, and includes both previously adopted measures and measures newly proposed in this proposed rule.

Proposed and Previously Finalized Hospital OQR Program Measure Set for the CY 2020 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

Proposed and Previously Finalized Hospital OQR Program Measure Set for the CY 2020 Payment Determination and Subsequent Years	
NQF #	**Measure Name**
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: ED- 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****

Proposed and Previously Finalized Hospital OQR Program Measure Set for the CY 2020 Payment Determination and Subsequent Years	
NQF #	**Measure Name**
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 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).
****New measure proposed for the CY 2020 payment determination and subsequent years.

6. Hospital OQR Program Measures and Topics for Future Consideration

In this proposed rule, we are seeking 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 inviting public comments on possible measure topics for future consideration in the Hospital OQR Program. We are moving towards the use of outcome measures and away from the use of clinical process measures across the Medicare program. We specifically request comment on any outcome measures that would be useful to add to the Hospital OQR Program as well as any clinical process measures that should be eliminated from the Hospital OQR Program

b. 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 are inviting public comments on future implementation of eCQMs as well as specific future eCQMs 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.[50] 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.[51] 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 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.[52] 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

[50] 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.

[51] 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.

[52] 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.

medical history.[53] 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.[54] 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 overlapping opioid and benzodiazepine prescriptions across all settings.[55, 56, 57]

The 2016 *CDC Guideline for Prescribing Opioids for Chronic Pain*[58] recommends that providers avoid concurrently prescribing opioids and benzodiazepines because rates of fatal overdose are ten times higher in patients who are co-dispensed opioid analgesics and benzodiazepines than opioids alone[59] and concurrent use of benzodiazepines with opioids was prevalent in 31 percent to 51 percent of fatal overdoses.[60] ED visit rates involving both opioid analgesics and benzodiazepines

---

[53] 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.

[54] 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.

[55] 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.

[56] 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/.

[57] 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.

[58] 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.

[59] Dasgupta, N., et al. "Cohort Study of the Impact of High-dose Opioid Analgesics on Overdose Mortality," Pain Medicine, Wiley Periodicals, Inc., 2015.

[60] 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.

increased from 11.0 in 2004 to 34.2 per 100,000 population in 2011.[61] Opioid overdose events resulting in ED use can cost the United States approximately $800 million per year.[62]

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 are requesting 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

---

[61] 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.

[62] 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.

through the MMS Listserv at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Listserv.html.

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=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1196289981244.

We refer readers to the CY 2013 OPPS/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 OPPS/ASC final rule with comment period (73 FR 68766 through 68767). We are not proposing 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 this proposed rule, we are formalizing our current public display practices regarding timing of public display and the preview period, as discussed in more detail below. We are also proposing how we will announce the preview period timeframes.

In the CY 2014 OPPS/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 this proposed rule, therefore, we are proposing 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 are proposing that hospitals will generally have approximately 30 days to preview their data, also consistent with current practice. Lastly, moving forward, we are proposing 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 are inviting public comments on our public display proposals as discussed above.

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 OPPS/ASC final rule with comment period (78 FR 75108 through 75109). In that final rule with comment period, we codified these procedural requirements at 42 CFR 419.46(a). We are not proposing any changes to these requirements.

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519) for requirements for participation and withdrawal from the Hospital OQR Program. We also codified procedural requirements at 42 CFR 419.46(b). We are not proposing 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 OPPS/ASC final rule with comment period (78 FR 75110 through 75111) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519

through 70520), we specified our data submission deadlines. We also codified our submission requirements at 42 CFR 419.46(c).

We also refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519 through 70520), where we finalized our proposal to shift the quarters upon which the Hospital OQR Program payment determinations are based. 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

We are not proposing 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: ED – Median Time to Pain Management for Long Bone Fracture (NQF #0662); and
- OP-23: ED – 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 OPPS/ASC final rule with comment period (77 FR 68481 through 68484) for a discussion of the form, manner, and timing for data submission requirements of these measures for the CY 2014 payment determination and subsequent years.

We are not proposing any changes to our policies regarding the submission of chart abstracted measure data where patient-level data are submitted directly to CMS.

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 OPPS/ASC final rule with comment period (78 FR 75111 through 75112), for a discussion of the general claims-based measure data submission requirements for the CY 2015 payment determination and subsequent years. We are not proposing any changes to these policies for the CY 2019 payment determination.

However, in sections XIII.B.5.a. and b. of this proposed rule, we are proposing to adopt 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 would also apply to these proposed measures, if they are adopted.

If these proposals are adopted, 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).

We are not proposing any changes to our claims-based measures submission policies for the CY 2020 payment determination and subsequent years.

4. Proposed Data Submission Requirements for the Proposed 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 proposed rule, we are proposing 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. In this section, we are

proposing requirements related to survey administration, vendors, and oversight activities. We note that we are making similar proposals in the ASCQR Program in section XIV.D.5. of this proposed rule.

a. Survey Requirements

The proposed 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 are proposing 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 are proposing 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 are proposing 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 proposed rule, 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 USC 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 are proposing 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 HQRP (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 are proposing 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 are inviting 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.

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: ED – 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 #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 OPPS/ASC final rule with comment period (78 FR 75112 through 75115) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70521) and the CMS QualityNet Web site (https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1205442125082) for a discussion of the requirements for measure data submitted via the CMS QualityNet Web site for the CY 2017 payment determination and subsequent years. In addition, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75097 through 75100) for a discussion of the requirements for measure data (specifically, the Influenza Vaccination Coverage Among Healthcare Personnel measure (NQF #0431)) submitted via the CDC NHSN Web site.

We are not proposing 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 OPPS/ASC final rule with comment period (75 FR 72100 through 72103) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74482 through 74483) for discussions of our 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. We are not proposing any changes to our population and sampling requirements.

7. Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS for the CY 2019 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68484 through 68487) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66964 through 66965) for a discussion of finalized policies regarding our validation requirements. We also refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68486 through 68487), for a discussion of finalized policies regarding our medical record validation procedure requirements. We codified these policies at 42 CFR 419.46(e). For the CY 2018 payment determination and subsequent years, validation is based on four quarters of data ((validation quarter 1 (January 1 – March 31), validation quarter 2 (April 1 – June 30), validation quarter 3 (July 1 – September 30), and validation quarter 4 (October 1 – December 31)) (80 FR 70524).

We are not proposing any changes to our validation requirements.

8. Proposed 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 this proposed rule, we are proposing 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 proposed rule (81 FR 25205; 25233 through 25234), we proposed deadlines 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 proposed rule, we also are proposing a deadline of 90 days following an event causing hardship for the ASCQR Program.

We are inviting 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.

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 this proposed rule, we are clarifying 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.

E. Proposed 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 this proposed rule, which is available via the Internet on the CMS Web site): "J1," "J2," "P," "Q1," "Q2," "Q3," "R," "S," "T," "V," or "U." Payment for all services assigned to these status indicators will be subject to the reduction of the national unadjusted payment rates for hospitals that fail to meet Hospital OQR Program requirements, with the exception of services assigned to New Technology APCs with assigned status indicator "S" or "T." We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68770 through 68771) for a discussion of this policy.

The OPD fee schedule increase factor is an input into the OPPS conversion factor, which is used to calculate OPPS payment rates. To reduce the OPD fee schedule increase factor for hospitals that fail to meet reporting requirements, we calculate two conversion factors--a full market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the "reporting ratio" to indicate that it applies to payment for hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative payment weights by the reduced conversion factor. For example, to determine the reduced national unadjusted payment rates that applied to hospitals that failed to meet their quality reporting requirements for the CY 2010 OPPS, we multiplied the final full national unadjusted payment rate found in Addendum B of the CY 2010 OPPS/ASC final rule with comment period by the CY 2010 OPPS final reporting ratio of 0.980 (74 FR 60642).

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable,

for the service. Under this policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for services provided by hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to § 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPS national unadjusted payment rates apply when the OPD fee schedule increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard adjustments apply to the reduced national unadjusted payment rates: the wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; the rural sole community hospital adjustment; and the adjustment for devices furnished with full or partial credit or without cost. Similarly, OPPS outlier payments made for high cost and complex procedures will continue to be made when outlier criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. We established this policy in the OPPS beginning in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642).

For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G. of this proposed rule.

2. Proposed Reporting Ratio Application and Associated Adjustment Policy for CY 2017

We are proposing to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 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 are proposing to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2017 OPPS, we are proposing to apply the reporting ratio, when applicable, to all HCPCS codes to which we have proposed status indicator assignments of "J1," "J2," "P," "Q1," "Q2," "Q3," "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 are proposing to continue to exclude services paid under New Technology APCs. We are proposing to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements. We also are proposing to continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we are proposing to

continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements.

We are inviting public comments on these proposals.

XIV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

We refer readers to section XIII.A.1. of this proposed rule for a general overview of our quality reporting programs.

2. Statutory History of the ASCQR Program

We refer readers to section XIV.K.1. of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74494) for a detailed discussion of the statutory history of the ASCQR Program.

3. Regulatory History of the ASCQR Program

We 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. We are not proposing 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). We are not proposing 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. We are not proposing 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 Web-based tool for the CY 2015 payment determination and subsequent years, and one process of care, preventive service measure submitted via an online, Web-based 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 Web-based 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 #	**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

† 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%2FPage%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. Proposed 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 this proposed rule, we are proposing to adopt a total of seven measures for the CY 2020 payment determination and subsequent years: 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 Web-based 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;[63] surgical site infections;[64] impaired coagulation;[65] and colligation of drug effects;[66] 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.[67] 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

[63] 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.
[64] 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.
[65] 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.
[66] Kurz A. Physiology of thermoregulation. *Best Pract Res Clin Anaesthesiol.*2008;22(4):627-644.
[67] Mahoney CB, Odom J. Maintaining intraoperative normothermia: A meta-analysis of outcomes with costs. *AANA Journal*. 1999;67(2): 155-164.

maintaining normothermia has been demonstrated in other clinical care settings.[68] 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 are proposing to adopt the ASC-13: Normothermia Outcome measure, which is based on aggregate measure data collected by the ASC and submitted via a CMS Web-based tool (QualityNet), 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 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

[68] 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.

Consideration for December 1, 2014."[69] 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.[70] The MAP agreed that 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.[71]

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

---

[69] 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.

[70] 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.

[71] Ibid.

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,[72] 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 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

[72] ASC Quality Collaboration. "ASC Quality Collaboration." Available at: http://www.ascquality.org/.

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 Web-based tool (that is, QualityNet).

We are proposing that the data collection period for the proposed ASC-13 measure would be the calendar years 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 are proposing that ASCs submit these data to CMS during the time period of January 1 to May 15 in the year prior to the affected payment determination year. For example, for the CY 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 proposed rule for a more detailed discussion of the requirements for data submitted via a CMS online data submission tool.

(4) Measure Calculation

The outcome measured in the proposed ASC-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 are inviting 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.

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.[73] Each year, approximately 1.5 million patients undergo cataract surgery to improve their vision.[74] While unplanned anterior vitrectomy rates are relatively low, this procedure complication may result in poor visual outcomes and other complications, including retinal detachment.[75] Cataract surgery is the most common surgery performed in ASCs; therefore, this measure is of interest to the ASC Program.[76]

(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 are proposing 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

[73] National Eye Institute. "Cataracts." *Cataracts.* National Institutes of Health, n.d. Available at: https://www.nei.nih.gov/eyedata/cataract#1.
[74] "Measure Application Partnership Hospital Workgroup", National Quality Forum. Dec. 2014, Transcript. Available at: http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369.
[75] 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 Ophthamlol.* 2014 Feb 5;8:375-378.
[76] "Measure Application Partnership Hospital Workgroup", National Quality Forum. Dec. 2014, Transcript. Available at: http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369.

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.[77]

The ASC-14 measure we are proposing was included on a publicly available document entitled "List of Measures under Consideration for December 1, 2014."[78] 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.[79] The MAP agreed that this measure is highly impactful and meaningful to patients.[80] 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.[81] 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.[82] Unplanned anterior vitrectomy is a recognized adverse intraoperative event during cataract surgery occurring in two to

[77] 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.

[78] 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.

[79] 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.

[80] Ibid.

[81] Ibid.

[82] Ibid.

four percent of all cases,[83] with some research showing that rates of unplanned anterior vitrectomy are higher among less experienced surgeons.[84] 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.[85] The MAP agreed that this is an outcome measure that fills the workgroup identified priority gap of procedure complications.[86]

The proposed ASC-14 measure is not NQF-endorsed. However, this measure is maintained by the ASC Quality Collaboration,[87] 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

---

[83] 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 vitrectomy—is it bad news?. *Eye*. 2002 March;16:117-120.

[84] Tan JHY and Karawatowski. Phacoemulsification cataract surgery and unplanned anterior vitrectomy—is it bad news?. *Eye*. 2002 March;16:117-120.

[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?LinkIdentifier=id&ItemID=78711.

[86] Ibid.

[87] ASC Quality Collaboration. "ASC Quality Collaboration." Available at: http://www.ascquality.org/.

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.

(3) Data Sources

This measure is based on aggregate measure data collected via chart-abstraction by the ASC and submitted via a CMS Web-based tool (that is, QualityNet).

We are proposing that the data collection period for the proposed ASC-14 measure would be the calendar years 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 are proposing that ASCs submit these data to CMS during the time period of January 1 to May 15 in the year prior to the affected payment determination year. For example, for the CY 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 proposed rule for a more detailed discussion of the requirements for data submitted via a CMS online data submission tool.

(4) Measure Calculation

The outcome measured in the proposed ASC-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 are inviting 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.

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.[88] 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 HHS' Transparency Initiative to measure patient experiences with ASC care.[89] 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 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 HQRP (80 FR 47141 through 47207).

---

[88] CMS National Quality Strategy 2016. Available at: https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/qualityinitiativesgeninfo/downloads/cms-quality-strategy.pdf.

[89] 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.

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 are proposing 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 are making similar proposals in the Hospital OQR Program in section XIII.B.5.c. of this 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 are proposing were included on the CY 2014 MUC list,[90] and reviewed by the MAP.[91] 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.[92] The MAP stated that these are high impact measures that will improve both quality and efficiency of care and be meaningful to consumers.[93] 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.[94] It also stated that these measures would begin to fill a gap MAP has previously identified for

---

[90] 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.

[91] 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.

[92] Ibid.

[93] Ibid.

[94] Ibid.

this program including patient reported outcomes and patient and family engagement.[95] 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.[96]

These measures have been fully developed since submission to the MUC List. The survey development process followed the principles and guidelines outlined by the AHRQ[97] and its CAHPS® Consortium[98] 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 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

---

[95] Ibid.
[96] Ibid.
[97] Agency for Healthcare Research and Quality. "Principles Underlying CAHPS Surveys." Available at: https://cahps.ahrq.gov/about-cahps/principles/index.html.
[98] Agency for Healthcare Research and Quality. "The CAHPS Program." Available at: https://cahps.ahrq.gov/about-cahps/cahps-program/index.html.

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.[99]

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 proposed rule, the Hospital VBP Program is proposing to remove the three Pain Management dimension questions of the HCAHPS Survey from the total Hospital VBP Program performance score due to confusion about the intent of these questions and the public health concern about the ongoing prescription opioid overdose epidemic. 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 proposed rule.

[99] Outpatient and Ambulatory Surgery CAHPS Survey. "National Implementation" Available at: https://oascahps.org/General-Information/National-Implementation.

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. 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?[100]

- 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

[100] 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.

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. In addition, we note that, unlike the Hospital VBP Program, there is no link between scoring well on the questions and higher hospital payments. However, we also recognize that questions remain about the ongoing prescription opioid epidemic. For these reasons, we are proposing 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 welcome 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 proposed rule 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 are proposing 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 (Q1-Q24). The list of approved vendors is available at: https://oascahps.org.

We also are proposing 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 proposed rule 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, see http://www.hhs.gov/civil-rights.

We are proposing 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 are further proposing 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 Manual (https://oascahps.org/Survey-Materials). We are also proposing 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 are proposing 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 proposed rule 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 proposed rule below, we also are proposing 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 are proposing 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 proposed rule, 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 are proposing 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 proposed rule. 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. 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:

$$\text{ASC Publicly Reported Score} = \frac{(0.5 + 0.8 + 1 + 0.7 + 0.9 + 0.8)}{6}$$

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 proposed rule. 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 are proposing to adopt two global OAS CAHPS Survey measures. ASC-15d asks the patient to rate the care provided by the HOPD on a scale of 0 to 10, and ASC-15e asks about the patient's willingness to recommend the HOPD 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 proposed rule, 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 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 administration manual (https://oascahps.org/Survey-Materials); 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 are proposing 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 are proposing 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 provides ASCs with 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 subsequent payment determination year (42 CFR 416.305(c)). For example, an ASC as identified by 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, while 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 proposed rule, 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 are not proposing a format or timing for public reporting of OAS CAHPS Survey data at this time.

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 are inviting 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.

If these proposals are finalized, the measure set for the ASCQR Program CY 2020 payment determination and subsequent years would be as listed below.

ASCQR Program Measure Set Previously Finalized and Proposed 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

ASCQR Program Measure Set Previously Finalized and Proposed for the CY 2020 Payment Determination and Subsequent Years		
ASC #	**NQF #**	**Measure Name**
		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%2FPage%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 proposed for the CY 2020 payment determination and subsequent years.

5. ASCQR Program Measures 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 OPPS/ASC final rule with comment period (79 FR 66979), in considering future ASCQR Program

measures, we are focusing on the following NQS and CMS Quality Strategy measure domains: make care safer by reducing harm caused in the delivery of care; strengthen person and family engagement as partners in their care; promote effective communication and coordination of care; promote effective prevention and treatment of chronic disease; work with communities to promote best practices of healthy living; and make care affordable.

In this proposed rule, we are inviting public 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.[101] 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.[102] Prevention requires careful attention to solutions, medications, and ophthalmic devices and to cleaning and sterilization of surgical equipment because of the numerous potential etiologies.[103] Despite a recent focus on prevention, cases of TASS continue to occur, sometimes in

[101] 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.
[102] 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.
[103] 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.

clusters.[104] 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 list[105] 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.[106] A summary of the MAP recommendations can be found at: http://www.qualityforum.org/Projects/i-m/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:

---

[104] 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.

[105] http://www.qualityforum.org/2015_Measures_Under_Consideration.aspx, under "2015 Measures Under Consideration List (PDF)."

[106] https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593.

http://ascquality.org/documents/ASC%20QC%20Implementation%20Guide%203.2%20October%202015.pdf.

We are inviting public comments on the possible inclusion of this measure in the ASCQR Program measure set in the future.

6. Maintenance of Technical Specifications for Quality Measures

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74513 through 74514), where we finalized our proposal to follow the same process for updating the ASCQR Program measures that we adopted for the Hospital OQR Program measures, including the subregulatory process for making updates to the adopted measures. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68496 through 68497), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75131), and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66981), we provided additional clarification regarding the ASCQR Program policy in the context of the previously finalized Hospital OQR Program policy, including the processes for addressing nonsubstantive and substantive changes to adopted measures. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70531), we provided clarification regarding our decision to not display the technical specifications for the ASCQR Program on the CMS Web site, but stated that we will continue to display the technical specifications for the ASCQR Program on the QualityNet Web site. In addition, our policies regarding the maintenance of technical specifications for the ASCQR Program are codified at 42 CFR 416.325. We are not

proposing any changes to our policies regarding the maintenance of technical specifications for the ASCQR Program.

7. Public Reporting of ASCQR Program Data

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74514 through 74515), we finalized a policy to make data that an ASC submitted for the ASCQR Program publicly available on a CMS Web site after providing an ASC an opportunity to review the data to be made public. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70531 through 70533), we finalized our policy to publicly display data by the National Provider Identifier (NPI) when the data are submitted by the NPI and to publicly display data by the CCN 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 proposed rule, we are formalizing our current public display practices regarding timing of public display and the preview period, as discussed in more detail below and proposing 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 OPPS/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 this proposed rule, therefore, we are proposing 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 are proposing that ASCs will generally have approximately 30 days to preview their data, also consistent with current practice.

Lastly, moving forward, we are proposing 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 are inviting public comments on our proposals regarding the timing of public display and the preview period as discussed above.

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). We are not proposing any changes to these policies.

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75133 through 75135) for a complete discussion of the participation status requirements for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70534), we codified these requirements regarding participation status for the ASCQR Program at 42 CFR 416.305. We are not proposing any changes to these policies.

D. Form, Manner, and Timing of Data Submitted for the ASCQR Program

1. Requirements Regarding Data Processing and Collection Periods for Claims-Based Measures Using Quality Data Codes (QDCs)

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75135) for a complete summary of the data processing and collection periods for the claims-based measures using QDCs for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70534), we codified the requirements regarding data processing and collection periods for claims-based measures using QDCs for the ASCQR Program at 42 CFR 416.310(a)(1) and (2). We are not proposing any changes to these requirements.

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). We are not proposing any changes to these policies.

3. Requirements for Data Submitted Via an Online Data Submission Tool

In this proposed rule, we are proposing changes to requirements for data submitted via a CMS online data submission tool (QualityNet.org). We are not proposing 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). We are not proposing 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 this proposed rule, we are proposing 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 Web-based tool in the ASCQR Program for the CY 2019 payment determination and subsequent years. We are also proposing 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 Web-based 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 Web-based tool. Furthermore, the proposed submission deadlines for measures submitted via a CMS Web-based tool would align the above-listed measures with the submission deadline for ASC-8, resulting in a single deadline for all data submitted via a Web-based tool by ASCs (via CMS and non-CMS Web-based 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 Web-based tool outweigh previously stated stakeholder concerns with this deadline.

Therefore, we are proposing 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 proposal 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).[107]

[107] We note that ASC-11 is a voluntary measure for the CY 2017 payment determination and 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 2018 payment determination and subsequent years.

In addition, this proposal would apply to the following proposed measures should they be finalized for the CY 2020 payment determination and subsequent years:

- ASC-13: Normothermia Outcome, and
- ASC-14: Unplanned Anterior Vitrectomy.

Lastly, we also are proposing 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 are inviting 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.

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). We are not proposing any changes to these requirements.

5. Proposed Data Submission Requirements for the Proposed 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 proposed rule, above, we are proposing 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. In this section, we are proposing requirements related to survey administration, vendors, and oversight activities. We note that we are making similar proposals in the Hospital OQR Program in section XIII.B.5.c. of this proposed rule.

a. Survey Requirements

The proposed 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 are proposing 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 are proposing 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 are proposing 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 the proposed rule, above. These submission deadlines will be posted on the OAS CAHPS Survey Web site (https://oascahps.org). Late submissions will 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 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. We, therefore, strongly encourage ASCs to be fully appraised of the methods and actions of their survey vendors—especially the vendors' full compliance

with OAS CAHPS Survey Administration protocols—and to carefully inspect all data warehouse reports in a timely manner.

We 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 USC 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 are proposing 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 HQRP (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 are proposing 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 are inviting 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.

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 OPPS/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.[108] In the CY 2016 OPPS/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).

We are proposing one modification to the ASCQR Program's extraordinary circumstances extensions or exemptions policy for the CY 2019 payment determination and subsequent years. Specifically, we are proposing 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

[108] In the CY 2015 OPPS/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.

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 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 proposed rule (81 FR 25205; 25233 through 25234), we proposed 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 proposed rule, we also are proposing a similar deadline of 90 days following an event causing hardship for the Hospital OQR Program.

In addition, we are proposing to make a corresponding change to the regulation text at 42 CFR 416.310(d)(1). Specifically, we are proposing to state that ASCs may request an extension or exemption within 90 days of the date that the extraordinary circumstance occurred.

We are inviting 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.

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 OPPS/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 OPPS/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. We are not proposing any changes to this policy.

E. Payment Reduction for ASCs That Fail to Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to section XV.C.1. of the CY 2014 OPPS/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 proposed rule.

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), in order to implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we finalized our proposal that we would calculate two conversion factors: a full update conversion factor and an ASCQR Program reduced update conversion factor. We finalized our proposal to calculate the reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for that calendar year payment determination. We finalized our proposal that application of the 2.0 percentage point reduction to the annual update may result in the update to the ASC payment system being less than zero prior to the application of the MFP adjustment.

The ASC conversion factor is used to calculate the ASC payment rate for services with the following payment indicators (listed in Addenda AA and BB to this 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 OPPS 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 this CY 2017 OPPS/ASC proposed rule, we are not proposing 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.[109] The 1984 National Organ and Transplantation Act (NOTA)[110] created the OPTN and Organ Procurement Organizations (OPOs), amongst 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.[111] 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.[112]

The SRTR contains detailed information regarding: (1) donor characteristics (for example, age, hypertension, diabetes, stroke, and body mass index); (2) organ

---

[109] Hamilton, T.E. 2009, "Accountability in Health Care – Transplant Community Offers Leadership," *American Journal of Transplantation*, Vol. 9, pp. 1287-1293.

[110] National Organ Transplant Act (NOTA; Pub. L. 98-507), codified at 42 U.S.C. 274, "Organ procurement and transplantation network."

[111] 42 U.S.C. 274a, "Scientific registry."

[112] Available at: http://srtr.org/who.aspx.

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 observed/expected 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 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.[113]

On March 30, 2007, we issued a final rule, setting 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

[113] 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.

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 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 the CMS' enforcement of the outcomes standard.[114] 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 had an opportunity to demonstrate compliance with the CMS outcomes requirements before the

[114] Hamilton, T.E. 2008, "Improving Organ Transplantation in the U.S. – A Regulatory Perspective," *American Journal of Transplantation*. Vol. 8 (12), pp. 2404-2405.

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 proposed rule, we discuss 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. We believe this is partly due to the improvement efforts of both high-performing and low-performing transplant programs, and efforts of the larger transplant community itself, whose members have demonstrated a track record of consistent improvement, innovation, and research. Such community-wide endeavors, combined with OPTN and CMS work with the lowest-performing transplant centers, have resulted 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 later in this proposed rule. 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. 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 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."[115] 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."[116]

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

---

[115] 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.

[116] 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.

(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, 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. Characteristics that historically defined an ECD kidney include age of donor at or greater than 60 years, or organs 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 organ use. ECD organ 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 organ that might be appropriate to use compared with one that involves too much risk. Therefore, ECD organ use may have been a particularly sensitive indicator of risk aversion. We note that, in 2014, the OPTN replaced the ECD organ 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 organ acceptance, but may have limited effect on undue risk aversion.

B. Proposed Revisions to Performance Thresholds

For the reasons described above, we are proposing 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 this proposed rule, we are following 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 one 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 one 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 to use more of the increasing number of viable organs.

For consistency and to avoid unneeded complexity, we are proposing 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 are proposing 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 proposed rule).

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 Bayesian methodology has 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 in this proposed rule 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 are inviting public comment on this issue. Specifically, we are inviting 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.

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 she 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."[117]

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 Provisions

1. Definition of "Eligible Death"

OPOs submit donor data to the SRTR on a continuous basis. 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

[117] Available at: http://www.organdonor.gov/legislation/acotrecs55.html.

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 a change to its "eligible death" definition, which is scheduled to go into effect on January 1, 2017. The changes to the OPTN definition[118] 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 Hope Act.[119]

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

[118] 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.
[119] HIV Organ Policy Equity Act, Pub. L. 113–51 (November 21, 2013).

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 OPO conformance with § 486.318.

Therefore, in order to ensure more consistent requirements, we are proposing 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 request public comments on our proposed definition. If, as a result of the public comments we receive on this proposal, additional changes are necessary to this definition, we will work with the OPTN to harmonize the definition.

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 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, we are proposing 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 intend to revisit and revise the other OPO measures at a future date.

3. Organ Preparation and Transport-Documentation with the Organ

We are proposing 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 are proposing 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 are proposing a revision to § 486.346(b) to make it consistent with current OPTN policy at 16.5.A,[120] 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 can be accessed electronically by the transplant center.

XVII. Transplant Enforcement Technical Corrections and Proposals

A. Technical Correction to Transplant Enforcement Regulatory References

We are proposing 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

[120] OPTN Policies. Policy Number 16.5.A. Organ Documentation. Effective date 4/14/2016: Page 200. Available at: https://optn.transplant.hrsa.gov/governance/policies/.

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 are proposing to amend § 488.61(f)(1) which was added in that final rule (79 FR 50359) to correct the same incorrect citations.

B. Other Proposed Revisions to § 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.

We are proposing 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 this proposed rule, we are proposing 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. Proposed 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. For a more detailed explanation of the statutory basis for the Medicare and Medicaid EHR Incentive Programs, we refer readers to the July 28, 2010 Stage 1 final rule titled, "Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule" (75 FR 44316 through 44317).

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."[121] That final rule 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.

In the May 9, 2016 **Federal Register**, we published 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" proposed rule (81 FR 28161 through 28586), hereinafter referred to as the "2016 MIPS and APMs Proposed Rule," which included proposals under which the use of CEHRT by MIPS eligible clinicians would be evaluated under the advancing care information performance category of the MIPS as required by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (81 FR 28215 through 28233). If these proposals were to be finalized, the requirements for MIPS eligible clinician EHR use and reporting for the advancing care information performance category for MIPS would be different from the requirements of meaningful use for eligible hospitals and CAHs as established in the 2015 EHR Incentive Programs Final Rule. For a full discussion of our proposals for MIPS and its impacts on requirements for MIPS eligible clinicians relating

[121] 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).

to EHR use and reporting, we refer readers to the 2016 MIPS and APMs Proposed Rule (81 FR 28215 through 28233).

B. Summary of Proposals Included in this Proposed Rule

We are proposing 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 are also proposing 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, as described in section XVIII.C. of this proposed rule. 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. We have chosen to limit these proposed changes to Medicare only because we are concerned that States would have to implement major process changes within a short period of time if the changes were to apply to Medicaid, including the burden of updating technology and reporting systems, which would incur both additional cost and time.

We are proposing to change the EHR reporting period in 2016 for all returning EPs, eligible hospitals and CAHs that have previously demonstrated meaningful use in the Medicare and Medicaid EHR Incentive Programs as described in section XVIII.D. of this proposed rule.

We are proposing 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 attest to the Modified Stage 2 objectives and measures as described in section XVIII.E. of this proposed rule.

We are proposing 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, as described in section XVIII.F. of this proposed rule.

We are proposing to change the policy on measure calculations for actions outside the EHR reporting period for the Medicare and Medicaid EHR Incentive Programs as described in section XVIII.G. of this proposed rule. Specifically, for all meaningful use measures, unless otherwise specified, we are proposing that 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.

We believe that these proposals would result in continued advancement of certified EHR technology utilization, particularly among those EPs, 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. We discuss these proposals in detail in the following sections.

C. Proposed Revisions to Objectives and Measures for Eligible Hospitals and CAHs

We are making 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 Patient Care Record 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 this proposed rule, our goal is 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.

1. Removal of the Clinical Decision Support (CDS) and Computerized Provider Order Entry (CPOE) Objectives and Measures for Eligible Hospitals and CAHs

We are proposing to amend 42 CFR 495.22 (by revising section 495.22(e) and by adding a new section 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. For the reasons stated above, this proposal would not apply to eligible hospitals and CAHs attesting under a State's Medicaid EHR Incentive Program. 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 apply 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 as compared to the required measure threshold. In applying these criteria to the objectives and measures for Modified Stage 2 and Stage 3, we have determined that the CPOE objective and measures are topped out. We performed a significance test using 2015 attestation data to determine the performance rate at the 75th and 99th percentile. The result of this statistical analysis proved that the performance for this objective and the associated measures were over 90 percent. Using the same attestation data, we performed an analysis at the 25th, 50th, and 75th percentiles to determine the distribution regarding the percentage above the required thresholds attested by eligible hospitals and CAHs. Eligible hospitals and CAHs at the 25th percentile have attested to performance rates of over 75 percent for the measures associated with this objective. Eligible hospitals and CAHs at the 50th percentile have attested to performance rates of over 87 percent for the measures associated with this

objective. Eligible hospitals and CAHs at the 75th percentile have attested to performance rates of over 95 percent for the measures associated with this objective. Therefore, based on these criteria, we consider the CPOE objective and measures topped out. Based on the 2015 attestation data, we believe that these objectives and measures have widespread adoption among eligible hospitals and CAHs and we are proposing to remove them from the Medicare EHR Incentive Program to reduce hospital administrative burden.

We also are proposing to remove the CDS objective and its associated measures for eligible hospitals and CAHs; however, these measures do not have percentage-based thresholds (hospitals attest "yes/no" to these measures) and thus do not have performance distribution that can be measured by statistical analysis. For these measures, we note that 99 percent of eligible hospitals and CAHs have attested "yes" to meeting these measures based on attestation data for 2015. We believe that the high level of successful attestation indicates achievement of widespread adoption of this objective and measures among eligible hospitals and CAHs, and that the objective and measures are no longer useful in gauging performance. Therefore, we consider this objective and measures to be "topped out" and are proposing to remove them from the Medicare EHR Incentive Program to reduce hospital administrative burden. In addition, eligible hospitals and CAHs may continue to independently measure and track activities related to the CDS objective and measures for their own quality improvement goals or preferences as the functionality will continue as part of the 2015 Edition of CEHRT. For more information on the performance data used to determine the topped out measures we refer readers to the EHR

Incentive Programs Objective and Measure Performance Report by Percentile available at: http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html.

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. For example, in the 2015 EHR Incentive Programs Final Rule, the Stage 1 Objective to Record Demographics was removed, but the technology and standard for this function in the EHR is still required (80 FR 62784) as a part of CEHRT. We note that the CDS and CPOE objectives and associated measures that we are proposing to remove for eligible hospitals and CAHs would still be required as part of the eligible hospital 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 are inviting public comments on our proposals.

2. Reduction of Measure Thresholds for Eligible Hospitals and CAHs for 2017 and 2018

In the 2015 EHR Incentive Programs Final Rule (80 FR 62762 through 62955), we finalized certain thresholds for the objectives and measures adopted for eligible hospitals and CAHs. In this proposed rule, we are proposing 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 year 2017 and 2018 for Stage 3. For the reasons stated above, 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. We have received correspondence from numerous hospital associations and health systems after the publication of the 2015 EHR Incentive Programs Final Rule specifically expressing concerns that they have had to resort to workarounds and processes that they believe do not add value for their patients in order to meet the current objective and measure thresholds. In the measure specifications outlined below, we are proposing to reduce a subset of the reporting thresholds to the Modified Stage 2 thresholds, as previously stated. For example, in the 2015 EHR Incentive Programs Final Rule, we finalized a threshold of more than 35 percent for the Stage 3 Patient Specific Education measure (42 CFR 495.24(d)(5)(ii)(B)(2)). In this proposed rule, we are proposing to reduce that threshold for 2018 for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program to more than 10 percent (proposed 42 CFR 495.24(c)(5)(ii)(B), which aligns with the Modified Stage 2 threshold for this same measure.

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. However, for the reasons discussed in further detail below, at this time we believe reducing the thresholds of certain existing measures would reduce unnecessary reporting burden and enable eligible hospitals and CAHs to focus more on patient care.

a. Proposed Changes to the Objectives and Measures for Modified Stage 2 (42 CFR 495.22) in 2017

For EHR reporting periods in calendar year 2017, we are proposing to modify the threshold of the Modified Stage 2 View, Download, 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 are proposing 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 stated above, these proposals would not apply to eligible hospitals and CAHs attesting under a State's Medicaid EHR Incentive Program.

Specifically, we are proposing 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 are proposing to add a new section 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 are also proposing a new naming convention for certain measures (shown in the table summarizing the Proposed Modified Stage 2 Objectives and Measures in 2017 for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program, below) as well as minor conforming changes to sections 495.22(a), (c)(1), and (d)(1).

Patient Electronic Access (VDT) (proposed 42 CFR 495.22(f)(8)(ii)(B))

View Download 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 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 are proposing to reduce the threshold of the VDT Measure from more than 5 percent to at least one patient. We are proposing 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 include, 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 recognize that eligible hospitals and CAHs may need additional time to educate patients on how to use health information technology and believe that reducing the threshold for 2017 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. We believe that with time patients will become more willing to use the technology to access their health records.

Proposed Modified Stage 2 Objectives and Measures in 2017 for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program

Objective	Previous Measure Name/Reference	Measure Name	Threshold Requirement
Protect Patient Health Information	Measure	Security Risk Analysis Measure	Yes/No attestation
*CDS (Clinical Decision Support)	Measure 1	Clinical Decision Support Interventions Measure	Five CDS
	Measure 2	Drug Interaction and Drug-Allergy Checks Measure	Yes/No
*CPOE (Computerized Provider Order Entry	Measure 1	Medication Orders Measure	>60%
	Measure 2	Laboratory Orders Measure	>30%
	Measure 3	Radiology Orders Measure	>30%
eRx (electronic prescribing)	Measure	e-Prescribing	>10%
Health Information Exchange	Measure	Health Information Exchange Measure	>10%
Patient Specific Education	Eligible Hospital/CAH Measure	Patient-Specific Education Measure	>10%
Medication Reconciliation	Measure	Medication Reconciliation Measure	>50%
Patient Electronic Access	Eligible Hospital/CAH Measure 1	Patient Access Measure	>50%
	Eligible Hospital/CAH Measure 2	** View Download Transmit (VDT) Measure	At least 1 patient
Public Health Reporting	Immunization Reporting Syndromic Surveillance Reporting Specialized Registry Reporting Electronic Reportable Laboratory Result Reporting	Immunization Measure Syndromic Surveillance Measure Specialized Registry Measure Electronic Reportable Laboratory Result Reporting Measure	Public Health Reporting to 3 Registries

* We note that we are proposing to remove CDS and CPOE for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program in section XVIII.C.1. of this proposed rule.
** We note that we are proposing to reduce the threshold for the VDT measure.

We are seeking public comments on the proposed changes.

b. Proposed 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 are proposing 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 stated above, these proposed modifications would not apply to eligible hospitals and CAHs attesting under a State's Medicaid EHR Incentive Program. We also are proposing, 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 (see the table summarizing Proposed Stage 3 Objectives and Measures for 2017 and 2018 for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program, below).

(1) Objective: Patient Electronic Access to Health Information (proposed 42 CFR 495.24(c)(5))

Objective: The eligible hospital or CAH provides patients (or patient-authorized representative) with timely electronic access to their health information and patient-specific education.

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 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 Patient Access Measure Threshold for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program

We are proposing, in proposed 42 CFR 495.24(c)(5)(ii)(A), to reduce the threshold for the 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 continue 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. Additional concerns were stated by vendors through written correspondence to CMS that stated in part 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. They went on further to provide that it will likely be difficult for hospitals to achieve the threshold of 80 percent at the implementation of Stage 3. Vendors have also expressed concerns around the likely issues surrounding compatibility and varying API interface functionalities that could possibly hinder interoperability among certified EHR technology. We are proposing 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.

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.

- 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 are proposing, in proposed 42 CFR 495.24(c)(5)(ii)(B), 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 continue 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 have indicated that they believe patients benefit from this information at the time of their interaction with the health care 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.

(2) Objective: Coordination of Care Through Patient Engagement (proposed 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.

View, Download, 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; 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, Transmit (VDT) Threshold

As discussed above, under the Modified Stage 2 Objectives and Measures, we are proposing to reduce the threshold of the View, Download 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 are proposing, in proposed 42 CFR 495.24(c)(6)(ii)(A), to reduce the threshold for Stage 3 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 include 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 recognize that eligible hospitals and CAHs may need additional time to educate patients on how to use health information technology and believe that reducing the threshold 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. We believe with time patients will become more willing to use the technology to access their health records.

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 are proposing, in proposed 42 CFR 495.24(c)(6)(ii)(B), 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 are proposing to reduce the threshold because we have 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 have 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 meet this threshold as a result of their patients' limited knowledge of, proficiency with, and access to information technology. We understand that hospitals have faced challenges meeting this measure. We believe the goal of this measure is to leverage HIT solutions to enhance patient and provider engagement. This type of platform is also meant to be of value for communication between multiple providers in the care team and patient which could promote care coordination and better outcomes for the patient. Therefore we would like to provide eligible hospitals and CAHs additional time to determine the best ways to relay the importance for patients to use secure messaging as a communication tool with their healthcare provider. We do believe that with time patients will become more willing to use secure messages as a means to communicate with their health care provider.

(3) Objective: Health Information Exchange (HIE) (proposed 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 would only be required to successfully meet the threshold for two of the three measures to meet the Health Information Exchange Objective.

Patient Care Record Exchange Measure: 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 Patient Care Record Exchange Measure for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program

We are proposing, in proposed 42 CFR 495.24(c)(7)(ii)(A), to reduce the threshold for the Patient Care Record Exchange 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 show that there are still challenges to achieving wide scale interoperable health information exchange[122]. 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. For example, reports note that adoption of health IT may be less extensive among common hospital trading partners such as occupational and physical therapists, behavioral health providers, and long term post-acute care facilities. 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 believe the threshold of more than 10 percent for exchange of summary of care is reasonable, and could likely be raised over time as providers gain experience with health IT supported information exchange and as barriers to interoperability are lessened.

[122] ONC Data Brief: No. 36 ■ May 2016 https://www.healthit.gov/sites/default/files/briefs/onc_data_brief_36_interoperability.pdf.

Request/Accept Patient Care Record 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.

- 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 Patient Care Record Threshold for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program

We are proposing, in proposed 42 CFR 495.24(c)(7)(ii)(B), to reduce the threshold for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for the Request/Accept Patient Care Record 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 show that there are still challenges to achieving wide scale interoperable health information exchange.[123] 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. For example, reports note that adoption of health IT may be less extensive among common hospital trading partners such as occupational and physical therapists, behavioral health providers, and long term post-acute care facilities. 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 believe the threshold of more than 10 percent for request/accept patient care record measure is appropriate, and could likely be raised over time as providers gain experience with health IT supported information exchange and as barriers to interoperability are lessened.

[123] Ibid.

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; 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 are proposing, in proposed 42 CFR 495.24(c)(7)(ii)(C), 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 Patient Care Record Exchange measure and the Request/Accept Patient Care Record 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 believe the threshold of more than 50 percent for clinical information reconciliation is reasonable, and could likely be raised over time as providers gain experience with health IT supported information exchange and as barriers to interoperability are lessened. We will continue to review adoption and performance and consider increasing the threshold in future rulemaking.

(4) Objective: Public Health and Clinical Data Registry Reporting (proposed 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 Measure (proposed 42 CFR 495.24(c)(8)(A))

Syndromic Surveillance Reporting Measure (proposed 42 CFR 495.24(c)(8)(B))

Electronic Case Reporting Measure (proposed 42 CFR 495.24(c)(8)(C))

Public Health Registry Reporting Measure (proposed 42 CFR 495.24(c)(8)(D))

Clinical Data Registry Reporting Measure (proposed 42 CFR 495.24(c)(8)(E))

Electronic Reportable Laboratory Result Reporting Measure (proposed 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 are proposing to reduce the reporting requirement for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for Public Health and Clinical Data Registry Reporting, in proposed 42 CFR 495.24(c)(8)(ii), 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 successfully attest. Hospitals and hospital associations have 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 have received written correspondence from hospitals indicating that in some instances

additional technologies were required to transmit data, which prevented them from doing so. Because of these concerns, we believe that reducing the reporting requirements to any combination of three measures would still add value while minimizing the administrative burden.

Proposed Stage 3 Objectives and Measures for 2017 and 2018 for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program

Objective	**Previous Measure Name/Reference**	**Measure Name**	**Threshold Requirement**
Protect Patient Health Information	Measure	Security Risk Analysis Measure	Yes/No attestation
eRx (electronic prescribing)	Eligible hospital/CAH Measure	e-Prescribing	>25%
*CDS (Clinical Decision Support)	Measure 1	Clinical Decision Support Interventions Measure	Five CDS
	Measure 2	Drug Interaction and Drug-Allergy Checks Measure	Yes/No
*CPOE (Computerized Provider Order Entry	Measure 1	Medication Orders Measure	>60%
	Measure 2	Laboratory Orders Measure	>60%
	Measure 3	Diagnostic Imaging Orders Measure	>60%
Patient Electronic Access to Health Information	Measure 1	**Patient Access Measure	>50%
	Measure 2	**Patient- Specific Education Measure	>10%
Coordination of Care through Patient Engagement	Measure 1	**View, Download Transmit (VDT) Measure	>At least 1 patient
	Measure 2	**Secure Messaging	>5%
	Measure 3	Patient Generated Health Data Measure	>5%
Health Information Exchange	Measure 1	**Patient Care Record Exchange Measure	>10%
	Measure 2	**Request/Accept Patient Care Record Measure	>10%
	Measure 3	**Clinical Information	>50%

Objective	Previous Measure Name/Reference	Measure Name	Threshold Requirement
		Reconciliation Measure	
Public Health and Clinical Data Registry Reporting	Immunization Registry Reporting Syndromic Surveillance Reporting Case Reporting Public Health Registry Reporting Clinical Data Registry Reporting Electronic Reportable Laboratory Result Reporting	Immunization Registry Reporting Measure Syndromic Surveillance Reporting Measure Case Reporting Measure Public Health Registry Reporting Measure Clinical Data Registry Reporting Measure Electronic Reportable Laboratory Result Reporting Measure	Report to 3 Registries or claim exclusions

*We note that we are proposing to remove CDS and CPOE for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program in section XVIII.C.1. of this proposed rule. These objectives are included in the table to demonstrate what their measures and thresholds would be if we were not to finalize our proposal to remove them.

** We note that we are proposing to reduce the thresholds for these measures.

We are inviting public comments on our proposals. We also are seeking 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. For example, we welcome comments on the proposed thresholds or whether different thresholds would be more appropriate. In addition, we are seeking public comments on new and more stringent measures for future years of the EHR Incentive Program. We 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 note 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 request 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.

As stated in the previous sections, we are not proposing 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 under 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 are proposing these changes only for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program. We request comments on whether these proposed changes should also apply for eligible hospitals and CAHs attesting under a State's Medicaid EHR Incentive Program. Specifically, 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 request 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.

D. Proposed Revisions 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 2015 EHR Incentive Programs Final Rule, we finalized the EHR reporting periods in 2015, 2016, 2017, 2018, and subsequent years for the incentive payments under Medicare and Medicaid (80 FR 62776 through 62781) and the downward payment adjustments under Medicare (80 FR 62904 through 62910), and made corresponding revisions to the definitions of "EHR reporting period" and "EHR reporting period for a payment adjustment year" under 42 CFR 495.4. For 2016, the EHR reporting period is any continuous 90-day period in CY 2016 for EPs, eligible hospitals, and CAHs that have not successfully demonstrated meaningful use in a prior year (new participants) and the full CY 2016 for EPs, eligible hospitals, and CAHs that have successfully demonstrated meaningful use in a prior year (returning participants). For the payment adjustments for EPs and eligible hospitals that are new participants, the EHR reporting period is any continuous 90-day period in CY 2016 and applies for the 2017 payment adjustment year and 2018 payment adjustment year; and for EPs and eligible hospitals that are returning participants, the EHR reporting period is the full CY 2016 and applies for the 2018 payment adjustment year. For the payment adjustments for CAHs that are new participants, the EHR reporting period is any continuous 90-day period in CY 2016 and applies for the 2016 payment adjustment year; and for CAHs that are returning participants, the EHR reporting period is the full CY 2016 and applies for the 2016

payment adjustment year. Certain attestation deadlines and other program requirements must be satisfied in order for an EP, eligible hospital, or CAH to avoid a payment adjustment for a particular year.

In the 2015 EHR Incentive Programs Final Rule (80 FR 62778 through 62779), we noted that many commenters overwhelmingly supported a 90-day EHR reporting period in 2015, while several commenters recommended a 90-day EHR reporting period for all providers in 2016 and subsequent years. In that rule, we explained a 90-day EHR reporting period in 2015 will allow providers additional time to address any remaining issues with the implementation of EHR technology certified to the 2014 Edition and to accommodate the proposed changes to the objectives and measures of meaningful use for 2015. We declined to extend the 90-day EHR reporting period beyond 2015 for returning participants because, in 2012 and 2013, thousands of returning providers successfully attested to program requirements for an EHR reporting period of one full calendar year and hardship exceptions may be available for providers experiencing extreme and uncontrollable circumstances.

Following the publication of the 2015 EHR Incentive Programs Final Rule, we received additional feedback from hospitals, hospital associations, eligible professionals and other clinical associations stating concerns regarding the finalized requirements. We now understand from those stakeholders that more time is needed to accommodate some of the updates from the 2015 EHR Incentive Programs Final Rule. These updates include, but are not limited to, system changes to the CEHRT, including implementation of an API which is a unique user interface that allows patients, through an application of

their choice (including third-party applications), to pull certain components of their unique health data directly from the provider's CEHRT. We understand from hospitals and EHR vendors that APIs require a great deal of time to configure the software to accommodate such changes, including the user interface. We also received correspondence from eligible professionals expressing concern related to the requirements under MIPS and their transition to that program, and have shared interest in ensuring their readiness to report under the MIPS program in 2017. We believe this proposal is responsive to additional stakeholder feedback received through both correspondence and in-person meetings which requested that we allow a 90-day EHR reporting period in 2016 in order to reduce the reporting burden and increase flexibility in the program.

Therefore, we are proposing 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 are proposing corresponding changes to the definition of "EHR reporting period" "and EHR reporting period for a payment adjustment year" at 42 CFR 495.4.

We are inviting public comments on our proposal.

2. Clinical Quality Measurement

In connection with our proposal to establish a 90-day EHR reporting period in 2016, and for the reasons discussed in the preceding section, we also are proposing 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 note that this proposal would have no impact on the requirements for CQM data that are electronically reported as established in prior rulemaking. In 2016, we are proposing 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 note 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.

We are inviting public comment on our proposal.

E. Proposal to Require Modified Stage 2 for New Participants in 2017

In the 2015 EHR Incentive Programs Final Rule (80 FR 62873), we outlined the requirements for EPs, eligible hospitals, and CAHs using CEHRT in 2017 as it relates to the objectives and measures they select to report. Specifically, we stated that:

- A provider that has technology certified to the 2015 Edition may attest to Stage 3 or to the Modified Stage 2 requirements.

- A provider that has technology certified to a combination of 2015 Edition and 2014 Edition may attest to: (1) the Modified Stage 2 requirements; or (2) potentially to the Stage 3 requirements if the mix of certified technologies would not prohibit them from meeting the Stage 3 measures.

- A provider that has technology certified to the 2014 Edition only may attest to the Modified Stage 2 requirements and may not attest to Stage 3.

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, we are proposing 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 under 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 are proposing 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 are proposing 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 are inviting public comments on our proposals.

F. Proposed Significant Hardship Exception for New Participants Transitioning to MIPS in 2017

In the September 4, 2012 Stage 2 final rule (77 FR 54093 through 54097), we finalized that eligible professionals (EPs) who have not successfully demonstrated

meaningful use in a prior year (new participants) in the EHR Incentive Program may attest by October 1 to avoid a payment adjustment under section 1848(a)(7)(A) of the Act in the subsequent year. We note that these new participants are not necessarily newly enrolled in Medicare, but have been enrolled and have not previously attested to meaningful use for the EHR Incentive Program.

In the 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 example, an EP could use a 90-day reporting period from June through August 2017 to report under the Medicare EHR Incentive Program and, in the same time period, collect data for reporting under the Advancing Care Information performance category in MIPS. We understand that this overlap of reporting and performance periods in 2017 could be confusing to EPs who are new participants in the EHR Incentive Program and are also making the transition to MIPS because although both programs require the use of certified EHR technology, the measures and other requirements for meaningfully using that technology under the EHR Incentive Program are different from the measures and other requirements proposed under the advancing care information performance category of the MIPS. In addition, there are also different systems in which participants will have to register and attest. We also understand that these EPs, being new participants and likely new to EHR use and measurement, may be actively working with their vendors to build out their EHR

technology and day-to-day EHR functions to align with the various and different requirements of the EHR Incentive Program and MIPS.

For these reasons, we are proposing 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 are limiting 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. This proposed significant hardship exception is based upon our proposal in the MIPS and APMs Proposed Rule to establish 2017 as the first performance period of the MIPS. In the event we decide not to finalize that proposal, and instead adopt a different performance period for the MIPS that does not coincide with the final year for EPs to attest to meaningful use under the Medicare EHR Incentive Program, we may determine that this proposed significant hardship exception is not necessary.

To apply for this significant hardship exception, 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 six years post attestation.

We believe 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 under the MIPS APMs Proposed Rule. 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 are also proposing to amend the regulations by adding new section 495.102(d)(4)(v) to include this new category of significant hardship exception.

We are inviting public comment on our proposal.

G. Proposed Modifications to Measure Calculations for Actions Outside the EHR Reporting Period

In the 2015 EHR Incentive Programs Final Rule (80 FR 62808), we referenced FAQ 8231(https://questions.cms.gov/faq.php?isDept=0&search=8231&searchType=faqId&submitSearch=1&id=5005) which states that for all meaningful use measures, unless otherwise specified, actions may fall outside the EHR reporting period timeframe but must take place no earlier than the start of the reporting year and no later than the date of attestation. We realize this open-ended timeframe could be confusing to providers and could vary widely among providers as their date of attestation could fall anywhere from

January 1 through February 28 (or other date specified by CMS) after the year in which their EHR reporting period occurs. For these reasons, and to be consistent with incorporation of data from one EHR reporting period we are proposing 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 this 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 are inviting public comment on our proposal.

XIX. Proposed 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 proposed rule for a full discussion of the Hospital VBP Program and its proposed policies (81 FR 25099 through 25117).

B. Proposed 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.hcahpsonline.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.

2. Background of the Patient- and Caregiver-Centered Experience of Care/Care Coordination Domain Performance Scoring Methodology

As finalized beginning with the FY 2018 program year (80 FR 49565 through 49566), 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. Proposed 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,[124] 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

[124] Available at: http://www.hcahpsonline.org/surveyinstrument.aspx.

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 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.[125]

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

[125] 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.

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 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 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 modifications to the Pain Management dimension questions, we are proposing 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, we intend to propose to adopt them in future rulemaking.

If our proposal to remove the Pain Management dimension is finalized, this would leave eight dimensions in the HCAHPS Survey for use in the Hospital VBP Program, 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 HCAHPS Pain Management dimension from the Hospital VBP Program, we are proposing 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). 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 this proposed rule, we are proposing 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.

Proposed 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 0^{th} 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). We are proposing 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 that proposed rule, we also proposed to change the name of this domain to Person and Community Engagement domain beginning with the FY 2019 program year (81 FR 25100 through 25101).) The proposed performance standards for the other eight dimensions would remain unchanged, as the table below illustrates.

Proposed Performance Standards for the FY 2019 Program Year			
HCAHPS Survey Dimension	**Floor* (percent)**	**Achievement Threshold** (percent)**	**Benchmark*** (percent)**
Communication with Nurses	16.32	78.59	86.81
Communication with Doctors	22.56	80.33	88.55
Responsiveness of Hospital Staff	21.91	65.00	80.27
Pain Management	N/A	N/A	N/A
Communication about Medicines	6.19	63.18	73.51
Hospital Cleanliness & Quietness	13.78	65.64	79.12
Discharge Information	60.58	86.88	91.73
3-Item Care Transition	4.26	51.35	62.73
Overall Rating of Hospital	30.52	70.58	84.68

* 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 are inviting public comments on these proposals.

XXI. Files Available to the Public via the Internet

The Addenda to the OPPS/ASC proposed rules and the final rules with comment period are published and available only via the Internet on the CMS Web site. To view the Addenda to this proposed rule pertaining to proposed CY 2017 payments under the OPPS, 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-P" from the list of regulations. All OPPS Addenda to this proposed rule are contained in the zipped folder entitled "Proposed 2017 OPPS 1656-P Addenda" at the bottom of the page. To view the Addenda to this proposed rule pertaining to the proposed 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-P" from the list of regulations. All ASC Addenda to this proposed rule are contained in the zipped folders entitled "Addendum AA, BB, DD1, DD2, and EE".

XXII. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection

should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In this proposed rule, we are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

B. ICRs for the Hospital OQR Program

1. Background

As we stated in section XIV. of the CY 2012 OPPS/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 OPPS/ASC final rules with comment periods (75 FR 72111 through 72114; 76 FR 74549 through 74554; 77 FR 68527 through 68532; 78 FR 75170 through 75172; 79 FR 67012 through 67015; 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 proposed rule.

2. Estimated Burden of Hospital OQR Program Proposals for the CY 2018 Payment Determination and Subsequent Years

In section XIII.B.8. of this proposed rule, we are proposing 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 proposing that hospitals will generally have approximately 30 days to preview their data. Both of these proposals are consistent with current practice. Lastly, we are proposing 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 proposed changes to the public display policies because hospitals would not be required to submit additional data or forms to CMS.

3. Estimated Burden of Hospital OQR Program Proposals for the CY 2019 Payment Determination and Subsequent Years

a. Extraordinary Circumstances Extension or Exemptions Process

In section XIII.D.8. of this proposed rule, we are proposing 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 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), and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524).

We believe that the proposed 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 would 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 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 proposed rule, we are proposing 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 Proposals for the CY 2020 Payment Determination and Subsequent Years

In sections XIII.B.5.a. and XIII.B.5.b. of this proposed rule, we are proposing 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 proposed rule, we also are proposing 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.

The data used to calculate scores on the proposed OP-35 or OP-36 measures are derived from Medicare FFS claims. As noted in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68530), we calculate the claims-based measures using Medicare FFS claims data that do not require additional hospital data submissions. As a result, we do not anticipate that the proposed OP-35 or OP-36 measures would 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 OAS CAHPS Survey-based measures (proposed OP-37a, OP-37b, OP-37c, OP-37d, and OP-37e) are

currently approved under OMB Control Number 0938-1240. For this reason, we are not providing an independent estimate of the burden associated with OAS CAHPS Survey-based measures for the Hospital OQR Program. We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70580 through 70582) for burden information already discussed.

We are inviting public comment on the burden associated with these proposed information collection requirements.

C. ICRs for the ASCQR Program

1. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74554), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53672), and the CY 2013, CY 2014, CY 2015 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 proposed rule.

2. Proposed 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 proposing to update our burden calculation methodology to standardize elements within our burden calculation. Specifically, we are proposing 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, we are proposing 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, we are proposing to align these numbers and use one hourly labor cost across programs for purposes of burden calculations. Specifically, we are proposing 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 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."[126] 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 would 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.[127]

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, we are proposing to calculate the cost over 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

[126] http://www.bls.gov/bls/infohome.htm.
[127] http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.

method. We note that in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25251 through 25152, 25256, and 25319) we are using a similar adjustment for several other quality reporting programs. Therefore, we are proposing to apply an hourly labor cost of $32.84 ($16.42 base salary + $16.42 fringe and overhead) to our burden calculations.

3. Estimated Burden of ASCQR Program Proposals for the CY 2018 Payment Determination

For the CY 2018 payment determination and subsequent years, we are making one new proposal. In section XIV.B.7 of this proposed rule, we are proposing 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 proposing that ASCs will generally have approximately 30 days to preview their data. Both of these proposals are consistent with current practice. Lastly, we are proposing 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 proposed 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.

4. Estimated Burden of ASCQR Program Proposals for the CY 2019 Payment Determination

For the CY 2019 payment determination and subsequent years, we are making two new proposals. In section XIV.D.3. of this proposed rule, we are proposing to implement a submission deadline with an end date of May 15 for all data submitted via a

Web-based tool (CMS or non-CMS) beginning with the CY 2019 payment determination. We do not anticipate additional burden as the data collection and submission requirements have not changed; only the deadline would be moved to a slightly earlier date that we anticipate would alleviate burden by aligning data submission deadlines. We also are proposing to make corresponding changes to the regulations at 42 CFR 416.310(c)(1)(ii). 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 proposed rule, we are proposing 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. We do not anticipate that there would 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 proposing to make corresponding changes to the regulations at 42 CFR 416.310(d)(1). We do not anticipate any additional burden to ASCs as a result of codifying this policy.

5. Estimated Burden of ASCQR Program Proposals for the CY 2020 Payment Determination

For the CY 2020 payment determination and subsequent years, we are proposing 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 proposed rule, we are proposing 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 proposing 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 would incur a financial burden associated with abstracting numerators, denominators, and exclusions for the two proposed measures collected and reported via a CMS online data submission tool (proposed ASC-13 and ASC-14). Using the proposed burden estimate values for chart-abstracted measures discussed in section XXI.C.2. of this proposed rule, we estimate that each participating ASC would 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 x 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 proposed ASC-13 and ASC-14 would be 1,315 hours and $42,185 (1,315 hours x $32.84 per hour), and 82,845 hours (1,315 x 63 cases) and $2,720,630 (82,845 hours x $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 proposed OAS CAHPS Survey-based measures (proposed ASC-15a, ASC-15b, ASC-15c, ASC-15d, and

ASC-15e) are currently approved under OMB Control Number 0938-1240. For this reason, we are not providing an independent estimate of the burden associated with OAS CAHPS Survey administration for the ASCQR Program. We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70582 through 70584) for burden information already discussed.

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). We are not proposing to make 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 are inviting public comment on the burden associated with these information collection requirements.

D. ICRs Relating to Proposed Changes in Transplant Enforcement Performance Thresholds

In section XV. of this proposed rule, we discuss proposed changes to the enforcement performance thresholds relating to patient and graft survival outcomes. The proposed revisions would impose no new burdens on transplant programs. These

proposals 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 Proposed Changes Relating to Organ Procurement Organizations (OPOs)

In section XVI. of this proposed rule, we are proposing several changes to definitions, outcome measures and documentation requirements for OPOs. In section XVI.B.1. of this proposed rule, we are proposing a revision to the definition of "eligible death." In section XVI.B.2 of this proposed rule, we are proposing to adjust the outcome performance yield measure to align CMS with the SRTR yield metric. In section XVI.B.3. of this proposed rule, we are proposing to reduce the amount of hard copy documentation that is packaged and shipped with each organ. These proposals 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 proposed rule, we are proposing to make a technical correction to the enforcement provisions for transplant centers and to clarify our policy regarding SIAs. These proposals 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 Proposed Changes to the Electronic Health Record (EHR) Incentive Program

In section XVIII. of this proposed rule, we discuss our proposals for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program 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 would reduce the total burden associated with these measures by a total of 11 minutes. This would 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 would 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 proposals to change the EHR reporting period in 2016 from the full CY 2016 to any continuous 90-day period within CY 2016 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 the Modified Stage 2 objectives and measures. We do not believe that modifying the EHR reporting period would 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 proposals 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 Proposed Additional Hospital VBP Program Policies

In section XIX. of this proposed rule, we discuss proposed changes in the requirements for the Hospital VBP Program. Specifically, we are proposing to change the scoring methodology for the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain 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, its inclusion in the Hospital VBP Program does not

result in any additional burden because the Hospital VBP Program uses data that are required for the Hospital IQR Program. The proposed change to the scoring methodology for the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain in the Hospital VBP Program also would not result in any additional reporting burden.

H. ICRs for Payment for Off-Campus Provider-Based Departments Proposals for CY 2017

In section X.A. of this proposed rule, we discuss proposals for the implementation of section 603 of the Bipartisan Budget Act of 2015. The proposals would impose no new burdens on hospitals or providers. These proposals do not impose any new information collection or recordkeeping 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.

We are inviting public comments on the burden associated with these information collection requirements.

XXIII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

XXIV. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this proposed rule, as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995, Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Contract with America Advancement Act of 1996 (Pub. L. 104-121) (5 U.S.C. 804(2)). This section of the proposed rule contains the impact and other economic analyses for the provisions that we are proposing 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 proposed rule has been designated as an economically significant rule under section 3(f)(1) of Executive Order 12866 and a major rule under the Contract with America Advancement Act of 1996 (Pub. L. 104-121). Accordingly, this proposed rule has been reviewed by the Office of

Management and Budget. We have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of this proposed rule. We are soliciting comments on the regulatory impact analysis in this proposed rule, and we will address the public comments we receive in the final rule with comment period as appropriate.

2. Statement of Need

This proposed rule is necessary to propose updates to the Medicare hospital OPPS rates. It is necessary to make proposed 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 OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We are proposing to revise the APC relative payment weights using claims data for services furnished on and after January 1, 2015, through and including December 31, 2015, and processed through December 31, 2015, and updated cost report information.

This proposed rule also is necessary to propose 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 OPPS 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 OPPS relative payment weights. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be performed in an ASC not less frequently than every 2 years.

3. Overall Impacts for the Proposed 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 proposed changes in this proposed rule, would be approximately $671 million. Taking into account our estimated changes in enrollment, utilization, and case-mix, we estimate that the proposed OPPS expenditures for CY 2017 would be approximately $5.1 billion higher relative to expenditures in CY 2016. We note that this estimate of $5.1 billion does not include the proposed implementation of section 603 of the Bipartisan Budget Act of 2015 in CY 2017, which we estimate would reduce OPPS expenditures by $500 million in CY 2017. Because this proposed rule is economically significant as measured by the threshold of an additional $100 million in expenditures in 1 year, we have prepared this regulatory impact analysis that, to the best of our ability, presents its costs and benefits. Table 30 displays the distributional impact of the proposed CY 2017 changes in OPPS payment to various groups of hospitals and for CMHCs.

We estimate that the proposed update to the conversion factor and other proposed adjustments (not including the effects of proposed outlier payments, the proposed pass-through estimates, and the proposed application of the frontier State wage adjustment for CY 2016) would increase total OPPS payments by 1.6 percent in

CY 2017. The proposed changes to the APC relative payment weights, the proposed changes to the wage indexes, the proposed continuation of a payment adjustment for rural SCHs, including EACHs, and the proposed payment adjustment for cancer hospitals would not increase OPPS payments because these proposed changes to the OPPS are budget neutral. However, these proposed updates would change the distribution of payments within the budget neutral system. We estimate that the proposed total change in payments between CY 2016 and CY 2017, considering all payments, proposed changes in estimated total outlier payments, pass-through payments, and the application of the frontier State wage adjustment outside of budget neutrality, in addition to the application of the OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G), and 1833(t)(17) of the Act, would increase total estimated OPPS payments by 1.6 percent.

We estimate the proposed total increase (from proposed changes to the ASC provisions in this proposed rule as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures under the ASC payment system for CY 2017 compared to CY 2016 to be approximately $214 million. Because the proposed provisions for the ASC payment system are part of a proposed rule that is economically significant as measured by the $100 million threshold, we have prepared a regulatory impact analysis of the proposed changes to the ASC payment system that, to the best of our ability, presents the costs and benefits of this portion of the proposed rule. Table 31 and Table 32 of this proposed rule display the redistributive impact of the proposed

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 Proposed OPPS Changes in this Proposed Rule

(1) Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the proposed CY 2017 policy changes on various hospital groups. We post on the CMS Web site our proposed hospital-specific estimated payments for CY 2017 with the other supporting documentation for this proposed rule. To view the proposed 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-P" from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this proposed rule. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 30 below. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A. of this proposed rule for a discussion of the hospitals whose claims we do not use for ratesetting and impact purposes.

We estimate the effects of the proposed individual policy changes by estimating payments per service, while holding all other proposed payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our

policy changes. In addition, we have not made adjustments for future changes in variables such as service volume, service-mix, or number of encounters. We are soliciting public comment and information about the anticipated effects of our proposed changes on providers and our methodology for estimating them. Any public comments that we receive will be addressed in the applicable sections of the final rule with comment period that discuss the specific policies.

(2) Estimated Effects of Proposed OPPS Changes on Hospitals

Table 30 below shows the estimated impact of this proposed rule on hospitals. Historically, the first line of the impact table, which estimates the proposed change in payments to all facilities, has always included cancer and children's hospitals, which are held harmless to their pre-BBA amount. We also include CMHCs in the first line that includes all providers. We now include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 30, 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 proposing to pay CMHCs for partial hospitalization services under only one proposed APC 5853 (Partial Hospitalization for CMHCs), and we are proposing to pay hospitals for partial hospitalization services under only one proposed APC 5863 (Partial Hospitalization for Hospital-Based PHPs).

The estimated increase in the proposed total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory

methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor as discussed in detail in section II.B. of this proposed rule. Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The proposed IPPS market basket percentage increase for FY 2017 is 2.8 percent (81 FR 25077). Section 1833(t)(3)(F)(i) of the Act reduces that 2.8 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is proposed to be 0.5 percentage point for FY 2017 (which is also the proposed MFP adjustment for FY 2017 in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25077)), and sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(v) of the Act further reduce the market basket percentage increase by 0.75 percentage point, resulting in the proposed OPD fee schedule increase factor of 1.55 percent. We are using the proposed OPD fee schedule increase factor of 1.55 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 30.

To illustrate the impact of the proposed 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 30 shows the estimated redistribution of the proposed 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 proposed APC reconfiguration and recalibration changes between CY 2016 and CY 2017 (Column 2); the proposed wage indexes and the proposed provider adjustments (Column 3); the combined impact of all of the proposed changes described in the preceding columns plus the proposed 1.55 percent OPD fee schedule increase factor update to the conversion factor; and the estimated impact taking into account all proposed payments for CY 2017 relative to all payments for CY 2016, including the impact of proposed changes in estimated outlier payments, the frontier State wage adjustment, and proposed changes to the pass-through payment estimate (Column 5).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are proposing to maintain the current adjustment percentage for CY 2017. Because the proposed updates to the conversion factor (including the proposed update of the OPD fee schedule increase factor), the estimated cost of the proposed rural adjustment, and the estimated cost of proposed projected pass-through payment for CY 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 proposed wage index changes on the hospital. However, proposed total payments made under this system and the extent to which this

proposed rule would redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2016 and CY 2017 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the proposed rates for CY 2017 would increase Medicare OPPS payments by an estimated 1.6 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in a proposed estimated 1.7 percent increase in Medicare payments to all other hospitals. These proposed estimated payments would not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 30 shows the total number of facilities (3,862), 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 proposed 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 proposed 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 proposed rule. At this time, we are unable to calculate a disproportionate share hospital (DSH) variable for hospitals that are not also paid under the IPPS, since 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 (3,747), 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 49 CMHCs at the bottom of the impact table and discuss that impact separately below.

Column 2: APC Recalibration – All Proposed Changes

Column 2 shows the estimated effect of proposed APC recalibration. Column 2 also reflects any proposed changes in multiple procedure discount patterns or conditional packaging that occur as a result of the proposed changes in the relative magnitude of payment weights. As a result of proposed APC recalibration, we estimate that urban hospitals would experience no change, with the impact ranging from an increase of 0.2 percent to a decrease of 0.3 percent, depending on the number of beds. Rural hospitals would experience a 0.4 percent increase, with the impact ranging from an increase of 0.6 percent to no change, depending on the number of beds. Major teaching hospitals would experience a decrease of 0.3 percent overall.

Column 3: Proposed Wage Indexes and the Effect of the Proposed Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the proposed APC recalibration; the proposed updates for the wage indexes with the proposed fiscal year

(FY) 2017 IPPS post-reclassification wage indexes; and the proposed rural adjustment. We modeled the independent effect of the proposed budget neutrality adjustments and the proposed OPD fee schedule increase factor by using the relative payment weights and wage indexes for each year, and using a CY 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 proposed updated wage indexes, including the application of proposed budget neutrality for the proposed rural floor policy on a nationwide basis. This column excludes the effects of the proposed frontier State wage index adjustment, which is not budget neutral and is included in Column 5. We did not model a proposed budget neutrality adjustment for the proposed rural adjustment for SCHs because we are proposing to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2017, as described in section II.E. of this proposed rule.

We modeled the independent effect of proposing to update the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the proposed CY 2017 scaled weights and a CY 2016 conversion factor that included a budget neutrality adjustment for the effect of the proposed changes to the wage indexes between CY 2016 and CY 2017. The proposed FY 2017 wage policy results in modest redistributions.

There is no difference in impact between the CY 2016 cancer hospital payment adjustment and the proposed CY 2017 cancer hospital payment adjustment because we

are proposing to use the same payment-to-cost ratio target in CY 2017 as in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70362 through 70363).

Column 4: All Proposed Budget Neutrality Changes Combined with the Proposed Market Basket Update

Column 4 demonstrates the combined impact of all of the proposed changes previously described and the proposed update to the conversion factor of 1.55 percent. Overall, these proposed changes would increase payments to urban hospitals by 1.5 percent and to rural hospitals by 2.3 percent. Most classes of hospitals would receive an increase in line with the proposed 1.6 percent overall increase after the proposed update is applied to the proposed budget neutrality adjustments.

Column 5: All Proposed Changes for CY 2017

Column 5 depicts the full impact of the proposed CY 2017 policies on each hospital group by including the effect of all of the proposed 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 proposed OPD fee schedule increase; the impact of the proposed frontier State wage index adjustment; the impact of estimated proposed OPPS outlier payments as discussed in section II.G. of this proposed rule; the proposed change in the Hospital OQR Program payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XIII. of this proposed rule); and the difference in proposed total OPPS payments dedicated to transitional pass-through payments.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2016 update (and assumed, for modeling purposes, to be the same number for CY 2017), we included 48 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 proposed changes for CY 2017 would increase payments to all facilities by 1.6 percent for CY 2017. We modeled the independent effect of all of the proposed changes in Column 5 using the final relative payment weights for CY 2016 and the proposed relative payment weights for CY 2017. We used the final conversion factor for CY 2016 of $73.725 and the proposed CY 2017 conversion factor of $74.909 discussed in section II.B. of this proposed rule.

Column 5 contains simulated outlier payments for each year. We used the proposed 1-year charge inflation factor used in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25270) of 4.4 percent (1.0440) to increase individual costs on the CY 2015 claims, and we used the most recent overall CCR in the April 2016 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2016. Using the CY 2015 claims and a proposed 4.4 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 would 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 proposed charge inflation factor of 9.0 percent (1.0898) and the CCRs in the April 2016 OPSF, with an adjustment of 0.9696, to reflect relative changes in cost and charge inflation between CY 2015 and

CY 2017, to model the proposed CY 2017 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a proposed fixed-dollar threshold of $3,825. The charge inflation and CCR inflation factors are discussed in detail in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25270 through 25273).

Overall, we estimate that facilities would experience an increase of 1.6 percent under this proposed rule in CY 2017 relative to total spending in CY 2016. This projected increase (shown in Column 5) of Table 30 reflects the proposed 1.55 percent OPD fee schedule increase factor, plus 0.03 percent to account for our proposal to package unrelated laboratory tests into OPPS payment, plus 0.02 percent for the proposed 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 (proposed 1.0 percent). We estimate that the combined effect of all of the proposed changes for CY 2017 would increase payments to urban hospitals by 1.6 percent. Overall, we estimate that rural hospitals would experience a 2.3 percent increase as a result of the combined effects of all of the proposed changes for CY 2017.

Among hospitals by teaching status, we estimate that the impacts resulting from the combined effects of all proposed changes would include an increase of 1.2 percent for major teaching hospitals and an increase of 1.9 percent for nonteaching hospitals. Minor teaching hospitals would experience an estimated increase of 1.7 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals would experience an increase of

1.7 percent, proprietary hospitals would experience an increase of 1.6 percent, and governmental hospitals would experience an increase of 1.5 percent.

TABLE 30.—ESTIMATED IMPACT OF THE PROPOSED CY 2017 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

		(1)	(2)	(3)	(4)	(5)
		Number of Hospitals	**APC Recalibration (all proposed changes)**	**New Wage Index and Provider Adjustments**	**All Proposed Budget Neutral Changes (combined cols 2,3) with Proposed Market Basket Update**	**All Proposed Changes**
ALL FACILITIES *		3,862	0.0	0.0	1.6	1.6
ALL HOSPITALS		3,747	0.0	0.0	1.6	1.7
(excludes hospitals permanently held harmless and CMHCs)						
URBAN HOSPITALS		2,917	0.0	0.0	1.5	1.6
	LARGE URBAN	1,609	-0.1	-0.1	1.4	1.4
	(GT 1 MILL.)					
	OTHER URBAN	1,308	0.0	0.1	1.7	1.7
	(LE 1 MILL.)					
RURAL HOSPITALS		830	0.4	0.3	2.3	2.3
	SOLE COMMUNITY	378	0.4	0.4	2.4	2.3
	OTHER RURAL	452	0.4	0.3	2.2	2.2
BEDS (URBAN)						
	0 - 99 BEDS	,	0.0	0.2	1.8	1.9
	100-199 BEDS	827	0.2	-0.1	1.6	1.6
	200-299 BEDS	463	0.1	-0.1	1.6	1.7
	300-499 BEDS	403	0.0	0.0	1.6	1.6
	500 + BEDS	214	-0.3	-0.1	1.2	1.3
BEDS (RURAL)						
	0 - 49 BEDS	330	0.4	0.4	2.4	2.3
	50- 100 BEDS	304	0.6	0.4	2.5	2.5
	101- 149 BEDS	111	0.5	0.1	2.2	2.1
	150- 199 BEDS	47	0.2	0.5	2.4	2.3
	200 + BEDS	38	0.0	0.3	2.0	2.0
REGION (URBAN)						
	NEW ENGLAND	147	0.0	-1.1	0.5	0.5
	MIDDLE ATLANTIC	348	0.0	-0.4	1.1	1.1
	SOUTH ATLANTIC	460	0.0	0.0	1.7	1.7

		(1)	(2)	(3)	(4)	(5)
		Number of Hospitals	**APC Recalibration (all proposed changes)**	**New Wage Index and Provider Adjustments**	**All Proposed Budget Neutral Changes (combined cols 2,3) with Proposed Market Basket Update**	**All Proposed Changes**
	EAST NORTH CENT.	467	0.0	0.3	1.9	2.0
	EAST SOUTH CENT.	175	-0.3	0.2	1.5	1.6
	WEST NORTH CENT.	178	-0.1	0.2	1.6	1.5
	WEST SOUTH CENT.	512	-0.4	0.5	1.7	1.8
	MOUNTAIN	203	0.2	-0.1	1.7	1.8
	PACIFIC	377	0.3	-0.3	1.6	1.7
	PUERTO RICO	50	-0.2	-0.2	1.2	1.2
REGION (RURAL)						
	NEW ENGLAND	21	1.0	0.4	3.0	2.9
	MIDDLE ATLANTIC	56	0.1	1.1	2.9	2.5
	SOUTH ATLANTIC	125	0.3	-0.1	1.8	1.8
	EAST NORTH CENT.	121	0.5	0.5	2.6	2.6
	EAST SOUTH CENT.	158	0.2	0.1	1.9	2.0
	WEST NORTH CENT.	100	0.4	0.5	2.5	2.4
	WEST SOUTH CENT.	167	0.2	0.8	2.6	2.6
	MOUNTAIN	58	0.6	-0.4	1.8	1.6
	PACIFIC	24	0.6	-0.3	1.9	1.9
TEACHING STATUS						
	NON-TEACHING	2,691	0.2	0.1	1.9	1.9
	MINOR	719	0.1	0.1	1.8	1.7
	MAJOR	337	-0.3	-0.2	1.1	1.2
DSH PATIENT PERCENT						
	0	15	-2.2	0.1	-0.5	0.7
	GT 0 - 0.10	311	-0.2	-0.1	1.2	1.3
	0.10 - 0.16	275	0.2	0.0	1.8	1.8
	0.16 - 0.23	602	0.2	0.1	1.9	1.9
	0.23 - 0.35	1,148	0.1	0.1	1.7	1.7
	GE 0.35	858	0.0	-0.1	1.5	1.5
	DSH NOT AVAILABLE **	538	-3.7	-0.1	-2.3	-2.2
URBAN TEACHING/DSH						
	TEACHING & DSH	962	-0.1	-0.1	1.4	1.4

		(1)	(2)	(3)	(4)	(5)
		Number of Hospitals	**APC Recalibration (all proposed changes)**	**New Wage Index and Provider Adjustments**	**All Proposed Budget Neutral Changes (combined cols 2,3) with Proposed Market Basket Update**	**All Proposed Changes**
	NO TEACHING/DSH	1,426	0.2	0.0	1.8	1.8
	NO TEACHING/NO DSH	15	-2.2	0.1	-0.5	0.7
	DSH NOT AVAILABLE**	514	-3.3	-0.2	-1.9	-1.9
TYPE OF OWNERSHIP						
	VOLUNTARY	1,981	0.1	0.0	1.7	1.7
	PROPRIETARY	1,259	-0.1	0.0	1.5	1.6
	GOVERNMENT	507	0.0	-0.1	1.4	1.5
CMHCs		49	-9.7	-0.2	-8.5	-8.4

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all proposed 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 proposed FY 2017 hospital inpatient wage index, including all hold harmless policies and transitional wages. The proposed rural adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the cancer hospital adjustment is 1.000 because the payment-to-cost ratio target remains the same as in the CY 2016 OPPS/ASC final rule (80 FR 70362 through 70364).

Column (4) shows the impact of all budget neutrality adjustments and the addition of the proposed 1.55 percent OPD fee schedule update factor (2.8 percent reduced by 0.5 percentage points for the proposed productivity adjustment and further reduced by 0.75 percentage point in order to satisfy statutory requirements set forth in the Affordable Care Act).

Column (5) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate, adding estimated outlier payments, and applying the frontier State wage adjustment.

*These 3,862 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 Proposed OPPS Changes on CMHCs

The last line of Table 30 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPPS. 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 proposing to combine APCs 5851 and 5852 into proposed new APC 5853 (Partial Hospitalization (3 or more services) for CMHCs). We modeled the impact of this proposed APC policy assuming that CMHCs would continue to provide the same number of days of PHP care as seen in the CY 2015 claims data used for this proposed rule. We excluded days with 1 or 2 services because our policy only pays a per diem rate for partial hospitalization when 3 or more qualifying services are provided to the beneficiary. We estimate that CMHCs would experience an overall 8.4 percent decrease in payments from CY 2016 (shown in Column 5). We note that this would include the proposed trimming methodology described in section VIII.B. of this proposed rule.

Column 3 shows that the estimated impact of adopting the proposed FY 2017 wage index values would result in a small decrease of 0.2 percent to CMHCs. Column 4 shows that combining this proposed OPD fee schedule increase factor, along with proposed changes in APC policy for CY 2017 and the proposed FY 2017 wage index updates, would result in an estimated decrease of 8.5 percent. Column 5 shows that adding the proposed changes in outlier and pass-though payments would result in a total 8.4 percent decrease in payment for CMHCs. This reflects all proposed changes to CMHCs for CY 2017.

(4) Estimated Effect of Proposed OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary's payment would increase for services for which the OPPS payments would rise and would decrease for services for which the OPPS payments

would fall. For further discussion on the calculation of the proposed national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.I. of this proposed rule. In all cases, section 1833(t)(8)(C)(i) of the Act limits beneficiary liability for copayment for a procedure performed in a year to the hospital inpatient deductible for the applicable year.

We estimate that the aggregate beneficiary coinsurance percentage would be 18.5 percent for all services paid under the OPPS in CY 2017. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the proposed CY 2017 comprehensive APC payment policy discussed in section II.A.2.e. of this proposed rule.

(5) Estimated Effects of Proposed OPPS Changes on Other Providers

The relative payment weights and payment amounts established under the OPPS affect the payments made to ASCs as discussed in section XII. of this proposed rule. No types of providers or suppliers other than hospitals, CMHCs, and ASCs would be affected by the proposed changes in this proposed rule.

(6) Estimated Effects of Proposed OPPS Changes on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be an increase of $671 million in program payments for OPPS 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 XX.A. of this proposed rule.

(7) Alternative OPPS Policies Considered

Alternatives to the OPPS changes we are proposing and the reasons for our selected alternatives are discussed throughout this proposed rule.

b. Estimated Effects of Proposed 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 proposed rule, we are proposing to set the CY 2017 ASC relative payment weights by scaling the proposed CY 2017 OPPS relative payment weights by the ASC scalar of 0.9030. The estimated effects of the proposed updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 31 and 32 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 proposed CY 2017 ASC conversion factor by adjusting the CY 2016 ASC conversion factor by 0.9992 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between

CY 2016 and CY 2017 and by applying the proposed CY 2017 MFP-adjusted CPI-U update factor of 1.2 percent (projected CPI-U update of 1.7 percent minus a proposed projected productivity adjustment of 0.5 percentage point). The proposed CY 2017 ASC conversion factor is $44.684.

(1) Limitations of Our Analysis

Presented here are the projected effects of the proposed 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 proposed CY 2017 changes would be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs would experience changes in payment that differ from the aggregated estimated impacts presented below.

(2) Estimated Effects of Proposed 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 proposed update to the CY 2017 payments would depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of

specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion presents tables that display estimates of the impact of the proposed CY 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 31 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 proposed CY 2017 payments, and Table 32 shows a comparison of estimated CY 2016 payments to estimated proposed CY 2017 payments for procedures that we estimate would receive the most Medicare payment in CY 2016.

Table 31 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 31.

- 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 Proposed 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 proposed updates to ASC payment rates for CY 2017 compared to CY 2016.

As seen in Table 31, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the proposed update to ASC payment rates for CY 2017 would result in a 1-percent increase in aggregate payment amounts for eye and ocular adnexa procedures, a 1-percent decrease in aggregate payment amounts for digestive system procedures, a 3-percent increase in aggregate payment amounts for nervous system procedures, a 6-percent increase in aggregate payment amounts for musculoskeletal system procedures, no change in aggregate payment amounts for genitourinary system procedures, and a 2-percent decrease in aggregate payment amounts for integumentary system procedures.

Also displayed in Table 31 is a separate estimate of Medicare ASC payments for the group of separately payable covered ancillary items and services. The payment

estimates for the covered surgical procedures include the costs of packaged ancillary items and services. We estimate that aggregate payments for these items and services would be $32 million for CY 2017.

TABLE 31.—ESTIMATED IMPACT OF THE PROPOSED CY 2017 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PROPOSED 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 Proposed CY 2017 Percent Change (3)
Total	$4,020	2%
Eye and ocular adnexa	$1,567	1%
Digestive system	$819	-1%
Nervous system	$692	3%
Musculoskeletal system	$469	6%
Genitourinary system	$180	0%
Integumentary system	$133	-2%

Table 32 below shows the estimated impact of the proposed updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 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 Proposed CY 2017 Percent Change reflects the percent differences between the estimated ASC payment for CY 2016 and the estimated proposed payment for CY 2017 based on the proposed update.

TABLE 32.--ESTIMATED IMPACT OF THE PROPOSED CY 2017 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code (1)	**Short Descriptor** (2)	**Estimated CY 2016 ASC Payment (in millions)** (3)	**Estimated CY 2017 Percent Change** (4)
66984	Cataract surg w/iol 1 stage	$1,115	-1%
43239	Egd biopsy single/multiple	$187	-13%
45380	Colonoscopy and biopsy	$181	12%
45385	Colonoscopy w/lesion removal	$119	12%
66982	Cataract surgery complex	$97	-1%
64483	Inj foramen epidural l/s	$87	18%
63685	Insrt/redo spine n generator	$82	2%
64493	Inj paravert f jnt l/s 1 lev	$71	-16%
63650	Implant neuroelectrodes	$66	14%
66821	After cataract laser surgery	$65	3%
64635	Destroy lumb/sac facet jnt	$55	1%
29827	Arthroscop rotator cuff repr	$54	9%
G0105	Colorectal scrn; hi risk ind	$54	-12%
45378	Diagnostic colonoscopy	$53	-14%
G0121	Colon ca scrn not hi rsk ind	$51	-12%
0191T	Insert ant segment drain int	$42	43%
64590	Insrt/redo pn/gastr stimul	$38	5%
64721	Carpal tunnel surgery	$33	1%
29881	Knee arthroscopy/surgery	$32	-9%
15823	Revision of upper eyelid	$32	-3%

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2016 ASC Payment (in millions) (3)	Estimated CY 2017 Percent Change (4)
29880	Knee arthroscopy/surgery	$28	-9%
26055	Incise finger tendon sheath	$25	-14%
43235	Egd diagnostic brush wash	$24	-13%
64490	Inj paravert f jnt c/t 1 lev	$24	-16%
67042	Vit for macular hole	$23	-4%
52000	Cystoscopy	$21	4%
G0260	Inj for sacroiliac jt anesth	$21	-5%
50590	Fragmenting of kidney stone	$21	-1%
64555	Implant neuroelectrodes	$19	19%
67904	Repair eyelid defect	$19	2%

(3) Estimated Effects of Proposed ASC Payment System Policies on Beneficiaries

We estimate that the proposed CY 2017 update to the ASC payment system would be generally positive for beneficiaries with respect to the new procedures that we are proposing to add to the ASC list of covered surgical procedures and for those that we are proposing to designate as office-based for CY 2017. First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with section 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs under the OPPS, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment (other than for certain preventive services). Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPPS. Therefore, the beneficiary coinsurance

amount under the ASC payment system will almost always be less than the OPPS copayment amount for the same services. (The only exceptions would be if the ASC coinsurance amount exceeds the inpatient deductible. The statute requires that copayment amounts under the OPPS not exceed the inpatient deductible.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the revised ASC payment system, depending on the particular service and the relative payment amounts under the MPFS compared to the ASC. However, for those additional procedures that we are proposing to designate as office-based in CY 2017, the beneficiary coinsurance amount under the ASC payment system generally would be no greater than the beneficiary coinsurance under the MPFS because the coinsurance under both payment systems generally is 20 percent (except for certain preventive services where the coinsurance is waived under both payment systems).

(4) Alternative ASC Payment Policies Considered

Alternatives to the ASC changes we are proposing and the reasons for our selected alternatives are discussed throughout this proposed rule.

c. Accounting Statements and Tables

As required by OMB Circular A-4 (available on the Office of Management and Budget Web Site at: https://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 proposed rule. The first accounting statement, Table 33 below, illustrates the classification of expenditures for the proposed CY 2017 estimated hospital OPPS

incurred benefit impacts associated with the proposed CY 2017 OPD fee schedule increase, based on the 2016 Trustee's Report,. The second accounting statement, Table 34 below, illustrates the classification of expenditures associated with the proposed 1.2 percent CY 2017 update to the ASC payment system, based on the provisions of this proposed rule and the baseline spending estimates for ASCs in the 2016 Trustee's Report. Lastly, the tables classify most estimated impacts as transfers.

TABLE 33.--ACCOUNTING STATEMENT: PROPOSED CY 2017 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2016 TO CY 2017 ASSOCIATED WITH THE PROPOSED CY 2017 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$671 million
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS
Total	$671 million

TABLE 34.--ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2016 TO CY 2017 AS A RESULT OF THE PROPOSED CY 2017 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$39 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	$39 million

d. Effects of Proposed Requirements for the Hospital OQR Program

We refer readers to the CY 2016 OPPS/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 proposed rule,

we are proposing 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 2015 payment determination. We estimate that approximately 108 to 121 hospitals would not receive the full OPD fee schedule increase factor for the CY 2018 payment determination and subsequent years.

In section XIII. of this proposed rule, we are proposing to make 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 note that while there is burden associated with filing a reconsideration request, section 3518(c)(1)(B) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3518(c)(1)(B)) excludes collection activities during the conduct of administrative actions such as reconsiderations. We do not believe that any of the other changes we are proposing would increase burden, as further discussed below.

For the CY 2018 payment determination and subsequent years, we are proposing 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 proposing that hospitals will generally have approximately 30 days to preview their data. Both of these proposals are consistent with current practice. Lastly, we are proposing 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 proposed changes to the public display policies because hospitals would not be required to submit additional data or forms to CMS.

For the CY 2019 payment determination and subsequent years, we are proposing to extend the time for filing an extraordinary circumstance exception or exemption request from 45 days to 90 days. We do not anticipate additional burden to hospitals as a result of this proposal because the requirements for filing a request have not otherwise changed.

For the CY 2020 payment determination and subsequent years, we are proposing to adopt 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 proposing to adopt 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.3. of this proposed rule, we do not believe that the OP-35 and OP-36 measures would 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 proposed OAS CAHPS Survey-based

measures (proposed 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 proposed rule (information collection requirements) for a detailed discussion of the burden of the proposed additional requirements for submitting data to the Hospital OQR Program.

e. Effects of Proposed Requirements for the ASCQR Program

In section XIV. of this proposed rule, we discuss our proposals to adopt 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 OPPS/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).

For the CY 2018 payment determination and subsequent years, we are making a few proposals. In section XIV.B.7. of this proposed rule, we are proposing 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 proposing that ASCs will generally have approximately 30 days to preview their data. Both of these proposals are consistent with current practice. Lastly, we are proposing 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 proposed

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 making two new proposals. In section XIV.D.3. of this proposed rule, we are proposing to implement a submission deadline with an end date of May 15 for all data submitted via a Web-based tool (CMS or non-CMS) beginning with the CY 2019 payment determination. We do not anticipate additional burden as the data collection and submission requirements have not changed; only the deadline would be moved to a slightly earlier date that we anticipate would alleviate burden by aligning data submission deadlines. In section XIV.D.6. of this proposed rule, we proposing to extend the time for filing an extraordinary circumstance exception or exemption request from 45 days to 90 days. We do not believe this proposal will result in additional burden to ASCs because the requirements for filing a request have not otherwise changed. We are not proposing to add any quality measures to the ASCQR measure set for the CY 2019 payment determination, nor do we believe that the other measures we previously adopted would cause any additional ASCs to fail to meet the ASCQR Program requirements. (We refer readers to 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 proposals would 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 proposed rule, we are proposing to add two new measures collected via a CMS online data submission tool to the ASCQR program measure set for the CY 2020 payment determination—ASC-13: Normothermia Outcome and ASC-14: Unplanned Anterior Vitrectomy—and five new OAS CAHPS Survey-based measures for 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 proposed rule, 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 proposed ASC-14 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 for proposed 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 proposed OAS CAHPS Survey-based measures is already accounted for in a previously approved OMB Control Number 0938-1240.

We refer readers to the information collection requirements in section XXI.C.2. of this proposed rule for a detailed discussion of the financial and hourly burden of the ASCQR Program's current and proposed requirements.

We are inviting public comment on the burden associated with these proposals.

f. Effects of the Proposed Changes to Transplant Performance Thresholds

In section XV. of this proposed rule, we discuss proposed 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 ensure that the barrier presented by 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 as a result of 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.[128] 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 these proposed changes would 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 proposed performance threshold were set at

---

[128] 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: 10.111/1465-6773.12188.

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 proposed 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 would 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 would 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 would be $1 million per year ($1 million plus $30,000), and conclude that our proposed policies would not have a significant impact on a substantial number of small businesses or other small entities. Nor would they have a significant impact on small rural hospitals.

g. Effects of the Proposed Changes Relating to Organ Procurement Organizations (OPOs)

In section XVI. of this proposed rule, we discuss our proposals 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 would be affected by the proposed requirements to a greater or lesser degree. Many OPOs have already put into practice many of the proposed requirements. Thus, while we do not believe these proposals would 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 proposals 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 would be fully paid under the Medicare program. In addition, these proposals would have no identifiable economic impact on transplant hospitals. It is expected that improved OPO performance would

result from the proposals and increase organ donation and the number of organs available for transplantation.

The proposed definition and yield metric changes would 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 would not be asked to report additional data as a result of the proposals.

The proposal to change the documentation requirements of donor information sent to the transplant center with the organs would reduce burden for the OPOs. This proposed change would reduce the amount of hard copy documentation that is packaged and shipped with each organ and would free up the OPO transplant coordinator's time to focus on the critical donor management and organ preparation tasks. We estimate that this proposed change would 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 would 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 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 proposals would lie with their potential to increase organ donation. However, it is difficult to predict precisely what that impact would be, but we estimate that, by increasing OPOs' efficiency and adherence to continuous quality improvement measures, these proposals could increase the number of organ donors in the regulation's first year.

With regard to the impact of the proposed OPO transplant enforcement technical corrections discussed in section XVII. of this proposed rule, there is no economic impact.

h. Effects of the Proposed Changes to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs

In section XVIII. of this proposed rule, we discuss proposed requirements for the Medicare and Medicaid EHR Incentive Programs. Specifically, in this proposed rule, for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program, we are proposing to eliminate the Clinical Decision Support (CDS) and Computerized Provider Order Entry (CPOE) objectives and measures for Modified Stage 2 and Stage 3 as well as to reduce the reporting thresholds on a subset of the remaining objectives and measures to the Modified Stage 2 thresholds. We do not believe that the proposals would increase burden on eligible hospitals and CAHs as the objectives and measures remain the same, only a subset of thresholds would be reduced. In addition, the proposals 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 would be a score near the maximum. While the functions of

measures and the processes behind them would continue even without a requirement to report the results, the provisions would result in a reduction in reporting requirements.

We are also proposing to modify the EHR reporting period in 2016 for all returning EPs, eligible hospitals and CAHs that have previously demonstrated meaningful use to any continuous 90-day period within CY 2016. We do not believe that the modification of the EHR reporting period in 2016 to any continuous 90-day period would 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 proposing to modify 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 proposing to require new participants in 2017 to attest to Modified Stage 2 objectives and measures would 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 would have the necessary technical capabilities to attest to the Modified Stage 2 objectives and measures.

We are proposing 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 proposal 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 proposal would affect the burden on meaningful users.

Finally, we are proposing 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 proposal to allow a one-time significant hardship exception from the 2018 payment adjustment for certain EPs would increase their burden, rather, we believe this would reduce the reporting burden for 2017 because this proposal would reduce confusion on the different reporting requirements for the EHR Incentive Program and MIPs as well as the different systems to which participants would need to register and attest.

i. Effects of Proposed Requirements for the Hospital VBP Program

In section XIX. of this proposed rule, we discuss proposed requirements for the Hospital VBP Program. Specifically, in this proposed rule, we are proposing to remove the HCAHPS Pain Management dimension in the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain.

As required under section 1886(o)(2)(A) of the Act, the HCAHPS Survey is included the Hospital IQR Program. Therefore, its inclusion in the Hospital VBP Program does not result in any additional burden because the Hospital VBP Program uses data that are required for the Hospital IQR Program. The proposed removal of the HCAHPS Pain Management dimension from the Hospital VBP Program also would not result in any additional reporting burden.

j. Effects of Proposed Implementation of Section 603 of the Bipartisan Budget Act of 2015 Relating to Payment for Certain Items and Services Furnished by Certain Off-Campus Departments of a Provider

In section X.A. of this proposed rule, we discuss the proposed implementation of section 603 of the Bipartisan Budget Act of 2015 relating to payments for certain items and services furnished by certain 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 proposed rule 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 proposed rule 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. We estimate that section 603 would increase payments to physicians under the MPFS by $170 million in CY 2017, resulting in a net Medicare Part B impact from the provision of reducing CY 2017 Part B expenditures by $330 million. These estimates include both the FFS impact of the provision and the Medicare Advantage impact of the provision. These estimates also 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.

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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this proposed rule would increase payments to small rural hospitals by less than 3 percent; therefore, it should not have a significant impact on approximately 634 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 proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

D. Conclusion

The changes we are proposing to make in this proposed rule would affect all classes of hospitals paid under the OPPS and would affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS would experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2017. Table 31 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that would result in a 1.6 percent increase in payments for all services paid under the OPPS in CY 2017, after considering all of the proposed changes to APC reconfiguration and recalibration, as well as the proposed OPD fee schedule increase factor, proposed wage index changes, including the proposed frontier State wage index adjustment, proposed estimated payment for outliers, and proposed changes to the pass-through payment estimate. However, some classes of providers that are paid under the OPPS would experience more significant gains or losses in OPPS payments in CY 2017.

The proposed updates to the ASC payment system for CY 2017 would 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 32 demonstrates the estimated distributional impact among ASC surgical specialties of the proposed MFP-adjusted CPI-U update factor of 1.2 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 OPPS and ASC provisions included in this proposed rule in accordance with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on State, local or tribal governments, preempt State law, or otherwise have a Federalism implication. As reflected in Table 30 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would increase by 1.6 percent under this proposed rule. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that it is small. The analyses we have provided in this section of this proposed rule, in conjunction with the remainder of this

document, demonstrate that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This proposed rule would affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant.

List of Subjects

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

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.

CMS-1656-P

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 proposing to amend 42 CFR chapter IV as set forth below:

PART 416—AMBULATORY SURGICAL SERVICES

1. The authority citation for part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. Section 416.171 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 OPPS APC ratesetting methodology.

* * * * *

3. 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.

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

4. 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).

5. 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 are provided by an off-campus provider-based department (as defined at § 419.48(b)) that do not meet the definition of excepted items and services under § 419.48(a).

6. 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.

* * * * *

7. 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.

* * * * *

8. 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.

9. 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.

10. 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) In a dedicated emergency department (as defined at § 489.24(b) of this chapter); or

(2) By an off-campus provider-based department that submitted a bill for a covered OPD service prior to November 2, 2015, are furnished at the same location that the department was furnishing such services as of November 1, 2015, and are in the same clinical family of services as the services that the department furnished prior to November 2, 2015.

(b) For the purpose of this section, "off-campus provider-based department" means a department of a provider (as defined at § 413.65(a)(2) of this chapter as in effect as of November 2, 2015) that is not 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 of this chapter) that meets the requirements for provider-based status under § 413.65 of this chapter.

11. 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

12. 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.

13. 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.

* * * * *

14. 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

15. 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).

16. 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 or 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 hypokinesis;

(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.

* * * * *

17. Section 486.318 is amended by revising paragraphs (a)(3) and (b)(3) to read as follows:

§ 486.318 Condition: Outcome measures.

(a) * * *

(3) At least 2 of the 3 yield measures specified in paragraph (a)(3)(i) of this section are no more than 1 standard deviation below the national mean, averaged over the 4 years of the recertification cycle, and the OPO data reports 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) A difference of at least 11 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 yield measures include pancreata used for islet cell transplantation as required by section 371(c) of the Public Health Service Act (42 U.S.C. 273(c)).

(b) * * *

(3) At least 2 out of the 3 following yield measures specified in paragraph (b)(3)(i) of this section are no more than 1 standard deviation below the national mean, averaged over the 4 years of the recertification cycle, and the OPO data reports 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 yield measures include pancreata used for islet cell transplantation as required by section 371(c) of the Public Health Service Act (42 U.S.C. 273(c)).

* * * * *

18. 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

19. 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.

20. 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

21. 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).

22. Section 495.4 is amended by—

a. In the definition of "EHR reporting period" revising paragraphs (1)(ii)(B)(2) and (2)(ii)(B)(2).

b. In the definition of "EHR reporting period for a payment adjustment year" revising paragraphs (1)(ii)(B)(2), (2)(ii)(B)(2), and (3)(ii)(B)(2).

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.

* * * * *

(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.

* * * * *

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.

* * * * *

(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.

* * * * *

23. Section 495.22 is amended by revising paragraphs (a), (c)(1) introductory text, (d)(1), (e) subject 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 under the Medicare 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 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 under a state's 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 paragraph (d) 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.

* * * * *

(e) <u>Meaningful use objectives and measures for EPs for 2015 through 2017, for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for 2015 and 2016, and for eligible hospitals and CAHs attesting under a State's Medicaid EHR Incentive Program for 2015 through 2017</u>.

* * * * *

(f) Meaningful use objectives and measures for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program 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) e-Rx (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) 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, 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 measure. The eligible hospital or CAH is in active engagement with a public health agency to submit immunization data.

(B) Syndromic surveillance measure. The eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data.

(C) Specialized registry 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.

24. 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 under the Medicare EHR Incentive Program 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 under a State's 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 this 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 under the Medicare EHR Incentive Program 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) eRx (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) 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, 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. 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 measure. 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), (B), and (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), (B), and (C) of this section. Subject to paragraph (b)(5) of this section—

(A) Patient care record exchange 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 patient care record 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) 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 under a State's 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) 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.

(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) 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) eRx (electronic prescribing)—(i) EP eRx (electronic prescribing)—

(A) Objective. Generate and transmit permissible prescriptions electronically (eRx).

(B) e-Prescribing 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 eRx (electronic prescribing)—(A) Objective. Generate and transmit permissible discharge prescriptions electronically (eRx).

(B) 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.

(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) Clinical decisions support intervention measure. 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) Drug interaction and drug allergy checks measure. 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) Clinical decisions support intervention measure. 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) Drug interaction and drug allergy checks measure. 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) Medication orders measure. More than 60 percent of medication orders created by the EP during the EHR reporting period are recorded using computerized provider order entry;

(2) Laboratory orders measure. 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) Diagnostic imaging orders measure. 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) Medication orders measure. 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) Laboratory orders measure. 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) Diagnostic imaging orders measure. 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) Patient access measure. 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) Patient specific education measure. 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) Patient access measure. 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) 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 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), (2), and (3) of this

section except those measures for which an EP qualifies for an exclusion under paragraph (a)(3) of this section.

(1) View, download, transmit (VDT) measure. 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), (2), and (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), (2), and (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), (2), and (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) View, download, transmit (VDT) measure. 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) Secure messaging measure. 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 measure. 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), (2), and (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), (2), and (3) of this section, in order to meet the objective. Subject to paragraph (c) of this section—

(1) Patient record exchange measure. 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) Request/accept patient care record measure. 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) Clinical information reconciliation measure. 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), (2), and (3) of this section. Subject to paragraph (b)(5) of this section—

(1) Patient record exchange measure. 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) Request/accept patient care record measure. 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) Clinical information reconciliation measure. 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 measure. 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 measure. 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 measure. The EP is in active engagement with a public health agency to submit case reporting of reportable conditions.

(4) Public health registry reporting measure. The EP is in active engagement with a public health agency to submit data to public health registries.

(5) Clinical data registry reporting measure. 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 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).

(2) 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.

(3) Case reporting measure. 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 measure. 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 measure. The eligible hospital or CAH is in active engagement to submit data to a clinical data registry.

(6) 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.

(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 standards required to meet the 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.

25. 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.

* * * * *

(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 under the Medicare 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(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 under a state's 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 under the Medicare EHR Incentive Program, satisfied the required objectives and associated measures under § 495.24(c) for meaningful use.

(2) For an eligible hospital or CAH attesting under a state's Medicaid EHR Incentive Program, satisfied the required objectives and associated measures under § 495.24(d) for meaningful use.

* * * * *

26. 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.

* * * * *

Dated: June 22, 2016.

_____

Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare and Medicaid

Services.

CMS-1656-P

Dated: June 23, 2016.

_____

Sylvia M. Burwell,

Secretary,

Department of Health and Human Services.

BILLING CODE 4120-01-P

[FR Doc. 2016-16098 Filed: 7/6/2016 4:15 pm; Publication Date: 7/14/2016]