PROPOSED RULE: MEDICARE 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; ELECTRONIC HEALTH RECORD INCENTIVE PROGRAMS; PAYMENT TO CERTAIN OFF CAMPUS DEPARTMENTS OF A PROVIDER (SECTION 603); HOSPITAL VALUE-BASED PURCHASING PROGRAM

CMS-1656-P

SUMMARY

The Centers for Medicare & Medicaid Services (CMS) released the calendar year 2017[1] proposed rule for Medicare's hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system on July 6, 2016; if finalized, policies in the proposed rule generally would take effect on January 1, 2017. The rule is scheduled for publication in the July 14th issue of the *Federal Register*. **The 60-day public comment period ends at close of business on September 6th.**

The proposed rule would update OPPS payment policies that apply to outpatient services provided to Medicare beneficiaries by general acute care hospitals, inpatient rehabilitation facilities, inpatient psychiatric facilities, long-term acute care hospitals, children's hospitals, and cancer hospitals, as well as for partial hospitalization services in community mental health centers (CMHCs). The document also includes updates and refinements to the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

Additional provisions in this proposed rule address implementation of section 603 of the Bipartisan Budget Act of 2015 pertaining to payment for certain off-campus departments; organ procurement organization (OPO) reporting and transplant outcome measures; the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs, and the inpatient hospital Value-Based Purchasing (VBP) program.

Unfortunately, the display copy of this proposed rule does not include numbered pages. As a result, in some cases, this summary refers to page numbers which can be identified only using the electronic version of the document.

Addenda containing relative weights, payment rates, wage indices and other payment information are available only on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1656-P.html

[1] Henceforth in this document, a year is a calendar year unless otherwise indicated.

TABLE OF CONTENTS

I. Overview

Estimated Impact on Hospitals

CMS estimates that, compared to 2016, policies in the proposed rule would increase total payments under the OPPS by $671 million, including beneficiary cost-sharing and excluding estimated changes in enrollment, utilization, and case-mix. Taking into account estimated changes in enrollment, utilization, and case-mix, the increase in OPPS expenditures for 2017 is estimated to be $5.1 billion; however this figure does not include an estimated $500 million in program savings resulting from the proposed implementation of section 603 of the Bipartisan Budget Act of 2015 (discussed in section X.A below). The OPPS makes payments to about 3,900 facilities, including general acute care hospitals, children's hospitals, cancer hospitals, and community mental health centers (CMHCs).

Payment rates under the OPPS would be increased by a conversion factor adjustment of 1.55 percent, 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)[2], minus the multifactor productivity adjustment of 0.5 percentage points, and minus an additional 0.75 percentage point adjustment required by the Affordable Care Act (ACA). Hospitals that satisfactorily report quality data will qualify for the full update of 1.55 percent, while hospitals that do not will be subject to the statutory reduction of 2.0 percentage points in

[2] The OPPS percentage update is based on the IPPS market basket, as provided by statute.

the update factor, resulting in a -0.45 percent update. The reduction in payments for hospitals not meeting the quality reporting requirements is implemented by applying a reporting factor of 0.980 to the OPPS payments and copayments for all applicable services. Of the 3,266 hospitals that met quality reporting eligibility requirements for the 2016 payment determination, CMS determined that 113 hospitals did not meet requirements to receive the full OPD fee schedule increase factor, with most of these hospitals (71 of the 113) choosing not to participate in the Hospital OQR Program.

Table 30 in the proposed rule (reproduced in the Appendix to this summary) includes the estimated impact of the proposed rule by provider type. It shows a projected increase of 1.6 percent for all facilities and 1.7 percent for all hospitals (all facilities except cancer and children's hospitals, which are held permanently harmless, and CMHCs). The following table shows components of the 1.6 percent total:

Proposed change	Percent change for all hospitals
All changes	+1.7
Fee schedule increase factor	+1.55
Package unrelated laboratory tests	+0.03
Difference in pass through estimates for 2016 and 2017	+0.02
Difference from 2016 outlier payments (0.96%)	+0.04

A proposed adjustment of +0.03 percent would increase the conversion factor to account for the proposal to package unrelated laboratory tests in 2017 (discussed in item II.A.7 below). Pass-through spending for drugs, biologicals and devices for 2017 are estimated to total $148 million, or 0.24 percent of projected OPPS spending. The proposed adjustment to the rates of +0.02 percent reflects the difference between this projection and the 0.26 percent estimate for 2016. In addition, CMS estimates that actual outlier payments in 2016 will represent 0.96 percent of total OPPS payments compared to the 1.0 percent set aside, for an estimated increase in 2017 payments of 0.04 percentage points. (This difference in outlier projections affects total payments but not the conversion factor. In the description of the conversion factor update, the proposed rule erroneously suggests otherwise.)

Changes to the Ambulatory Payment Classification (APC) weights, wage indices, continuation of a payment adjustment for rural sole community hospitals (SCHs), including essential access community hospitals (EACHs), and the payment adjustment for IPPS-exempt cancer hospitals do not affect aggregate OPPS payments because these adjustments are budget neutral. However, these factors have differential effects on individual facilities.

Although CMS projects an overall increase of 1.7 percent for all hospitals, the proposed rule would have a differential effect on facilities. As shown in the table below and in the full impact analysis included in the appendix to this summary, the largest difference is that rural hospitals are estimated to have an increase of 2.3 percent; this difference from the overall increase of 1.7 percent reflects the impact on rural facilities of APC recalibration (+0.4) and the wage index (+0.3). Major teaching hospitals also would see a smaller increase of 1.2 percent.

	Projected 2017 Impact
All Hospitals	+1.7%
All Facilities (includes CMHCs and cancer and children's hospitals)	+1.6%
Urban	+1.6%
Large Urban	+1.4%
Other Urban	+1.7%
Rural	+2.3%
Major Teaching	+1.2%
Type of ownership:	
Voluntary	+1.7%
Proprietary	+1.6%
Government	+1.5%
CMHCs	-8.4%

Other than the rural categories, those in the impact table with a difference from the average of 0.5 percent or more (i.e., increase is ≤1.1 percent or ≥2.1 percent) are:

Urban New England (147 facilities)	+0.5%
Urban Middle Atlantic (348)	+1.1%
Nonteaching/NonDSH (15)	+0.7

Estimated Impact on Beneficiaries

CMS estimates that the aggregate beneficiary coinsurance percentage would be 18.5 percent for all services paid under the OPPS in 2017. This reflects the requirement for a 20 percent copayment for most services, along with the proposed changes to the comprehensive APC payment policy.

II. Updates Affecting OPPS Payments

A. Recalibration of APC Relative Weights

CMS proposes to recalibrate the APC relative payment weights for 2017 using the same basic methodology used for many years. As discussed in succeeding sections of this summary, several changes are proposed, including expansion of packaging for lab services and the addition of 25 comprehensive APCs using the previously established criteria.

For this 2017 proposed rule, CMS uses hospital final action claims for services furnished from January 1, 2015 through December 31, 2015. Cost data are from the most recent filed cost reports, in most cases for cost reporting periods beginning in 2014. In a separate document available on the CMS website, CMS provides a detailed description of the claims preparation

process and an accounting of claims used in the development of the proposed rule payment rates, including the number of claims available at each stage of the process: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1656-P-OPPS-Claims-Accounting.pdf

Continuing past years' methodology, CMS calculates the cost of each procedure only from single procedure claims and "pseudo" single procedure claims created from bills containing multiple codes, using date of service stratification and a list of codes to be bypassed to convert multiple procedure claims to "pseudo" single procedure claims. Through bypassing specified codes that CMS believes do not have significant packaged costs, CMS is able to use more data from multiple procedure claims.

For the 2017 proposed rule, CMS bypasses the 194 Healthcare Common Procedure Coding System (HCPCS) codes identified in Addendum N to the proposed rule. These are codes that were reported on claims in 2015 but were deleted for 2016. Addendum N is available from the CMS website at: https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1656-P-OPPS-Addenda.zip

Table 1 of the proposed rule lists six HCPCS codes that CMS proposes to delete from the 2017 bypass list. The complete bypass list in Addendum N is open to public comment.

1. Calculation and use of cost-to-charge ratios

To convert billed charges on the outpatient claims to estimated costs, CMS multiplies the charges by a hospital-specific cost-to-charge ratio (CCR) associated with each revenue code and cost center. To calculate CCRs for 2017, CMS proposes to employ the same basic approach used for APC rate construction for 2007 and each subsequent year. CMS applies the appropriate hospital-specific CCR to the hospital's charges at the most detailed level possible based on a revenue code-to-cost center crosswalk containing a hierarchy, for each revenue code, of CCRs for estimating costs from charges. The current crosswalk is available for review and continuous comment on the CMS website https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/2017-Revised-Revenue-Code-to-Cost-Center-Crosswalks.zip. CMS notes that no new revenue codes were added for 2015, which is the year of claims data used for the proposed 2017 payment rates.

CCRs are calculated for the standard and nonstandard cost centers accepted by the electronic cost report data base. Generally, the most detailed level used is the hospital-specific departmental level.

2. Budget neutral weight scaler

To make the APC reclassification and recalibration changes budget neutral, CMS proposes to compare the estimated aggregate weight calculated using the proposed 2017 unscaled relative weights and service volume in the 2015 claims data to the aggregate weight calculated using the

final 2016 scaled relative weights and the service volume using the same 2015 claims data. Based on this comparison, the proposed rule unscaled APC payment weights were adjusted by a weight scaler of 1.4059. CMS proposes to continue to include payments for "specified covered outpatient drugs" (SCODs) in the budget neutrality calculation for 2017.

3. Recommendations of the Hospital Outpatient Payment Panel Regarding Data Development

At the March 14, 2016 meeting of the Hospital Outpatient Payment Panel, CMS discussed its standard analysis of APCs focusing on those APCs for which geometric mean costs in the Panel run of 2015 claims data varied significantly from the 2014 claims data used for the 2016 final rule. CMS accepted the Panel's three recommendations involving the data subcommittee: CMS will provide the data subcommittee a list of APCs fluctuating significantly in costs prior to each Panel meeting. The work of the data subcommittee will continue. The current Chair will remain. CMS has previously announced that beginning in 2017 the Panel will begin meeting once a year, to be scheduled in the summer.

4. Calculation of single procedure APC criteria-based costs

The calculation of geometric mean costs for some APCs follows various special rules, as described below.

Blood and blood products. For 2017, CMS proposes to continue, without change, to set payment rates for blood and blood products using the blood-specific CCR methodology that it has used since 2005. CMS calculated the procedure costs for setting the proposed 2017 payment rates for blood and blood products using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and using a hospital-specific simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

CMS also proposes to continue to include blood and blood products in the comprehensive APCs, which provide all-inclusive payments covering all services on the claim. When blood and blood products appear on claims with services assigned to a comprehensive APC, their costs are included in calculating the overall costs of these comprehensive APCs, with such costs determined based on the blood-specific CCR methodology. Because the costs of blood and blood products are reflected in the overall costs of the comprehensive APCs – and thus the payment rates of the comprehensive APCs – beginning in 2015, no separate payment is made for blood and blood products when they appear on the same claims as services assigned to a comprehensive APC. CMS notes that Addendum B to the proposed rule available on its website (link provided on page 1 of this summary) includes the proposed payment rates for blood and blood products.

CMS invites comments on continuing these policies and also seeks comments regarding the adequacy and necessity of the current descriptors for the HCPCS P-codes describing blood products. For each of three main categories of blood products (red blood cells; platelets; and plasma) the codes provide for terms that describe various treatments or preparations of the blood products, with each, in several cases, represented individually and in combination. CMS notes

that in some cases hospital costs are similar for blood products with different code descriptors, and wants to know whether these descriptors best describe the state of the current technology for blood products that hospitals currently provide to hospital outpatients. The current set of active HCPCS P-codes that describe blood products can also be found in Addendum B to the proposed rule.

Brachytherapy sources. The statute requires the Secretary to create additional groups of covered OPD services that classify devices of brachytherapy consisting of a seed or seeds (or radioactive source) – i.e., "brachytherapy sources" – separately from other services or groups of services, in order to reflect the number, isotope, and radioactive intensity of the brachytherapy sources furnished. In addition, separate groups are required for palladium-103 and iodine-125 sources, and for stranded and non-stranded devices. Since 2010, CMS has used the standard OPPS prospective payment methodology for brachytherapy sources, with payment rates based on source-specific costs as required by statute.

The proposed rule for 2017 would continue without change the policies used to set payment rates for brachytherapy sources; costs derived from the 2015 claims data would be used to set 2017 payment rates. The proposed payment rates appear in Addendum B to the proposed rule (link appears on page 1 of this summary), and are identified with status indicator "U."

With respect to HCPCS code C2644 (Brachytherapy cesium-131 chloride) which became effective on July 1, 2014, CMS reports that this code was not reported on any 2015 claims, and it was unable to calculate a proposed payment rate. It is 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. Unlike new brachytherapy sources HCPCS codes, CMS says it will not consider external data to determine a proposed payment rate for HCPCS code C2644 for CY 2017.

The proposed rule invites hospitals and other parties to submit recommendations to CMS for new HCPCS codes that describe new brachytherapy sources consisting of a radioactive isotope, including a detailed rationale to support recommended new sources. 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. CMS will continue to add new brachytherapy source codes and descriptors to its payment systems on a quarterly basis through program transmittals.

5. Comprehensive APCs

CMS established and implemented a new policy for comprehensive APCs (C-APCs) in 2015 based on policies finalized in the 2014 final OPPS rule, with a delayed effective date of January 1, 2015, and modified in the 2015 final rule. 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. CMS established C-APCs as a category broadly for OPPS payment and implemented 25 C-APCs beginning in 2015; 10 additional C-APCs were finalized for 2016.

Current Policy for C-APCs

CMS selects HCPCS codes for primary services to be assigned to a C-APC and designates them by status indicator "J1" as listed in Addendum J and Addendum B to the proposed rule. When such a primary service is reported on a hospital outpatient claim, Medicare makes a single payment for that service and all other items and services reported on the hospital outpatient claim that are provided during the delivery of the comprehensive service and are integral, ancillary, supportive, dependent, and adjunctive to the primary service; only services that are not covered OPD services or cannot by statute be paid for under the OPPS are excluded.

Status indicator "J2," new in 2016, designates C-APCs to which assignment is based on specific combinations of services performed in combination with each other rather the presence of a single primary service identified by status indicator "J1." Applying C-APC policies to these code combinations means that other OPPS payable services and items reported on the claim are treated as adjunctive to the comprehensive service. A single prospective payment is made for the comprehensive service based on the costs of all reported services on the claim.

Services included under the C-APC payment packaging policy 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;
- outpatient department services that are similar to therapy and delivered either by therapists or non-therapists as part of the comprehensive service;
- all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and drugs that are usually self-administered (SADs), unless they function as packaged supplies; and
- any other components reported by HCPCS codes that represent services which are provided during the complete comprehensive service, except the excluded services described below.

Services excluded from the C-APC payment policy include those that are not covered OPD services; services excluded from the OPPS; and services that are required to be separately paid. Addendum J to the proposed rule lists the following services proposed for exclusion from the C-APC payment policy:

- Ambulance services
- Brachytherapy
- Diagnostic and mammography screenings
- Physical therapy, speech-language pathology and occupational therapy services reported on a separate facility claim for recurring services
- Pass-through drugs, biologicals, and devices
- Preventive services defined in 42 CFR410.2

- Self-administered drugs (SADs) - Drugs that are usually self-administered and do not function as supplies in the provision of the comprehensive service
- Services assigned to OPPS status indicator "F" (certain CRNA services, Hepatitis B vaccines and corneal tissue acquisition)
- Services assigned to OPPS status indicator "L" (influenza and pneumococcal pneumonia vaccines)
- Certain Part B inpatient services – Ancillary Part B inpatient services payable under Part B when the primary "J1" service for the claim is not a payable Medicare Part B inpatient service (for example, exhausted Medicare Part A benefits, beneficiaries with Part B only)

For the minority of claims reporting more than one primary service with status indicator J1 or multiple units, CMS identifies one J1 service as the primary service for the claim based on a cost-based ranking of primary services using comprehensive geometric mean costs for single unit J1 services. The multiple J1 procedure claims are assigned to the C-APC to which the service designated as the primary service is assigned:

- If the multiple J1 services reported on a claim map to different C-APCs, CMS designates 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, CMS designates the most costly service (at the HCPCS code level) as the primary service for that claim.

CMS packages all add-on codes and assigns them status indicator "N" (unconditionally packaged). A set of these codes are evaluated for purposes of determining whether a complexity adjustment is appropriate. These are identified in Addendum J to this 2017 proposed rule.

Complexity adjustments. Certain combinations of comprehensive services are recognized for higher payment through complexity adjustments. Specifically, qualifying J1 service code combinations or code combinations of J1 services and certain add-on codes are reassigned from the originating C-APC (i.e., the C-APC to which the designated primary service is initially assigned) to a higher paying C-APC in the same clinical family of comprehensive APCs. (For purpose of the C-APC policy, CMS defines a clinical family of comprehensive APCs as a set of clinically related comprehensive APCs that represent different resource levels of clinically comparable services.) After designating a service as the primary service for a claim, CMS evaluates 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, CMS determines initial C-APC assignments and complexity adjustments using the best data available, cross-walking the new HCPCS codes to predecessor codes if possible.

CMS proposes to continue the following criteria for determining which combinations of primary service codes reported in conjunction with an add-on code may quality for a complexity adjustment:

- Frequency of 25 or more claims reporting the code combination (i.e., the frequency threshold); and

- Violation of the 2 times rule, that is, the comprehensive geometric mean cost of the complex code combination exceeds the comprehensive geometric mean cost of the lowest significant HCPCS code assigned to the comprehensive APC by more than 2 times (the cost threshold).[3]

For code combinations satisfying the complexity criteria, CMS proposes a change. Currently, code combinations satisfying the complexity criteria are moved to the next higher cost C-APC within the clinical family, unless (1) the APC reassignment is not clinically appropriate, (2) the reassignment would create a 2 times rule violation in the receiving APC, or (3) the primary service is already assigned to the highest cost APC within the C-APC clinical family. CMS does not create new APCs with a geometric mean cost that is higher than the highest cost C-APC in a clinical family just to accommodate potential complexity adjustments.

For 2017, CMS proposes to discontinue the requirement that a code combination also not create a 2 times rule violation in the higher level or receiving APC. CMS believes this requirement is not useful because the 2 times rule does not typically apply to complexity-adjusted code combinations. It says that most code combinations fall below the established frequency threshold for considering the 2 times rule violations.

Addendum J to the 2017 proposed rule shows that 30,423 code combinations were evaluated for a complexity adjustment and that 275 code combinations qualified. The qualifying code combinations in Addendum J are listed in an appendix to this summary. The full Addendum J also includes cost statistics for all the code combinations which were evaluated for a complexity adjustment and the ranking of HCPCS codes within each C-APC based on the geometric mean cost of single J1 unit claims; this is the ranking used to determine the primary assignment of comprehensive HCPCS codes.

C-APC Payment Policy for 2017

CMS proposes a total of 62 C-APCs to be paid under the existing C-APC payment policy in 2017. Table 2 of the proposed rule identifies 25 of them as newly proposed C-APCs; two of these were among the 35 C-APCs finalized in the 2016 OPPS/ASC final rule and are incorrectly identified as newly proposed.

Among the 62 C-APCs shown in Table 2 are four new C-APCs that are not discussed in the preamble or identified as newly proposed C-APCs. Addenda A and B show that these C-APCs are comprised of procedure codes moving from the highest-intensity C-APC in the family in 2016 to a higher level C-APC newly created for 2017. All proposed C-APCs for 2017, including current and reorganized C-APCs and those being newly proposed, are displayed in the table below (with modifications from the version that appears in the proposed rule.)

[3] In the 2015 final OPPS rule, CMS defined "significant HCPCS code" to mean frequency >1000 claims, or frequency > 99 claims and contributing at least 2 percent of the single major claims used to establish the originating comprehensive APC's geometric mean cost, including the claims reporting the complex code pair.

Table 2--Proposed 2017 C-APCs			
C-APC	**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	b
5112[a]	Level 2 Musculoskeletal Procedures	ORTHO	*
5113[a]	Level 3 Musculoskeletal Procedures	ORTHO	c
5114[a]	Level 4 Musculoskeletal Procedures	ORTHO	
5115[a]	Level 5 Musculoskeletal Procedures	ORTHO	
5116	Level 6 Musculoskeletal Procedures	ORTHO	b
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	c
5192	Level 2 Endovascular Procedures	VASCX	
5193	Level 3 Endovascular Procedures	VASCX	
5194	Level 4 Endovascular Procedures	VASCX	b
5200	Implantation Wireless PA Pressure Monitor	WPMXX	*
5211	Level 1 Electrophysiologic Procedures	EPHYS	
5212	Level 2 Electrophysiologic Procedures	EPHYS	
5213	Level 3 Electrophysiologic Procedures	EPHYS	
5222	Level 2 Pacemaker and Similar Procedures	AICDP	
5223	Level 3 Pacemaker and Similar Procedures	AICDP	
5224	Level 4 Pacemaker and Similar Procedures	AICDP	
5231	Level 1 ICD and Similar Procedures	AICDP	
5232	Level 2 ICD and Similar Procedures	AICDP	
5244	Level 4 Blood Product Exchange and Related Services	SCTXX	*
5302	Level 2 Upper GI Procedures	GIXXX	*
5303	Level 3 Upper GI Procedures	GIXXX	*
5313	Level 3 Lower GI Procedures	GIXXX	*
5331	Complex GI Procedures	GIXXX	
5341	Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX	*
5361	Level 1 Laparoscopy & Related Services	LAPXX	
5362	Level 2 Laparoscopy & Related Services	LAPXX	
5373	Level 3 Urology & Related Services	UROXX	*
5374	Level 4 Urology & Related Services	UROXX	*
5375	Level 5 Urology & Related Services	UROXX	

Table 2--Proposed 2017 C-APCs			
C-APC	**2017 APC Title**	**Clinical Family**	**Proposed New C-APC**
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	b
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.
a: These C-APCs have been renumbered (from 5123-5125).
b: Addenda A and B show that these C-APCs are comprised of procedure codes moving from the highest-intensity C-APC in the family in 2016 to a higher level C-APC newly created for 2017.
c: Proposed rule Table 2 incorrectly lists these as newly proposed C-APCs.

CLINICAL FAMILY DESCRIPTOR KEY:
C-APC Clinical Family Descriptor Key:
AENDO = Airway Endoscopy
AICDP = Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices.
BREAS = Breast Surgery
COCHL = Cochlear Implant
CMS-1656-P
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

Proposed New Allogeneic Hematopoietic Stem Cell Transplantation APC. Reviewing long-standing concerns raised by stakeholders regarding the accuracy of ratesetting for allogeneic Hematopoietic Stem Cell Transplantation (HCST), CMS proposes to create a new C-APC 5244 (Level 4 Blood Product Exchange and Related Services). Procedures described by CPT code

38240 (hematopoietic progenitor cell; allogeneic transplantation per donor) would be assigned to this C-APC and a "J1" status indicator assigned to this code. The costs for all covered OPD services included on the claim, including donor acquisition services, would be packaged into the C-APC rate. CMS would also analyze these costs using its comprehensive cost accounting methodology to establish future C-APC rates. The proposed 2017 payment rate for C-APC 5244 is $15,267.

For future ratesetting, CMS proposes to update the Medicare hospital cost report (CMS-2552-10) to include a new cost center (112.50) for "Allogeneic Stem Cell Acquisition." CMS notes that acquisition charges only apply to transplants for which stem cells are obtained from a donor; autologous transplants involve services to a beneficiary for which the hospital can bill and receive payment. In addition to the new cost center, CMS proposes 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.[4] Specifically, for 2017 and subsequent years, hospitals would be required 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 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 2017 and subsequent years, CMS proposes to longer use revenue code 0819 for the identification of stem cell acquisition charges for allogeneic bone marrow/stem cell transplants. **CMS invites public comments on these proposals.**

6. Calculation of composite APC criteria-based costs

Since 2008, CMS has used composite APCs to make 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. CMS is not proposing new composite APCs for 2017, but would continue composite policies for low dose rate (LDR) prostate brachytherapy, mental health services, and multiple imaging services.

LDR Prostate Brachytherapy Composite APC (APC 8001).

For 2017, CMS proposes to continue the composite APC policy that has been employed since 2008 for LDR Prostate Brachytherapy. Under this policy, the OPPS provides a single payment when the composite service, identified by 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), is furnished in a single hospital encounter. CMS bases the payment for composite APC 8001 on the cost derived from claims that contain both CPT codes 55875 and 77778 for the same date of service and that do not

[4] This code was approved by the National Uniform Billing Committee in 2016 for use beginning January 1, 2017.

contain other separately-paid codes which are not on the bypass list. When these services are billed individually, hospitals receive separate payments for the individual services.

Using a partial year of 2015 claims data available for the 2017 proposed rule, CMS calculates a geometric mean cost for composite APC 8001 of approximately $3,581 based on 202 claims containing both CPT codes 55875 and 77778.

Mental Health Services Composite APC (APC 8010)

For 2017, CMS proposes to continue its longstanding payment policy of limiting the combined payment for specified less intensive mental health services furnished on the same date to the payment for a day of partial hospitalization, which the agency considers to be the most resource intensive of all outpatient mental health treatment. Using the claims processing software, when the total payment for the individual services for specified mental health services – based on the payment rates associated with those APCs – provided by one hospital to a single beneficiary on one date of service exceeds the maximum per diem partial hospitalization payment, those specified mental health services are assigned to APC 8010 (Mental Health Services Composite) at the same payment rate that it is 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 would continue to be paid the payment rate for composite APC 8010. Under this policy, the code editor 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.

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

For 2017, CMS proposes to continue the multiple imaging composite APC policies that it has applied since 2009. Under the multiple imaging policy payment is based using five composite APCs:

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

One composite APC payment is made when a hospital bills more than one procedure described by HCPCS codes within an OPPS imaging family (per imaging family designations provided in each year's regulation) on a single date of service. If the hospital performs a procedure without contrast during the same session as at least one other procedure with contrast using the same imaging modality, then the hospital would receive payment for the "with contrast" composite APC. CMS assigns the status indicator "S" to the composite APCs, thus signifying that payment for the APC is not reduced when appearing on the same claim with other significant procedures.

When the conditions for a composite APC payment do not apply, CMS makes payment according to the standard OPPS methodology through the standard (sole service) imaging APCs; this rule applies when a single imaging procedure is performed, or when the imaging procedures performed have HCPCS codes assigned to different OPPS imaging families.

CMS continues current billing practices whereby hospitals use the same HCPCS codes to report imaging services and the integrated outpatient code editor determines when combinations of imaging procedures qualify for composite APC payment or map to standard APCs for payment.

Table 3 of the proposed rule (pages 103-107 of the display copy) lists the HCPCS codes that CMS proposes to be subject to the multiple imaging composite policy for 2017 and their respective families and approximate composite APC geometric mean costs for 2017 based on partial claims data for 2015. For the proposed rule, CMS identified approximately 599.294 "single session" claims out of an estimated 1.6 million potential composite APC cases from the ratesetting data, about 38 percent of all eligible claims, to calculate the proposed 2017 geometric mean costs for the multiple imaging composite APCs.

7. Changes to packaged items and services

For 2017, CMS proposes modifications to its packaging policies and to package the costs of two drugs that function as supplies in a surgical procedure.

Clinical Diagnostic Laboratory Test Packaging Policy

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 OPD. Laboratory tests are conditionally packaged and only paid separately when 1) they are the only services provided to a beneficiary on a claim; 2) they are unrelated tests, meaning they are on the same claim as other OPD services but are ordered for a different diagnosis and by a different practitioner; 3) they are molecular pathology tests; or 4) they are considered preventive.

For 2017, CMS proposes two changes to the laboratory test packaging policy, and invites public comment on each:

- Discontinue the unrelated laboratory test exception (and the associated "L1" modifier that designates separate payment). With this change, CMS proposes to package any and all laboratory tests that appear on a claim with other OPD services. CMS believes that in most cases, "unrelated" laboratory tests are not significantly different than most other packaged laboratory tests provided in the HOPD. It says that multiple hospitals have reported that the "unrelated" laboratory test exception is not useful 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. CMS also believes that the "different physician, different diagnosis" criteria do not necessarily correlate with whether a laboratory test is related to other HOPD services, and has concluded that the criteria do not clearly

distinguish laboratory tests that are integral, ancillary, supportive, dependent, or adjunctive to other hospital outpatient services provided to the beneficiary during the hospital stay.

- Expand the molecular pathology test exception to include all advanced diagnostic laboratory tests (ADLTs) that meet the criteria of section 1834A(d)(5)(A) of the Act. CMS agrees with past commenters who maintain that other tests that are relatively new and may have a different pattern of clinical use than more conventional laboratory tests, which results in making them less tied to a primary service in the OPD. Under the proposal CMS would assign status indicator "A" (separate payment under the CLFS) to laboratory tests designated as ADLTs under the CLFS.

Conditional Packaging Status Indicators "Q1" and "Q2"

To identify packaged payment versus separate payment of items and services, CMS uses status indicators applied to CPT and HCPCS codes. There are several different indicators for conditional packaging, which means that, under certain circumstances, items and services are packaged, and under other circumstances, they are paid separately. Two of these status indicators indicate packaging of services furnished on the same date: 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.

For 2017, CMS proposes to 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). CMS says this would align with other conditional packaging indicators and would 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. CMS notes that this proposed change would increase the conditional packaging of 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. **Comments are invited on this proposal.**

B. Conversion Factor Update

The proposed OPPS conversion factor for 2017 is $74.909. CMS began with the 2016 conversion factor of $73.725 and adjusted it by the fee schedule increase factor and various budget neutrality factors. (The proposed rule does not discuss the 2.0 percent reduction built into the 2016 conversion factor (and thus into the base for the 2017 update) resulting from the CMS actuaries' determination of excess packaged payment for laboratory tests associated with a policy change made in the OPPS 2014 final rule.) As discussed earlier, the fee schedule increase factor equals the proposed hospital inpatient market basket percentage increase, which is 2.8 percent, reduced by a multifactor productivity adjustment (MFP) of 0.5 percentage points as required by the ACA, and further reduced by an additional 0.75 percentage points as also required by the

ACA. This provides for a proposed fee schedule increase factor of 1.55 percent. The market basket and productivity adjustments may change in the final rule when more recent projections are used.

Hospitals that fail to meet the reporting requirements of the hospital Outpatient Quality Reporting program (OQR) are subject to a reduction of 2.0 percentage points, as discussed in section XIII below, resulting in a fee schedule increase factor of -0.45 percent for such hospitals.

The following additional adjustments are applied in calculating the proposed 2017 conversion factor: a wage index budget neutrality factor of 1.0000 and budget neutrality adjustment of 1.0000 for the proposed cancer hospital adjustment. The rural adjustment factor also is 1.000 – and therefore does not affect the conversion factor – because CMS makes no change in the rural adjustment policy. CMS estimates that 2017 pass-through spending for drugs, biological and devices will be $148.3 million, or 0.24 percent of total spending, compared with CMS' estimate that pass-through spending in 2016 would represent about 0.26 percent of total payments. The increase in projected pass-through spending for 2016 therefore results in an increase in the conversion factor of 0.02 percentage points. Finally, the proposal to package all unrelated laboratory tests described in II.A.7 above) results in a proposed conversion factor adjustment of +0.03 percent to make the change budget neutral. The table below shows the calculation of the proposed conversion factor for 2016.

2016 Final Rule Conversion Factor	Apply 2017 Pass - Through Adjustment (Net of 2016 adjustment)	Apply 2017 Wage Index Budget Neutrality Adjustment	Apply 2017 Cancer Adjustment Budget Neutrality	Adjustment for packaging of unrelated lab tests	2017 Fee Schedule Increase Factor	2017 Proposed Rule Conversion Factor
$73.725	1.0002	1.000	1.000	1.0003	1.0155	
	$73.74	$73.74	$73.74	$73.76	$74.909	$74.909

The combined effect of these factors yields a proposed 2017 conversion factor of $74.909 for hospitals satisfying the requirements of the quality reporting program. To calculate the proposed 2016 reduced market basket conversion factor for those hospitals that fail to meet the requirements of the OQR, the proposed rule applies a reduced fee schedule increase factor of +0.45 percent, rather than +1.55 percent, keeping all other adjustments the same, resulting in a reduced conversion factor for the 2016 proposed rule of $73.411.

C. Wage Index Changes

CMS proposes to continue its policy of adopting the final fiscal year IPPS post-classified wage index as the OPPS calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. The 2017 OPPS proposed rule wage index is based on the FY 2017 IPPS proposed post-classified wage index. This includes adoption of revisions to several labor market areas made by the Office of Management and Budget (OMB) in OMB Bulletin No. 15-01 issued on July 15, 2015. The wage index tables are available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-

Items/FY2017-Wage-Index-Home-Page.html. For non-IPPS hospitals paid under the OPPS, CMS proposes to continue its 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.

The proposed rule would retain the OPPS labor-related share of 60 percent for purposes of applying the wage index for 2017 and notes that the wage index adjustment is made in a budget neutral manner.

CMS proposes to continue its policy and would implement the wage index adjustments called for in the ACA in the same manner as it has since 2011. That includes the "frontier state" adjustment requiring a wage index floor of 1.0 in certain cases if the otherwise applicable wage index (including reclassification, rural floor, and rural floor budget neutrality adjustment) is less than 1.0. In the case of an OPD affiliated with a multi-campus hospital system, the OPD would continue to receive the wage index value of the specific inpatient hospital with which it is associated. If that hospital is in a frontier state, the frontier state wage index adjustment for that hospital would apply to the OPD.

CMS proposes to retain its policy allowing non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a county designated as an out-migration county under section 505 of the MMA. Those counties eligible for this out-migration adjustment, as well as the non-IPPS hospitals, are available in Addendum L (link to Addenda is on page 1 of this summary.)

In the 2015 final OPPS rule, CMS adopted a 3-year transition period for hospitals paid under the OPPS but not under the IPPS that are currently located in urban counties that would become rural under the new OMB delineations. Such hospitals will maintain the wage index of the CBSA in which they are physically located in FY 2014 for three years. Thus, for the 2017 OPPS, consistent with the FY 2017 IPPS proposed rule, the 3-year transition will continue for its final year.

In the FY 2017 IPPS proposed rule CMS proposed to continue the extension of the imputed floor policy (both the original methodology and alternative methodology) for another year, through September 30, 2017. For purposes of the 2017 OPPS, CMS proposes in this rule to also continue to apply the imputed floor policy to hospitals paid under the OPPS but not under the IPPS.

For CMHCs, CMS proposes 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, the 2015 final OPPS rule established policies to use a 3-year transition period for CMHCs, ending December 31, 2017. The proposed rule notes that consistent with its 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, which only applies to hospitals.

D. Statewide Average Default CCRs

In addition to using CCRs to estimate costs from charges on claims for rate-setting, 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. Default CCRs are used for hospitals for which the MACs cannot calculate a valid CCR, including certain hospitals that are new, hospitals that appear to have a CCR falling outside the predetermined ceiling threshold for a valid CCR, and hospitals whose most recent cost report reflects all-inclusive rate status, until a hospital's MAC is able to calculate the hospital's actual CCR from its most recently submitted Medicare cost report.

The proposed rule would update the default ratios for 2017 using the most recent cost report data and CMS' standard method for calculating this update; for Maryland, CMS would continue to use an overall weighted average CCR for all hospitals in the nation.

Table 4 in the proposed rule (pages 135-138 of the display copy) sets out the proposed statewide default CCRs for urban and rural areas in each state for 2017 and the comparable default CCRs for 2016. The proposed CCRs represent the ratio of total costs to total charges for those cost centers relevant to outpatient services from each hospital's most recently submitted cost report, weighted by Medicare Part B charges. Most CCR changes shown in Table 4 are small. The five largest changes are those for rural Utah (-0.125), rural Alaska (-0.116), rural Connecticut, (+0.079), rural Washington (-0.07), and urban Minnesota (-0.051).

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

For 2017, CMS proposes to continue to apply a 7.1 percent payment adjustment 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. The adjustment is budget neutral and is applied before calculating outliers and copayments.

F. OPPS Payments to Cancer Hospitals

Medicare law exempts 11 cancer hospitals meeting statutory classification criteria for exclusion from payment under the IPPS. Since the inception of the OPPS, Medicare has paid these hospitals under the OPPS for covered outpatient hospital services. The ACA requires a budget neutrality adjustment to the extent that the Secretary determines that the 11 cancer hospitals' OPPS costs are greater than other OPPS hospitals' costs, including consideration of the cost of drugs and biologicals. Cancer hospitals remain eligible for transitional outpatient payments, which are not budget neutral, and outlier payments, which are budget neutral.

For 2017, CMS proposes to continue the cancer adjustment policy used since 2012 to make additional payments to the 11 cancer hospitals sufficient to bring each hospital's payment-to-cost ratio (PCR) up to the level of the PCR for all other hospitals. Rather than a claims-based

adjustment, CMS makes an aggregate payment, as necessary, to each cancer hospital at cost report settlement. CMS determines the cancer hospital's PCR (before a cancer hospital payment adjustment) and determines the lump sum amount necessary (if any) to make the cancer hospital's final PCR 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 the final rule. If a cancer hospital's PCR (before the cancer hospital payment adjustment) is above the target PCR, the cancer hospital payment adjustment equals zero.

CMS recalculates the payment adjustment annually, in part because it believes that the ACA's expansion of the 340B drug purchasing program to cancer hospitals may lower their drug acquisition costs in the future. The target PCR is set in advance and is calculated using the same extract of cost report data from HCRIS as is used for OPPS rate-setting. For the 2017 proposed rule, CMS updated its calculations to determine the target PCR using the latest available cost data (cost report periods with fiscal year ends ranging from 2014 to 2015) and determined that 0.92 is the correct target PCR.

Table 5 in the proposed rule, copied below, shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals, with increases in OPPS payments for 2017 ranging from 15.3 percent to 60.4 percent. As noted, the actual amount of the 2017 cancer hospital payment adjustment for each cancer hospital would be determined at cost report settlement and would depend on each hospital's 2017 payments and costs.

The 2017 proposed rule budget neutrality adjustment to the OPPS conversion factor is 1.0000 for the cancer hospital adjustment reflecting CMS' projection that aggregate cancer hospital adjustments would be largely unchanged in 2017 compared to 2016.

TABLE 5.—PROPOSED ESTIMATED 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 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%

Provider Number	Hospital Name	Proposed Estimated Percentage Increase in OPPS Payments for 2017
390196	Fox Chase Cancer Center	17.9%
450076	M.D. Anderson Cancer Center	54.0%
500138	Seattle Cancer Care Alliance	60.4%

G. Hospital Outpatient Outlier Payments

The OPPS makes outlier payments on a service-by-service basis when the cost of a service exceeds the outlier threshold. For 2017, CMS proposes to continue to set aside 1.0 percent of the estimated aggregate total payments under the OPPS for outlier payments. It calculates the proposed fixed-dollar threshold using the same methodology that was used to set the threshold for 2016 and previously.

For the 2017 proposed rule, CMS provides that the outlier threshold would be met when a hospital's cost of furnishing a service or procedure exceeds 1.75 times the APC payment amount and also exceeds the APC payment rate plus a $3,825 fixed-dollar threshold (compared to $3,250 in 2016). CMS would continue to set the outlier payment equal to 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount when both the 1.75 multiple threshold and the fixed-dollar threshold ($3,825) are met.

CMS proposes that a portion of the 1.0 percent outlier pool, specifically an amount equal to less than 0.01 percent of outlier payments, be allocated to CMHCs for partial hospitalization program outlier payments. This is in contrast with amounts of 0.49 percent for 2016 and 0.47 percent for 2015. CMS proposes to continue its policy that if a CMHC's cost for partial hospitalization services paid under APC 5853 (Partial Hospitalization for CMHCs) exceeds 3.40 times the payment rate for APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 5853 payment rate.

Hospitals that fail to report data required for the quality measures selected by the Secretary incur a 2.0 percentage point reduction to their OPPS annual payment update factor, resulting in reduced OPPS payments for most services. For hospitals failing to satisfy the quality reporting requirements, CMS proposes to continue its policy that a hospital's costs for the service are compared to the reduced payment level for purposes of determining outlier eligibility and payment amount.

To model hospital outlier payments and set the outlier threshold for the proposed rule, CMS applied the hospital-specific overall ancillary CCRs available in the April 2016 update to the Outpatient Provider-Specific File after adjustment (using a proposed CCR inflation adjustment factor of 0.9696 to approximate 2017 CCRs), to charges on 2015 claims, after adjustment using a proposed charge inflation factors of 1.0440 to estimate 2016 charges and 1.0898 to approximate 2017 charges. The inflation adjustment factors for CCRs and charges are the same as were used for the FY 2017 IPPS proposed rule.

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

This section provides step by step instructions for calculating an adjusted Medicare payment from the national unadjusted Medicare payment amounts shown in Addenda A and B to the proposed rule. The steps show how to determine the APC payments that would be made under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: "J1," "J2," "P," "Q1," "Q2," "Q3,""Q4," "R," "S," "T," "U," or "V" (as defined in Addendum D1 to the proposed rule), 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. CMS notes 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.

I. Beneficiary Coinsurance

Medicare law provides that the maximum coinsurance rate for any service is 40 percent of the total OPPS payment to the hospital and the minimum coinsurance is 20 percent. The statute also limits a beneficiary's actual cost-sharing amount for a service to the inpatient hospital deductible for the applicable year, which is $1,288 in 2016. The inpatient hospital deductible limit is applied to the *actual* co-payment amount after adjusting for the wage index. For this reason, the co-insurance levels shown in the OPPS payment rate Addenda A and B to the proposed rule do not reflect application of the hospital deductible limit.

Although the last statutory reduction in the maximum coinsurance rate occurred in 2006, the methodology for calculating coinsurance rates ensures that beneficiary coinsurance amounts will continue to decrease gradually relative to the payment rates until all services have a coinsurance rate of 20 percent of the payment amount for the service.

For 2017, CMS proposes to determine copayment amounts for new and revised APCs using the methodology that was first implemented in 2004. CMS refers readers to the November 7, 2003 OPPS final rule with comment period (68 FR 63458) for a full description of this methodology, which is summarized in the 2017 proposed rule (pp. 158-159 of the display copy). Also, for 2016 as in prior years, CMS would reduce the beneficiary co-payment proportionately to the two percentage point conversion factor reduction when services are rendered in a hospital that does not report the required quality measures, or that reported them unsatisfactorily.

The proposed rule estimates that, in aggregate, the percentage of beneficiary liability for OPPS payments in 2017 will be 18.5 percent, a decrease from the 19.3 percent estimated for 2016 in the 2016 OPPS final rule.

III. OPPS Ambulatory Payment Classification (APC) Group Policies

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

Table 6 (copied below from the proposed rule) summarizes the process CMS uses for updating codes through the OPPS quarterly update Change Requests (CRs), seeking public comment, and finalizing the status and payment of these 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 1, 2016	Level II HCPCS Codes	April 1, 2016	CY 2017 OPPS/ASC proposed rule	CY 2017 OPPS/ASC final rule with comment period
July 1, 2016	Level II HCPCS Code	July 1, 2016	CY 2017 OPPS/ASC proposed rule	CY 2017 OPPS/ASC final rule with comment period
	Category I (certain vaccine codes) and Category 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 Category III CPT Codes	January 1, 2017	CY 2017 OPPS/ASC proposed rule	CY 2017 OPPS/ASC final rule with comment period

1. Treatment of New 2016 Level II HCPCS Codes and CPT Codes Effective April 1 and July 1, 2016, Which CMS Solicits Public Comments in this Proposed Rule

In the April 2016 OPPS quarterly update, CMS made effective 10 new Level II HCPCS codes and assigned them to interim OPPS status indicators and APCs (see Table 7). In the July 2016

OPPS quarterly update, CMS made effective 9 new Level II HCPS codes and 9 new Category III CPT codes and assigned them to interim OPPS status indicators and APCs (see Table 8). The proposed payment rates, where applicable, can be found in Addendum B to this proposed rule. **CMS solicits public comments on the proposed status indicators, APC assignments and payment rates for these new codes.**

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

CMS proposes to continue the practice of providing interim payment status indicators, APC assignments and payment rates, if applicable, for new Level II HCPCS codes that will be effective October 1, 2016 or January 1, 2017 in Addendum B to the 2016 final rule. These codes will be flagged with comment indicator "NI" in Addendum B, indicating that CMS has assigned the codes an interim OPPS payment status for 2017. CMS proposes that these status indicators and APC assignments would be applicable in 2017. CMS will invite public comment in the 2017 OPPS/ASC final rule about the status indicators, APC assignments, and payment rates for these codes and this information would be finalized in the 2018 OPPS/ASC final rule with comment period.

3. Treatment of New and Revised Category I and Category III CPT Codes That Will Be Effective January 1, 2017, Which CMS Solicits Public Comments in This Proposed Rule

CMS received the new and revised 2017 Category I and III CPT codes from the AMA in time for inclusion in this proposed rule. The new and revised CPT codes are included in Addendum B to this proposed rule. CMS assigned a new comment indicator "NP" and is requesting comments on the proposed APC assignment, payment rates and status indicators. (NP indicates that the code is new for the next CY or the code is an existing code with substantial revision to its code descriptor in the next CY as compared to the current CY, with a proposed APC assignment and that comments will be accepted on the proposed APC assignment and status indicator.) CMS proposes to finalize the status indicators and APC assignments for these codes in the 2017 OPPS/ASC final rule.

Because the CPT code descriptors in Addendum B are short descriptors, CMS included the long descriptors for the new and revised CPT codes in Addendum O. CMS notes that these new and revised CPT procedure codes have a placeholder for the fifth character and the final CPT code numbers will be included in the final rule.

B. OPPS Changes – Variations within APCs

1. Application of the 2 Times Rule

In accordance with section 1833(t)(2) of the Act, CMS annually reviews the items and services within an APC group to determine, with respect to comparability of the use of resources, if the highest cost item or service within an APC group is more than 2 times greater than the lowest

cost item or service within that same group. In making this determination, CMS considers only those HCPCS codes that are significant based on the number of claims. Specifically, CMS considers only those HCPCS codes that have more than 1,000 single major claims or 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.

2. APC Exceptions to the 2 Times Rule

CMS may make exceptions to the 2 times limit on the variation of costs within each APC group in unusual cases, such as low-volume items and services. CMS uses the following criteria to decide whether to propose exceptions: resource homogeneity; clinical homogeneity; hospital outpatient setting utilization; frequency of service (volume); and opportunity for upcoding and code fragments. CMS notes that in cases in which a recommendation by the Panel appears to result in or a violation of the 2 times rule, CMS generally accepts the Panel's recommendations because the Panel's recommendations are based on explicit consideration of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates.

Table 9 in the proposed rule lists the 4 APCs that CMS is proposing to exempt from the 2 times rule for 2016 based on established criteria and based on claims data from January 1, 2015, through December 31, 2015 and processed on or before December 31, 2015. For the final rule, CMS plans to use claims data for dates of service from January 1, 2015 and December 31, 2015 that were processed on or before June 30, 2016 and updated CCRs, if available.

C. New Technology APCs

1. Additional New Technology APC Groups

Currently, there are 48 levels of New Technology APC groups with two parallel status indicators; one set with a status indicator of "S" (S = Significant procedure, not discounted when multiple) and the other set with a status indicator of "T" (T = Significant procedure, multiple reduction applies). The New Technology APC levels range from the 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)). Payment for each APC is made at the mid-point of the APC's assigned cost band.

CMS is proposing to expand the New Technology APC groups by adding 3 more levels with two parallel status indicators, Levels 49 through 51 (see Table 10). These new levels range from the cost band assigned to proposed APC 1901 (New Technology – Level 49 ($100,001 - $120,000)) through the highest cost band assigned to proposed APC 1906 (New Technology – Level 51 ($140,001 - $160,000)). CMS is proposing this expansion to accommodate the assignment of the retinal prosthesis implantation procedure to another New Technology APC. The proposed payment rates for these New Technology APCs are included in Addendum A to this proposed rule.

2. Procedures Assigned to New Technology APC Groups for 2017

CMS proposes to continue their current policy to retain services within New Technology APC groups until they obtain sufficient claims data to justify reassignment of the service to a clinically appropriate APC. CMS notes, that in cases where it determines, based on additional information, that the initial New Technology APC assignment is no longer appropriate it will reassign the procedure or service to a different New Technology APC that more appropriately reflects its costs.

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. The retinal prosthesis device that is used in the procedure described by CPT code 0100T is described by HCPCS code C1841 (Retinal prosthesis, includes all internal and external components). Pass-through status was granted for HCPCS code C1841 beginning October 1, 2013 and expired on December 31, 2015. For 2016, the procedure described by C1841 was assigned to OPPS status indicator "N" (the payment for the procedure is packaged) and CPT code 0100T was assigned to APC 1599 (New Technology – Level 48 ($90,001 - $100,000)) with a 2016 OPPS payment of $95,000. This payment includes both the surgical procedure (CPT code 0100T) and the retinal prosthesis (HCPCS code C1841).

For 2017, CMS proposes 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. CMS notes this proposal is based on both OPPS claims data and its further understanding of the retinal prosthesis implant procedure (the Argus® II procedure).

D. OPPS APC-Specific Policies

Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and revise the groups and their relative payment weights to take into account various factors including changes in medical practices, changes in technology, the addition of new services and new cost data. The Secretary is also required to consult with an expert outside advisory panel composed of appropriate representatives of providers to review the clinical integrity of the APC groups and the relative payment weights and advise the Secretary about any issues. The Panel recommendations for specific services for the 2017 OPPS and CMS' responses are discussed throughout the proposed rule.

Addendum B to the proposed rule identifies with a comment indicator "CH" those HCPCS codes for which CMS is proposing a change to the APC assignment or status indicator. CMS states that in many cases, the proposed reassignments and associated APC reconfigurations for 2017 are related to changes in costs of services that were observed in the 2015 claims data used for 2017 rate setting. CMS is also proposing to change the status indicators for some codes because based on proposed policies; CMS believes another status indicator more accurately describes

their payment status. In addition, CMS is proposing to rename existing APCs or create new clinical APCs to complement proposed HCPCS code reassignments.

1. Imaging Services

In 2016, as part of the comprehensive reviews of the structure of APCs, CMS restructured the APCs groupings for imaging services to better reflect the costs and clinical characteristics of the procedures within each APC. CMS agrees with recommendations from stakeholders and proposes further restructuring of the OPPS imaging APCs. **The proposed restructuring would consolidate the imaging APCs from 17 APCs to 8 APCs.** (Table 11 shows the 2016 imaging APCs and Table 12 shows the proposed 2017 imaging APCs.) The specific APC assignments for each service grouping are listed in Addendum B. CMS notes that some of the imaging procedures are assigned to APCs that are not listed in tables in the proposed rule (e.g. vascular procedures APCs). In addition, nuclear medicine services APCs are not included in this proposal.

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

Based on review of procedures assigned to these APCs, CMS is proposing to revise the status indicator assignment for these procedures from "S" (Procedure or Service, Not Discounted When Multiple; Paid under OPPS; separate APC payment) to "T" (Procedure or Service, Multiple Procedure Reduction Applies; Paid under OPPS; separate APC payment). CMS states that because the procedures assigned to APCs 5101 and 5102 are primarily associated with surgical treatments, it believes the proposed reassignment of these procedures to status indicator "T" is appropriate.

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 with benign prostatic hyperplasia (BPH). The procedure was assigned to the New Technology APC 1564 on April 1, 2014. For 2016, CMS assigned HCPCS code 9740 to New Technology APC 1565 (New Technology – Level 28 ($5,000 - $5,500) with a payment rate of $5,250).

For the 2017 update, the review of claims data for HCPCS code C9740 shows a geometric mean cost of approximately $6,312 based on 585 single claims. Based on this information, CMS proposes to reassign C9740 from APC 1565 to APC 5376 (Level 6 Urology and Related Services), which has a geometric mean cost of approximately $7,723.

IV. OPPS Payment for Devices

A. Pass-Through Payments for Devices

1. Expiration of Transitional Pass-Through Payments for Certain Devices

CMS follows the statutory requirements that a category of devices is eligible for transitional pass-through payments for at least 2, but not more than 3 years. CMS' established policy is to base the pass-through status expiration date for a device category on the date on which pass-through payment is effective for the category, which is the first date on which pass-through payment may be made for any medical device. Further, except for brachytherapy sources, for devices that are no longer eligible for pass-through payments, CMS packages the costs of the devices into the procedures with which the devices are reported in the claims data used to set the payment rates.

Currently, there are four device categories eligible for pass-through payments:

- HCPCS code C2624 (Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components) was established effective January 1, 2015;
- HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser) was established effective April 1, 2015;
- HCPCS code C2613 (Lung biopsy plug with delivery system) was established effective July 1, 2015; and
- HCPCS code C1822 (Generator, neurostimulator (implantable), high frequency with rechargeable battery and charging system) was established effective January 1, 2016.

In accordance with CMS' established policy, for 2017, CMS is proposing to package the costs of the device described by HCPCS code C2624 into the costs related to the procedures with which the device is reported in the hospital claims data. CMS will continue the pass-through status in 2017 for the other three devices listed above.

2. New Device Pass-Through Applications

a. Background

Criteria for New Device Pass-Through Applications

Existing regulations at §419.66(b)(1) through (b)(3) specify that, to be eligible for transitional pass-through payment under the OPPS a device must meet the following criteria:

1. If required by the FDA, the device must have received FDA premarket approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has be classified as a Category B device by the FDA), or meets another appropriate FDA exemption from premarket approval or clearance; and the pass-through application must be submitted within 3 years form the date of the initial FDA approval or clearance, if required, unless there is a documented, verifiable delay in the US market availability 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 to improve the functioning of a malformed body part; and
3. The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion.

In addition, according to §419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following:

1. Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual; or
2. A material or supply furnished incident to a service (e.g. a suture, customized surgical kit, or a clip, other than a radiological site marker).

Separately, CMS also uses the following criteria established at §419.66(c) to determine whether a new category of pass-through devices should be established:

- Not appropriately described by an existing category or 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;
- Has 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 device 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, exempted from the cost requirements at §419.66(c)(3) and §419.66(e); and
- Demonstrates a substantial clinical improvement: 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.

Annual Rulemaking Process in Conjunction with Quarterly Review Process for Device Pass-Through Payment Applications

In 2016, CMS changed the OPPS device pass-through payment evaluation and determination process. Under the revised application process for device pass-through payments:

- CMS will continue to accept and review device pass-through applications on a quarterly basis, and approved applications will continue to be granted access to pass-through payment at the beginning of the next quarter following approval. These are, however,

considered to be preliminary decisions.

- CMS will include discussions of the preliminary decisions on pass-through applications (both approvals and denials) in the next OPPS proposed rule.
- CMS will accept public comments on the preliminary decisions and could change the decisions in the final rule in consideration of public comment.
  - For applications that are approved during the quarterly review process, based on public comments received in response to the proposed rulemaking, CMS will either continue to maintain the device pass-through payment status or finalize a policy to discontinue pass-through payment status. If CMS finalizes a policy to discontinue pass-through payment status, a situation CMS believes would be rare, the applicant could reapply with new information in advance of the following year's proposed rule through the regular quarterly process. The next year's proposed rule will include the application information and a proposal to approve or deny device pass-through status. A final decision would be published in the final rule after consideration of public comment.
  - For applications that are denied during the quarterly review process, CMS will include information in the next applicable OPPS proposed rule and after consideration of public comments and additional information submitted through the rulemaking process, CMS would either uphold the original decision of denial or approve the application, as set forth in the proposed rule. CMS will allow applicants whose applications are denied through the quarterly review process to withdraw their application if they do not wish to use the rulemaking process and have information about their application and denial made public.

The current deadline for device pass-through payment applications continues to be the first business day in March, June, September, and December of a year for consideration for the next quarter (at the earliest) of the calendar year involved. CMS notes that the decision on an application that is submitted by the first business day in March would likely be presented in that calendar year's OPPS proposed rule. Decisions on applications received after the first business day in March would be included in the OPPS proposed rule for the following calendar year. The process changes became effective January 1, 2016.

More details on the requirements for device pass-through applications are included in the application form on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payments?HospitalOutpatientPPS/passthrough_payment.html. CMS notes it is also available to meet with applicants or potential applicants to discuss research trial design in advance of submitting any application.

b. Applications Received for Device Pass-Through Payments for 2017

CMS received three applications by the March 1, 2016 quarterly deadline, the last quarterly deadline in time for this proposed rule. The summary below provides a high level discussion of each application; readers are advised to review the proposed rule for more detailed information. **CMS invites public comment on whether the three technologies in question meet the newness, cost, and substantial clinical improvement criteria.**

CMS notes that applications received for the remaining 2016 quarters (June1, September 1, and December 1) will be discussed in the 2018 OPPS/ASC proposed rule.

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

BioMonde US, LLC submitted an application for the BioBag® (Larval Debridement Therapy in a Contained Dressing), a biosurgical wound treatment consisting of disinfected, living larvae in a polyester net bag. The larvae remove dead tissue from wounds; BioBag® is indicated for debridement of nonhealing necrotic skin and soft tissue wounds. The other similar product is "free-range" or uncontained larvae.

With respect to the newness criterion, the applicant received FDA clearance for BioBag® through the premarket notification section 510(k) process on August 38, 2013 and its March 1, 2016 application was within 3 years of FDA clearance. Although the applicant claims BioBag® is an integral part of wound debridement and is used for only one patient, CMS is concerned that BioBag® is a surgical supply similar to a surgical dressing that facilitates debridement and therefore, it would not be eligible for device pass-through payments. **CMS invites comment on whether BioBag® should be eligible to be considered for device pass-through payment.**

With respect to the cost criterion, the applicant stated that BioBag® would be reported with CPT code 97603. This CPT code is assigned to APC 5051 with a 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 the bag size selected is based on the wound size. As discussed in the proposed rule, BioBag® meets all the three cost significance tests and satisfies the cost significance criterion.

With respect to the substantial clinical improvement criterion, CMS discusses the 18 articles submitted relating to wound debridement and is not convinced that BioBag® provides a substantial clinical improvement over other treatments for wound debridement.

2. Encore™ Suspension System

Siesta Medical, Inc. submitted an application for the Encore™ Suspension System, a kit of surgical instruments and implants that are used to perform an adjustable hyoid suspension. The Encore™ System is designed for hyoid bone suspension to the mandible bone using bone screws and suspension lines and is used for the treatment of mil or moderate sleep apnea and/or snoring, when the patient is unable to tolerate continuous positive airway pressure.

With respect to the newness criterion, the Encore™ System received FDA clearance through the section 510(k) process on March 24, 2014. CMS discusses how it considers several components of the Encore™ System to be either instruments or supplies, which are not eligible for pass-through. CMS notes that the only implantable devices in the kit are the bone screws, which are described by the existing pass-through category HCPCS code C1713. **CMS invites public comment 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 respect to the cost criterion, the applicant stated that the Encore™ System would be used in the procedure described by CPT code 21685. CPT code 21685 is assigned to APC 5164 with a 2016 payment rate of $1616.90 and the device offset is $15.85. The price of the Encore™ System is $2,200. As discussed in the proposed rule, based on the costs submitted by the applicant, the device meets all the three cost significance tests and satisfies the cost significance criterion. CMS is concerned, however, that the cost criterion would not 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 respect to the substantial clinical improvement criterion, CMS notes that the applicant did not provide any specific data addressing the substantial clinical improvement criterion. CMS is also concerned that based on information in the application, the Encore™ System is similar to the Medtronic AirVance System, another surgical kit used with CPT code 21685. CMS concludes that the clinical data provided by the applicant is insufficient to demonstrate substantial clinical improvement and invites comments.

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

Endophys Holdings, LLC submitted an application for the Endophys PSS, a stand-alone catheterization sheath that is inserted percutaneously during intravascular diagnostic or interventional procedures. The Endophys PSS is an introducer sheath with an integrated fiber optic pressure transducer for blood pressure monitoring; it is used with the Endophys Blood Pressure Monitor to display blood pressure measurements.

With respect to the newness criterion, the Endophys PSS received FDA clearance through the section 510(k) process on January 7, 2015. According to the applicant, the Endophys PSS is an integral part of several endovascular procedures, is used for one patient only, comes in contact with human skin, and is surgically implanted. Based on review of the application, CMS believes that the device may be described by HCPCS code C1894 (Introducer/sheath, other than guiding, other than intracardiac electrophysiological, nonlaser), which is consistent with the FDA section 510(k) Summary Product Description which describes the Endophys PSS as an introducer sheath with an integrated fiber optic pressure transducer. CMS believes the Endophys PSS is described by the previously existing category of HCPCS code C1894 established for transitional pass-through payments. **CMS invites 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. CPT code 36620 is assigned status indicator "N" (which means its payment is packaged under the OPPS). The applicant also stated that its device can be used in many endovascular procedures that are assigned to APCs 5188, 5191, 5526, 5183, 5181, 5182, and 5291. CMS used APC 5291 for the cost calculations, which has a 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. As discussed in the proposed rule, Endophys PSS meets all the three cost significance tests and satisfies the cost significance criterion.

With respect to the substantial clinical improvement criterion, CMS notes that the applicant provided minimal direct clinical data to support substantial clinical improvement. **CMS invites public comments on whether the Endophys PSS meets this criterion.**

3. Beginning Eligibility Date for Device Pass-Through Payment Status

The pass-through payment eligibility period currently begins on the date CMS establishes a category of devices. CMS proposes to amend § 419.66(g) to provide that the pass-through eligibility period would begin on the first date on which pass-through payment is made. It notes that the proposed change is unlikely to affect the pass-through expiration date, but could result in an expiration date that is later than it otherwise would have be in cases of significant delay from the date of establishment of a pass-through category to the date of the first pass-through payment. Such a result is more likely in combination with the proposed change described in section 4 below.

4. Making 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

By statute, transitional pass-through payments are 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. CMS accepts pass-through applications and begins pass-through payments for new pass-through devices on a quarterly basis. Pass-through status, however, currently expires on a calendar-year basis through notice-and-comment rulemaking. Device pass-through status 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. Thus the duration of the pass-through eligibility for a particular device depends on the quarter of initial eligibility for pass-through payment. 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.

CMS proposes, beginning with pass-through devices newly approved in 2017, to allow for a quarterly expiration of pass-through status for devices to provide for a pass-through period that is as close to a full 3 years as possible for all pass-through payment devices. Under the proposal, pass-through status would expire on September 30, 2020 for a device with pass-through payment first effective on October 1, 2017.

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

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). To address the effects of charge compression, in the FY 2009 IPPS final rule CMS created a cost center for "Medical Supplies Charged to Patients," which includes primarily low cost supplies, and another cost center for "Implantable Devices Charged to Patients," which typically includes high-cost implantable devices.

Responding to a request to consider using the "Implantable Devices Charged to Patients" CCR in the calculation of device pass-through payment, CMS analysis found that about two-thirds of providers report an "Implantable Devices Charged to Patients" CCR and that these hospitals have a median "Implantable Devices Charged to Patients" CCR of 0.3911 compared to a median hospital-wide CCR of 0.2035. Based on this finding, CMS proposes 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 2017.

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

As required by statute to avoid duplicative payment, CMS deducts from the charges adjusted to cost for the device, an amount that reflects the portion of the APC payment amount that it determines is associated with the cost of the device, defined as the device APC offset amount. To determine the offset amount for the eligible device, CMS uses claims data from the period for the most recent recalibration of the APC rates. CMS updates the applicable device APC offset amounts for eligible pass-through device categories through transmittals that implement the quarterly OPPS updates.

For 2017, CMS proposes to calculate the device offset amounts for each device-intensive procedure at the HCPCS code level rather than at the APC level (which is an average of all codes assigned to an APC). This proposal is discussed in section IV.B below. The list of device offsets for all device procedures will be posted on the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

B. Device-Intensive Procedures

Device-intensive APCs are defined as APCs with a device offset greater than 40 percent (79 FR 66795); the device costs of all procedures within the APC are calculated as well as their geometric mean device offset, which must exceed 40 percent. The no cost/full credit and partial credit device policy (79 FR 66872 through 66873) applies to device-intensive APCs (see discussion below). CMS requires that procedures assigned to certain APCs (formerly device-dependent) require the reporting of a device code on the claim.

1. HCPCS Code-Level Device-Intensive Determination

For 2017, CMS proposes a revised methodology for determining device-intensive status that would assign device-intensive status to all procedures requiring the implantation of a device and having an individual HCPCS code-level device offset of greater than 40 percent, regardless of the procedure's APC assignment. Under the revised methodology the determination would be procedure-based rather than APC-based. In addition to providing a more appropriate determination of which services are device-intensive, CMS notes that a HCPCS code-level device offset generally would 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.

Under the proposal, all procedures requiring the implantation of a medical device and having an individual HCPCS code-level device offset of greater than 40 percent would be identified as device-intensive and would be subject to the device edit and no cost/full credit and partial credit device policies.

For new HCPCS codes describing procedures requiring the implantation of medical devices that do not yet have associated claims data, CMS proposes 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. CMS notes that the proposal would ensure ASC access for new procedures until claims data become available. In certain rare instances, such as in the case of a very expensive implantable device, CMS may temporarily assign a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer. The full listing of proposed device-intensive procedures is included in a new Addendum P to the proposed rule (which is available on the CMS website using the link provided on page 1 of this summary).

2. Changes to Device Edit Policy

In the 2015 OPPS/ASC final rule, CMS relaxed its device claims processing edits to require simply that *any* device code used in prior device-to-procedure edits be included on a claim whenever a procedure code assigned to any of the APCs (formerly device-dependent APCs) identified by CMS were reported on a claim. For 2016, CMS further revised its policy and applied the device code reporting requirements to procedures assigned to all APCs that meet the device-intensive definition, not just the subset of such APCs that also were previously device-dependent APCs. For 2017, CMS proposes to apply the device claims editing policy on a procedure rather level rather than APC level, consistent with its proposal to make device-intensive determinations at the HCPCS code level. For 2017 and subsequent years, CMS would apply the device coding requirements to the newly defined (individual HCPCS code-level device offset greater than 40 percent) device-intensive procedures; any device code, when reported on a claim with a device-intensive procedure, would satisfy the edit.

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

CMS reduces OPPS payments by the full or partial credit a provider receives for a replaced device for the applicable device-dependent APCs. Hospitals report 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. CMS also limits the total amount of the device offset when the "FD" value code appears on a claim. CMS specifies a list of costly devices to which this APC payment adjustment would apply. For 2017, CMS proposes to continue the existing policy of reducing OPPS payment when a hospital furnishes a specified device without cost or with a full or partial credit.

In 2015 and prior years, CMS specified a list of costly devices to which this APC payment adjustment applied. For 2016, CMS applied the APC payment adjustment to all replaced devices furnished in conjunction with a procedure assigned to a device-intensive APC (listed in Table 42 of the 2016 OPPS/ASC final rule) when the hospital receives a credit for a replaced specified device that is 50 percent or greater than the cost of the device. For 2017, CMS proposes to identify the services to which the adjustment would apply using the newly defined set of device-intensive procedures – i.e., procedures with an individual HCPCS level device offset greater than 40 percent, as described above.

CMS also proposes to continue using the three criteria established in the 2007 OPPS/ASC final rule for determining the procedures to which the 2017 device-intensive policy will apply. Specifically, for 2017, (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.

4. Payment Policy for Low Volume Device-Intensive Procedures

For 2016, CMS used its equitable adjustment authority under section 1833(t)(2)(E) of the Act to use the median cost rather than the geometric mean cost to calculate the payment rate for the procedure described by CPT code 0308T (Insertion of ocular telescope prosthesis including removal or crystalline lens or intraocular lens prosthesis). The procedure is the only code assigned to APC 5494 (Level 4 Intraocular Procedure). 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 CMS concluded that the median cost is a more appropriate measure of the central tendency for purposes of calculating the cost and the payment rate because the median cost is impacted to a lesser degree than the geometric mean cost by more extreme observations. The median cost for 2016 of the procedure described by CPT code 0308T is $18,365 and the geometric mean cost is $13,833.

For 2017, proposes to reassign the procedure described by CPT code 0308T to APC 5495 (Level 5 Intraocular Procedures) for 2017, but it would be the only procedure code assigned to APC 5495, and CMS will continue to determine the payment rate using median cost.

CMS indicated in the 2016 OPPS/ASC final rule that, in future rulemaking, it would consider proposing a general policy for calculating the payment rate for very low-volume device-intensive APCs similar to APC 5494 (proposed APC 5495). Thus, for 2017, CMS proposes 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. CMS believes this policy will help to mitigate significant year-to-year payment rate fluctuations while preserving accurate claims data-based payment rates for low-volume device-intensive procedures. **CMS invites public comments on this proposal.** For 2017, the policy would apply only to 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.

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

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

1. Making 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

By statute, transitional pass-through payments are 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. CMS accepts pass-through applications and begins pass-through payments for new pass-through devices on a quarterly basis. Pass-through status, however, currently expires on a calendar-year basis through notice-and-comment rulemaking. As with devices, pass-through status for drugs, biologicals, and radiopharmaceuticals 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. Thus the duration of the pass-through eligibility for a particular drug, biological, or radiopharmaceutical depends on the quarter of initial eligibility for pass-through payment. A new pass-through item with pass-through status effective on April 1 would receive 2 years and 3 quarters of pass-through status while one with pass-through status effective on October 1 would receive 2 years and 1 quarter of pass-through status.

As described in section IV.A.4. above for devices, CMS similarly proposes, beginning with pass-through drugs, biologicals, and radiopharmaceuticals newly approved in 2017, to allow for a quarterly expiration of pass-through status for devices to provide for a pass-through period that is as close to a full 3 years as possible for all pass-through payment drugs, biologicals, and radiopharmaceuticals. Under the proposal, pass-through status would expire on September 30, 2020 for a drug, biological, or radiopharmaceutical with pass-through payment first effective on October 1, 2017. CMS invites public comment on this proposal.

2. Drugs and Biologicals with Expiring Pass-Through Payment Status in 2017

CMS proposes to terminate the pass-through payment status for the 15 drugs and biologicals effective January 1, 2017 (see Table 13 in the proposed rule). By that date, all of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and not more than 3 years. These items were approved for pass-through status on or before January 1, 2015. Except for the policy-packaged drugs, which are drugs and biologicals that are always packaged when they do not have pass-through payment status, CMS makes a separate payment if the product's estimated per day cost exceeds the OPPS drug packaging threshold, which is proposed at $110 for 2017. The "policy-packaged drugs" are: diagnostic radiopharmaceuticals; contrast agents; 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 (e.g., skin substitutes). 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 on the CMS website).

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

CMS proposes to continue pass-through status in 2017 for 38 drugs, biologicals and radiopharmaceuticals. None of these products will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2016. These items, which were approved for pass-through status between January 1, 2014 and July 1, 2016, are listed in Table 14 of the proposed rule. Pass-through drugs and biologicals are identified by status indicator "G" in Addenda A and B.

For 2017, CMS proposes to continue to pay for drugs and biologicals with pass-through status at average sales price plus 6 percent (ASP+6). For purposes of pass-through payment, CMS considers radiopharmaceuticals to be drugs under the OPPS and therefore also sets the payment rate for them at ASP+6; if ASP data are not available for a radiopharmaceutical, CMS provides 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, CMS provides payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

CMS proposes to continue to update the list of pass-through drugs on a quarterly basis on the CMS website during 2017 to reflect newly approved pass-through drugs and biologicals as well as to adjust payment rates for pass-through drugs as necessary based on later quarter ASP submissions (or more recent WAC or AWP information, as applicable).

The proposed rule continues CMS policy that the pass-through payment portion of the total drug payment is the difference between the pass-through payment rate of ASP+6 percent and the 2017 payment rate that CMS sets for nonpass-through, separately payable drugs. Except for the policy-packaged drugs, the pass-through portion is zero since CMS pays both pass-through and

nonpass-through drugs at ASP+6 percent. For policy-packaged drugs, their pass-through payment amount would be equal to ASP+6 percent for 2017 because, if not for their pass-through status, payment for these products would be packaged into the associated procedure.

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

When nonpass-through drugs, biologicals, and radiopharmaceuticals function as supplies for a diagnostic test or procedure, they are packaged under the OPPS. This category includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and other diagnostic drugs. Similarly, when nonpass-through drugs and biologicals function as supplies in a surgical procedure, such as skin substitutes and other surgical-supply drugs and biologicals, they are packaged under the OPPS.

Therefore, a payment offset is necessary in order to provide an appropriate transitional pass-through payment since the statute specifies that the transitional pass-through payment amount is the difference between the amount paid under section 1842(o) of the Act (i.e., ASP + 6 percent) and the otherwise applicable OPD fee schedule amount. CMS deducts from the pass-through payment for policy packaged drugs, biologicals, and radiopharmaceuticals an amount – the payment offset – reflecting the portion of the APC payment associated with predecessor products in order to ensure no duplicate payment is made. The payment offset policy applies to all policy packaged drugs, biologicals, and radiopharmaceuticals.

For 2017, CMS proposes to continue to apply the current offset policies for all of the "policy-packaged" drugs, biologicals, and radiopharmaceuticals[5]. CMS refers readers to the discussion in the 2016 OPPS/ASC final rule with comment period (80 FR 70430 through 70432) for a full description of the payment offset policy.

CMS will continue to post annually on the CMS website a file with the APC offset amounts to be used for purposes of both evaluating cost significance for candidate pass-through device categories and drugs and biologicals and for establishing any appropriate APC offset amounts. See http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

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

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

CMS currently pays for drugs, biologicals, and radiopharmaceuticals that do not have pass-through payment status in one of two ways: packaged into the payment for the associated

[5] Diagnostic radiopharmaceuticals; contrast agents; 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 (e.g., skin substitutes).

service; or separate payment (individual APCs). Hospitals do not receive a separate payment for packaged items and hospitals may not bill beneficiaries separately for any packaged items: these costs are recognized and paid within the OPPS payment rate for the associated procedure or service.

Cost Threshold for Packaging of "Threshold-Packaged Drugs"

"Threshold-packaged drugs" under the OPPS are drugs, non-implantable biologicals and therapeutic radiopharmaceuticals whose packaging status is determined by the packaging threshold. If a drug's average cost per day exceeds the annually determined packaging threshold, it is separately payable and, if not, it is packaged. For 2016, the packaging threshold for drugs, biologicals, and radiopharmaceuticals that are not new and do not have pass-through status is $100.

To calculate the proposed 2017 threshold, CMS used the most recently available four quarter moving average Producer Price Index (PPI) forecast levels for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics (BLS) series code WPUSI07003) from CMS' Office of the Actuary (OACT) to trend the $50 threshold forward from the third quarter of 2005 to the third quarter of 2017 and rounded the resulting dollar amount ($109.03) to the nearest $5 increment, which yielded a figure of $110. Based on this calculation, CMS proposes a packaging threshold for 2017 of $110.

For the proposed rule, CMS determined 2017 packaging status for all nonpass-through drugs and biologicals that are not policy packaged (with the exception of those drugs and biologicals with multiple HCPCS codes described below). Using 2015 claims data processed before January 1, 2016, CMS 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 2015 and were paid (either as packaged or separate payment) under the OPPS.

To calculate the per day cost, CMS used an estimated payment rate of ASP+6 percent for each HCPCS code. CMS used the manufacturer-submitted ASP data from the fourth quarter of 2015 (data that were used for payment purposes in the physician's office setting effective April 1, 2016). For products that do not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, CMS used their mean unit cost derived from the 2015 hospital claims data. Products with a per day cost of less than or equal to $110 are proposed to be packaged in 2017 and items with a per day cost greater than $110 are proposed to be separately payable.

CMS continues to use quarterly ASP updates as follows:

- 4th quarter of 2015: budget neutrality estimates, packaging determinations, impact analyses, and Addenda A and B for the 2017 OPPS proposed rule;
- 1st quarter of 2016: budget neutrality estimates, packaging determinations, and impact analyses for the 2017 OPPS final rule;

- 2nd quarter of 2016: payment rates for HCPCS codes for separately payable drugs and non-implantable biologicals included in Addenda A and B to the 2017 OPPS final rule; and
- 3rd quarter of 2016: payment rates effective January 1, 2017 for HCPCS codes for separately payable drugs and non-implantable biologicals included in Addenda A and B; these are the same ASP data used to calculate payment rates effective January 1, 2017 for drugs and biologicals furnished in the physician office setting.

ASP-based payment rates for both the OPPS and physician office settings are updated quarterly using quarterly reported ASP data with a two-quarter lag, and these updates are available on the CMS website. CMS proposes to continue its policy of making an annual packaging determination for a HCPCS code for the OPPS final rule and not updating that code's packaging status during the year. Only HCPCS codes which are identified as separately payable in this final rule would be subject to quarterly updates.

As in past years, CMS proposes to apply the following policies to determine the 2017 final rule packaging status of a threshold-packaged drug when the drug's packaging status as calculated for the final rule, using more current data, differs from its status in this proposed rule.

- HCPCS codes that were separately payable in 2016 and were proposed for separate payment in 2017 would be separately payable in 2017 even if the updated data used for the 2017 final rule indicate per day costs equal to or less than the $110 threshold.
- HCPCS codes that were packaged in 2016, proposed for separate payment in 2017, and have per day costs equal to or less than $110 based on the updated data used for the 2017 final rule would be packaged in 2017.
- HCPCS codes for which CMS proposed packaged payment in 2017 but have per day costs greater than $110 based on the updated data used for the 2017 final rule would be separately payable in 2017.

High/Low Cost Threshold for Packaged Skin Substitutes

In the 2014 OPPS final rule, CMS unconditionally packaged skin substitute products into the associated surgical procedures, including a methodology that divided the skin substitutes into a high cost group and a low cost group for packaging purposes. 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. CMS continued this policy, with modifications, in 2015 and 2016. For a discussion of the 2016 high cost/low cost methodology, CMS refers readers to the 2016 OPPS/ASC final rule with comment period (80 FR 70434 through 70435).

For 2017, as in 2016, CMS proposes 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. Based on 2015 claims data available for the proposed rule, CMS calculated a proposed

2017 MUC threshold of $25 per cm^2 (rounded to the nearest $1) and a proposed 2017 PDC threshold of $729 (rounded to the nearest $1).

CMS continues to assign skin substitutes with pass-through payment status to the high cost category. Skin substitutes with pricing information but without claims data to calculate a MUC or PDC are assigned 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, CMS uses 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 are assigned to the low cost category until pricing information is available to compare to the 2016 MUC threshold.

Table 15 in the 2017 proposed rule shows the proposed high/low cost status for each skin substitute product in 2017. CMS proposes to assign a skin substitute to the high cost group for 2017 if it was assigned to the high cost group in 2016 and exceeds either the MUC or PDC in this 2017 proposed rule even if it no longer exceeds the MUC or PDC 2017 thresholds based on updated claims data and pricing information used in the 2017 final rule.

For 2016, CMS removed all implantable biologicals from the skin substitute cost group list because these products are typically used in internal surgical procedures to reinforce or repair soft tissue, and are not typically used to promote healing of wounds on the skin. Implantable biologicals are treated as packaged surgical supplies under the OPPS. HCPCS code Q4107 (GraftJacket) was not removed from the skin substitute cost group list because this code describes an implantable biological that has dual usage as a skin substitute.

Packaging Determination for HCPCS Codes that Describe the Same Drug or Biological but Different Dosages

For 2017, CMS continues its policy of making packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, in the case of multiple HCPCS codes describing the same drug or biological but with different dosages. The codes to which this policy applies, and their proposed packaging status, are listed in Table 16 of the proposed rule.

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

For 2017, CMS proposes to reimburse separately payable drugs and biologicals at ASP+6 percent. This payment represents the combined acquisition and pharmacy overhead payment for drugs and biologicals. CMS also would continue to include payments for separately payable drugs and biologicals in determining budget neutrality adjustments (i.e., the budget neutral weight scaler). Following established policy, it does not, however, apply the budget neutral weight scaler in determining payments for these separately paid drugs and biologicals due to the statutory requirement that their payments are to be based on acquisition costs.

The payment rates shown for drugs and biologicals in Addenda A and B of the proposed rule will be updated through the quarterly update process to reflect the actual payment rates that will be used beginning January 1, 2017. Payment rates effective January 2017 will be released near

the end of December 2016 and will be based on ASP data submitted by manufacturers for the third quarter of 2016 (July 1, 2016 through September 30, 2016). 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 2015 claims data. If ASP information becomes available for payment for the quarter beginning in January 2017, CMS will price payment for these drugs and biologicals based on their newly available ASP information. For 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, payment would be paid based on mean unit cost data derived from 2015 hospital claims.

Biosimilar Biological Products

For 2016, CMS established these policies pertaining to biosimilar biological products under the OPPS: 1) to pay for biosimilar biological products under the OPPS based on the payment allowance of the product as determined under section 1847A(b)(8) of the Act, as provided by the Affordable Care Act; 2) to determine the packaging status of nonpass-through biosimilar biological products using the threshold-packaged drug policies as they apply to other products; and 3) to extend pass-through payment eligibility to biosimilar biological products and to establish the pass-through payment amount applying the policies applicable to other pass-through drugs, biologicals and radiopharmaceuticals. For 2016, CMS also proposed and finalized a policy that HCPCS coding and modifiers for biosimilar biological products would be based on policy established under the 2016 MPFS rule.

For 2017, CMS proposes to continue these policies for biosimilar biological products.

3. Payment Policy for Therapeutic Radiopharmaceuticals

For 2017, CMS proposes to continue to pay for all nonpass-through, separately payable therapeutic radiopharmaceuticals under the same ASP methodology that is used for separately payable drugs and biologicals, i.e. ASP+6 percent, when all manufacturers of a product submit the necessary ASP information for a "patient ready" dose. The payment rate is updated quarterly using the most recently available ASP data reported by manufacturers. Reporting ASP information remains optional for manufacturers. For therapeutic radiopharmaceuticals for which ASP data are unavailable, CMS would determines 2017 payment rates based on 2015 geometric mean unit cost data derived from 2015 hospital claims data.

4. Payment Adjustment Policy for Radioisotopes Derived From Non-Highly EnrichedUranium Sources

For 2013, CMS finalized a policy to provide an additional payment of $10 for the marginal cost for radioisotopes produced by non-HEU sources for a time period not to exceed 5 years (77 FR 68323). CMS indicated that it would evaluate annually the continuing need and amount of this transitional payment. For the 2017 proposed rule, CMS reassessed the $10 additional payment amount and did not identify any new information to cause a payment change. Thus, CMS

proposes to continue to provide an additional $10 payment for radioisotopes produced by non-HEU sources.

5. Payment for Blood Clotting Factors

For 2017, CMS proposes to continue to pay for blood clotting factors using the same methodology that it uses to pay other nonpass-through separately payable drugs and biologicals under the OPPS, i.e. ASP+6 percent. CMS will update the 2016 furnishing fee ($0.202 per unit) based on the percentage increase in the Consumer Price Index (CPI) for medical care following the same methodology it has used since 2008. For 2017, the updated amount will be based on the percentage increase in the CPI for medical care for the 12-month period ending in June 2016. Because this information will not be available to be included in the final rule, CMS will announce the actual fee through program instructions and will post the updated rate on the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-BDrugs/McrPartBDrugAvgSalesPrice/index.html. When blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee also is applied to the payment.

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

For 2017, CMS proposes to continue to use the same payment policy as in 2016 for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data (80 FR 70443). The proposed 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 the proposed rule, which is available on the CMS website.

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

The proposed rule estimate for total pass-through spending for drug and device pass-through payments during 2017 is approximately $148.3 million, or 0.24 percent of total OPPS projected payments for 2017, which is less than the applicable pass-through payment percentage statutory limit of 2.0 percent.

A. Devices

Using its established methodology, CMS projects $112.7 million in pass-through spending attributable to device categories in 2017. The proposed rule estimate for the first group of items (i.e., those device categories that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in 2017) is $102.7 million as follows:

HCPCS Code	Code Descriptor	Effective Date	Total (in millions)
C2623	Catheter, transluminal angioplasty, drug-coated, non-laser	4/1/2015	$97
C2613	Lung biopsy plug with delivery system	7/1/2015	$4.7
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system	1/1/2016	$1.0
Total			**$102.7**

CMS proposes an estimate of $10 million for the second group of device categories which consists of those device categories CMS knows or projects may be approved for pass-through status in 2017, and includes contingent projections for new device categories in 2017. CMS includes implantable biologicals newly eligible for pass-through payment in the estimate for the second group.

B. Drugs and Biologicals

For the proposed rule, CMS calculates a pass-through spending estimate of $35.6 million in 2017 attributable to drugs and non-implantable biologicals in the two groups described below. CMS considers radiopharmaceuticals as drugs for pass-through purposes and includes them in their estimates for drugs and biologicals.

The estimate for the first group of drugs and non-implantable biologicals is $19.0 million. The first group consists of drugs and biologicals recently eligible for pass-through payments that will continue for 2017. CMS projects utilization based on the most recent Medicare physician claims data, information in pass-through applications, historical hospital claims data, pharmaceutical industry information, and clinical information.

The estimate for the second group of drugs and non-implantable biologicals is $16.6 million. The second group consists of those drugs and biologicals CMS knows or projects could be approved for pass-through status in 2017, and includes contingent projections for new drugs and non-implantable biologicals that could initially be eligible in 2017. CMS projects utilization for this group using estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity. CMS also considers recent OPPS experience in approving new pass-through drugs and biologicals.

Because CMS pays for most nonpass-through separately payable drugs and biologicals and all pass-through drugs and biologicals at the same rate (ASP+6 percent), its estimates for this group of items is zero. However, the estimate of pass-through payment amounts for diagnostic radiopharmaceuticals and contrast agents with pass-through status is not zero because they are paid at ASP+6 percent in lieu of being packaged into associated procedures as is the case for nonpass-through radiopharmaceuticals and contrast agents. Additionally, if CMS determines

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, it will offset the amount of pass-through payment for the policy-packaged drug or biological and also provide for a corresponding reduction in the estimate of pass-through payments for those drugs or biologicals.

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

CMS proposes no changes to the current clinic and emergency department (ED) hospital outpatient visits payment policies, described in the 2016 OPPS/ASC final rule (80 FR 70448) or to the payment policy for critical care services also described in that rule (80 FR 70449). **CMS seeks public comment on any changes to these codes for consideration in future rulemaking; parties who comment are encouraged to provide the data and analysis necessary to justify any proposed changes.**

VIII. Payment for Partial Hospitalization Program (PHP) Services

A. PHP APC Update for 2017

For 2017, CMS proposes to continue its 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, CMS proposes to combine the Level 1 and Level 2 PHP APCs for Community Mental Health Centers (CMHCs) and to combine the Level 1 and Level 2 APCs for hospital-based PHPs. CMS believes that this would best reflect actual geometric mean per diem costs going forward, 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 2016 OPPS/ASC final rule (80 FR 70459).

CMS notes that 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 its proposal to replace the two-tiered PHP APCs with a single PHP APC for each provider type. For example, 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. This issue occurred in the calculation of the 2016 OPPS/ASC rates for hospital-based PHP providers, for which CMS made an adjustment, and would occur in 2017, if current policy was maintained. By combining these levels, CMS believes this should reduce cost fluctuations and provide more stability in the geometric mean per diem costs.

The proposed costs are contained in Table 19 of the proposed rule (reproduced below).

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

Note: APC 5853 would replace existing CMHC APCs 5851 and 5852. APC 5863 would replace existing hospital-based PHP APCs 5861 and 5862.

CMS considered several other alternatives to its proposal. CMS did not believe that maintaining its current policy would be appropriate given the potential cost inversion issues. Further, CMS considered an option of only combining the two-tiered PHP APC structure for the provider type with inverted data, but believes 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. In addition, CMS also considered whether to apply an adjustment if cost inversion occurs, but believes that providers would prefer predictability rather than an ad hoc adjustment.

CMS completed an extensive analysis of PHP claims and cost data, including provider service usage, coding practices and ratesetting methodology, and the agency identified aberrant data (defined as data so abnormal that they skew the resulting geometric mean per diem costs) from CMHCs and hospital-based providers which it excluded from the calculation of the proposed PHP geometric mean per diem costs. As finalized in its 2016 OPPS/ASC final rule, CMS proposes to continue its policy to exclude data from any CMHC when the CMHC's costs are more than ±2 standard deviations from the geometric mean cost per day for all CMHCs and to exclude hospital-based PHP services days when a CCR greater than 5 (CCR>5) is used to calculate costs for at least one of the component services.

CMS also provides a detailed description of the PHP ratesetting process to improve transparency and understanding of the steps it takes to calculate the geometric mean per diem costs and rates by provider type. CMS encourages CMHCs and hospital-based PHPs to review their accounting and billing processes to ensure greater accuracy in the procedures for calculating costs and rates for PHPs.

B. Outlier Policy for CMHCs

1. Estimated Outlier Threshold

For 2017, CMS proposes to designate less than 0.01 percent of the estimated 1.0 outlier target amount specifically for CMHCs for PHP outliers. This is consistent with the percentage of projected payments to CMHCs under the OPPS in 2017. CMS again proposes to set the outlier

threshold for CMHCs for 2017 at 3.4 times the highest CMHC PHP APC payment rate (proposed new CMHC PHP APC 5853), and to pay 50 percent of CMHC per diem costs over the threshold. Specifically, CMS will calculate a CMHC outlier payment equal to 50 percent of the difference between the CMHC's cost for the services and the product of 3.4 times the APC 5853 payment rate. CMS does not propose to set a dollar threshold for CHMC outlier payments as it proposes to apply to other OPPS outlier payments.

2. Proposed CMHC Outlier Cap

CMS expresses its concern that outlier payments are largely benefiting a small number of CMHCs. This 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. CMS' analysis of 2015 claims data showed that Medicare paid CMHCs $3.2 million in outlier payments, with over 99 percent of those payments made to 4 CMHCs. CMS notes its belief that these excessive outlier payments to some CMHCs are the result of inflated costs, which result from artificially inflated charges. While CMS has efforts geared towards limiting very high outlier payments, such as the outlier reconciliation process, these efforts are typically made after the outlier payments are made.[6]

Given these program integrity concerns, CMS proposes 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. CMS proposes that the CMHC outlier payment cap be set at 8 percent of the CMHC's total per diem payments for that same calendar year. CMS simulated the effect of varying outlier cap percentage options (see Table 20 in proposed rule) and found that 8 percent would have the intended effect of reducing outlier payments to those CMHCs with excessive outlier payments, while not harming those CMHCs with more reasonable outlier payment amounts. CMS notes that its existing outlier reconciliation policy would continue to remain in effect with the proposed CMHC outlier payment cap serving as a complement. This proposed policy would be included in §419.43(d) of the regulations.

CMS states that, if finalized, it would provide detailed information on its implementation strategy through sub-regulatory channels. However, CMS provides a summary of how this could work with its claims processing system. Specifically, under such an implementation approach, for each CMHC, the claims processing system would maintain a running tally of the year-to-date 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 year-to-date total payments.

C. Regulatory Impact

CMS estimates that payments to CMHCs will decrease by 8.4 percent. Almost all of the decrease is attributable to the CMS proposal to combine APCs 5851 and 5852 into proposed new APC

[6] The outlier reconciliation policy is applied at the time of cost report settlement if the CMHC's CCR changed by 0.10 or more.

5853 (Partial Hospitalization (3 or more services) for CMHCs). CMS' estimates also include the proposed trimming methodology, wage index, and other adjustments.

IX. Procedures That Would Be Paid Only as Inpatient Procedures

A. Changes to the Inpatient Only (IPO) List

CMS proposes to continue to use the same methodology to review the inpatient-only list. Under that methodology, CMS proposes to remove the following six procedures (four spine procedures and two laryngoplasty codes) from the inpatient-only list for 2017:

CPT Code	Code Descriptor	Proposed CY 2017 APC Assignment	Proposed CY 2017 Status Indicator
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.	N/A	N
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.	N/A	N
22845	Anterior instrumentation; 2 to 3 vertebral segments. List separately in addition to code for primary procedure.	N/A	N
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.	N/A	N
31584	Laryngoplasty; with open reduction of fracture	5165	J1
31587	Laryngoplasty, cricoid split	5165	J1

Addendum E to the proposed rule contains the complete list of codes that CMS proposes to be paid only as inpatient procedures for 2017.

B. Solicitation of Public Comments on the Possible Removal of Total Knee Arthoplasty Procedure from the IPO List

CMS is seeking public comments on whether it should remove total knee arthroplasty (TKA) or total knee replacement procedure, CPT code 27447, from the IPO list. In 2013, CMS had made a similar proposal, but did not finalize it. Most commenters had disagreed with the 2013 proposal and believed that it would be unsafe to perform outpatient TKA for Medicare beneficiaries (see 77 FR 68419). CMS reminds readers of two principles of the IPO list that may be misunderstood by the public as it considers this proposal. First, just because the procedure is

not on the IPO list *does not* mean that the procedure cannot be performed on an inpatient basis. Second, the IPO status of a procedure has no effect on the MPFS payment for the procedure.

CMS specifically ask for public comment on 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 (i.e., is it related to codes that CMS has already removed from the IPO list) ?

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. How could CMS modify the Comprehensive Care for Joint Replacement (CJR) and the Bundled Payment for Care Improvements (BPCI) models if the TKA procedure were to be moved off the IPO list? In particular, CMS is seeking comment on how to reflect the shift of some Medicare beneficiaries from an inpatient to an outpatient TKA procedure in the BPCI and CJR model pricing methodologies, including target price calculations and reconciliation process. For example, CMS would need to ensure target prices account for potentially higher risk profiles of Medicare beneficiaries who would continue to receive TKA procedures in inpatient settings.

X. Nonrecurring Policy Changes

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

Section 603 of the Bipartisan Budget Act of 2015 (Public Law 114–74) excludes from the definition of covered OPD services "applicable items and services" furnished on or after January 1, 2017 by certain off-campus outpatient departments of a provider (generally those that did not furnish billed covered OPD services before November 2, 2015) and provides for payment for those services furnished by what CMS refers to in the rule as off-campus provider-based departments (PBDs) under a Part B payment system other than the OPPS ("applicable payment system" under Part B). CMS proposes to implement section 603 as follows:

(1) To create and define the term "excepted items and services" to determine whether items

and services are excepted from the section 603 applicable payment system policy and paid under the OPPS.
(2) To define off-campus PBDs and establish requirements for those off-campus PBDs to maintain excepted status (both for the facility and for the items and services it furnishes).
(3) To establish payment policies for nonexcepted items and services.

Under the proposal, all excepted off-campus PBDs may continue to bill for excepted items and services under the OPPS, including those furnished in an emergency department (ED), in an on-campus PBD, or within the distance (250 yards) from a remote location of a hospital facility.

CMS notes that there is no legislative history to guide their implementation of section 603, but it observes that the Congressional Budget Office scored the provision as saving $9.3 billion over a 10-year budget period.

Definition of Excepted Items and Services (§419.48)

CMS proposes to add a new section 419.48 to the regulations to define the term "excepted items and services" as those items and services furnished on or after January 1, 2017 that are:
(a) Furnished in a dedicated emergency department (as defined in §489.24(b) of the regulations[7]), or
(b) Furnished by an off-campus PBD that meets all of the following requirements:
    a. The PBD submitted a bill for a covered OPD service before November 2, 2015.
    b. The items and services are furnished at the **same location** that the department was furnishing such services as of November 1, 2015.
    c. The items and services are **in the same clinical family of services** as the services that the department furnished before November 2, 2015.

Emergency Department (ED). CMS proposes that all items and services furnished in an ED would continue to be paid under the OPPS. CMS also proposes to define "applicable items and services" (for which payment would not be made under the OPPS) as all items and services not furnished by a dedicated ED.

Definition of Off-Campus PBD (§419.48(b))

CMS proposes to add a new paragraph (v) to §419.22 that, beginning January 1, 2017, would

[7] §489.24(b) defines an emergency department 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: (1) It is licensed by the State in which it is located under applicable State law as an emergency room or emergency department; (2) 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** (3) 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.

exclude payments for hospitals services from the OPPS provided by an off-campus provider-based department (as defined at §419.48(b)) that does not meet the definition of excepted items and services under §419.48(a) (see above for definitions). Thus, if an off-campus PBD fails to meet all three proposed requirements under §419.48(b) (i.e., billing for covered OPD services before November 2, 2015; same location; and same clinical family of services), it would no longer be paid for those hospital services under the OPPS.

On-Campus Locations. CMS proposes that on-campus PBDs and the items and services furnished by them would continue to be paid under the OPPS. CMS notes that the definition of the term department of a provider (as in effect on November 2, 2015) includes both the specific physical facility that is the site of service and the personnel and equipment required to furnish services at the facility. CMS does not propose to change the definition of campus under §413.65(a)(2) and believes hospitals may adequately determine whether departments are on campus, including through the provider-based attestation process. CMS may issue further guidance on provider-based attestations. However, CMS does not propose to require attestation for PDBs.

Distance from Remote Locations. Section 603 also provides for an exception for off-campus PBDs that are within the distance described in the definition of campus under §413.65(a)(2). Thus CMS proposes to except those off-campus PBDs located at or within 250 yards from a remote location of a hospital facility. CMS notes that hospitals should use surveyor reports or other documentation to ensure off-campus PBDs are within 250 yards (straight-line) from any point of a remote location.

Relocation. Section 603 provides that an off-campus PBD that billed for a covered OPD service before November 2, 2015 would continue to be paid under the OPPS. The statute does not address the issue of relocation that was of utmost concern to commenters. CMS interprets the exception for certain off-campus PBDs under section 1833(t)(21)(B)(ii) of the Act as applying to those facilities as they existed on that date, including items and services furnished and billed by the PBD before that date. CMS proposes a strict general rule that an excepted off-campus PBD would lose its excepted status if it is moved or relocated from the physical address (including a change in the unit number of the address) listed on the provider's hospital enrollment form as of November 1, 2015.

CMS acknowledges that some circumstances may require a facility move, such as natural disasters or federal or state requirements. **It seeks comment on whether it should develop a "clearly defined, limited relocation exception process, similar to the disaster/extraordinary circumstance exception process under the Hospital VBP program." CMS also seeks comment on other circumstances beyond the control of the hospital for additional exceptions.** CMS does not address the issue of relocations planned or begun (but not completed) by November 2, 2015.

Expansion of Clinical Family of Services. Stakeholders also expressed a desire to expand the number or type of services that an excepted off-campus PBD could furnish and still maintain excepted status. Again, CMS believes the statute requires a reading that to maintain excepted

status an off-campus PBD is limited to offering services only within the clinical family of services it furnished before November 2, 2015. CMS proposes to clarify that services furnished that are not part of the clinical family of services furnished and billed before November 2, 2015, would not be payable under the OPPS.

CMS proposes to define service types by 19 clinical families of hospital outpatient service types described in Table 21 of the proposed rule and reproduced below:

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

CMS also proposes that if an excepted off-campus PBD billed for any specific service within a clinical family of services before November 2, 2015, the clinical family of services would be eligible for OPPS reimbursement. Addendum B to the proposed rule shows a map of HCPCS codes to each clinical family of services. CMS considered but did not propose to require a specific timeframe during which service lines had to be billed under the OPPS (e.g., 2013 through November 1, 2015); **it seeks comment on this policy**. CMS does not propose to limit the volume of services furnished within a clinical family of services that the hospital billed before November 2, 2015, and **it seeks comment on this issue as well as on its proposal for clinical families of services generally**. All items and services furnished by a nonexcepted off-campus PBD and those nonexcepted items and services furnished by an excepted off-campus PBD would be considered applicable items and services and thus would not be reimbursed under the OPPS.

Change in Ownership. CMS notes that current policy provides that if a participating hospital, in its entirety, is sold or merged with another hospital, a PBD's provider-based status generally transfers to the new ownership if the transfer does not result in material change of the provider-based status. Consistent with that policy, CMS proposes that the excepted status of an off-campus PBD would transfer to new ownership only if (1) the main provider is also transferred, and (2) 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 them would lose their excepted status. CMS also proposes that an individual excepted off-campus PBD that is transferred from one hospital to another would lose its excepted status. **CMS seeks comments on these proposals**.

Data Collection. CMS notes that while hospitals identify names and addresses of off-campus PBDs under the Medicare enrollment process, the PBDs bill under the CMS Certification Number (CCN) of the hospitals. CMS notes that currently it is unable to automate a process to link hospital enrollment information to claims processing information to identify items and services specific to off-campus PBDs. **CMS seeks comment on whether it should require hospitals to separately identify (1) all individual excepted off-campus PBD locations, (2) the date each such PBD began billing, and (3) the clinical families of services provided by each such PBD before November 2, 2015.** CMS notes that if it proceeds with this requirement, it would collect the information through a new form available on the CMS website.

Payment for Nonexcepted Off-Campus PBDs

CMS observes that the statute calls for applicable items and services to be paid for under the "applicable payment system" under Part B, but the law does not describe or define what applicable payment system means (other than it is not the OPPS). CMS also observes that rules regarding provider and supplier enrollment, conditions of participation, coverage, payment, billing, cost reporting, and coding vary across the institutional payment systems. While CMS intends to develop a mechanism for an off-campus PBD to bill and be paid for furnishing nonexcepted items and services under the "applicable payment system," it states that there is no straightforward way to do that before January 1, 2017. The Multi-Carrier System (used to process physician and other supplier claims) does not accept or process institutional OPPS claims; CMS states it needs additional time to make significant changes to complex systems.

Physicians' Services. CMS proposes to use the Medicare Physician Fee Schedule (MPFS) as the applicable payment system for the majority of nonexcepted services furnished during 2017. It proposes that physicians furnishing services in off-campus PBDs would be paid based on the professional claim and at the nonfacility rate for services for which they are permitted to bill.

Facility Services. CMS proposes that there would not be a separate facility payment to the hospital for non-excepted services furnished during 2017. CMS does not believe there is a way for off-campus PBDs to bill for those nonexcepted services furnished during 2017 and notes it is exploring options to permit billing for these services beginning in 2018. Under the Provider Enrollment, Chain and Ownership System (PECOS), hospitals may only submit institutional

claims for payment of covered OPD services under the OPPS using the hospital CCN; hospitals do not meet requirements to bill under other payment systems. CMS believes it may be necessary to establish a new provider/supplier type for nonexcepted off-campus PBDs to bill and be paid under the MPFS using the professional claim. CMS does not propose new mechanisms to permit off-campus PBDs to bill and be paid for nonexcepted services as currently enrolled as a hospital-based department. **CMS solicits comments on changes required to enrollment forms, claims forms, hospital cost reports, as well as operational changes to permit off-campus PBDs to bill for these services to ensure accurate payments and minimize burden on providers and beneficiaries.** CMS will consider the comments in developing a new payment policy proposal for 2018.

CMS notes that a hospital may enroll a nonexcepted off-campus PBD as another provider or supplier type (such as an ASC or group practice) to meet the requirements of the non-OPPS Part B payment system involved, provided it meets all Medicare and other requirements.

Impact on Fraud and Abuse Laws and Other Requirements. CMS recognizes that its proposals may result in hospitals establishing business arrangements with physicians and nonphysician practitioners who bill under the MPFS. **CMS seeks comments on the impact of the reassignment rules (§424.73), the anti-markup prohibition (§414.50), and the physician self-referral prohibition (§§414.350 - 389) to compensation arrangements, as well as the anti-kickback statute (§1128B(b) of the Act) on arrangements, between hospitals and physicians and nonphysician practitioners**.

Laboratory Tests. Because some laboratory tests (e.g., molecular pathology lab tests, advanced diagnostic lab tests, lab tests that are preventive services, and lab tests that are the only service provided) are eligible currently for separate payment, CMS proposes that the hospital may continue to bill and be paid for those services under the clinical laboratory fee schedule. The claim may also be submitted under the MPFS by the practitioner if he or she meets all MPFS requirements. CMS notes that hospitals should report these laboratory services on a reimbursable cost center on the hospital cost report.

Partial Hospitalization Programs (PHPs). CMS notes that PHPs are furnished by a hospital to its outpatients or furnished by a community mental health center (CMHC). CMHCs are not eligible to be provider-based to a hospital; CMS notes 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.

Comments on Allowing Direct Billing and Payment for Nonexcepted Services.

CMS seeks comment on whether an off-campus PBD should be allowed to bill nonexcepted items and services on the professional claim (rather than the institutional claim) and receive payment under the MPFS, if the PBD meets all applicable MPFS requirements. The PBD would still be considered part of the hospital, and the hospital as a whole would continue to have to meet all applicable conditions of participation and regulations governing its provider-based

status. However, 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.

CMS seeks comments specifically on (1) administrative impediments for hospitals billing for such services, (2) the practical benefit of making administrative changes to permit the hospital to bill for these kinds of services under the MPFS, and (3) 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.

Beneficiary Cost-Sharing. CMS expects beneficiary cost-sharing for nonexcepted items and services would generally equal cost-sharing imposed for services provided at a freestanding facility.

Audits. CMS notes that audits of hospital billing will include an examination of whether off-campus PBDs are billing under the proper billing system. CMS 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 the agency and its contractors upon request.

Regulatory Impact

CMS states that its proposal does not impose any new information collection or recordkeeping requirements for 2017 and thus imposes no new burden on hospitals or providers.

CMS estimates a net reduction in Part B spending of $330 million in 2017 under its proposal. It estimates a reduction in OPPS payments of $500 million and an increase in payments under the MPFS of $170 million. The estimates reflect that reduced spending results in lower Part B premiums (which is slightly offset by lower aggregate Part B premium collections). CMS notes that the impact tables do not factor in changes in volume or service-mix in OPPS payments.

B. Changes for Payment for Film X-Ray

Section 502(b) of Division O, Title V of the Consolidated Appropriations Act, 2016 (Public Law 114–113) reduces payment under the OPPS by 20 percent for imaging services that are X-rays taken using film (including the X-ray component of a packaged service) furnished during 2017 and subsequent years. CMS proposes to establish a new modifier to be used on claims for these imaging services; beginning in 2017, hospitals must use this modifier for these claims. The applicable HCPCS codes describing these imaging services are found in Addendum B to the proposed rule (available on the CMS website).

Section 502(b) also reduces payment for imaging services that are X-rays using computed radiography (including the X-ray component of a packaged service) as follows:

- For such imaging services furnished during 2018 through 2022, by 7 percent.

- For such imaging services furnished during 2023 or a subsequent year, by 10 percent.

CMS will propose a modifier to be used for these claims in future rulemaking.
The payment reductions for these imaging services are applied before any other adjustment and are not implemented in a budget neutral manner.

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

CMS finalized the required CCM scope of service elements for hospitals to bill and receive OPPS payment for furnishing CCM services in the 2016 OPPS/ASC final rule. CMS is proposing what it describes as minor changes to certain CCM scope of service elements in the 2017 MPFS proposed rule that would also apply to CCM services furnished to hospital outpatients under the OPPS. For example, CMS proposes that electronic sharing of care plan information must be timely but not necessarily on a 24 hour a day/7 day per week basis. Please see the 2017 MPFS proposed rule, or the HPA summary of that rule, for further details.

D. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Section 218(b) of PAMA directs CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. CMS addressed the initial component of the AUC program, including specifying applicable AUC and establishing CMS authority to identify clinical priority areas for making outlier determinations in the 2016 MPFS final rule. (See 42 CFR 414.94.) The program's criteria and requirements are established and updated through MPFS rulemaking.

CMS notes 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 2017 MPFS proposed rule includes proposed requirements and processes for the second component of the Medicare AUC program: 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. The 2017 MPFS proposed rule also proposes specific clinical priority areas and exceptions to the AUC consultation and reporting requirements. Please see the 2017 MPFS proposed rule, or the HPA summary of that rule, for further details.

XI. CY 2017 OPPS Payment Status and Comment Indicators

Proposed 2017 OPPS Payment Status Indicator Definitions. For 2017, CMS proposes to revise the current definition of status indicator "E" by creating two new status indicators as follows:

- "E1" Specific to items and services not covered by Medicare; and
- "E2" Exclusive to items and services for which pricing information or claims data are not available.

The proposed 2017 status indicator assignments for APCs and HCPCS codes (displayed in Addendum A and Addendum B, respectively, to the proposed rule) and the complete list of proposed 2017 status indicators and their definitions (displayed in Addendum D1) are available from the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

Proposed Comment Indicator Definitions. For 2017, CMS proposes to use four comment indicators. CMS proposes to continue to use the same three comment indicators that are in effect for the 2016 OPPS ("CH", "NI", and "NP"), and to create a new comment indicator "NC." Comment indicator "NC" would be used in the final rule to indicate the HCPCS codes that were assigned to comment indicator "NP" in the proposed rule. Codes assigned the comment indicator "NC" in the final rule would not be subject to comment in the final rule. The four proposed comment indicators and their descriptions 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 CMS requested in the proposed rule, final APC assignment; comments will be not be accepted on the final APC assignment for the new code.

The definitions of the OPPS comment indicators for 2017 are listed in Addendum D2 to the proposed rule and are available at the CMS website hyperlink immediately above.

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

Summary of selected key elements of proposed ASC payment rates for 2017		
	ASCs reporting quality data	**ASCs not reporting quality data**
2016 ASC Conversion Factor	$44.190	
Wage index budget neutrality adjustment	0.9992	
Proposed 2017 Update		
CPI-U update	1.7%	
Multi-factor productivity adjustment (MFP)	-0.5%	
Net MFP adjusted update	1.2%	
Penalty for not reporting quality data	0.0%	-2.0%

Summary of selected key elements of proposed ASC payment rates for 2017		
Net MFP and quality adjusted update	1.2%	-0.8%
Proposed 2017 ASC Conversion Factor	$44.684	$43.801

CMS notes that the projections may be updated in the final rule based on more recent data. As with the rest of the OPPS proposed rule and other CMS rules, addenda related to the ASC section (and referenced in this summary) are available only on the CMS website, at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1656-P.html.

A. Background

CMS reviews the legislative history and regulatory policies regarding changes to the lists of codes and payment rates for ASC covered surgical procedures and covered ancillary services.

- Covered surgical procedures in an ASC are surgical procedures that are separately paid under the OPPS and that would not be expected to:
  - Pose a significant risk to beneficiary safety when performed in an ASC; or
  - Require an "overnight stay": active medical monitoring and care at midnight following the procedure.
- Separate ASC payments are made for selected ancillary items and services when they are provided integral to ASC covered procedures. Payment for ancillary items and services that are not paid separately are packaged into the ASC payment.
- ASC payments are based on the OPPS payment policies.
- CMS provides quarterly update change requests (CRs) for ASC services throughout the year and makes new codes effective outside the formal rulemaking process via these quarterly updates. The annual rulemaking process is used to solicit comments and finalize decisions.

B. Proposed Treatment of New and Revised Codes

CMS continues to 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 products, supplies, temporary procedures, and services not described by CPT codes.

CMS continues its policy to evaluate all new Category I and III CPT codes and Level II HCPCS codes that describe surgical procedures in order to make preliminary determinations during the annual rulemaking process about whether they meet the criteria for payment in an ASC setting, and if so, whether they are office-based procedures. CMS also identifies new and revised codes as ASC covered ancillary services based on the final payment policies in the revised ASC payment system.

CMS sets out proposals for new codes in two categories:

- proposed treatment of codes previously identified during the year in the quarterly update process and on which it is seeking comments in this proposed rule; and
- a proposed process for new codes for which it will be seeking comments in the final rule with comment period.

CMS clarifies that it considers revised codes to be new when they have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator.

CMS sets out in Table 22 its process and timeline for updating codes through the quarterly update CRs, seeking public comment, and finalizing treatment of the new codes.

Comment and Finalization Timeframes for 2017 for New and Revised Category I and III CPT Codes and Level II HCPCS Codes (from CMS Table 22)				
ASC Quarterly Update CR	**Type of Code**	**Effective Date**	**Comments Sought**	**When Finalized**
April 1, 2016	Level II HCPS Codes	April 1, 2016	2017 OPPS/ASC proposed rule	2017 OPPS/ ASC final rule with comment
July 1, 2016	Level II HCPCS codes Category 1 (certain vaccine codes) and III CPT codes	July 1, 2016		
October 1, 2016	Level II HCPCS Codes	October 1, 2016	2017 OPPS/ ASC final rule with comment	2018 OPPS/ ASC final rule with comment
January 1, 2017	Level II HCPCS Codes	January 1, 2017		

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

CMS, in April and July of 2016 change requests (CRs), made effective 19 new Level II HCPCS codes and 9 new Category III CPT Codes describing covered ASC services that were not included in the 2016 OPPS final rule. Tables 23-25 copied below set out the codes, descriptors, and proposed 2017 payment indicators.

New Level II HCPCS Codes for Covered Surgical Procedures for Covered Ancillary Services Implemented in April 2016 (Table 23)		
2016 HCPCS Code	**2016 Long Descriptor**	**Proposed 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 injection, 1 mg	K2
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
New Level II HCPCS Codes for Covered Ancillary Services Implemented in July 2016 (Table 24)		
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 F 18, 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 was deleted on June 30, 2016 and replaced with HCPCS Code Q9982 effective July 1,2016 **HCPCS Code C9458 was deleted on June 30, 2016 and replaced with HCPCS Code Q9983 effective July 1, 2016		

New Category III CPT Codes For Covered Surgical Procedures or Covered Ancillary Services Implemented in July 2016 (CMS Table 25)		
2016 CPT Code	**2016 Long Descriptor**	**Proposed 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, periprostatic (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 was deleted on June 30, 2016 and replaced with CPT code 0438T effective July 1, 2016.		

CMS notes that the proposed payment rates, where applicable can be found in Addendum BB to the proposed rule at the CMS website referenced above. **CMS solicits comments on these proposals.**

Proposed Process for Recognizing New and Revised Category I and Category III CPT Codes That Will Be Effective January 1, 2017 for Which CMS is Accepting Comments in This 2017 Proposed Rule

For new and revised Category I and III CPT codes effective January 1, 2017 that are received in time to be included in the proposed rule, CMS proposes Ambulatory Payment Classification (APC) and status indicator assignments, as well as proposed payment rates. Such codes are assigned new comment indicator "NP". Those new and revised codes are listed in Addendums

AA and BB, and the long descriptors are in Addendum O at the ACS website. **CMS seeks comments and proposes to finalize the payment indicators in the 2017 final rule.**

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

CMS proposes to continue to assign comment indicator "NI" in Addendum B to the 2017 OPPS/ASC final rule with comment for those new and revised Level II HCPCS codes that are effective October 1, 2016 and January 1, 2017. They will be included in Addendum B to that final rule.

CMS will invite public comments in that 2017 final rule with comment period, with the proposed status indicators, APC assignments and payment rates finalized in the 2018 OPPS/ASC final rule.

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

Covered Surgical Procedures Designated as Office-Based

CMS annually reviews volume and utilization data to identify "office-based" procedures that are added to the ASC list of covered surgical procedures and are performed more than 50 percent of the time in physicians' offices and that CMS' medical advisors believe are of a level of complexity consistent with other procedures performed routinely in physicians' offices.

Based on its review of 2015 data, CMS proposes to permanently designate one additional procedure as office-based: CPT Code 0377T (Anoscopy with directed submucosal injection of bulking agent for fecal incontinence), with proposed payment indicator of "R2" in 2017. **CMS invites comment on the proposal.**

CMS also reviews 2015 volume and utilization data for the eight procedures finalized for temporary office-based status in last year's final rule. CMS found that there were very few or no claims data for these procedures, and proposes to maintain the temporary office-based designations for these eight codes for 2017. Table 27 in the proposed rule lists the procedures and CMS' proposed payment indicators for 2017.
CMS proposes to designate two new 2017 codes for ASC covered surgical procedures as temporarily office-based. Because CMS has no utilization data, it proposes to make the office-based designations temporary. Table 28 provides the proposed codes. **CMS invites public comment.**

ASC Covered Surgical Procedures Designated as Device-Intensive – Finalized Policy for 2016 and Proposed Policy for 2017:

CMS previously implemented its APC policy under the OPPS under which comprehensive APCs

replaced most of the then-current device-dependent APCs. CMS did not, however, implement comprehensive APCs in the ASC payment system. CMS continued its policy that all separately paid ancillary services provided integral to surgical procedures that map to a comprehensive APC would continue to be separately paid under the ASC payment system instead of being packaged into the payment for the comprehensive APC as under the OPPS.

CMS continues using the standard OPPS APC rate-setting methodology to calculate the device offset percentage for purposes of identifying device-intensive procedures and to calculate payment rates for device-intensive procedures assigned to comprehensive APCs. CMS defines an ASC device-intensive procedure as one that is assigned to any APC with a device offset percentage greater than 40 percent based on the standard OPPS APC rate setting methodology.

However, CMS in the 2016 rulemaking cycle also solicited and received comments about calculating device intensity at the HCPCS level rather than at the APC level, but finalized no changes. CMS now believes that it is no longer appropriate to designate ASC device-intensive procedures based on APC assignment, because APC groupings of clinically similar procedures do not necessarily factor in device cost similarity.

CMS proposes for 2017 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 an ASC device-intensive procedure, and proposes to modify 42 CFR 416.171(b)(2) to reflect that change.

In addition, CMS proposes that for new HCPCS codes requiring the implantation of medical devices that do not yet have associated claims data, it would 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. The purpose of the proposal is to ensure ASC access for new procedures until claims become available. CMS notes that in certain rare instances, such as very expensive implantable device, it may apply a higher offset percentage if warranted by additional information provided by a manufacturer.

For 2017, CMS proposes to update the ASC list of covered surgical procedures that are eligible for payment according to the device-intensive payment methodology, consistent with its proposed revise definition of device-intensive procedures. Addendum AA at the CMS ACS website lists the procedures, including the CPT code and short-descriptor, the proposed 2017 payment indicator, device offset percentage, and an indication of the full credit/partial credit device adjustment policy that would apply.
CMS invites public comment on the proposed list.

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

CMS finalized a modification in payment for devices furnished with full or partial credit under the OPPS in the 2014 final rule, but there is no mechanism in the ASC claims processing system for ASCs to submit the actual amount received when furnishing a device without cost or with full or partial credit. CMS proposes to continue its policy for ASCs, for 2017:

- When the device is furnished at no cost or with full credit from the manufacturer, the contractor would reduce payment to the ASC by 100 percent of the device offset amount, which is the amount that CMS estimates as the cost of the device. The ASC would append the HCPCS "FB" modifier on the claim line with the procedure to implant the device.

- When the device is furnished with partial credit of 50 percent or more of the cost of the new device, CMS proposes that the contractor would reduce payments to the ASC by 50 percent of the device offset amount. In order to report a partial credit, the ASC would have the option of either submitting the claim after the procedure, but prior to manufacturer acknowledgement of credit for the device, and having the contractor make a claim adjustment, or holding the claim for payment until a determination is made by the manufacturer. The ASC would then submit the claim with a "FC" modifier if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the replacement device.

CMS proposes to continue to apply the full credit/partial credit policy to all device-intensive procedures in 2017. **CMS solicits comments on these proposals.**

Additions to the List of ASC Covered Surgical Procedures

CMS conducted its annual review of procedures paid under the OPPS but not included on the list of covered ASC procedures. CMS proposes to add eight procedures to the list of covered surgical procedures that could meet the standards for inclusion – that is, they could be safely performed in the ASC setting and would not require an overnight stay. The eight proposed additions are provided in Table 29. CMS notes that, as in prior years, this update includes review of procedures proposed for removal from the OPPS inpatient list for possible inclusion on the ASC list of covered surgical procedures. Three of the eight proposed additions to the list of ASC covered surgical procedures are procedure codes that are proposed from removal from the OPPS inpatient list. Those are CPT codes 22840, 22842, and 22845 which are presented in Table 29. Based on its review, three other codes proposed for removal from the OPPS inpatient list (CPT codes 22858, 31584 and 31587) are not proposed for inclusion for the ASC list because the procedures would generally be expected to require at least an overnight stay

Covered Ancillary Services:

CMS proposes to update the ASC list of covered ancillary services to reflect the payment status for the services under the OPPS. ASC covered ancillary services and their payment indicators for 2017 are included in Addendum BB at the ASC website. **CMS invites comments.**

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

Payment for Covered Surgical Procedures; Proposed Update to ASC Covered Surgical Procedure Payment Rates for 2017

CMS proposes to update payments for office-based procedures and device-intensive procedures using its previously established methodology, and using its proposed modified definition for device-intensive procedures. CMS notes that because the proposed OPPS relative payment weights are based on geometric mean costs for 2017 and subsequent years, the ASC system will use geometric means to determine the proposed relative payment weights under the ASC standard methodology. CMS would update the payment amount for the service portion of device-intensive procedures using the ASC standard ratesetting methodology, and the payment amount for the device portion based on the proposed 2017 OPPS device offset percentages. CMS would make payment for office-based procedures at the lesser of the proposed 2017 MPFS nonfacility PE RVU-based amount, or the proposed 2017 ASC payment amount calculated according to the standard methodology. CMS proposes to continue its policy for device removal procedures – such procedures that are conditionally packaged in the OPPS would be assigned the current ASC payment indicators and continue to be paid separately under the ASC payment system. **CMS invites comment on the proposal.**

Payment for Covered Ancillary Services

CMS proposes to update payments and make changes necessary to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services. CMS also proposes to continue to set payment methodologies for brachytherapy services and separately payable drugs and biologicals equal to the proposed 2017 OPPS rates.

CMS proposes to continue to base payment for separately payable covered radiology services based on the lower of the 2017 MPFS nonfacility PE RVU-based amounts and the proposed 2017 ASC rate calculated under standard ratesetting methodology (except in the case of nuclear medicine procedures and services that use contrast agents). If the radiology service is packaged or conditionally packaged under the OPPS, payment for the radiology service would be packaged into the payment for the ASC. Addendum BB indicates the payment status for each radiology service.

In the case of nuclear medicine procedures designated as radiology services paid separately when provided integral to a surgical procedure on the ASC list, CMS proposes to continue to set payments based on the OPPS relative payment weights, and therefore would include the cost of the diagnostic radiopharmaceutical. In the case of radiology services that use contrast agents, CMS proposes to continue to set payment based on the OPPS relative payment rate, and will, therefore, include the cost of the contrast agent.

CMS proposes to continue to not make separate payment for procurement of corneal tissue when used in any noncorneal transplant procedure.

With regards to contractor-priced codes, CMS proposes 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. In addition, consistent with its established ASC payment policy, CMS proposes that the 2017 payment for devices that are eligible for pass-through payment under the OPPS would be separately paid under the ASC payment system and contractor-priced. The four devices eligible for pass-through payment in the OPPS are HCPCS codes C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system); HCPCS code C2613 (Lung biopsy plug with delivery system); C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser); C2613 (Lung biopsy plug with delivery system); and C2624 (Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components).

Consistent with its current policy, CMS proposes that certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS be covered ancillary services when they are integral to an ASC covered surgical procedure. CMS proposes to pay for the tests at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard rate-setting methodology. CMS identifies no new codes that meet this criterion for 2017.

E. New Technology Intraocular Lenses (NTIOL)

CMS did not receive any requests for review to establish a new NTIOL class for 2017 by the March 1, 2016 deadline. CMS is not proposing any change to its payment adjustment of $50 per lens for a 5-year period from the implementation date of a new NTIOL class.

F. Proposed ASC Payment and Comment Indicators

CMS proposes to continue using the current comment indicators “NP” and “CH.” CMS proposes that Category I and III CPT codes that are new and revised for 2017 and any new and existing Level II HCPCS codes with substantial revisions would be labeled with the new comment indicator ‘NP” to indicate that these codes are open for comment as part of this 2017 proposed rule.
Addenda DD1 and DD2 provide a complete list of the ASC payment and comment indicators proposed for 2017. CMS will respond to public comment on the proposed payment and comment indicators and finalize their ASC assignment in the final rule.

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

Updating the ASC Relative Payment Rates for 2017 and Future Years

CMS proposes to continue to update relative weights using the national OPPS relative weights and the MPFS nonfacility PE RVU-based amounts when applicable. CMS proposes to scale the relative weights as under prior policy. Holding ASC use and mix of services constant from 2015, CMS computes the ratio of:

- Total payments using the 2016 relative payment rates, to
- Total payments using the 2017 relative payment rates.

The resulting ratio, 0.9030, is the proposed weight scaler for 2017. The scaler would apply to the payment for covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes for which the ASC payments are based on OPPS relative weights. The scaler would not apply to ASC payments for separately payable covered ancillary services that have a predetermined national payment amount and are not based on OPPS relative payment weights. That includes drugs and biologicals that are separately paid, and services that are contractor-priced or paid at reasonable cost in ASCs.

Updating the ASC Conversion Factor

CMS proposes to compute the budget neutrality adjustment factor for changes in wage index values as under prior policy. Holding constant ASC use and mix of services in 2015 and the proposed 2017 national payment rates after application of the weight scalar, CMS proposes to compute the ratio of:

- ASC payments using the 2016 ASC wage indices, to
- ASC payments using the 2017 ASC wage indices.

The resulting ratio, 0.9992, is the proposed wage index budget neutrality adjustment for 2017.

CMS proposes to continue its policy of updating the conversion factor by the CPI-U estimated for the 12-month period ending with the mid-point of 2017. CMS uses the IHS Global Insight (IGI) 2016 first quarter forecast, which yields a projected CPI-U update of 1.7 percent and a multifactor productivity adjustment of -0.5 percent.

That yields a proposed update of 1.2 percent for ASCs meeting quality reporting requirements. CMS proposes to continue its policy of reducing the update by 2.0 percentage points for ASCs not meeting the quality reporting requirements, yielding an update of -0.8 percent (a 0.992 update factor) for such ASCs. CMS notes that, as in prior years, it proposes to revise the updates if more current CPI-U or MFP data are available when the final rule is issued.
The resulting 2017 ASC conversion factor proposed by CMS is $44.684 for ASCs reporting quality data, and $43.801 for those that do not, computed as follows:

	ASC reporting quality data	**ASC not reporting quality data**
2016 ASC conversion factor:	$44.190	
Wage adjustment for budget neutrality	x 0.9992	
Net MFP-adjusted update	x 1.012	x 0.992
Proposed 2016 ASC conversion factor	$44.684	$43.801

Impact

CMS sets out estimated aggregate increases by surgical specialty group for the six groups that account for the most ASC utilization and spending in Table 31 of the proposed rule, replicated below, which assumes the same mix of services as reflected in 2015 claims data.

The eye and ocular adnexa group remains the largest source of payments, with a 1 percent increase attributable to the proposed payment changes in 2017. The second largest group, digestive system, is estimated to see a 1 percent decrease.

Summary of Table 31: Aggregate Proposed 2017 Medicare Program Payments by Surgical Specialty, for the six largest groups		
Surgical Specialty Group	**Estimated 2016 ASC Payments (in Millions)**	**Estimated 2017 Percent Change**
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%

Notes: The six items total $3,860 million, $160 million less than the total provided. The difference is presumed to be spending for specialty groups with lower volume and spending that were included in the table in previous years but not included this year: respiratory system, cardiovascular system, ancillary items and services, auditory system and hematologic & lymphatic systems. CMS states in the text that the costs of separately payable covered ancillary items and services is estimated to be $32 million for 2016.

CMS sets out estimated increases for 30 selected procedures in Table 32 in the proposed rule; the top 10 procedures are replicated below. CPT code 66984 (Cataract surgery with intraocular lens, 1 stage) is the largest aggregate payment procedure by far, and is estimated to see a 1 percent decrease.

Excerpt from Table 32: Estimated Impact of the Proposed 2017 Update to the ASC Payment System on Aggregate Payments for the top 10 procedures			
CPT/ HCPS Code	**Short Descriptor**	**Estimated 2016 ASC Payments (in Millions)**	**Estimated 2017 Percent Change**
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%

Excerpt from Table 32: Estimated Impact of the Proposed 2017 Update to the ASC Payment System on Aggregate Payments for the top 10 procedures			
CPT/ HCPS Code	**Short Descriptor**	**Estimated 2016 ASC Payments (in Millions)**	**Estimated 2017 Percent Change**
63685	Insert redo spine n generator	$82	2%
64493	Inj paravert f jnt 1/s 1 lev	$71	-16%
63650	Implant neuroelectrodes	$66	14%
66821	After cataract laser surgery	$65	3%
See Table 32 for full list of 30 procedures.			

As noted at the beginning of this ASC section, Addenda tables available only on the website provide additional details; they are at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1656-P.html.

- AA -- Proposed List of ASC Covered Surgical Procedures for 2017 (Including surgical procedures for which payment is packaged)
- BB -- Proposed ASC Covered Ancillary Services Integral to Covered Surgical Procedures for 2017 (Including Ancillary Services for Which Payment is Packaged)
- DD1 -- Proposed ASC Payment Indicators for 2017
- DD2 -- Proposed ASC Comment Indicators for 2017
- EE -- Surgical Procedures Proposed to be Excluded from Payment in ASCs for 2017

XIII. Hospital Outpatient Quality Reporting Program Updates

CMS proposes changes to the Hospital Outpatient Quality Reporting (OQR) Program including adoption of seven new measures beginning with the 2020 payment determination. In addition, a change is proposed to the deadline for extraordinary circumstances exemptions. A summary table at the end of this section shows all adopted and proposed OQR Program measures for the 2014 through 2020 payment determinations.

A. Background

CMS reviews the history of the various quality reporting programs currently in place and discusses its goal of aligning clinical quality measures across these programs, including the OQR Program.

No changes are proposed to existing policies regarding the retention and removal of OQR Program measures. As established under the CY2013 OPPS final rule, once a measure is adopted for the Hospital OQR Program for a payment determination year it is automatically adopted for subsequent years until CMS removes, suspends, or replaces it. In this rule, no measures are proposed for removal. Previously, CMS adopted 23 measures for the 2017 payment determination, and 25 mandatory (plus 1 voluntary) measures for the 2018 and 2019 payment determinations.

B. New Measures Beginning with the 2020 Payment Determination

CMS proposes seven new OQR Program measures to begin with the 2020 payment determination. Two are claims-based measures and five are measures from the Outpatient and Ambulatory Surgery Center Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey, which hospitals would have to begin to collect and report via a CMS-approved vendor. For the two proposed claim measures and the OAS CAHPS the proposed rule discusses the rationale for the measure, data sources, the measure calculation, cohort, and risk adjustment.

1. Admissions and Emergency Department Visits for Patient Receiving Outpatient Chemotherapy Treatment

This claims-based measure aims to reduce the number of potentially avoidable inpatient admissions and ED visits among cancer patients receiving chemotherapy in the OPD. It includes calculation of two mutually exclusive outcomes within 30 days of chemotherapy in the OPD:

(1) one or more inpatient admissions, and
(2) one or more ED visits for any of ten diagnoses (anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia or sepsis).

An individual patient will only be counted toward one outcome, and a patient experiencing both would count only in the inpatient admission score. CMS says that both adverse events are signals of quality and important patient outcomes, but should be treated separately because the severity and cost of an inpatient admission is greater than an ED visit.

The two components of the measure would each be risk standardized rates calculated as the ratio of predicted to expected outcomes multiplied by the national observed rate. CMS notes that the Measure Applications Partnership (MAP) conditionally supported the measure pending NQF endorsement with special consideration for sociodemographic status (SDS) adjustments and the selection of exclusions. CMS repeats its past concern that risk adjustment for SDS could minimize incentives to improve outcomes of disadvantaged populations, and notes again that it is monitoring the work of the Assistant Secretary for Planning and Evaluation on the impact of SDS on quality measures.

The proposed performance period for this measure is one year; claims data for patients receiving OPD chemotherapy during calendar year 2018 would be used for the 2020 payment determination. CMS cites literature supporting the need for the measure and for selecting 30 days as the window, and provides the following link to additional details on the measure calculation including risk adjustment: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

2. Hospital Visits after Hospital Outpatient Surgery (NQF #2687)

The second proposed claims-based measure addresses hospital visits after same-day surgery in the OPD. The specific outcomes measured are inpatient admissions directly after the surgery and unplanned hospital visits defined as an ED visit, observation stay, or unplanned hospital

admission within 7 days of the surgery. If more than one unplanned hospital visit occurs, only the first visit is counted in the measure. Information on measure methodology, including risk adjustment is available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

Same day surgeries are substantive surgeries and procedures on Medicare's covered list of ASC procedures, excluding eye surgeries. Eye surgeries are excluded because the risk profile is more representative of minor surgery. The ASC list for 2016 is included in ASC 2016 Addendum AA available 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.

This proposed measure was endorsed by the NQF in September 2015; the MAP supported the inclusion of this measure in the OQR but noted that the NQF endorsement occurred prior to the start of the SDS trial period and should be re-examined during measure maintenance to determine whether SDS adjustments are needed. CMS repeats its long-standing position regarding risk adjustment for SDS, as summarized above.

3. Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems

The OAS CAHPS survey contains 37 questions that cover access to care, communications, experience at the facility, and interactions with facility staff. Global ratings and demographic information are also collected. Voluntary implementation of the OAS CAHPS began in January 2016. More information can be found on the OAS CAHPS Survey website at https://oascahps.org/.The survey questions can be found under the "Survey Materials" tab.

Five OAS CAHPS-based measures are proposed for addition to the OQR program for 2020 payment. (The same measures are proposed for addition to the ASC Quality Reporting Program, as discussed in section XIV below.) The proposed measures are listed here and include three composite measures, each of which consist of at least 6 OAS CAHPS survey questions, and two global rating measures, involving one survey question each. More information about the OAS CAHPS and these measures, including the survey cohort and risk adjustment, can be found at the OAS CAHPS Survey website noted above.

- OP-37a: OAS CAHPS – About Facilities and Staff
- OP-37b: OAS CAHPS – Communication About Procedure
- OP-37c: OAS CAHPS – Preparation for Discharge and Recovery
- OP-37d: OAS CAHPS – Overall Rating of Facility
- OP-37e: OAS CAHPS – Recommendation of Facility.

The OAS CAHPS is not NQF-endorsed, but CMS says it will be submitted under an applicable call for measures "in the near future." The MAP encouraged continued development of the measures, although CMS says that subsequent to the MAP submission the five measures were "fully developed." CMS reports that stakeholder input on the survey was received through a January 2013 request for information (78 FR 5460) and through a Technical Advisory Panel.

CMS notes that the OAS CAHPS survey includes two questions regarding pain management which would be included in the proposed communications composite measure. Section XIX of this summary describes a CMS proposal to remove the pain management dimension (involving three survey questions) from the inpatient hospital patient survey (HCAHPS) for purposes of performance scoring in the hospital VBP Program. In this part of the proposed rule CMS discusses why it believes the proposed OAS CAHPS pain management questions are very different from the HCAHPS. In particular, CMS says the OAS CAHPS questions do not address the adequacy of the hospital's pain management efforts and the proposed OAS CAHPS would be used only for public reporting so that hospital payment would not be affected by performance on these measures. Nonetheless, CMS understands there are concerns about pain management questions in light of the ongoing prescription opioid overdose epidemic and it welcomes feedback on the questions for possible future revisions to the survey. CMS will continue to evaluate the appropriateness and responsiveness of these questions to patient experience and public health concerns.
The current specific pain management questions on the OAS CAHPS are as follows:

> 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?
> A1: Yes.
> A2: No.

With respect to the second question, CMS notes that this is a control question used to determine whether the hospital should have given the patient additional guidance on how to handle pain after leaving the facility. It says the facility is not scored on this question.

Administering and Scoring the OAS CAHPS Survey

Hospitals would be required to contract with a CMS-approved vendor to collect survey data on a monthly basis for quarterly reporting to CMS. Hospitals may elect to also collect data on up to 15 supplemental questions. For the 2020 payment determination, data would be collected during calendar year 2018; the performance period would generally be the calendar year 2 years prior to the affected payment year. Nondiscrimination requirements for effective communication with persons with disability and language access for persons with limited English proficiency would apply (http://www.hhs.gov/civil-rights).

Hospitals would be required to survey a random sample of eligible patients each month. The OAS CAHPS Protocols and Guidelines Manual lists acceptable sampling methods (https://oascahps.org/Survey-Materials). Over each 12-month reporting period, hospitals would be required to collect at least 300 completed surveys (an average of 25 per month). As discussed

below, low-volume hospitals could apply for an exemption but absent an exemption, smaller hospitals that cannot collect 300 completed surveys over a 12-month reporting period would only be required to collect as many completed surveys as possible during that time period without sampling, that is, by surveying all eligible patients.

Hospital eligibility to perform the OAS CAHPS Survey would be determined at the individual Medicare participating hospital level. All data collection and submission, and also public reporting, for these 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.

CMS proposes an exemption from the OAS CAHPS Survey-based measures for hospitals that treat fewer than 60 survey-eligible patients during an "eligibility period," which is the calendar year before the data collection period (e.g., calendar year 2017 for the 2020 payment determination). Hospitals may submit a participation exemption request form, on the https://oascahps.org website by May 15 of the data collection calendar year (e.g., May 15, 2018 for the 2020 payment determination).

Other requirements for administration of the OAS CAHPS survey are discussed in item XIII.D.2 below.

Scores for public reporting purposes would be based on "top box" responses ("Yes" or "Yes Definitely"). For each composite measure, the percentage of top box responses for each survey question would be calculated. These would be summed across all the survey questions for that composite and then divided by the number of survey questions in that composite to obtain the raw measure score. The raw score would be risk adjusted for patient characteristics such as age, education, overall health status, mental status, type of surgical procedure and English proficiency.

CMS intends to propose a format and timing for public reporting of OAS CAHPS Survey data in future rulemaking prior to implementation of the measures. It intends to use data from this voluntary national implementation which began in January 2016 to inform the displays for public reporting of OAS CAHPS Survey data.

4. Possible Hospital OQR Program Measure Topics for Future Consideration

With respect to possible future measures, CMS seeks comment on outcome rather than process of care measures and implementation of electronic clinical quality measures (eCQMs). In particular, CMS indicates that it is in the early development of a new eCQM for that would measure the proportion of adults who have an active prescription for an opioid and have additional opioids or benzodiazepine prescribed to them during a care encounter. CMS seeks comments on this measure concept specifically for the OPD setting, but is also developing the measure for the hospital Inpatient Quality Reporting Program.

C. Administrative and Data Submission Requirements and Public Reporting

1. Continuation of Policies

CMS describes but proposes no changes to policies related to the following: the QualityNet account and security administrator; requirements regarding participation in the OQR program; data submission deadlines; requirements for reporting chart-abstracted measures; requirements for claims-based measures, which would also apply to the two additional claims-based measures proposed for addition to the OQR program beginning with 2020 payment; requirements for measures submitted via a web-based tool; population and data sampling requirements; and data validation requirements.

2. Data Submission Requirements for the Proposed OAS CAHPS Measures

For the proposed new OAS CAHPS measures, CMS proposes that hospitals meet the following requirements:

- Contract with a CMS-approved OAS CAHPS Survey vendor to administer the survey. A list of approved vendors is available at the OAS CAHPS website (https://oascahps.org). Hospitals would register on that website to authorize the CMS-approved vendor to administer the survey and submit data on their behalf.
- 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 and report the survey data to CMS on a quarterly basis by the deadlines posted on the OAS CAHPS Survey website.
- Through the vendor collect survey data via mail-only, telephone-only and mixed mail/telephone modes. Guidelines on these modes are available on the https://oascahps.org website under the Survey Materials tab.
- Initiate data collection no later than 21 days after the month in which a patient has a surgery or procedure at a hospital and complete it with 6 weeks (42 days) after initial contact of an eligible patient.
- Make multiple attempts to contact patients unless they refuse participation or are found to be ineligible.

The proposed OAS CAHPS Survey administration requirements for hospitals and survey vendors under the Hospital OQR Program would be codified in proposed new regulatory text at 42 CFR 419.46(g).

CMS encourages hospitals to participate in the voluntary implementation of OAS CAHPS that began in January 2016 and urges hospitals to be fully appraised of the methods and actions of their survey vendor and to inspect all data warehouse reports in a timely manner. CMS notes 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. To the extent that any existing CMS technical guidance conflicts with the TCPA, its implementing regulations, or any other applicable law, CMS expects vendors to comply with applicable law. Readers are referred 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.

3. Extension for Extraordinary Circumstances Exemption Request Deadline

CMS proposes to extend the extraordinary circumstances exemption (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 be effective with ECEs requested on or after January 1, 2017 for the 2019 payment determination. CMS believes that under some circumstances it may be difficult for hospitals to timely evaluate the impact of certain extraordinary events within 45 days. The proposed 90-day deadline would align with the ECE request deadlines for the Hospital VBP Program, the Hospital-Acquired Condition Reduction Program, and the Hospital Readmissions Reduction Program. In addition, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25205; 25233 through 25234), CMS proposed a similar 90 day deadline for the Hospital IQR Program and for the long term care hospital quality reporting program. A parallel proposal is made below with respect to the ASCQR Program.

4. Public Display of OQR Measures

CMS proposes to formalize its current practices regarding the timing of public display and the preview period. Specifically, CMS proposes to

- publicly display data on *Hospital Compare* Web or another CMS website, as soon as possible after measure data have been submitted to CMS;
- generally give hospitals approximately 30 days to preview their data; and
- announce the timeframes for the preview period starting with the CY 2018 payment determination on a CMS website or applicable listservs.

5. Clarification Regarding OQR Program Reconsideration and Appeals

The process by which participating hospitals may submit requests for reconsideration was previously codified at 42 CFR 419.46(f), and language at § 419.46(f)(3) addresses appeals to the Provider Reimbursement Review Board. In this proposed rule, CMS clarifies that if a hospital fails to submit a timely reconsideration request to CMS via the QualityNet website by the applicable deadline, the hospital will not subsequently be eligible to file an appeal with the Provider Reimbursement Review Board. This clarification is effective January 1, 2017 for the 2017 payment determination and subsequent years.

D. Payment Reduction for Hospitals That Fail to Meet the Hospital OQR Program Requirements for the 2016 Payment Determination

CMS proposes to continue for the 2017 update factor the existing policies with respect to computing and applying the payment reduction for hospitals that fail to meet the Hospital OQR Program requirements. The reduction ratio for hospitals that fail to meet OQR Program requirements, called the “reporting ratio”, is 0.98. It is calculated by dividing the proposed reduced conversion factor of $73.411 by the full conversion factor of $74.909. Continuing

previous policies, when applicable the reporting ratio is applied to all services calculated using the OPPS conversion factor. CMS proposes that it will be applied to all HCPCS codes to which CMS has assigned status indicators J1, J2, P, Q1, Q2, Q3, Q4, R, S, T, V, or U, excluding services paid under the New Technology APCs to which CMS has assigned status indicators S and T.

The reporting ratio would continue to be applied to the national unadjusted payment rates and minimum unadjusted and national unadjusted copayment rates of all applicable services. All other applicable standard adjustments to the OPPS national unadjusted payment rates would apply, and OPPS outlier eligibility and outlier payment would be based on the reduced payment rates. Beneficiaries and secondary payers share in the reduced payment to hospitals that are subject to the payment reduction.

E. Impact Analysis

In the Collection of Information Requirements and economic impact sections of the proposed rule, CMS discusses the potential effects of the OQR Program proposals on hospitals. The burden on hospitals associated with fielding and reporting the OAS CAHPS Survey are acknowledged, but no estimates are provided. Readers are referred to the 2016 final rule (80 FR 70582 through 70584) which does not appear to include any estimates associated with this proposed survey measure.

F. Summary Table of OQR Program Measures

The table below shows the proposed measures for the 2020 payment determination along with OQR measures previously adopted for payment determinations from 2014 through 2019. (In some cases measures were adopted but data collection suspended prior to the measure being removed. These measures are not listed here.) Specifications for previously adopted measures are available on the QualityNet website: https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1196289981244.

NQF		2014	2015	2016	2017	2018	2019	2020
0287+	OP-1: Median Time to Fibrinolysis (NQF 0287)	X	X	X	X	X	X	X
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED arrival	X	X	X	X	X	X	X
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention	X	X	X	X	X	X	X
0286+	OP-4: Aspirin at Arrival	X	X	X	X	X	X	X
0289+	OP-5: Median Time to ECG	X	X	X	X	X	X	X
	OP-6: Timing of Antibiotic Prophylaxis	X	X	X	Removed			
	OP-7: Prophylactic Antibiotic Selection for Surgical Patients	X	X	X	Removed			
0514	OP-8: MRI Lumbar Spine for Low Back Pain	X	X	X	X	X	X	X

NQF		2014	2015	2016	2017	2018	2019	2020
	OP-9: Mammography Follow-up Rates	X	X	X	X	X	X	X
	OP-10: Abdomen CT – Use of Contrast Material	X	X	X	X	X	X	X
0513	OP-11: Thorax CT – Use of Contrast Material	X	X	X	X	X	X	X
	OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC Certified EHR System as Discrete Searchable Data	X	X	X	X	X	X	X
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery	X	X	X	X	X	X	X
	OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)	X	X	X	X	X	X	X
0491+	OP-17: Tracking Clinical Results between Visits	X	X	X	X	X	X	X
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients	X	X	X	X	X	X	X
	OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional	X	X	X	X	X	X	X
0662	OP-21: ED- Median Time to Pain Management for Long Bone Fracture	X	X	X	X	X	X	X
0499+	OP-22: ED- Left Without Being Seen	X	X	X	X	X	X	X
0661	OP-23: ED- Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival	X	X	X	X	X	X	X
	OP-25: Safe Surgery Checklist Use	X	X	X	X	X	X	X
	OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures (see note below)	X	X	X	X	X	X	X
0431	OP-27: Influenza Vaccination Coverage among Healthcare Personnel			X	X	X	X	X
0658	OP-29: Appropriate Follow- up Interval for Normal Colonoscopy in Average Risk Patients			X	X	X	X	X
0659	OP-30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use			X	X	X	X	X

NQF		2014	2015	2016	2017	2018	2019	2020
1536	OP-31: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery			Adopted, then excluded	Voluntary			
2539	Op-32: Facility Seven Day Risk Standardized Hospital Visit Rate After Outpatient Colonoscopy					X	X	X
1822	OP-33: External Beam Radiotherapy for Bone Metastases					X	X	X
	OP-35 Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy							*Proposed*
2687	*OP-36 Hospital Visits After Hospital Outpatient Surgery*							*Proposed*
	OP 37a OAS CAHPS – About Facilities and Staff							*Proposed*
	OP-37b: OAS CAHPS – Communication About Procedure							*Proposed*
	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery							*Proposed*
	OP-37d: OAS CAHPS – Overall Rating of Facility							*Proposed*
	OP-37e: OAS CAHPS – Recommendation of Facility							*Proposed*

[+] CMS notes that NQF endorsement of these measures was removed.
Notes: For OP-26, procedure categories and corresponding HCPCS codes are shown in the Specifications Manual available at https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1196289981244
The proposed rule table of measures for 2020 incorrectly flags OP-30 as a voluntary measure.

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

In the 2012 OPPS/ASC final rule, CMS finalized the implementation of the ASCQR Program beginning with the 2014 payment determination. That rule finalized measures for the 2014, 2015 and 2016 payment determinations. In several subsequent rules, additional program requirements were finalized and additional measures were adopted through 2019.

A. ASCQR Program Measures

In this rule, CMS proposes seven new measures for addition to the ASCQR Program beginning in 2020; no changes are proposed to the previously adopted measures, which continue unless proposed for removal. The proposed new measures involve two web-based measures on which comments were sought in last year's rulemaking as possible future measures, and five ASC CAHPS measures that are also proposed in this rule for addition to the OQR Program. For the two proposed web-based measures and the OAS CAHPS the proposed rule discusses the rationale for the measure, data sources, the measure calculation, measure cohort and exclusions, and risk adjustment. Specifications for the two proposed web-based measures are available at http://ascquality.org/documents/ASC%20QC%20Implementation%20Guide%203.2%20October%202015.pdf.

1. Normothermia Outcome Measure

This proposed measure assesses the percentage of patients having surgical procedures under general or neuraxial anesthesia of 60 minutes or more in duration who are normothermic within 15 minutes of arrival in the post-anesthesia care unit. CMS discusses it views regarding the relevance of this measure to the ASCQR program because impairment of thermoregulatory control due to anesthesia may result in perioperative hypothermia, which is associated with numerous adverse outcomes including cardiac complications; surgical site infections; impaired coagulation; and colligation of drug effects. The proposed rule includes citations to a number of studies regarding these outcomes. The measure is not NQF endorsed, and the MAP conditionally supported its inclusion in the ASCQR Program pending completion of reliability testing and NQF endorsement. CMS notes that this measure is maintained by the ASC Quality Collaboration, which is recognized in the community as an expert in measure development for the ASC setting. CMS believes the measure is reliable and reports results of testing completed by the measure steward to support this view.

The proposed data collection period for this measure would be the calendar year two years prior to the payment determination year (e.g., 2018 for the 2020 payment determination). Data would be submitted between January 1 and May 15 of the following year (e.g., 2019 for the 2020 payment determination).

2. Unplanned Anterior Vitrectomy

This proposed measure assesses the percentage of cataract surgery patients who have an unplanned anterior vitrectomy (removal of the vitreous present in the anterior chamber of the eye). This procedure is performed when the vitreous inadvertently prolapses into the anterior segment of the eye during cataract surgery. CMS cites literature on the value of this measure and notes that rates of this procedure are between 2 to 4 percent of all cases. The measure is not NQF endorsed; the MAP supported its inclusion conditionally. CMS notes that the measure is also maintained by the ASC Quality Collaboration and has been found to be reliable.

Like the proposed normothermia outcome measure, the proposed data collection period for this measure would be the calendar year two years prior to the payment determination year (e.g., 2018 for the 2020 payment determination). Data would be submitted between January 1 and May 15 of the following year (e.g., 2019 for the 2020 payment determination).

3. Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems

CMS proposes to adopt for the ASCQR Program the same five OAS CAHPS measures proposed for the OQR Program as discussed above in item XIII.B.3. More information about the OAS CAHPS and the proposed measures, including the survey cohort and risk adjustment, can be found at the OAS CAHPS Survey website at https://oascahps.org/. The five proposed measures are:

- ASC-15a: OAS CAHPS – About Facilities and Staff
- ASC-15b: OAS CAHPS – Communication About Procedure
- ASC-15c: OAS CAHPS – Preparation for Discharge and Recovery
- ASC-15d: OAS CAHPS – Overall Rating of Facility
- ASC-15e: OAS CAHPS – Recommendation of Facility

As is the case for hospitals, ASCs would be required to contract with a CMS-approved OAS CAHPS vendor to collect survey data on eligible patients on a monthly basis and report to CMS by the quarterly deadlines. These requirements for ASCs would be codified at 42 CFR 416.310(e). Parallel proposals to the OQR Program are made for the ASCQR Program with respect to the data collection period (e.g., 2018 for 2020 payment), sampling requirements (at least 300 surveys per 12 month reporting period) and an exemption process for smaller ASCs. Proposed measure calculations and scoring (for purposes of public reporting) are also the same as those proposed for hospitals.

CMS notes that ASCs with fewer than 240 Medicare claims (Medicare primary and secondary payer) in a year are not required to participate in the ASCQR Program (42 CFR 416.305(c)). For example, an ASC with fewer than 240 Medicare claims in 2017 (for the 2019 payment determination year) would not be required to participate in the ASCQR Program in 2018 (for the 2020 payment determination year).

An individual ASC that meets the exemption criteria could 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.

4. ASCQR Program Measures for Future Consideration

CMS invites public comments on a 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. The TASS measure assesses the number of ophthalmic anterior segment surgery patients diagnosed with TASS within 2 days of surgery. CMS believes this topic is of interest to the ASCQR Program because cataract surgery is an anterior segment surgery commonly performed at ASCs. The TASS measure was included on reviewed by the MAP, which conditionally supported its inclusion pending review and endorsement by the NQF. Specifications for this measure for the ASC setting can be found at: http://ascquality.org/documents/ASC%20QC%20Implementation%20Guide%203.2%20October%202015.pdf.

B. Administrative and Data Submission Requirements

No changes are proposed to previously adopted ASCQR Program policies regarding QualityNet account and administrator; participation status; data collection periods for claims-based measures; minimum threshold, case volume and data completeness requirements for claims based measures; requirements for data submitted via a non-CMS online tool; or program reconsideration procedures.

1. Data Submission Deadline for CMS Online Tool

CMS proposes to change the deadline for data submitted via a QualityNet website tool from August 15 of the year prior to the payment determination year to May 15 of that year. This change would be effective beginning with the 2019 payment determination. Five existing measures and the two web-based proposed measures would be affected (ASC-6, ASC-7, ASC-9 ASC-10 ASC-11, ASC-13, ASC-14). A proposed change to the regulatory text would be made to reflect this policy.

CMS previously proposed this change but did not finalize it due to concerns about administrative burden (80 FR 70535). In making this proposal now, CMS says that it would align the ASCQR Program deadline with that of the OQR Program, and would align the seven affected measures with the deadline for ASC-8. In addition, CMS believes it would allow public reporting by December of the same year which would provide the public with more up-to-date information, which it says outweighs stakeholder concerns with moving up the deadline.

2. Data Submission Requirements for the OAS CAHPS Survey-based Measures

Data submission proposals for ASCs for the OAS CAHPS measures parallel those for hospitals described in item XIII.D.2 above.

3. Extension for Extraordinary Circumstances Exemption Request Deadline

CMS proposes to extend the extraordinary circumstances exemption (ECE) request deadline from 45 days following an event causing hardship to 90 days following an event causing hardship. This proposal would be effective beginning with the 2019 payment determination. The proposal would align with the ECE request deadlines for other programs as well as the proposed change for the OQR Program discussed in section XIII.D.3 above.

4. Public Reporting of ASCQR Program Data

CMS proposes to formalize its current practices regarding the timing of public display and the preview period. Specifically, CMS proposes to

- publicly display data on *Hospital Compare* or another CMS website, as soon as possible after measure data have been submitted to CMS;
- generally give ASCs approximately 30 days to preview their data; and

- announce the timeframes for the preview period starting with the CY 2018 payment determination on a CMS website or applicable listservs.

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

No changes are proposed to the policies for determining the payment reduction for ASCs that fail to meet the ASCQR Program requirements. Medicare law requires that a 2.0 percentage point reduction to the ASC annual update is applied to ASCs that fail to meet the requirements. The reduction applies to services calculated using the ASC conversion factor with the payment indicators of A2, G2, P2, R2, Z2, and the service portion of device-intensive procedures identified by J8. The reduction does not apply to services that are assigned other status indicators for which payments are not calculated using the conversion factor, including separately payable drugs and biologicals, pass through devices that are contractor-prices, brachytherapy sources that are paid based on OPPS payment rates, and others. When the 2.0 update reduction is applied to a facility's update, beneficiary copayments are based on the reduced payment rate.

CMS reports that for the 2016 payment determination, 261 of the 5,260 ASCs that met eligibility requirements for the ASCQR Program failed to meet the requirements for a full payment update.

D. Impact Analysis

In the Collection of Information Requirements section of the proposed rule, CMS estimates that the reporting burden associated with each of the two proposed web-based measures would total $2.7 million across all ASCs. With respect to the OAS CAHPS Survey measures, readers are referred to the 2016 final rule (80 FR 70582 through 70584) which does not appear to include any estimates associated with this proposed survey measure.

E. Summary Table of ASCQR Program Measures

A table of proposed ASCQR Program measures along with previously adopted measures follows. Specifications for ASCQR measures are available on the QualityNet website: https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772475754.

ASCQR Program Measures Previously Adopted and Proposed for 2020, by Payment Determination Year						
	2014	**2015**	**2016**	**2017**	**2018 and 2019**	**2020**
ASC-1: Patient Burn (NQF #0263)	X	X	X	X	X	X
ASC-2: Patient Fall (NQF #0266)	X	X	X	X	X	X
ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267)	X	X	X	X	X	X
ASC-4: All-Cause Hospital Transfer/Admission (NQF #0265)	X	X	X	X	X	X
ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing (NQF #0264)	X	X	X	X	X	X
ASC-6: Safe Surgery Checklist Use		X	X	X	X	X

ASCQR Program Measures Previously Adopted and Proposed for 2020, by Payment Determination Year						
	2014	**2015**	**2016**	**2017**	**2018 and 2019**	**2020**
ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures (see below)		X	X	X	X	X
ASC-8: Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)			X	X	X	X
ASC-9 Endoscopy/Poly Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658)			X	X	X	X
ASC-10 Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use (NQF #0659)			X	X	X	X
ASC-11 Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536)			Previously adopted, then excluded	Voluntary		
ASC-12 Facility Seven Day Risk Standardized Hospital Visit Rate after Outpatient Colonoscopy					X	X
ASC-13 Normothermia Outcome						*Proposed*
ASC-14 Unplanned Anterior Vitrectomy						*Proposed*
ASC 15a OAS CAHPS – About Facilities and Staff						*Proposed*
ASC 15b: OAS CAHPS – Communication About Procedure						*Proposed*
ASC 15c: OAS CAHPS – Preparation for Discharge and Recovery						*Proposed*
ASC 15d: OAS CAHPS – Overall Rating of Facility						*Proposed*
ASC 15e: OAS CAHPS – Recommendation of Facility						*Proposed*
Note: For ASC-7, specific surgical procedure codes for which volume data must be reported are identified by organ system (gastrointestinal, eye, nervous system, musculoskeletal, skin, genitourinary, cardiovascular, respiratory and other) and procedure category. These are available in the measure specifications at QualityNet.org.						

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

As part of the Medicare Conditions of Participation (CoP) for solid organ transport programs, the regulations specify certain thresholds that a program could not exceed and be in compliance.[8] Specifically, the regulations specify that a program would not be in compliance with the CoPs for patient and graft survival if three thresholds were all crossed: (1) the observed to expected (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 exceeded, the program would not be in compliance with the CMS standard.

8 The CoPs for data submission, clinical experience, and outcome requirements are codified at 42 CFR 482.80 and 482.82. Solid organ transplantation includes kidney, heart, liver, lung, intestine, and pancreas.

CMS proposes to change the O/E ratio related to patient deaths and graft failures programs from 1.5 to 1.85 in the CoPs for solid organ transport programs. Specifically, the O/E ratio reports the aggregate number of patient deaths and graft failures that occurred within one year after each transplant patient's receipt of an organ compared to the expected events. An O/E ratio of 1.5 means that the patient deaths or graft failures were 150 percent of the risk-adjusted expected number.[9] CMS also proposes for consistency and to avoid unneeded complexity, to use the same 1.85 threshold for all organ types and for both graft and patient survival.

As part of its rationale for this proposed change, CMS states as national outcomes have improved it has become more difficult for an individual transplant program to meet the CMS outcomes standard. The ratio is based on a transplant program's outcomes in relation to the risk-adjusted national average. As a result, CMS expresses concern that transplant programs may elect not to use certain available organs out of fear that such use would adversely affect their outcome statistics. CMS cites, for example, that the percent of adult kidneys donated and recovered—but not used—increased from 16.6 percent in 2006 to 18.3 percent in 2007 to 18.7 percent in 2014 and 19.3 percent in 2015. During 2007 to 2015, the number of unused adult kidneys increased from 2,632 to 3,159. CMS believes 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.

CMS states that for future consideration, it may explore other approaches that are aimed at optimizing the effective use of available organs instead of adjusting the CMS outcomes threshold further. **CMS invites public comment on this issue. In particular, CMS invites comment on whether this proposal is effectively balancing its dual goals of improved beneficiary outcomes and increased beneficiary access.**

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

CMS makes several proposals to ensure more consistent requirements with Organ Procurement Organizations (OPOs). OPOs are responsible for the identification of eligible donors, recovering organs from deceased donors, reporting information to the United Network for Organ Sharing (UNOS) and Organ Procurement and Transplantation Network (OPTN), and compliance with all CMS outcome and process performance measures.

1. Definition of "Eligible Death"

To ensure more consistent requirements, CMS proposes 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 Multi-System Organ Failure with the clinical criteria listed in the definition, that specify the suitability for procurement. **CMS invites public comments on its**

9 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.

proposed definition. CMS states that if changes are needed based on comments received it will work with the OPTN to harmonize the definition.

2. Aggregate Donor Yield for OPO Outcome Performance Measures

CMS also proposes to revise its regulations at §486.318(a)(3) and §486.318(b)(3) to be consistent with the current aggregate donor yield metric in use by Scientific Registry of Transplant Recipients (SRTR), that was revised in 2014. CMS states that its current donor yield measure may have created a hesitancy on the part of OPOs to pursue donors for only one organ due to the impact on the CMS yield measure. CMS states that the OPTN/SRTR yield metric is a more accurate measure for organ yield performance and accounts for differences between donor case-mixes across donation service areas. This metric is based on 29 donor medical characteristics and social complexities. CMS also states its intent to revisit and revise the other OPO measures at a future date.

3. Organ Preparation and Transport-Documentation with the Organ

In addition, CMS proposes 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. Specifically, CMS proposes 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. CMS also proposes to make the documentation requirement consistent with current OPTN policy,[10] which requires that blood type source documentation and infectious disease testing results be physically sent in hard copy with the organ.

CMS notes that the current 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. By reducing this documentation, CMS states that this would increase OPO transplant coordinators' time, allowing them to focus on donor management and organ preparation.

XVII. Transplant Enforcement Technical Corrections and Proposals

CMS proposes a technical correction to the preamble and regulatory language it recently adopted in 2015 regarding enforcement provisions for organ transplant centers. CMS corrects a typographical in the final citations in a response to a commenter: the response should have stated "In the final regulation, at §488.61(f)(1) and elsewhere, we [CMS] 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." CMS also proposes to amend §488.61(f)(1) to correct the same incorrect citations.
CMS makes two additional proposals in this section:

[10] 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/.

- CMS proposes 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).

- CMS also proposes to revise §488.61(h)(2) to clarify that a signed Systems Improvement Agreement (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. CMS states, in its sole discretion, that it may shorten the timeframe or allow modification to any portion of the elements of the SIA.

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

CMS proposes to further modify the Modified Stage 2 and Stage 3 objectives and measures under the Medicare EHR Incentive Program for 2017 and 2018, and to change the 2016 reporting period for eligible professionals (EPs), eligible hospitals, and CAHs that have previously demonstrated meaningful use under the program. Other proposals relate to EPs, eligible hospitals and CAHs that have not previously demonstrated meaningful use and are seeking to do so for the first time in 2017. Finally, changes are proposed with respect to measure calculations for actions occurring outside the EHR reporting period.

A. Revisions to Objectives and Measures for Eligible Hospitals and CAHs

Responding to concerns about reporting burden, CMS proposes a set of changes to the objectives and measures of meaningful use for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for 2017 and later years. Further, 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 would be reduced.

The proposals relate only to the Medicare EHR Incentive Program; they would not affect requirements for an eligible hospital or CAH attesting under a state Medicaid EHR Incentive Program. CMS says it considered applying the changes to the Medicaid program as well but is concerned about the burden on states to update technology and reporting systems in a short period of time. Comments are invited as to whether the proposed changes should also apply to eligible hospitals and CAHs attesting under a state's Medicaid EHR Incentive Program.

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

CMS has determined that, based on 2015 attestation data, performance on the CPOE objective and measures meets the criteria as "topped out," and proposes to remove them from the Medicare EHR Incentive Program. The criteria involve statistically indistinguishable performance at the 5^{th} and 99^{th} percentiles and performance distribution curves at the 25^{th}, 50^{th} and 75^{th} percentiles as compared to the required measure threshold.

While the CDS objective includes "yes/no" measures that cannot be analyzed as a performance distribution, CMS believes that the high level of successful attestation (99 percent for 2015) indicates widespread adoption of this objective and measures, and that they are no longer useful in comparing performance of eligible hospitals and CAHs.

CMS notes that in the 2015 EHR Incentive Program final rule, it established that when a measure is removed, the technology requirements will remain in the definition of Certified EHR Technology (CEHRT). Therefore, under the proposal, the two objectives and measures to be removed would remain as part of CEHRT requirements, but an eligible hospital/CAH attesting to meaningful use under Medicare would not be required to report on them.

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

For a subset of measures, CMS proposes to reduce the required reporting thresholds. CMS believes the proposed changes would reduce reporting burden and allow eligible hospitals and CAHs to focus on quality patient care as well as on updating and optimizing CEHRT functionalities and preparing for Stage 3 of meaningful use. In general, the proposed changes would replace Stage 3 thresholds with Modified Stage 2 levels. CMS notes that it plans to work with providers toward adopting more stringent thresholds in the future, and welcomes comments on modifying the proposed thresholds for the future or on adding new and more stringent measures.

The proposed specific threshold changes follow. In discussing each of these changes CMS emphasizes the feedback it has heard from stakeholders regarding challenges in meeting the current thresholds. For example, providers have described the need to educate and communicate with patients that have limited knowledge of or proficiency with information technology and with patients declining to access portals made available to them on the importance of accessing their health information. Vendors have raised concerns that the fledgling state of development of applicable programming interface (API) technology, the need for market testing, and the lack of compatibility functionalities will make it very difficult for hospitals to meet current patient access measure thresholds. Further, many hospital stakeholders have identified the lack of health IT adoption among other provider partners as a barrier to achieving wide scale interoperable health information exchange.

<u>Modified Stage 2 in 2017</u>

Objective: Patient Electronic Access

- View Download Transmit (VDT) Measure: At least ***1 patient*** (or patient authorized representative) [currently 5 percent of patients] who is discharged from the inpatient or emergency department (Place of service (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.

Stage 3 in 2017 and 2018

Objective: Patient Electronic Access to Health Information Objective

- Patient Access Measure: For more than ***50 percent*** [currently 80 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.
- 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*** [currently 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.

Objective: Coordination of Care Through Patient Engagement

- VDT Measure (same as proposed Modified Stage 2 above): At least ***1 patient*** (or patient authorized representative) [currently 5 percent of patients] 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.
- Secure Messaging: For more than ***5 percent*** [currently 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 the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative).

Objective: Health Information Exchange

- Patient Care Record Exchange Measure: For more than ***10 percent*** [currently 50 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.
- Request/Accept Patient Care Record Measure: For more than ***10 percent*** [currently 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.
- Clinical Information Reconciliation Measure: For more than ***50 percent*** [currently 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: (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.

(For this objective, the proposed rule does not change the requirement that the provider must attest to all three measures but must only successfully meet the thresholds for two of them.)

Objective: Public Health and Clinical Data Registry Reporting

- Eligible hospitals/CAHs must successfully attest to reporting any combination of ***three*** measures [currently six]. (The six measures from which providers would choose involve immunization registry reporting, syndromic surveillance reporting, electronic case reporting, public health registry reporting, clinical data registry reporting, and electronic reportable laboratory result reporting).

The proposed rule includes tables that summarize the proposed Modified Stage 3 and Stage 3 objectives and measures. These tables are reproduced here.

Proposed Modified Stage 2 Objectives and Measures for 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	Immunization Reporting	Immunization Measure	Public Health

and Reporting	Syndromic Surveillance Reporting Specialized Registry Reporting Electronic Reportable Laboratory Result Reporting	Syndromic Surveillance Measure Electronic Reportable Laboratory Result Measure	Reporting to 3 Registries
*Objective is proposed for removal. ** Threshold is the proposed reduced level.			

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 Reconciliation Measure	>50%
Public Health and Clinical Data Registry Reporting	Immunization Registry Reporting Syndromic Surveillance Reporting Case Reporting	Immunization Registry Reporting Measure Syndromic Surveillance Reporting Measure Case Reporting Measure	Report to 3 Registries or claim exclusions

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**
	Public Health Registry Reporting Clinical Data Registry Reporting Electronic Reportable Laboratory Result Reporting	Public Health Registry Reporting Measure Clinical Data Registry Reporting Measure Electronic Reportable Laboratory Result Reporting Measure	
*Objective is proposed for removal. ** Thresholds shown are the proposed reduced levels.			

B. Revisions to the EHR Reporting Period in 2016 for EPs, Eligible Hospitals and CAHs

CMS previously finalized the reporting period for 2016 under the Medicare and Medicaid EHR Incentive Programs as any continuous 90-day period in calendar year 2016 for EPs, eligible hospitals and CAHs that have not successfully demonstrated meaningful use in a prior year (new participants) and the full calendar year 2016 for EPs, eligible hospitals and CAHs that have successfully demonstrated meaningful use in a prior year (returning participants).

In this rule, CMS proposes to change the 2016 EHR reporting periods for returning participants from the full calendar year to any continuous 90-day period within calendar year 2016. After considering feedback from stakeholders, CMS says it now understands that more time is needed to accommodate updates in the 2015 EHR Incentive Program final rule, such as system changes to CEHRT and implementation of an API and to provide transition for EPs who transitioning to reporting under the Medicare Incentive Payment System (MIPS) in 2017.

A continuous 90-day reporting period is also proposed for reporting clinical quality measures (CQMs) for all EPs, eligible hospitals and CAHs that choose to report CQMs by attestation in 2016. This would not affect previously adopted requirements for electronic reporting of CQM data. The 90-day period used for CQM data submitted via attestation does not have to be the same 90-day reporting period that the provider uses for demonstrating meaningful use.

C. Requirement for Modified Stage 2 for New Participants in 2017

The 2015 EHR Incentive Program final rule provides for the following in 2017:

- 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.

CMS has subsequently determined that 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. Therefore, in this rule CMS proposes that any EP or eligible hospital new participant seeking to avoid the 2018 payment adjustment by attesting for an EHR reporting period in 2017 or any CAH new participant seeking to avoid the FY 2017 payment adjustment by attesting for an EHR reporting period in 2017 would be required to attest to the Modified Stage 2 objectives and measures. CMS says 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.

This proposal does not apply to returning participants attesting for an EHR reporting period in 2017. CMS notes that in early 2018, 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 2016 is the final year of the incentive payment under section 1848(o)(1)(A)(ii) of the Act.

D. Significant Hardship Exemption for New Participants Transitioning to MIPS in 2017

CMS discusses overlap between the new MIPS program performance period and previously adopted reporting for meaningful use. Specifically, in the MIPS and Alternative Payment Model (APM) Proposed Rule (81 FR 28161) CMS has proposed 2017 as the initial MIPS performance period. Previously, 2017 was established as the last year in which new participants may attest to meaningful use (for a 90-day period period) to avoid the 2018 EHR Incentive Program payment adjustment. Therefore, an EP could use a 90-day reporting period in 2017 to demonstrate meaningful use and report under the Advancing Care Information (ACI) performance category in MIPS.

Recognizing that new participants may find it difficult to manage separate requirements, CMS proposes to allow certain EPs to apply for a significant hardship exception from the 2018 payment adjustment. This would be limited to EPs who have not previously demonstrated meaningful use in a prior year and intend to make such an attestation by October 1, 2017 to avoid the payment adjustment and who also intend to transition to MIPS and report on measures in the ACI category under the MIPS in 2017. CMS notes that this proposal is based on its earlier proposal to make calendar year 2017 the initial MIPS performance period, and if that performance period is modified in the MIPS final rule so that it does not coincide with the final year for EPs to attest to meaningful use under the EHR Incentive Program, an exception may not be necessary.

Under the proposal, an EP would apply by October 1, 2017 or a later date that CMS specifies. The application would have to explain why demonstrating meaningful use for the first time in 2017 and reporting on the ACI performance category would result in a significant hardship. EPs would be required to maintain documentation of the hardship application for six years.

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

CMS describes confusion that has arisen from its policy under which 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 (FAQ 8231). CMS notes that attestation dates, and therefore these timeframes, can vary by provider. For purposes of consistency, CMS now proposes 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 2017, the action must occur between January 1 and December 31, 2017, but it does not have to occur within the 90-day EHR reporting period timeframe. CMS says that a small number of actions may occur after December 31 of the year in which the EHR reporting period occurs. However, it notes that the proposed reduced thresholds would significantly reduce the impact that these actions would have on performance. In addition, actions occurring after December 31 of the reporting year would count toward the next calendar year's EHR reporting period.

XIX. Additional Hospital Value-Based Purchasing Program Policies

CMS proposes to remove the HCAHPS pain management dimension from the inpatient hospital VBP Program beginning with the 2018 payment determination year (calendar year 2016 are the performance period.) This dimension is based on three survey questions addressing whether during the hospital stay the patient needed pain medicine, how often pain was well controlled, and the frequency with which hospital staff did everything they could to help with pain. The proposal is made in light of ongoing stakeholder concerns that the link between these survey questions and VBP payment adjustment creates incentives for hospital staff to prescribe more opioids to achieve higher scores on this dimension. While it is unaware of any scientific studies that support an association between scores on the Pain Management dimension and opioid prescribing practices, CMS is concerned about "possible confusion" over the appropriate use of the Pain Management questions and the prescription opioid overdose epidemic.

In discussing these issues, CMS states its belief that pain management is an important part of routine patient care, and notes that the current questions do not specify an particular type of pain control method. Further, it says many factors other than CMS quality program requirements may contribute to the perception of a link between the pain management dimension and opioid prescribing practices. As examples, it cites misuse of the survey such as using it for ED care rather than inpatient care, disaggregating hospital survey results to assess individual physician

and staff performance, and failure to recognize that the HCAHPS survey sampling frame excludes individuals with a primary substance use disorder.[11]

Removing this dimension would necessitate changes in VBP scoring. CMS proposes that for purposes of scoring the HCAHPS measure beginning in 2018 it would continue to assign 10 points for each of the remaining eight dimensions and award up to 20 consistency points for performance across those remaining eight dimensions. (As previously finalized beginning in 2018, nine HCAHPS dimensions would be scored at 10 points each and then multiplied by 8/9 to total up to 80 HCAHPS base points with up to 20 consistency points additionally awarded based on performance across all nine dimensions.) The proposed rule includes tables setting forth the performance standards for the HCAHPS measure dimensions, excluding the pain management dimension, for the 2018 and 2019 payment years. The standards for the other dimensions are unchanged from those that were previously finalized.

Modified pain management questions are being developed, and when these become available for the HCAHPS Survey it intends to propose to adopt them for the VBP Program in future rulemaking. In particular, CMS intends to use its standard survey development process to "remove any potential ambiguity" in the HCAHPS Survey pain management questions. It says this involves 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 understand stakeholder concerns and determine if there are any unintended consequences that link the Pain Management dimension questions to opioid prescribing practices. CMS also says it is in the early stages of developing several related measures. One is an electronically-specified process measure for the inpatient and outpatient hospital settings that would measure concurrent prescribing of an opioid and benzodiazepine. Another is a process measure that would assess whether inpatient psychiatric facilities are regularly monitoring for adverse drug events of opioid and psychotropic drugs. Specifications for these measures will be posted on the CMS website and public input will be invited before these measures are proposed for quality reporting purposes.

XX. Files Available to the Public via the Internet

Addenda this 2017 OPPS/ASC proposed rule are available on the following CMS website by selecting "1656-P" from the list of regulations: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.

For addenda related to 2017 ASC payments, please see http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html and select 1656-P from the list of regulations. The ASC Addenda are contained in the zipped folders entitled "Addendum AA, BB, DD1, DD2, and EE".

[11] CMS says the HCAHPS survey was never intended to assess individual physicians or hospital staff or to measure hospital emergency and outpatient departments. It references the following article in support: 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.

XXI. Collection of Information Requirements

CMS discusses collection of information requirements. Costs associated with ASCQR Program requirements are discussed in section XIV above. No other data collection costs are identified.

APPENDIX: SELECTED TABLES REPRODUCED FROM THE PROPOSED RULE

TABLE 30.—ESTIMATED IMPACT OF THE PROPOSED CY 2017 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

ADDENDUM J FOR 2017 COMPLEXITY ADJUSTMENTS OF COMBINATIONS OF COMPREHENSIVE HCPCS CODES

TABLE 30.—ESTIMATED IMPACT OF THE PROPOSED CY 2017 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

		(1) Number of Hospitals	(2) APC Recalibration (all proposed changes)	(3) New Wage Index and Provider Adjustments	(4) All Proposed Budget Neutral Changes (combined cols 2,3) with Proposed Market Basket Update	(5) 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
	EAST NORTH CENT.	467	0.0	0.3	1.9	2.0
	EAST SOUTH CENT.	175	-0.3	0.2	1.5	1.6

		(1) Number of Hospitals	(2) APC Recalibration (all proposed changes)	(3) New Wage Index and Provider Adjustments	(4) All Proposed Budget Neutral Changes (combined cols 2,3) with Proposed Market Basket Update	(5) All Proposed Changes
	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
	DSH ≥ 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
	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

		(1) Number of Hospitals	(2) APC Recalibration (all proposed changes)	(3) New Wage Index and Provider Adjustments	(4) All Proposed Budget Neutral Changes (combined cols 2,3) with Proposed Market Basket Update	(5) All Proposed Changes
	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.

ADDENDUM J FOR 2017 COMPLEXITY ADJUSTMENTS OF COMBINATIONS OF COMPREHENSIVE HCPCS CODES

Primary HCPCS Code	Primary Short Descriptor	Primary SI	Primary APC Assignment	Secondary J1 or Add-on HCPCS Code	Secondary Short Descriptor	Secondary SI	Secondary APC Assignment	Complexity Adjusted HCPCS Assignment	Complexity Adjusted APC Assignment
10140	Drainage of hematoma/fluid	J1	5072	10140	Drainage of hematoma/fluid	J1	5072	1014X	5073
11044	Deb bone 20 sq cm/<	J1	5072	11044	Deb bone 20 sq cm/<	J1	5072	1104D	5073
11406	Exc tr-ext b9+marg >4.0 cm	J1	5072	11404	Exc tr-ext b9+marg 3.1-4 cm	J1	5072	1140G	5073
11406	Exc tr-ext b9+marg >4.0 cm	J1	5072	11406	Exc tr-ext b9+marg >4.0 cm	J1	5072	1140G	5073
11406	Exc tr-ext b9+marg >4.0 cm	J1	5072	11422	Exc h-f-nk-sp b9+marg 1.1-2	J1	5072	1140G	5073
11423	Exc h-f-nk-sp b9+marg 2.1-3	J1	5072	11404	Exc tr-ext b9+marg 3.1-4 cm	J1	5072	1142C	5073
11426	Exc h-f-nk-sp b9+marg >4 cm	J1	5072	11406	Exc tr-ext b9+marg >4.0 cm	J1	5072	1142G	5073
11426	Exc h-f-nk-sp b9+marg >4 cm	J1	5072	11423	Exc h-f-nk-sp b9+marg 2.1-3	J1	5072	1142G	5073
11426	Exc h-f-nk-sp b9+marg >4 cm	J1	5072	11426	Exc h-f-nk-sp b9+marg >4 cm	J1	5072	1142G	5073
11606	Exc tr-ext mal+marg >4 cm	J1	5072	11406	Exc tr-ext b9+marg >4.0 cm	J1	5072	1160G	5073
11606	Exc tr-ext mal+marg >4 cm	J1	5072	11606	Exc tr-ext mal+marg >4 cm	J1	5072	1160G	5073
11606	Exc tr-ext mal+marg >4 cm	J1	5072	11623	Exc s/n/h/f/g mal+mrg 2.1-3	J1	5072	1160G	5073
11606	Exc tr-ext mal+marg >4 cm	J1	5072	11624	Exc s/n/h/f/g mal+mrg 3.1-4	J1	5072	1160G	5073
11606	Exc tr-ext mal+marg >4 cm	J1	5072	11643	Exc f/e/e/n/l mal+mrg 2.1-3	J1	5072	1160G	5073
11606	Exc tr-ext mal+marg >4 cm	J1	5072	11644	Exc f/e/e/n/l mal+mrg 3.1-4	J1	5072	1160G	5073

Primary HCPCS Code	Primary Short Descriptor	Primary SI	Primary APC Assignment	Secondary J1 or Add-on HCPCS Code	Secondary Short Descriptor	Secondary SI	Secondary APC Assignment	Complexity Adjusted HCPCS Assignment	Complexity Adjusted APC Assignment
11624	Exc s/n/h/f/g mal+mrg 3.1-4	J1	5072	11623	Exc s/n/h/f/g mal+mrg 2.1-3	J1	5072	1162D	5073
11624	Exc s/n/h/f/g mal+mrg 3.1-4	J1	5072	11643	Exc f/e/e/n/l mal+mrg 2.1-3	J1	5072	1162D	5073
11644	Exc f/e/e/n/l mal+mrg 3.1-4	J1	5072	11643	Exc f/e/e/n/l mal+mrg 2.1-3	J1	5072	1164D	5073
19081	Bx breast 1st lesion strtctc	J1	5072	19083	Bx breast 1st lesion us imag	J1	5072	1908A	5073
19081	Bx breast 1st lesion strtctc	J1	5072	38505	Needle biopsy lymph nodes	J1	5072	1908A	5073
19083	Bx breast 1st lesion us imag	J1	5072	38505	Needle biopsy lymph nodes	J1	5072	1908C	5073
19085	Bx breast 1st lesion mr imag	J1	5072	19083	Bx breast 1st lesion us imag	J1	5072	1908E	5073
20205	Deep muscle biopsy	J1	5072	20205	Deep muscle biopsy	J1	5072	2020E	5073
20220	Bone biopsy trocar/needle	J1	5072	20220	Bone biopsy trocar/needle	J1	5072	2022X	5073
20225	Bone biopsy trocar/needle	J1	5072	20225	Bone biopsy trocar/needle	J1	5072	2022E	5073
20225	Bone biopsy trocar/needle	J1	5072	32405	Percut bx lung/mediastinum	J1	5072	2022E	5073
21931	Exc back les sc 3 cm/>	J1	5072	21931	Exc back les sc 3 cm/>	J1	5072	2193A	5073
32405	Percut bx lung/mediastinum	J1	5072	20206	Needle biopsy muscle	J1	5072	3240E	5073
32405	Percut bx lung/mediastinum	J1	5072	38505	Needle biopsy lymph nodes	J1	5072	3240E	5073
32405	Percut bx lung/mediastinum	J1	5072	47000	Needle biopsy of liver	J1	5072	3240E	5073
38220	Bone marrow aspiration	J1	5072	38220	Bone marrow aspiration	J1	5072	3822X	5073
38221	Bone marrow biopsy	J1	5072	38221	Bone marrow biopsy	J1	5072	3822A	5073
38221	Bone marrow biopsy	J1	5072	38505	Needle biopsy lymph nodes	J1	5072	3822A	5073
38221	Bone marrow biopsy	J1	5072	49180	Biopsy abdominal mass	J1	5072	3822A	5073

Primary HCPCS Code	Primary Short Descriptor	Primary SI	Primary APC Assignment	Secondary J1 or Add-on HCPCS Code	Secondary Short Descriptor	Secondary SI	Secondary APC Assignment	Complexity Adjusted HCPCS Assignment	Complexity Adjusted APC Assignment
49180	Biopsy abdominal mass	J1	5072	20206	Needle biopsy muscle	J1	5072	4918X	5073
49180	Biopsy abdominal mass	J1	5072	32405	Percut bx lung/mediastinum	J1	5072	4918X	5073
49180	Biopsy abdominal mass	J1	5072	38505	Needle biopsy lymph nodes	J1	5072	4918X	5073
49180	Biopsy abdominal mass	J1	5072	47000	Needle biopsy of liver	J1	5072	4918X	5073
49405	Image cath fluid colxn visc	J1	5072	49405	Image cath fluid colxn visc	J1	5072	4940E	5073
49406	Image cath fluid peri/retro	J1	5072	49406	Image cath fluid peri/retro	J1	5072	4940G	5073
19301	Partial mastectomy	J1	5091	38505	Needle biopsy lymph nodes	J1	5072	1930A	5092
38500	Biopsy/removal lymph nodes	J1	5091	11623	Exc s/n/h/f/g mal+mrg 2.1-3	J1	5072	3850X	5092
38500	Biopsy/removal lymph nodes	J1	5091	11626	Exc s/n/h/f/g mal+mrg >4 cm	J1	5073	3850X	5092
38500	Biopsy/removal lymph nodes	J1	5091	11646	Exc f/e/e/n/l mal+mrg >4 cm	J1	5073	3850X	5092
38500	Biopsy/removal lymph nodes	J1	5091	19101	Biopsy of breast open	J1	5091	3850X	5092
38500	Biopsy/removal lymph nodes	J1	5091	19125	Excision breast lesion	J1	5091	3850X	5092
38500	Biopsy/removal lymph nodes	J1	5091	19301	Partial mastectomy	J1	5091	3850X	5092
38500	Biopsy/removal lymph nodes	J1	5091	19304	Mast subq	J1	5091	3850X	5092
38500	Biopsy/removal lymph nodes	J1	5091	38500	Biopsy/removal lymph nodes	J1	5091	3850X	5092
38510	Biopsy/removal lymph nodes	J1	5091	11624	Exc s/n/h/f/g mal+mrg 3.1-4	J1	5072	3851X	5092
38510	Biopsy/removal lymph nodes	J1	5091	11626	Exc s/n/h/f/g mal+mrg >4 cm	J1	5073	3851X	5092

Primary HCPCS Code	Primary Short Descriptor	Primary SI	Primary APC Assignment	Secondary J1 or Add-on HCPCS Code	Secondary Short Descriptor	Secondary SI	Secondary APC Assignment	Complexity Adjusted HCPCS Assignment	Complexity Adjusted APC Assignment
38510	Biopsy/removal lymph nodes	J1	5091	11643	Exc f/e/e/n/l mal+mrg 2.1-3	J1	5072	3851X	5092
38510	Biopsy/removal lymph nodes	J1	5091	11644	Exc f/e/e/n/l mal+mrg 3.1-4	J1	5072	3851X	5092
38510	Biopsy/removal lymph nodes	J1	5091	11646	Exc f/e/e/n/l mal+mrg >4 cm	J1	5073	3851X	5092
38510	Biopsy/removal lymph nodes	J1	5091	38500	Biopsy/removal lymph nodes	J1	5091	3851X	5092
38525	Biopsy/removal lymph nodes	J1	5091	11406	Exc tr-ext b9+marg >4.0 cm	J1	5072	3852E	5092
38525	Biopsy/removal lymph nodes	J1	5091	11606	Exc tr-ext mal+marg >4 cm	J1	5072	3852E	5092
38525	Biopsy/removal lymph nodes	J1	5091	11626	Exc s/n/h/f/g mal+mrg >4 cm	J1	5073	3852E	5092
38525	Biopsy/removal lymph nodes	J1	5091	19101	Biopsy of breast open	J1	5091	3852E	5092
38525	Biopsy/removal lymph nodes	J1	5091	19125	Excision breast lesion	J1	5091	3852E	5092
38525	Biopsy/removal lymph nodes	J1	5091	19301	Partial mastectomy	J1	5091	3852E	5092
38525	Biopsy/removal lymph nodes	J1	5091	19304	Mast subq	J1	5091	3852E	5092
38525	Biopsy/removal lymph nodes	J1	5091	38500	Biopsy/removal lymph nodes	J1	5091	3852E	5092
38525	Biopsy/removal lymph nodes	J1	5091	38510	Biopsy/removal lymph nodes	J1	5091	3852E	5092
38530	Biopsy/removal lymph nodes	J1	5091	19301	Partial mastectomy	J1	5091	3853X	5092
19307	Mast mod rad	J1	5092	19340	Immediate breast prosthesis	J1	5092	1930Q	5093
19340	Immediate breast prosthesis	J1	5092	19303	Mast simple complete	J1	5092	1934X	5093
19340	Immediate breast prosthesis	J1	5092	38525	Biopsy/removal lymph nodes	J1	5091	1934X	5093

Primary HCPCS Code	Primary Short Descriptor	Primary SI	Primary APC Assignment	Secondary J1 or Add-on HCPCS Code	Secondary Short Descriptor	Secondary SI	Secondary APC Assignment	Complexity Adjusted HCPCS Assignment	Complexity Adjusted APC Assignment
25111	Remove wrist tendon lesion	J1	5112	26055	Incise finger tendon sheath	J1	5112	2511A	5113
25111	Remove wrist tendon lesion	J1	5112	26160	Remove tendon sheath lesion	J1	5112	2511A	5113
25111	Remove wrist tendon lesion	J1	5112	29848	Wrist endoscopy/surgery	J1	5112	2511A	5113
26160	Remove tendon sheath lesion	J1	5112	26160	Remove tendon sheath lesion	J1	5112	2616X	5113
27266	Treat hip dislocation	J1	5112	27266	Treat hip dislocation	J1	5112	2726G	5113
28080	Removal of foot lesion	J1	5112	28080	Removal of foot lesion	J1	5112	2808X	5113
28108	Removal of toe lesions	J1	5112	28108	Removal of toe lesions	J1	5112	2810R	5113
28232	Incision of toe tendon	J1	5112	28232	Incision of toe tendon	J1	5112	2823B	5113
29848	Wrist endoscopy/surgery	J1	5112	25000	Incision of tendon sheath	J1	5112	2984R	5113
29848	Wrist endoscopy/surgery	J1	5112	26055	Incise finger tendon sheath	J1	5112	2984R	5113
29848	Wrist endoscopy/surgery	J1	5112	26145	Tendon excision palm/finger	J1	5112	2984R	5113
29848	Wrist endoscopy/surgery	J1	5112	26160	Remove tendon sheath lesion	J1	5112	2984R	5113
25447	Repair wrist joints	J1	5113	26860	Fusion of finger joint	J1	5113	2544Q	5114
25447	Repair wrist joints	J1	5113	29848	Wrist endoscopy/surgery	J1	5112	2544Q	5114
26530	Revise knuckle joint	J1	5113	26530	Revise knuckle joint	J1	5113	2653X	5114
26535	Revise finger joint	J1	5113	26535	Revise finger joint	J1	5113	2653E	5114
26615	Treat metacarpal fracture	J1	5113	26615	Treat metacarpal fracture	J1	5113	2661E	5114
26735	Treat finger fracture each	J1	5113	26735	Treat finger fracture each	J1	5113	2673E	5114
27006	Incision of hip tendons	J1	5113	27062	Remove femur lesion/bursa	J1	5113	2700G	5114
27650	Repair achilles tendon	J1	5113	27687	Revision of calf tendon	J1	5113	2765X	5114
27650	Repair achilles tendon	J1	5113	28100	Removal of ankle/heel lesion	J1	5113	2765X	5114
27650	Repair achilles tendon	J1	5113	28118	Removal of heel bone	J1	5113	2765X	5114

Primary HCPCS Code	Primary Short Descriptor	Primary SI	Primary APC Assignment	Secondary J1 or Add-on HCPCS Code	Secondary Short Descriptor	Secondary SI	Secondary APC Assignment	Complexity Adjusted HCPCS Assignment	Complexity Adjusted APC Assignment
27650	Repair achilles tendon	J1	5113	28119	Removal of heel spur	J1	5113	2765X	5114
27650	Repair achilles tendon	J1	5113	28120	Part removal of ankle/heel	J1	5113	2765X	5114
28119	Removal of heel spur	J1	5113	27687	Revision of calf tendon	J1	5113	2811S	5114
28200	Repair of foot tendon	J1	5113	28200	Repair of foot tendon	J1	5113	2820X	5114
28289	Corrj halux rigdus w/o implt	J1	5113	28270	Release of foot contracture	J1	5113	2828S	5114
28289	Corrj halux rigdus w/o implt	J1	5113	28285	Repair of hammertoe	J1	5113	2828S	5114
28292	Correction hallux valgus	J1	5113	28308	Incision of metatarsal	J1	5113	2829B	5114
28296	Correction hallux valgus	J1	5113	28110	Part removal of metatarsal	J1	5113	2829G	5114
28296	Correction hallux valgus	J1	5113	28122	Partial removal of foot bone	J1	5113	2829G	5114
28296	Correction hallux valgus	J1	5113	28270	Release of foot contracture	J1	5113	2829G	5114
28296	Correction hallux valgus	J1	5113	28285	Repair of hammertoe	J1	5113	2829G	5114
28296	Correction hallux valgus	J1	5113	28288	Partial removal of foot bone	J1	5113	2829G	5114
28296	Correction hallux valgus	J1	5113	28289	Corrj halux rigdus w/o implt	J1	5113	2829G	5114
28296	Correction hallux valgus	J1	5113	28292	Correction hallux valgus	J1	5113	2829G	5114
28296	Correction hallux valgus	J1	5113	28308	Incision of metatarsal	J1	5113	2829G	5114
28296	Correction hallux valgus	J1	5113	28313	Repair deformity of toe	J1	5113	2829G	5114
28296	Correction hallux valgus	J1	5113	28645	Repair toe dislocation	J1	5113	2829G	5114
28299	Correction hallux valgus	J1	5113	28110	Part removal of metatarsal	J1	5113	2829S	5114

Primary HCPCS Code	Primary Short Descriptor	Primary SI	Primary APC Assignment	Secondary J1 or Add-on HCPCS Code	Secondary Short Descriptor	Secondary SI	Secondary APC Assignment	Complexity Adjusted HCPCS Assignment	Complexity Adjusted APC Assignment
28299	Correction hallux valgus	J1	5113	28270	Release of foot contracture	J1	5113	2829S	5114
28299	Correction hallux valgus	J1	5113	28285	Repair of hammertoe	J1	5113	2829S	5114
28299	Correction hallux valgus	J1	5113	28288	Partial removal of foot bone	J1	5113	2829S	5114
28299	Correction hallux valgus	J1	5113	28308	Incision of metatarsal	J1	5113	2829S	5114
28299	Correction hallux valgus	J1	5113	28313	Repair deformity of toe	J1	5113	2829S	5114
28299	Correction hallux valgus	J1	5113	28645	Repair toe dislocation	J1	5113	2829S	5114
28308	Incision of metatarsal	J1	5113	28289	Corrj halux rigdus w/o implt	J1	5113	2830R	5114
28308	Incision of metatarsal	J1	5113	28308	Incision of metatarsal	J1	5113	2830R	5114
28310	Revision of big toe	J1	5113	28296	Correction hallux valgus	J1	5113	2831X	5114
28313	Repair deformity of toe	J1	5113	28308	Incision of metatarsal	J1	5113	2831C	5114
28645	Repair toe dislocation	J1	5113	28308	Incision of metatarsal	J1	5113	2864E	5114
29822	Shoulder arthroscopy/surgery	J1	5113	23120	Partial removal collar bone	J1	5113	2982B	5114
29823	Shoulder arthroscopy/surgery	J1	5113	23120	Partial removal collar bone	J1	5113	2982C	5114
29824	Shoulder arthroscopy/surgery	J1	5113	29823	Shoulder arthroscopy/surgery	J1	5113	2982D	5114
29825	Shoulder arthroscopy/surgery	J1	5113	29822	Shoulder arthroscopy/surgery	J1	5113	2982E	5114
29882	Knee arthroscopy/surgery	J1	5113	29881	Knee arthroscopy/surgery	J1	5113	2988B	5114
22513	Perq vertebral augmentation	J1	5114	20225	Bone biopsy trocar/needle	J1	5072	2251C	5115
22513	Perq vertebral augmentation	J1	5114	20982	Ablate bone tumor(s) perq	J1	5114	2251C	5115

Primary HCPCS Code	Primary Short Descriptor	Primary SI	Primary APC Assignment	Secondary J1 or Add-on HCPCS Code	Secondary Short Descriptor	Secondary SI	Secondary APC Assignment	Complexity Adjusted HCPCS Assignment	Complexity Adjusted APC Assignment
22513	Perq vertebral augmentation	J1	5114	22511	Perq lumbosacral injection	J1	5113	2251C	5115
22513	Perq vertebral augmentation	J1	5114	22515	Perq vertebral augmentation	N		2251C	5115
22514	Perq vertebral augmentation	J1	5114	20225	Bone biopsy trocar/needle	J1	5072	2251D	5115
22514	Perq vertebral augmentation	J1	5114	20982	Ablate bone tumor(s) perq	J1	5114	2251D	5115
22514	Perq vertebral augmentation	J1	5114	22510	Perq cervicothoracic inject	J1	5113	2251D	5115
22514	Perq vertebral augmentation	J1	5114	22511	Perq lumbosacral injection	J1	5113	2251D	5115
22514	Perq vertebral augmentation	J1	5114	22515	Perq vertebral augmentation	N		2251D	5115
22514	Perq vertebral augmentation	J1	5114	63030	Low back disk surgery	J1	5114	2251D	5115
22514	Perq vertebral augmentation	J1	5114	63047	Remove spine lamina 1 lmbr	J1	5114	2251D	5115
25607	Treat fx rad extra-articul	J1	5114	25545	Treat fracture of ulna	J1	5114	2560Q	5115
25609	Treat fx radial 3+ frag	J1	5114	25545	Treat fracture of ulna	J1	5114	2560S	5115
26531	Revise knuckle with implant	J1	5114	26531	Revise knuckle with implant	J1	5114	2653A	5115
26536	Revise/implant finger joint	J1	5114	26536	Revise/implant finger joint	J1	5114	2653G	5115
28297	Correction hallux valgus	J1	5114	28300	Incision of heel bone	J1	5114	2829Q	5115
28740	Fusion of foot bones	J1	5114	28298	Correction hallux valgus	J1	5114	2874X	5115
28740	Fusion of foot bones	J1	5114	28300	Incision of heel bone	J1	5114	2874X	5115
28740	Fusion of foot bones	J1	5114	28740	Fusion of foot bones	J1	5114	2874X	5115
28740	Fusion of foot bones	J1	5114	28750	Fusion of big toe joint	J1	5114	2874X	5115
29888	Knee arthroscopy/surgery	J1	5114	29882	Knee arthroscopy/surgery	J1	5113	2988R	5115

Primary HCPCS Code	Primary Short Descriptor	Primary SI	Primary APC Assignment	Secondary J1 or Add-on HCPCS Code	Secondary Short Descriptor	Secondary SI	Secondary APC Assignment	Complexity Adjusted HCPCS Assignment	Complexity Adjusted APC Assignment
31238	Nasal/sinus endoscopy surg	J1	5153	31237	Nasal/sinus endoscopy surg	J1	5153	3123R	5154
31625	Bronchoscopy w/biopsy(s)	J1	5153	31624	Dx bronchoscope/lavage	J1	5153	3162E	5154
31635	Bronchoscopy w/fb removal	J1	5153	31625	Bronchoscopy w/biopsy(s)	J1	5153	3163E	5154
31528	Laryngoscopy and dilation	J1	5154	31541	Larynscop w/tumr exc + scope	J1	5154	3152R	5155
31630	Bronchoscopy dilate/fx repr	J1	5154	31628	Bronchoscopy/lung bx each	J1	5154	3163X	5155
31630	Bronchoscopy dilate/fx repr	J1	5154	31641	Bronchoscopy treat blockage	J1	5154	3163X	5155
31641	Bronchoscopy treat blockage	J1	5154	31629	Bronchoscopy/needle bx each	J1	5154	3164A	5155
30117	Removal of intranasal lesion	J1	5164	31238	Nasal/sinus endoscopy surg	J1	5153	3011Q	5165
30140	Resect inferior turbinate	J1	5164	31240	Nasal/sinus endoscopy surg	J1	5153	3014X	5165
30520	Repair of nasal septum	J1	5164	31020	Exploration maxillary sinus	J1	5164	3052X	5165
30520	Repair of nasal septum	J1	5164	31237	Nasal/sinus endoscopy surg	J1	5153	3052X	5165
30520	Repair of nasal septum	J1	5164	31238	Nasal/sinus endoscopy surg	J1	5153	3052X	5165
30520	Repair of nasal septum	J1	5164	31240	Nasal/sinus endoscopy surg	J1	5153	3052X	5165
30520	Repair of nasal septum	J1	5164	42826	Removal of tonsils	J1	5164	3052X	5165
30630	Repair nasal septum defect	J1	5164	30520	Repair of nasal septum	J1	5164	3063X	5165
41874	Repair tooth socket	J1	5164	21031	Remove exostosis mandible	J1	5164	4187D	5165
42826	Removal of tonsils	J1	5164	43191	Esophagoscopy rigid trnso dx	J1	5302	4282G	5165
93451	Right heart cath	J1	5191	93451	Right heart cath	J1	5191	9345A	5192

Primary HCPCS Code	Primary Short Descriptor	Primary SI	Primary APC Assignment	Secondary J1 or Add-on HCPCS Code	Secondary Short Descriptor	Secondary SI	Secondary APC Assignment	Complexity Adjusted HCPCS Assignment	Complexity Adjusted APC Assignment
93458	L hrt artery/ventricle angio	J1	5191	93454	Coronary artery angio s&i	J1	5191	9345R	5192
93458	L hrt artery/ventricle angio	J1	5191	93458	L hrt artery/ventricle angio	J1	5191	9345R	5192
93459	L hrt art/grft angio	J1	5191	93458	L hrt artery/ventricle angio	J1	5191	9345S	5192
92920	Prq cardiac angioplast 1 art	J1	5192	92974	Cath place cardio brachytx	N		9292X	5193
37221	Iliac revasc w/stent	J1	5193	37221	Iliac revasc w/stent	J1	5193	3722A	5194
37226	Fem/popl revasc w/stent	J1	5193	37226	Fem/popl revasc w/stent	J1	5193	3722G	5194
37238	Open/perq place stent same	J1	5193	37239	Open/perq place stent ea add	N		3723R	5194
C9600	Perc drug-el cor stent sing	J1	5193	C9600	Perc drug-el cor stent sing	J1	5193	C960X	5194
C9604	Perc d-e cor revasc t cabg s	J1	5193	C9601	Perc drug-el cor stent bran	N		C960D	5194
C9604	Perc d-e cor revasc t cabg s	J1	5193	C9604	Perc d-e cor revasc t cabg s	J1	5193	C960D	5194
C9604	Perc d-e cor revasc t cabg s	J1	5193	C9605	Perc d-e cor revasc t cabg b	N		C960D	5194
93620	Electrophysiology evaluation	J1	5212	93613	Electrophys map 3d add-on	N		9362X	5213
33206	Insert heart pm atrial	J1	5223	33225	L ventric pacing lead add-on	N		3320G	5224
33207	Insert heart pm ventricular	J1	5223	33225	L ventric pacing lead add-on	N		3320Q	5224
33208	Insrt heart pm atrial & vent	J1	5223	33225	L ventric pacing lead add-on	N		3320R	5224
33214	Upgrade of pacemaker system	J1	5223	33225	L ventric pacing lead add-on	N		3321D	5224
33228	Remv&replc pm gen dual lead	J1	5223	33225	L ventric pacing lead add-on	N		3322R	5224

Primary HCPCS Code	Primary Short Descriptor	Primary SI	Primary APC Assignment	Secondary J1 or Add-on HCPCS Code	Secondary Short Descriptor	Secondary SI	Secondary APC Assignment	Complexity Adjusted HCPCS Assignment	Complexity Adjusted APC Assignment
43191	Esophagoscopy rigid trnso dx	J1	5302	31525	Dx laryngoscopy excl nb	J1	5153	4319A	5303
43191	Esophagoscopy rigid trnso dx	J1	5302	31526	Dx laryngoscopy w/oper scope	J1	5153	4319A	5303
43191	Esophagoscopy rigid trnso dx	J1	5302	31622	Dx bronchoscope/wash	J1	5153	4319A	5303
43242	Egd us fine needle bx/aspir	J1	5302	43245	Egd dilate stricture	J1	5302	4324B	5303
43242	Egd us fine needle bx/aspir	J1	5302	43249	Esoph egd dilation <30 mm	J1	5302	4324B	5303
43242	Egd us fine needle bx/aspir	J1	5302	43251	Egd remove lesion snare	J1	5302	4324B	5303
43246	Egd place gastrostomy tube	J1	5302	43246	Egd place gastrostomy tube	J1	5302	4324G	5303
43254	Egd endo mucosal resection	J1	5302	43238	Egd us fine needle bx/aspir	J1	5302	4325D	5303
43254	Egd endo mucosal resection	J1	5302	43242	Egd us fine needle bx/aspir	J1	5302	4325D	5303
43254	Egd endo mucosal resection	J1	5302	43249	Esoph egd dilation <30 mm	J1	5302	4325D	5303
43254	Egd endo mucosal resection	J1	5302	43251	Egd remove lesion snare	J1	5302	4325D	5303
43254	Egd endo mucosal resection	J1	5302	43255	Egd control bleeding any	J1	5302	4325D	5303
43254	Egd endo mucosal resection	J1	5302	43259	Egd us exam duodenum/jejunum	J1	5302	4325D	5303
43255	Egd control bleeding any	J1	5302	43255	Egd control bleeding any	J1	5302	4325E	5303
43270	Egd lesion ablation	J1	5302	43254	Egd endo mucosal resection	J1	5302	4327X	5303
43270	Egd lesion ablation	J1	5302	43259	Egd us exam duodenum/jejunum	J1	5302	4327X	5303
47525	Change bile duct catheter	J1	5302	47525	Change bile duct catheter	J1	5302	4752E	5303

Primary HCPCS Code	Primary Short Descriptor	Primary SI	Primary APC Assignment	Secondary J1 or Add-on HCPCS Code	Secondary Short Descriptor	Secondary SI	Secondary APC Assignment	Complexity Adjusted HCPCS Assignment	Complexity Adjusted APC Assignment
47525	Change bile duct catheter	J1	5302	49423	Exchange drainage catheter	J1	5302	4752E	5303
49423	Exchange drainage catheter	J1	5302	49423	Exchange drainage catheter	J1	5302	4942C	5303
49440	Place gastrostomy tube perc	J1	5302	49446	Change g-tube to g-j perc	J1	5302	4944X	5303
47511	Insert bile duct drain	J1	5341	47525	Change bile duct catheter	J1	5302	4751A	5331
47511	Insert bile duct drain	J1	5341	47555	Biliary endoscopy thru skin	J1	5341	4751A	5331
47555	Biliary endoscopy thru skin	J1	5341	47630	Remove bile duct stone	J1	5341	4755E	5331
49507	Prp i/hern init block >5 yr	J1	5341	54520	Removal of testis	J1	5374	4950Q	5331
49561	Rpr ventral hern init block	J1	5341	49507	Prp i/hern init block >5 yr	J1	5341	4956A	5331
32609	Thoracoscopy w/bx pleura	J1	5361	31622	Dx bronchoscope/wash	J1	5153	3260S	5362
32609	Thoracoscopy w/bx pleura	J1	5361	32550	Insert pleural cath	J1	5341	3260S	5362
44970	Laparoscopy appendectomy	J1	5361	58661	Laparoscopy remove adnexa	J1	5361	4497X	5362
47556	Biliary endoscopy thru skin	J1	5361	47511	Insert bile duct drain	J1	5341	4755G	5362
47562	Laparoscopic cholecystectomy	J1	5361	43264	Ercp remove duct calculi	J1	5303	4756B	5362
47563	Laparo cholecystectomy/graph	J1	5361	43262	Endo cholangiopancreatograph	J1	5303	4756C	5362
47563	Laparo cholecystectomy/graph	J1	5361	43264	Ercp remove duct calculi	J1	5303	4756C	5362
49652	Lap vent/abd hernia repair	J1	5361	49505	Prp i/hern init reduc >5 yr	J1	5341	4965B	5362
49652	Lap vent/abd hernia repair	J1	5361	49652	Lap vent/abd hernia repair	J1	5361	4965B	5362

Primary HCPCS Code	Primary Short Descriptor	Primary SI	Primary APC Assignment	Secondary J1 or Add-on HCPCS Code	Secondary Short Descriptor	Secondary SI	Secondary APC Assignment	Complexity Adjusted HCPCS Assignment	Complexity Adjusted APC Assignment
49652	Lap vent/abd hernia repair	J1	5361	58661	Laparoscopy remove adnexa	J1	5361	4965B	5362
49653	Lap vent/abd hern proc comp	J1	5361	49329	Laparo proc abdm/per/oment	J1	5361	4965C	5362
49653	Lap vent/abd hern proc comp	J1	5361	49650	Lap ing hernia repair init	J1	5361	4965C	5362
50593	Perc cryo ablate renal tum	J1	5361	50200	Renal biopsy perq	J1	5072	5059C	5362
50949	Laparoscope proc ureter	J1	5361	58661	Laparoscopy remove adnexa	J1	5361	5094S	5362
50382	Change ureter stent percut	J1	5373	50398	Change kidney tube	J1	5373	5038B	5374
50398	Change kidney tube	J1	5373	49423	Exchange drainage catheter	J1	5302	5039R	5374
50398	Change kidney tube	J1	5373	50398	Change kidney tube	J1	5373	5039R	5374
51040	Incise & drain bladder	J1	5373	52204	Cystoscopy w/biopsy(s)	J1	5373	5104X	5374
51040	Incise & drain bladder	J1	5373	52281	Cystoscopy and treatment	J1	5373	5104X	5374
51102	Drain bl w/cath insertion	J1	5373	52281	Cystoscopy and treatment	J1	5373	5110B	5374
52005	Cystoscopy & ureter catheter	J1	5373	51102	Drain bl w/cath insertion	J1	5373	5200E	5374
52204	Cystoscopy w/biopsy(s)	J1	5373	51102	Drain bl w/cath insertion	J1	5373	5220D	5374
52204	Cystoscopy w/biopsy(s)	J1	5373	55700	Biopsy of prostate	J1	5373	5220D	5374
52214	Cystoscopy and treatment	J1	5373	52204	Cystoscopy w/biopsy(s)	J1	5373	5221D	5374
52214	Cystoscopy and treatment	J1	5373	52224	Cystoscopy and treatment	J1	5373	5221D	5374
52214	Cystoscopy and treatment	J1	5373	55700	Biopsy of prostate	J1	5373	5221D	5374
52224	Cystoscopy and treatment	J1	5373	52276	Cystoscopy and treatment	J1	5373	5222D	5374

Primary HCPCS Code	Primary Short Descriptor	Primary SI	Primary APC Assignment	Secondary J1 or Add-on HCPCS Code	Secondary Short Descriptor	Secondary SI	Secondary APC Assignment	Complexity Adjusted HCPCS Assignment	Complexity Adjusted APC Assignment
52224	Cystoscopy and treatment	J1	5373	55700	Biopsy of prostate	J1	5373	5222D	5374
52276	Cystoscopy and treatment	J1	5373	54161	Circum 28 days or older	J1	5373	5227G	5374
52287	Cystoscopy chemodenervation	J1	5373	51040	Incise & drain bladder	J1	5373	5228Q	5374
52287	Cystoscopy chemodenervation	J1	5373	51102	Drain bl w/cath insertion	J1	5373	5228Q	5374
52287	Cystoscopy chemodenervation	J1	5373	52005	Cystoscopy & ureter catheter	J1	5373	5228Q	5374
52287	Cystoscopy chemodenervation	J1	5373	52204	Cystoscopy w/biopsy(s)	J1	5373	5228Q	5374
52287	Cystoscopy chemodenervation	J1	5373	52214	Cystoscopy and treatment	J1	5373	5228Q	5374
52287	Cystoscopy chemodenervation	J1	5373	52224	Cystoscopy and treatment	J1	5373	5228Q	5374
52287	Cystoscopy chemodenervation	J1	5373	52260	Cystoscopy and treatment	J1	5373	5228Q	5374
52351	Cystouretero & or pyeloscope	J1	5373	52204	Cystoscopy w/biopsy(s)	J1	5373	5235A	5374
52351	Cystouretero & or pyeloscope	J1	5373	52214	Cystoscopy and treatment	J1	5373	5235A	5374
52351	Cystouretero & or pyeloscope	J1	5373	52224	Cystoscopy and treatment	J1	5373	5235A	5374
55700	Biopsy of prostate	J1	5373	52310	Cystoscopy and treatment	J1	5373	5570X	5374
50392	Insert kidney drain	J1	5374	52005	Cystoscopy & ureter catheter	J1	5373	5039B	5375
50393	Insert ureteral tube	J1	5374	52005	Cystoscopy & ureter catheter	J1	5373	5039C	5375
50393	Insert ureteral tube	J1	5374	52332	Cystoscopy and treatment	J1	5374	5039C	5375
52332	Cystoscopy and treatment	J1	5374	50392	Insert kidney drain	J1	5374	5233B	5375

Primary HCPCS Code	Primary Short Descriptor	Primary SI	Primary APC Assignment	Secondary J1 or Add-on HCPCS Code	Secondary Short Descriptor	Secondary SI	Secondary APC Assignment	Complexity Adjusted HCPCS Assignment	Complexity Adjusted APC Assignment
52240	Cystoscopy and treatment	J1	5375	50392	Insert kidney drain	J1	5374	5224X	5376
52240	Cystoscopy and treatment	J1	5375	50393	Insert ureteral tube	J1	5374	5224X	5376
52356	Cysto/uretero w/lithotripsy	J1	5375	50393	Insert ureteral tube	J1	5374	5235G	5376
52356	Cysto/uretero w/lithotripsy	J1	5375	52648	Laser surgery of prostate	J1	5375	5235G	5376
57155	Insert uteri tandem/ovoids	J1	5414	57155	Insert uteri tandem/ovoids	J1	5414	5715E	5415
57260	Repair of vagina	J1	5415	57267	Insert mesh/pelvic flr addon	N		5726X	5416
57265	Extensive repair of vagina	J1	5415	57267	Insert mesh/pelvic flr addon	N		5726E	5416
64635	Destroy lumb/sac facet jnt	J1	5431	64635	Destroy lumb/sac facet jnt	J1	5431	6463E	5432
64708	Revise arm/leg nerve	J1	5431	28035	Decompression of tibia nerve	J1	5431	6470R	5432
64708	Revise arm/leg nerve	J1	5431	64708	Revise arm/leg nerve	J1	5431	6470R	5432
64708	Revise arm/leg nerve	J1	5431	64718	Revise ulnar nerve at elbow	J1	5431	6470R	5432
67113	Repair retinal detach cplx	J1	5492	66982	Cataract surgery complex	J1	5491	6711C	5493
67911	Revise eyelid defect	J1	5503	67917	Repair eyelid defect	J1	5503	6791A	5504
67912	Correction eyelid w/implant	J1	5503	67900	Repair brow defect	J1	5503	6791B	5504
67912	Correction eyelid w/implant	J1	5503	67917	Repair eyelid defect	J1	5503	6791B	5504
67912	Correction eyelid w/implant	J1	5503	67950	Revision of eyelid	J1	5503	6791B	5504
67950	Revision of eyelid	J1	5503	67900	Repair brow defect	J1	5503	6795X	5504
67950	Revision of eyelid	J1	5503	67904	Repair eyelid defect	J1	5503	6795X	5504
67950	Revision of eyelid	J1	5503	67950	Revision of eyelid	J1	5503	6795X	5504
67950	Revision of eyelid	J1	5503	67961	Revision of eyelid	J1	5503	6795X	5504

Primary HCPCS Code	Primary Short Descriptor	Primary SI	Primary APC Assignment	Secondary J1 or Add-on HCPCS Code	Secondary Short Descriptor	Secondary SI	Secondary APC Assignment	Complexity Adjusted HCPCS Assignment	Complexity Adjusted APC Assignment
67966	Revision of eyelid	J1	5503	67966	Revision of eyelid	J1	5503	6796G	5504
67971	Reconstruction of eyelid	J1	5503	67961	Revision of eyelid	J1	5503	6797A	5504
369X2	Intro cath dialysis circuit	J1	5192	368X8	Stent plmt ctr dialysis seg	N		369XB	5193
369X3	Intro cath dialysis circuit	J1	5193	368X8	Stent plmt ctr dialysis seg	N		369XC	5194
369X4	Thrmbc/nfs dialysis circuit	J1	5192	368X8	Stent plmt ctr dialysis seg	N		369XD	5193
369X5	Thrmbc/nfs dialysis circuit	J1	5193	368X8	Stent plmt ctr dialysis seg	N		369XE	5194