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CY17 Medicare Hospital Outpatient Prospective Payment System Proposed Rule Summary

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.**

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.

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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.*

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 the update factor, resulting in a -0.45 percent update.

Table 30 in the proposed rule includes the estimated impact of the proposed rule by provider type. It shows a projected increase of 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 1.7 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. 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.

Although CMS projects an overall increase of 1.7 percent for all hospitals, the proposed rule would have a differential effect on facilities. The table below provides the estimated impact for different types of providers.

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

	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%

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.

1. 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.

2. Comprehensive APCs

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.

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.

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.

3. C-APC Payment Policy for 2017

Using the proposed criteria, CMS proposes 25 additional C-APCs to be paid under the existing C-APC payment policy beginning in 2017. All proposed C-APCs for 2017, including current C-APCs and those being proposed for 2017 are displayed in Table 2 below.

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	
5112	Level 2 Musculoskeletal Procedures	ORTHO	*
5113	Level 3 Musculoskeletal Procedures	ORTHO	*
5114	Level 4 Musculoskeletal Procedures	ORTHO	
5115	Level 5 Musculoskeletal Procedures	ORTHO	
5116	Level 6 Musculoskeletal Procedures	ORTHO	
5153	Level 3 Airway Endoscopy	AENDO	*
5154	Level 4 Airway Endoscopy	AENDO	*
5155	Level 5 Airway Endoscopy	AENDO	*
5164	Level 4 ENT Procedures	ENTXX	*
5165	Level 5 ENT Procedures	ENTXX	
5166	Cochlear Implant Procedure	COCHL	

[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.

C-APC	2017 APC Title	Clinical Family	Proposed New C-APC
5191	Level 1 Endovascular Procedures	VASCX	*
5192	Level 2 Endovascular Procedures	VASCX	
5193	Level 3 Endovascular Procedures	VASCX	
5194	Level 4 Endovascular Procedures	VASCX	
5200	Implantation Wireless PA Pressure Monitor	WPMXX	*
5211	Level 1 Electrophysiologic Procedures	EPHYS	
5212	Level 2 Electrophysiologic Procedures	EPHYS	
5213	Level 3 Electrophysiologic Procedures	EPHYS	
5222	Level 2 Pacemaker and Similar Procedures	AICDP	
5223	Level 3 Pacemaker and Similar Procedures	AICDP	
5224	Level 4 Pacemaker and Similar Procedures	AICDP	
5231	Level 1 ICD and Similar Procedures	AICDP	
5232	Level 2 ICD and Similar Procedures	AICDP	
5244	Level 4 Blood Product Exchange and Related Services	SCTXX	*
5302	Level 2 Upper GI Procedures	GIXXX	*
5313	Level 3 Lower GI Procedures	GIXXX	*
5331	Complex GI Procedures	GIXXX	
5341	Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX	*
5361	Level 1 Laparoscopy & Related Services	LAPXX	
5362	Level 2 Laparoscopy & Related Services	LAPXX	
5373	Level 3 Urology & Related Services	UROXX	*
5374	Level 4 Urology & Related Services	UROXX	*
5375	Level 5 Urology & Related Services	UROXX	
5376	Level 6 Urology & Related Services	UROXX	
5377	Level 7 Urology & Related Services	UROXX	
5414	Level 4 Gynecologic Procedures	GYNXX	*
5415	Level 5 Gynecologic Procedures	GYNXX	
5416	Level 6 Gynecologic Procedures	GYNXX	
5431	Level 1 Nerve Procedures	NERVE	*
5432	Level 2 Nerve Procedures	NERVE	*
5462	Level 2 Neurostimulator & Related Procedures	NSTIM	
5463	Level 3 Neurostimulator & Related Procedures	NSTIM	
5464	Level 4 Neurostimulator & Related Procedures	NSTIM	
5471	Implantation of Drug Infusion Device	PUMPS	
5491	Level 1 Intraocular Procedures	INEYE	*
5492	Level 2 Intraocular Procedures	INEYE	
5493	Level 3 Intraocular Procedures	INEYE	
5494	Level 4 Intraocular Procedures	INEYE	
5495	Level 5 Intraocular Procedures	INEYE	
5503	Level 3 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	*
5504	Level 4 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	*
5627	Level 7 Radiation Therapy	RADTX	
5881	Ancillary Outpatient Services When Patient Dies	N/A	

C-APC	2017 APC Title	Clinical Family	Proposed New C-APC
8011	Comprehensive Observation Services	N/A	

*Proposed New C-APC for CY 2017.

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
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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. 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.

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

4. 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. 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 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. Using the claims processing software, when the total payment for the individual services for specified mental health services 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). It is paid 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). 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.

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.

5. 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

- 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.

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."

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 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.

B. Conversion Factor Update

The proposed OPPS conversion factor for 2017 is $74.909.

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.

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.

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.
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 for rate-setting, CMS uses overall hospital-specific CCRs 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.

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 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 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

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. Table 5 in the proposed rule, copied below, shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals. 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%
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

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 continues 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.

H. 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.

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. 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.

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).

B. OPPS APC-Specific Policies

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.

TABLE 11—CY 2016 IMAGING APCS

CY 2016 APC	CY 2016 APC Group title	CY 2016 status indicator
5521	Level 1 X-Ray and Related Services	S
5522	Level 2 X-Ray and Related Services	S
5523	Level 3 X-Ray and Related Services	S
5524	Level 4 X-Ray and Related Services	S
5525	Level 5 X-Ray and Related Services	S
5526	Level 6 X-Ray and Related Services	S
5531	Level 1 Ultrasound and Related Services	S
5532	Level 2 Ultrasound and Related Services	S
5533	Level 3 Ultrasound and Related Services	S
5534	Level 4 Ultrasound and Related Services	S
5561	Level 1 Echocardiogram with Contrast	S
5562	Level 1 Echocardiogram with Contrast	S
5570	Computed Tomography without Contrast	S
5571	Level 1 Computed Tomography with Contrast and Computed Tomography Angiography	S
5572	Level 2 Computed Tomography with Contrast and Computed Tomography Angiography	S
5581	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast	S
5582	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast	S

TABLE 12—PROPOSED CY 2017 IMAGING APCS

Proposed CY 2017 APC	Proposed CY 2017 APC group title	Proposed CY 2017 status indicator
5521	Level 1 Diagnostic Radiology without Contrast	S
5522	Level 2 Diagnostic Radiology without Contrast	S
5523	Level 3 Diagnostic Radiology without Contrast	S
5524	Level 4 Diagnostic Radiology without Contrast	S
5525	Level 5 Diagnostic Radiology without Contrast	S
5571	Level 1 Diagnostic Radiology with Contrast	S
5572	Level 2 Diagnostic Radiology with Contrast	S
5573	Level 3 Diagnostic Radiology with Contrast	S

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

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). 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 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

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 (Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components) 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

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.

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.

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.

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.

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 below.

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.

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

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

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.

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. 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).

2. Changes to Device Edit Policy

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.

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 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.

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.

For 2017, CMS proposes 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. 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

As described in section IV.A.3. 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.

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.

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

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

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. These items, 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.

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

CY 2016 HCPCS Code	CY 2017 HCPCS Code	CY 2017 Long descriptor	Proposed CY 2017 status indicator	Proposed CY 2017 APC
A9586	A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	1664
C9137	C9137	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U..	G	1844
C9138	C9138	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), 1 I.U.	G	1846
C9349	C9349	PuraPly, and PuraPly Antimicrobial, any type, per square centimeter	G	1657
C9447	C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	1663
C9460	C9460	Injection, cangrelor, 1 mg	G	9460
C9461	C9461	Choline C 11, diagnostic, per study dose	G	9461
C9470	C9470	Injection, aripiprazole lauroxil, 1 mg	G	9470
C9471	C9471	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg	G	9471
C9472	C9472	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU).	G	9472
C9473	C9473	Injection, mepolizumab, 1 mg	G	9473
C9474	C9474	Injection, irinotecan liposome, 1 mg	G	9474
C9475	C9475	Injection, necitumumab, 1 mg	G	9475
C9476	C9476	Injection, daratumumab, 10 mg	G	9476
C9477	C9477	Injection, elotuzumab, 1 mg	G	9477
C9478	C9478	Injection, sebelipase alfa, 1 mg	G	9478
C9479	C9479	Instillation, ciprofloxacin otic suspension, 6 mg	G	9479
C9480	C9480	Injection, trabectedin, 0.1 mg	G	9480
J0596	J0596	Injection, c1 esterase inhibitor (recombinant), Ruconest, 10 units	G	9445
J0695	J0695	Injection, ceftolozane 50 mg and tazobactam 25 mg	G	9452
J0875	J0875	Injection, dalbavancin, 5 mg	G	1823
J1833	J1833	Injection, isavuconazonium sulfate, 1 mg	G	9456
J2407	J2407	Injection, oritavancin, 10 mg	G	1660
J2502	J2502	Injection, pasireotide long acting, 1 mg	G	9454
J2547	J2547	Injection, peramivir, 1 mg	G	9451
J2860	J2860	Injection, siltuximab, 10 mg	G	9455
J3090	J3090	Injection, tedizolid phosphate, 1 mg	G	1662
J7313	J7313	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg	G	9450
J7503	J7503	Tacrolimus, extended release, (envarsus xr), oral, 0.25 mg	G	1845
J8655	J8655	Netupitant 300 mg and palonosetron 0.5 mg	G	9448
J9032	J9032	Injection, belinostat, 10 mg	G	1658
J9039	J9039	Injection, blinatumomab, 1 microgram	G	9449
J9271	J9271	Injection, pembrolizumab, 1 mg	G	1490
J9299	J9299	Injection, nivolumab, 1 mg	G	9453
Q5101	Q5101	Injection, Filgrastim (G–CSF), Biosimilar, 1 microgram	G	1822
Q9950	Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9457
Q9982	Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	G	9459
Q9983	Q9983	Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries	G	9458

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).

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

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 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. CMS proposes a packaging threshold for 2017 of $110.

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.

[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).

- 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 continues this policy, with modifications.

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).

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

4. Payment Adjustment Policy for Radioisotopes Derived From Non-Highly Enriched Uranium 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). In 2017 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 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.

VI. 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).

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.

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. 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 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.

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 5853 (Partial Hospitalization (3 or more services) for CMHCs).

[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.

VII. 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. 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.

VIII. 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 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.

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 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

[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.

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. 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). 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. 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.

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.

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.

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 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 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 HFMA summary of that rule (available at http://www.hfma.org/2015factsheets/), 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 HFMA summary of that rule (available at http://www.hfma.org/2015factsheets/), for further details.

IX. 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%
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. Proposed Treatment of New and Revised Codes

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.

B. 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 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.

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

CY 2017 CPT code	CY 2017 long descriptor	CY 2016 ASC payment indicator *	CY 2017 ASC proposed payment indicator **
0299T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound.	R2 *	R2 **
0402T	Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed).	R2 *	R2 **
10030	Image-guided fluid collection drainage by catheter (*e.g.*, abscess, hematoma, seroma, lymphocele, cyst), soft tissue (*e.g.*, extremity abdominal wall, neck), percutaneous.	P2 *	P2 **
64461	Paravertebral block (PVB) (paraspinous block), thoracic; single injection site (includes imaging guidance, when performed).	P3 *	P3 **
64463	Continuous infusion by catheter (includes imaging guidance, when performed)	P3 *	P3 **
65785	Implantation of intrastromal corneal ring segments	R2 *	P2 **
67229	Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (*e.g.*, retinopathy of prematurity), photocoagulation or cryotherapy.	R2 *	R2 **
C9800	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies.	R2 *	R2 **

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

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.

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

Proposed CY 2017 OPPS/ASC proposed rule 5-digit CMS placeholder code ***	CY 2017 long descriptor	Proposed CY 2017 ASC payment indicator **
369X1 ***	Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report.	P2 *
36X41 ***	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated.	P2 *

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

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

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.

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.

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.

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.

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 below.

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

CY 2017 HCPCS code	CY 2017 long descriptor	Proposed CY 2017 ASC payment indicator
20936	Autograft for spine surgery only (includes harvesting the graft); local (eg, ribs, spinous process, or laminar fragments) obtained from the same incision (List separately in addition to code for primary procedure).	N1
20937	Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision) (List separately in addition to code for primary procedure).	N1
20938	Autograft for spine surgery only (includes harvesting the graft); structural, biocortical or tricortical (through separate skin fascial incision).	N1
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical C2, each additional interspace (List separately in addition to code for separate procedure).	N1
22840	Posterior non-segmental instrumentation (eg, Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation).	N1
22842	Posterior non-segmental instrumentation (eg, Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation).	N1
22845	Anterior instrumentation; 2 to 3 vertebral segments	N1
22851	Application of intervertebral biomechanical device(s) (eg, synthetic cage(s), methlmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure).	N1

C. **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%
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.			

X. 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

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.

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. 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.

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.

Eye surgeries are excluded because the risk profile is more representative of minor surgery.

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.

Five OAS CAHPS-based measures are proposed for addition to the OQR program for 2020 payment.

- 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.

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).

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).

C. Administrative and Data Submission Requirements and Public Reporting

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.

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

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.

XI. 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.

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.

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.

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. 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)).

B. Administrative and Data Submission Requirements

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).

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.

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

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 does not apply to services 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.

XII. 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 thresholds that a program could not exceed and be in compliance.[8] 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.

XIII. 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.

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 5th and 99th percentiles and performance distribution curves at the 25th, 50th and 75th percentiles as compared to the required measure threshold.

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.

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.

Modified Stage 2 in 2017

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 and Reporting	Immunization Reporting Syndromic Surveillance Reporting Specialized Registry Reporting Electronic Reportable Laboratory Result Reporting	Immunization Measure Syndromic Surveillance Measure Electronic Reportable Laboratory Result Measure	Public Health 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 Public Health Registry Reporting Clinical Data Registry Reporting Electronic Reportable Laboratory Result Reporting	Immunization Registry Reporting Measure Syndromic Surveillance Reporting Measure Case Reporting Measure Public Health Registry Reporting Measure Clinical Data Registry Reporting Measure Electronic Reportable Laboratory Result Reporting Measure	Report to 3 Registries or claim exclusions
*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.

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. Requirements 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.

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 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.

XIV. 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.

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.

XV. 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”.

XVI. Addendum A: 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
	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

NQF		2014	2015	2016	2017	2018	2019	2020
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
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*

NQF		2014	2015	2016	2017	2018	2019	2020
[+] 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.								

XVIII. Appendix 1: 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
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.						