FINAL RULE: MEDICARE PROGRAM: HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEMS AND QUALITY REPORTING PROGRAMS; ORGAN PROCUREMENT ORGANIZATION REPORTING AND COMMUNICATION; TRANSPLANT OUTCOME MEASURES AND DOCUMENTATION REQUIREMENTS; ELECTRONIC HEALTH RECORD (EHR) INCENTIVE PROGRAMS; PAYMENT TO NONEXCEPTED OFF-CAMPUS PROVIDER-BASED DEPARTMENT OF A HOSPITAL; HOSPITAL VALUE-BASED PURCHASING (VBP) PROGRAM;

CMS-1656-FC and IFC

SUMMARY

The Centers for Medicare & Medicaid Services (CMS) released the calendar year 2017[1] final rule with comment for Medicare's hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system on November 1, 2016; policies in the final rule generally take effect on January 1, 2017. The final rule with comment also includes an interim final rule with comment that will pay certain off-campus provider-based departments a Medicare Physician Fee Schedule (MPFS) amount equal to 50 percent of the OPPS payment.

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

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-FC.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending

[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 final rule will increase total payments under the OPPS by $773 million, including beneficiary cost-sharing and excluding estimated changes in enrollment, utilization, and case-mix. Taking into account estimated changes in enrollment, utilization, and case-mix, the increase in OPPS expenditures for 2017 is estimated to be $5.0 billion; however, this figure does not include an estimated $50 million in program savings resulting from the proposed implementation of section 603 of the Bipartisan Budget Act of 2015 (discussed in section X.A below).

Payment rates under the OPPS will be increased by a conversion factor adjustment of 1.65 percent (1.55 percent in the proposed rule), based on the hospital inpatient market basket percentage increase of 2.7 percent (2.8 percent in the proposed rule) for inpatient services paid under the hospital inpatient prospective payment system (IPPS)[2], minus the multifactor productivity adjustment of 0.3 percentage points (0.5 percentage points in the proposed rule), and

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

minus an additional 0.75 percentage point adjustment required by the ACA. Hospitals that satisfactorily report quality data will qualify for the full update of 1.65 percent, while hospitals that do not will be subject to the statutory reduction of 2.0 percentage points in the update factor. The reduction in payments for hospitals not meeting the quality reporting requirements is implemented by applying a reporting factor adjustment of 0.980 to the OPPS payments and copayments for all applicable services.

Table 52 in the final rule (reproduced in the Appendix to this summary) includes the estimated impact of the final rule by provider type. It shows a projected increase of 1.7 percent for all facilities and 1.8 percent for all hospitals (all facilities except cancer and children's hospitals, which are held permanently harmless, and CMHCs).

Although CMS projects an overall increase of 1.7 percent for all hospitals, the final rule will have a differential effect on facilities. As shown in the table below and in the full impact analysis included in the appendix to this summary, the largest difference is that rural hospitals are estimated to have an increase of 2.2 percent; this difference from the overall increase of 1.7 percent reflects the impact on rural facilities of APC recalibration (+0.2) and the wage index (+0.3). Major teaching hospitals also will see a smaller increase than average of 1.5 percent due to APC recalibration (-0.2).

	Projected 2017 Impact
All Hospitals	+1.8%
All Facilities (includes CMHCs and cancer and children's hospitals)	+1.7%
Urban	+1.8%
Large Urban	+1.7%
Other Urban	+1.8%
Rural	+2.2%
Major Teaching	+1.5%
Type of ownership:	
Voluntary	+1.9%
Proprietary	+1.8%
Government	+1.6%
CMHCs	-13.7%

Other than the rural categories, those in the impact table with a difference from the average of 0.5 percent or more (i.e., increase is ≤1.2 percent or ≥2.2 percent) are:

Urban Mountain (206 hospitals)	+3.0%
Non-teaching/Non-DSH (10)	-0.2%
DSH Patient Percent = 0 (10)	-0.2%

Estimated Impact on Beneficiaries

CMS estimates that the aggregate beneficiary coinsurance percentage will be 18.5 percent for all services paid under the OPPS in 2017. This reflects the requirement for beneficiaries to pay a 20

percent coinsurance after meeting the annual deductible. The final rule indicates "general system adjustments" along with the changes to the comprehensive APC payment policy result in the 18.5 percent aggregate coinsurance expected to be paid by beneficiaries.

II. Updates Affecting OPPS Payments

A. Recalibration of APC Relative Weights

CMS is recalibrating 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 adopted, including expansion of packaging for lab services and the addition of 25 comprehensive APCs using the previously established criteria.

1. Comprehensive APCs

CMS established and implemented a new policy for comprehensive APCs (C-APCs) in 2015 based on policies finalized in the 2014 final OPPS rule, with a delayed effective date of January 1, 2015, and modified in the 2015 final rule. A C-APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. CMS established C-APCs as a category broadly for OPPS payment and implemented 25 C-APCs beginning in 2015; 10 additional C-APCs were finalized for 2016.

Current Policy for C-APCs

CMS selects HCPCS codes for primary services to be assigned to a C-APC and designates them by status indicator "J1" as listed Addendum B and Addendum J to the final 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 from Medicare's C-APC payment.

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

Services included under the C-APC payment packaging policy include:

- diagnostic procedures, laboratory tests, and other diagnostic tests and treatments that assist in the delivery of the primary procedure;
- visits and evaluations performed in association with the procedure;
- uncoded services and supplies used during the service;

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

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

- Ambulance services
- Brachytherapy
- Diagnostic and mammography screenings
- Physical therapy, speech-language pathology and occupational therapy services reported on a separate facility claim for recurring services
- Pass-through drugs, biologicals, and devices
- Preventive services defined in 42 CFR §410.2
- Self-administered drugs (SADs) - Drugs that are usually self-administered and do not function as supplies in the provision of the comprehensive service
- Services assigned to OPPS status indicator "F" (certain CRNA services, Hepatitis B vaccines and corneal tissue acquisition)
- Services assigned to OPPS status indicator "L" (influenza and pneumococcal pneumonia vaccines)
- Certain Part B inpatient services – Ancillary Part B inpatient services payable under Part B when the primary "J1" service for the claim is not a payable Medicare Part B inpatient service (for example, exhausted Medicare Part A benefits, beneficiaries with Part B only).

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

- If the multiple J1 services reported on a claim map to different C-APCs, CMS designates the J1 service assigned to the C-APC with the highest comprehensive geometric mean cost as the primary service for that claim.
- If the reported multiple J1 services on a claim map to the same C-APC, CMS designates the costliest service (at the HCPCS code level) as the primary service for that claim.

CMS packages all add-on codes and assigns them status indicator "N" (unconditionally packaged). A set of these codes are evaluated for purposes of determining whether a complexity adjustment is appropriate. These are identified in Addendum J to the 2017 final rule. Addendum J can be found at: https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1656-FC-2017-OPPS-FR-Addenda.zip

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. After designating a service as the primary service for a claim, CMS evaluates that service in combination with each of the other procedure codes reported on the claim assigned to status indicator J1 (or certain add-on codes) to determine if they meet the complexity adjustment criteria. For new HCPCS codes, CMS determines initial C-APC assignments and complexity adjustments using the best data available, cross-walking the new HCPCS codes to predecessor codes if possible.

CMS is continuing to follow the criteria for determining which combinations of primary service codes reported in conjunction with an add-on code may qualify 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 finalized a change as proposed to not apply the 2 times rule to the receiving APC when a code combination results in assignment to a higher cost C-APC. 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 proposed 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 2 times rule violations.

[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 Payment Policy for 2017

CMS finalizes a total of 62 C-APCs to be paid under the existing C-APC payment policy in 2017. The final rule identifies 25 of these as new C-APCs beginning in CY 2017 All C-APCs for 2017 are displayed in the table below.

Final Rule 2017 C-APCs			
C-APC	**2017 APC Title**	**Clinical Family**	**New C-APC**
5072	Level 2 Excision/ Biopsy/ Incision and Drainage	EBIDX	*
5073	Level 3 Excision/ Biopsy/ Incision and Drainage	EBIDX	*
5091	Level 1 Breast/Lymphatic Surgery and Related Procedures	BREAS	*
5092	Level 2 Breast/Lymphatic Surgery and Related Procedures	BREAS	*
5093	Level 3 Breast/Lymphatic Surgery & Related Procedures	BREAS	
5094	Level 4 Breast/Lymphatic Surgery & Related Procedures	BREAS	b
5112[a]	Level 2 Musculoskeletal Procedures	ORTHO	*
5113[a]	Level 3 Musculoskeletal Procedures	ORTHO	c
5114[a]	Level 4 Musculoskeletal Procedures	ORTHO	
5115[a]	Level 5 Musculoskeletal Procedures	ORTHO	
5116	Level 6 Musculoskeletal Procedures	ORTHO	b
5153	Level 3 Airway Endoscopy	AENDO	*
5154	Level 4 Airway Endoscopy	AENDO	*
5155	Level 5 Airway Endoscopy	AENDO	*
5164	Level 4 ENT Procedures	ENTXX	*
5165	Level 5 ENT Procedures	ENTXX	
5166	Cochlear Implant Procedure	COCHL	
5191	Level 1 Endovascular Procedures	VASCX	c
5192	Level 2 Endovascular Procedures	VASCX	
5193	Level 3 Endovascular Procedures	VASCX	
5194	Level 4 Endovascular Procedures	VASCX	b
5200	Implantation Wireless PA Pressure Monitor	WPMXX	*
5211	Level 1 Electrophysiologic Procedures	EPHYS	
5212	Level 2 Electrophysiologic Procedures	EPHYS	
5213	Level 3 Electrophysiologic Procedures	EPHYS	
5222	Level 2 Pacemaker and Similar Procedures	AICDP	
5223	Level 3 Pacemaker and Similar Procedures	AICDP	
5224	Level 4 Pacemaker and Similar Procedures	AICDP	
5231	Level 1 ICD and Similar Procedures	AICDP	
5232	Level 2 ICD and Similar Procedures	AICDP	
5244	Level 4 Blood Product Exchange and Related Services	SCTXX	*
5302	Level 2 Upper GI Procedures	GIXXX	*
5303	Level 3 Upper GI Procedures	GIXXX	*
5313	Level 3 Lower GI Procedures	GIXXX	*
5331	Complex GI Procedures	GIXXX	
5341	Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX	*

Final Rule 2017 C-APCs			
C-APC	**2017 APC Title**	**Clinical Family**	**New C-APC**
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	b
5503	Level 3 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	*
5504	Level 4 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	*
5627	Level 7 Radiation Therapy	RADTX	
5881	Ancillary Outpatient Services When Patient Dies	N/A	
8011	Comprehensive Observation Services	N/A	

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

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
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

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 (HSCT), CMS finalized with modification its proposal 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) will be assigned to this C-APC and a "J1" status indicator assigned to this code. The costs for all covered OPD services included on the claim, including donor acquisition services, would be packaged into the C-APC rate. CMS would also analyze these costs using its comprehensive cost accounting methodology to establish future C-APC rates. CMS establishes a 2017 payment rate for C-APC 5244 of $15,267.

For future ratesetting, CMS will 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 will 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 will 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 new revenue code 0815 would map to 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 is instructing hospitals to no longer use revenue code 0819 for the identification of stem cell acquisition charges for allogeneic bone marrow/stem cell transplants.

The final payment rate for new C-APC 5244 is $27,752 for CY 2017.

2. 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

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

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 proposed to continue the composite APC policy that has been employed since 2008 for LDR Prostate Brachytherapy. Under this policy, the OPPS provides a single payment when the composite service, identified by CPT code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) and CPT code 77778 (Interstitial radiation source application; complex), is furnished in a single hospital encounter.

CMS calculates the geometric mean cost of approximately $3,598 ($3,581 in the proposed rule) for these procedures upon which the final CY 2017 payment rate for composite APC 8001 is based.

Mental Health Services Composite APC (APC 8010)

For 2017, CMS finalized without change its proposal to continue its longstanding payment policy of limiting the combined payment for specified less intensive mental health services furnished on the same date to the payment for a day of partial hospitalization, which the agency considers to be the most resource intensive of all outpatient mental health treatments. Using the claims processing software, when the total payment for the individual services for specified mental health services – based on the payment rates associated with those APCs – provided by one hospital to a single beneficiary on one date of service exceeds the maximum per diem partial hospitalization payment, those specified mental health services are assigned to APC 8010 (Mental Health Services Composite) at the same payment rate that it is establishing for APC 5862 (Level 2 Partial Hospitalization (4 or more services) for hospital-based PHPs) which is the maximum partial hospitalization per diem payment rate for a hospital, and that the hospital will continue to be paid the payment rate for composite APC 8010. Under this policy, the code editor would continue to determine whether to pay for these specified mental health services individually, or to make a single payment at the same payment rate established for APC 5862 for all of the specified mental health services furnished by the hospital on that single date of service.

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

For 2017, CMS is continuing 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 final rule lists the HCPCS codes that CMS is making subject to the multiple imaging composite policy for 2017.

3. Changes to packaged items and services

For 2017, CMS finalized 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

For 2017, CMS made two changes to the laboratory test packaging policy:

- Discontinue the unrelated laboratory test exception (and the associated "L1" modifier that designates separate payment). With this change, CMS proposed 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.

- CMS is finalizing the above policies as proposed that were largely supported by commenters. CMS declined to expand the molecular pathology/ADLT exception to all multi-analyte with algorithmic analysis tests as requested by commenters.

Conditional Packaging Status Indicators "Q1" and "Q2"

To identify packaged payment versus separate payment of items and services, CMS uses status indicators applied to CPT and HCPCS codes. There are several different indicators for conditional packaging, which means that, under certain circumstances, items and services are packaged, and under other circumstances, they are paid separately. Two of these status indicators indicate packaging of services furnished on the same date: status indicator "Q1," which packages items or services on the same date of service with services assigned status indicator "S" (Procedure or Service, Not Discounted When Multiple), "T" (Procedure or Service, Multiple Procedure Reduction Applies), or "V" (Clinic or Emergency Department Visit); and status

indicator “Q2,” which packages items or services on the same date of service with services assigned status indicator “T.” Other conditional packaging status indicators, “Q4” (Conditionally packaged laboratory tests) and “J1”/“J2” (Hospital Part B services paid through a comprehensive APC), package services on the same claim, regardless of the date of service.

For 2017, CMS finalized without change a proposal 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).

B. Conversion Factor Update

The OPPS conversion factor for 2017 is $75.001.

Hospitals that fail to meet the reporting requirements of the hospital Outpatient Quality Reporting program (OQR) are subject to a reduction of 2.0 percentage points, as discussed in section XI.

The table below shows the calculation of the conversion factor for 2017.

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 Final Rule Conversion Factor
$73.725	1.0002	0.9999	1.0003	1.0004	1.0165	
	$73.740	$73.732	$73.754	$73.784	$75.001	$75.001

To calculate the 2017 reduced market basket conversion factor for those hospitals that fail to meet the requirements of the OQR, the final rule applies a reduced fee schedule increase factor such that the conversion factor for hospitals that do not report quality data is 0.98 of the conversion factor for hospitals that do report quality data. The 2017 final rule conversion factor for hospitals that do not report quality data is $73.501. (Note: This conversion factor is slightly less than if a 2 percentage point reduction was applied to the 1.65 percent increase factor for hospitals that report quality data. If an update of -0.35 percent was applied (1.65 – 2.0), the conversion factor for hospitals that do not report quality data would be $73.526 or about 2.5 cents higher).

C. Wage Index Changes

CMS is continuing 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 final rule wage index is based on the FY 2017 IPPS final rule post-classified wage index. This includes adoption of revisions to several labor market areas made by the Office of Management and Budget (OMB) in OMB Bulletin No. 15-01 issued on July 15, 2015. The wage index tables are available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-

Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2017-Wage-Index-Home-Page.html.

For non-IPPS hospitals paid under the OPPS, CMS is continuing its policy to assign the wage index that would be applicable if the hospital were paid under the IPPS, based on its geographic location and any applicable wage index adjustments.

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

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

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

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

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

For CMHCs, CMS will 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 final 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 for rate-setting, CMS uses 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 final rule updates the default ratios for 2017 using the most recent cost report data and CMS' standard method for calculating this update; for Maryland, CMS continues to use an overall weighted average CCR for all hospitals in the nation.

Table 4 in the final rule sets out the statewide default CCRs for urban and rural areas in each state for 2017 and the comparable default CCRs for 2016. Most CCR changes shown in Table 4 are small. The five largest changes are those for rural Utah (-0.144), rural Alaska (-0.139), rural Washington (-0.078), Puerto Rico (-0.063) and urban Minnesota (-0.058).

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

For 2017, CMS is continuing to apply a 7.1 percent payment adjustment for rural SCHs, including Essential Access Community Hospitals (EACH), 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 is continuing 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 final rule, copied below, shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals, with increases in OPPS payments for 2017 ranging from 14.0 percent to 58.7 percent. As noted, the actual amount of the 2017 cancer hospital payment adjustment for each cancer hospital is determined at cost report settlement and depends on each hospital's 2017 payments and costs.

The 2017 final 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.—FINAL ESTIMATED 2017 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for 2017
050146	City of Hope Comprehensive Cancer Center	25.8%
050660	USC Norris Cancer Hospital	14.0%
100079	Sylvester Comprehensive Cancer Center	32.4%
100271	H. Lee Moffitt Cancer Center & Research Institute	27.3%
220162	Dana-Farber Cancer Institute	49.8%
330154	Memorial Sloan-Kettering Cancer Center	50.4%
330354	Roswell Park Cancer Institute	30.0%
360242	James Cancer Hospital & Solove Research Institute	37.9%
390196	Fox Chase Cancer Center	16.6%
450076	M.D. Anderson Cancer Center	52.3%
500138	Seattle Cancer Care Alliance	58.7%

G. Hospital Outpatient Outlier Payments

For the 2017 final 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 (same as the proposed rule and compared to $3,250 in 2016). CMS is continuing to set the outlier payment equal to 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount when both the 1.75 multiple threshold and the fixed-dollar threshold ($3,825) are met.

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

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

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 final rule do not reflect application of the hospital deductible limit.
The final rule estimates that, in aggregate, the percentage of beneficiary liability for OPPS payments in 2017 will be 18.5 percent, a decrease from the 19.3 percent estimated for 2016 in the 2016 OPPS final rule.

III. OPPS Ambulatory Payment Classification (APC) Group Policies

A. OPPS Changes – Variations within APCs

1. APC Exceptions to the 2 Times Rule

After considering the public comments, CMS adopted its proposals with modifications. Table 9 below of the final rule lists 7 APCs that CMS is excepting from the 2 times rule for CY 2017.

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

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

B. 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 finalizes the expansion of the New Technology APC groups by adding 3 more levels with two parallel status indicators, Levels 49 through 51. 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 proposed this expansion to accommodate the assignment of the retinal prosthesis implantation procedure to another New Technology APC.

2. Procedures Assigned to New Technology APC Groups for 2017

CMS is continuing its current policy to retain services within New Technology APC groups until it obtains sufficient claims data to justify reassignment of the service to a clinically appropriate APC.

Retinal Prosthesis Implant Procedure

For 2017, CMS proposed 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). Commenters generally supported CMS' proposal related to the Argus® II New Technology APC assignment and CMS is finalizing the proposal without change.

C. OPPS APC-Specific Policies

Addendum B to the final rule identifies with a comment indicator "CH" those HCPCS codes for which CMS is making a change to the APC assignment or status indicator. CMS states that in many cases, the 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 changing the status indicators for some codes because, based on new policies, CMS believes another status indicator more accurately describes their payment status. In addition, CMS is renaming existing APCs or creating new clinical APCs to complement 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 proposed further restructuring of the OPPS imaging APCs. The proposed restructuring would consolidate the imaging APCs from 17 APCs to 8 APCs. (Table 11 of the proposed rule showed the 2016 imaging APCs and Table 12 of the proposed rule showed the proposed 2017 imaging APCs.) The specific APC assignments for each service grouping were listed in Addendum B of the proposed rule. CMS noted 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.

In the final rule, CMS modified its proposal in response to public comment by changing the title of the diagnostic radiology series of APCs to "Level […] Imaging" (either without contrast or with contrast) instead of "Diagnostic Radiology." In addition, CMS received many code-specific

comments requesting a different reassignment than CMS proposed. CMS changed the APC assignment for some of these codes but not for others. The final APC assignment for individual HCPCS codes can be found in Addendum B of the final rule.

Table 19 (page 293 of the display copy of the final rule) is a list of services requested to be reassigned to the next higher level imaging APC. The table shows the proposed and final 2017 APC and whether or not CMS agreed with the request. Table 20 (page 296 of the display copy of the final rule) is a list of services requested to be reassigned to non-imaging APCs. The table shows the proposed and final 2017 APC and whether or not CMS agreed with the request. Table 21 (page 301 of the display copy of the final rule) shows the final 2017 imaging APCs (number and title; 5521 – 5524 corresponding to Level 1- 4 Imaging APCs without contrast and 5571 - 5573 corresponding to Level 1 – 3 Imaging APCs with contrast).

TABLE 21—FINAL CY 2017 IMAGING APCS

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

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

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

3. Transprostatic Urethral Implant Procedure

The procedure described by HCPCS code C9740 (Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants) is one of two procedure codes associated with the UroLift System, which is used to treat patients with benign prostatic hyperplasia (BPH). The procedure was assigned to the New Technology APC 1564 on April 1, 2014. For 2016, CMS assigned HCPCS code C9740 to New Technology APC 1565 (New Technology – Level 28 ($5,000 - $5,500) with a payment rate of $5,250).

For the 2017 update, the review of claims data for HCPCS code C9740 shows a geometric mean cost of approximately $6,312 based on 585 single claims. Based on this information, CMS proposed 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.

Commenters generally supported CMS' proposed policy and CMS finalized it without modification.

IV. OPPS Payment for Devices

A. Pass-Through Payments for Devices

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

CMS finalizes the following device categories will continue to be eligible for pass-through payments in 2017:

- 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.

For 2017, CMS will package the costs of the device described by HCPCS code C2624 I (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.

2. New Device Pass-Through Applications

a. 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 the 2017 OPPS/ASC proposed rule. Applicants received for the remaining 2016 quarters (June 1, September 1, and December 1) will be presented in the 2018 OPPS/ASC proposed rule.

CMS does not approve device pass-through payment status for 2017 for the three applicants:

1. BioBag® (Larval Debridement Therapy in a Contained Dressing)
2. Encore™ Suspension System
3. Endophys Pressure Sensing System (Endophys PSS) or Endophys Pressure Sensing Kit

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

CMS finalizes its proposal pass-through eligibility period would begin on the first date on which pass-through payment is made. It notes that this 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. CMS notes this policy allows for more robust data collection for the purposes of setting future APC rates to accurately include the device costs.

4. Making the Transitional Pass-Through Payment Period 3 Years for All Pass-Through Devices and Expire Pass-Through Status on a Quarterly Rather Than Annual Basis

CMS finalizes its proposal, 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 this policy pass-through status would expire on September 30, 2020 for a device with pass-through payment first effective on October 1, 2017.

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

CMS finalizes its proposal to use the "Implantable Devices Charged to Patients CCR instead of the average hospital-wide CCR to calculate transitional pass-through payments for devices beginning with device pass-through payments in 2017. If the CCR for the "Implantable Devices Charged to Patients" CCR is not available for a particular hospital, CMS will use the hospital-wide CCR to calculate pass-through payments.

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

For 2017, CMS finalizes its proposal 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 policy 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

CMS adopts its proposal to assign device-intensive status to all procedures that require the implantation of a device and have an individual HCPCS code-level device offset of greater than 40 percent, regardless of the APC assignment. 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 finalizes applying a device-intensive status with a default device offset set at 41 percent until claims data are available to establish the HCPCS code-level device offset. CMS also finalizes that in certain rare instances, such as in the case of a very expensive implantable device, CMS may temporarily assign a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer.

The full listing of device-intensive procedures is posted at the CMS Web site at: http://www,cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.htnl.

2. Changes to Device Edit Policy

For 2017, CMS finalizes its proposal to apply the device claims editing policy on a procedure level rather than APC level, consistent with its finalized policy to make device-intensive determinations at the HCPCS code level. For 2017 and subsequent years, CMS will apply the device coding requirements to the newly defined (individual HCPCS code-level device offset greater than 40 percent) device-intensive procedures.

CMS is creating HCPCS code C1889 to recognize devices furnished during a device intensive procedure that are not described by a specific Level II HCPCS Category C-code. Any device code, including C1889, when reported on a claim with a device-intensive procedure, will satisfy the edit requiring a device code to be reported on a claim with a device-intensive procedure.

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 will 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 finalizes its proposal 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 will also continue using the three criteria for determining the procedures to which the 2017 device-intensive policy will apply. Specifically, for 2017:

- all procedures must involve implantable devices that would be reported if device insertion procedures were performed;

- 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);
- (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

CMS finalizes its proposal that the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC will be calculated using the median cost instead of the geometric mean cost. For 2017, CMS reassigns the procedure described by CPT code 0308T to APC 5495 (Level 5 Intraocular Procedures). CMS notes it will be the only procedure code assigned to APC 5495 and it will continue to determine the payment rate using median cost. The final 2017 payment rate, calculated using the median cost, is approximately $18,984.

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.4. above for devices, CMS proposed, 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 as possible to a full 3 years all pass-through payment drugs, biologicals, and radiopharmaceuticals. Under the proposal, pass-through status would expire on September 30, 2020 for a drug, biological, or radiopharmaceutical with pass-through payment first effective on October 1, 2017. CMS finalized this proposal without modification. The new policy will apply to all drugs, biologicals and radiopharmaceuticals that are newly approved in 2017 for pass-through status. CMS declined a commenters' request to apply the new policy to drugs, biologicals and radiopharmaceuticals already receiving pass-through payment as of January 1, 2017.

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

CMS finalized it proposal to terminate the pass-through payment status for the 15 drugs and biologicals effective January 1, 2017. These items were approved for pass-through status on or before January 1, 2015. Except for the policy-packaged drugs, which are drugs and biologicals that are always packaged when they do not have pass-through payment status, CMS makes a separate payment if the product's estimated per day cost exceeds the OPPS drug packaging threshold, which will be $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).

Table 35 (below) of the final rule includes a list of those drugs and biologicals with expiring pass-through payment status in 2017. The packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B to the final rule (which is available on the CMS website).

TABLE 35—DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS EXPIRES DECEMBER 31, 2016

CY 2017 HCPCS code	CY 2017 long descriptor	Final CY 2017 status indicator	Final CY 2017 APC
C9497	Loxapine, inhalation powder, 10 mg	K	9497
J1322	Injection, elosulfase alfa, 1 mg	K	1480
J1439	Injection, ferric carboxymaltose, 1 mg	N	N/A
J1447	Injection, TBO-Filgrastim, 1 microgram	N	N/A
J3145	Injection, testosterone undecanoate, 1 mg	N	N/A
J3380	Injection, vedolizumab, 1 mg	K	1489
J7181	Injection, factor xiii a-subunit, (recombinant), per iu	N	N/A
J7200	Factor ix (antihemophilic factor, recombinant), Rixubus, per i.u	N	N/A
J7201	Injection, factor ix, fc fusion protein (recombinant), per iu	N	N/A
J7205	Injection, factor viii fc fusion (recombinant), per iu	K	1656
J7508	Tacrolimus, extended release, (astagraf xl), oral, 0.1 mg	N	N/A
J9301	Injection, obinutuzumab, 10 mg	N	N/A
J9308	Injection, ramucirumab, 5 mg	K	1488
J9371	Injection, Vincristine Sulfate Liposome, 1 mg	K	1466
Q4121	Theraskin, per square centimeter	N	N/A

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

CMS finalized its proposal with modification to continue pass-through status in 2017 for 38 drugs, biologicals and radiopharmaceuticals. None of these products will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2016.

For 2017, CMS will 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 will 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).

CMS will continue its policy that the pass-through payment portion of the total drug payment is the difference between the pass-through payment rate of ASP+6 percent and the 2017 payment rate that CMS sets for non-pass-through, separately payable drugs. Except for the policy-packaged drugs, the pass-through portion is zero since CMS pays both pass-through and non-pass-through drugs at ASP+6 percent. For policy-packaged drugs, their pass-through payment amount would be equal to ASP+6 percent for 2017 because, if not for having pass-through status, payment for these products would be packaged into the associated procedure.

Table 36 of the final rule lists the items, which were approved for pass-through status between January 1, 2014 and July 1, 2016. Pass-through drugs and biologicals are identified by status indicator "G" in Addenda A and B.

TABLE 36—DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS IN CY 2017

CY 2016 HCPCS code	CY 2017 HCPCS code	CY 2017 long descriptor	CY 2017 status indicator	CY 2017 APC
A9586	A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	1664
N/A	A9588	Fluciclovine f-18, diagnostic, 0.1 mCi	G	9052
N/A	A9587	Gallium Ga-68, dotatate, diagnostic, 1 mCi	G	9056
N/A	C9140	Injection, Factor VIII (antihemophilic factor, recombinant) (Afstyla), 1 I.U	G	9043
C9137	J7207	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U	G	1844
C9138	J7209	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), per i.u	G	1846
C9139	J7202	Injection, Factor IX, albumin fusion protein (recombinant), Idelvion, 1 i.u	G	9171
C9349	Q4172	PuraPly, and PuraPly Antimicrobial, any type, per square centimeter	G	1657
C9447	C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	1663
C9460	C9460	Injection, cangrelor, 1 mg	G	9460
C9461	A9515	Choline C 11, diagnostic, per study dose	G	9461
C9470	J1942	Injection, aripiprazole lauroxil, 1 mg	G	9470
C9471	J7322	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg	G	9471
C9472	J9325	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)	G	9472
C9473	J2182	Injection, mepolizumab, 1 mg	G	9473
C9474	J9205	Injection, irinotecan liposome, 1 mg	G	9474
C9475	J9295	Injection, necitumumab, 1 mg	G	9475
C9476	J9145	Injection, daratumumab, 10 mg	G	9476
C9477	J9176	Injection, elotuzumab, 1 mg	G	9477

C9478	J2840	Injection, sebelipase alfa, 1 mg	G	9478
C9479	J7342	Instillation, ciprofloxacin otic suspension, 6 mg	G	9479
C9480	J9352	Injection, trabectedin, 0.1 mg	G	9480
C9481	J2786	Injection, reslizumab, 1 mg	G	9481
C9482	C9482	Injection, sotalol hydrochloride, 1 mg	G	9482
C9483	C9483	Injection, atezolizumab, 10 mg	G	9483
N/A	J0570	Buprenorphine implant, 74.2 mg	G	9058
J0596	J0596	Injection, c-1 esterase inhibitor (human), Ruconest, 10 units	G	9445
J0695	J0695	Injection, ceftolozane 50 mg and tazobactam 25 mg	G	9452
J0875	J0875	Injection, dalbavancin, 5 mg	G	1823
J1833	J1833	Injection, isavuconazonium sulfate, 1 mg	G	9456
J2407	J2407	Injection, oritavancin, 10 mg	G	1660
J1833	J1833	Injection, isavuconazonium sulfate, 1 mg	G	1660
J2502	J2502	Injection, pasireotide long acting, 1 mg	G	9451
J2860	J2860	Injection, siltuximab, 10 mg	G	9455
J3090	J3090	Injection, tedizolid phosphate, 1 mg	G	1662
N/A	J7179	Injection, von willebrand factor (recombinant), (Vonvendi), 1 i.u. vwf:rco	G	9059
J7313	J7313	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg	G	9450
J7503	J7503	Tacrolimus, extended release, (envarsus xr), oral, 0.25 mg	G	1845
J8655	J8655	Netupitant (300 mg) and palonosetron (0.5 mg)	G	9448
J9032	J9032	Injection, belinostat, 10 mg	G	1658
J9039	J9039	Injection, blinatumomab, 1 mcg	G	9449
J9271	J9271	Injection, pembrolizumab, 1 mg	G	1490
J9299	J9299	Injection, nivolumab, 1 mg	G	9453
Q5101	Q5101	Injection, Filgrastim (G–CSF), Biosimilar, 1 microgram	G	1822
Q9950	Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9459
C9458	Q9983	Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries	G	9458

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 finalized its proposal 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 its 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 https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/2017-OPPS-HCPCS-Device-Offset.zip

[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).

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"

CMS finalizes its proposed policy without modification. As background, "threshold-packaged drugs" under the OPPS are drugs, non-implantable biologicals and therapeutic radiopharmaceuticals whose packaging status is determined by the packaging threshold. If a drug's average cost per day exceeds the annually determined packaging threshold, it is separately payable and, if not, it is packaged. For 2016, the packaging threshold for drugs, biologicals, and radiopharmaceuticals that are not new and do not have pass-through status is $100. CMS is finalizing a packaging threshold for 2017 of $110.

High/Low Cost Threshold for Packaged Skin Substitutes

For 2017, as in 2016, CMS finalized as proposed without a policy 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). The final CY 2017 MUC threshold is $33 per cm^2 (rounded to the nearest $1) and the final CY 2017 PDC threshold is $716 (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 37 in the 2017 final rule shows the high/low cost status for each skin substitute product in 2017. CMS assigns 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 the 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.

TABLE 37—SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2017

CY 2017 HCPCS code	CY 2017 short descriptor	CY 2017 High/low assignment
C9363	Integra Meshed Bil Wound Mat	High.
Q4100	Skin Substitute, NOS	Low.
Q4101	Apligraf	High.
Q4102	Oasis Wound Matrix	Low.
Q4103	Oasis Burn Matrix	High.
Q4104	Integra BMWD	High.
Q4105	Integra DRT	High.
Q4106	Dermagraft	High.
Q4107	GraftJacket	High.
Q4108	Integra Matrix	High.
Q4110	Primatrix	High.
Q4111	Gammagraft	Low.
Q4115	Alloskin	Low.
Q4116	Alloderm	High.
Q4117	Hyalomatrix	Low.
Q4119	Matristem Wound Matrix	Low.
Q4120	Matristem Burn Matrix	High.
Q4121	Theraskin	High.
Q4122	Dermacell	High.
Q4123	Alloskin	High.
Q4124	Oasis Tri-layer Wound Matrix	Low.
Q4126	Memoderm/derma/tranz/integup	High.
Q4127	Talymed	High.
Q4128	Flexhd/Allopatchhd/Matrixhd	High.
Q4129	Unite Biomatrix	High.
Q4131	Epifix	High.
Q4132	Grafix Core	High.
Q4133	Grafix Prime	High.
Q4134	hMatrix	Low.
Q4135	Mediskin	Low.
Q4136	Ezderm	Low.
Q4137	Amnioexcel or Biodexcel, 1cm	High.
Q4138	Biodfence DryFlex, 1cm	High
Q4140	Biodfence 1cm	High.
Q4141	Alloskin ac, 1cm	High.
Q4143	Repriza, 1cm	High.
Q4146	Tensix, 1CM	High
Q4147	Architect ecm, 1cm	High.
Q4148	Neox 1k, 1cm	High.
Q4150	Allowrap DS or Dry 1 sq cm	High.
Q4151	AmnioBand, Guardian 1 sq cm	High.
Q4152	Dermapure 1 square cm	High.
Q4153	Dermavest 1 square cm	High.
Q4154	Biovance 1 square cm	High.
Q4156	To sell100 1 square cm	High.
Q4157	Revitalon 1 square cm	High.

Q4158	MariGen 1 square cm	High.
Q4159	Affinity 1 square cm	High.
Q4160	NuShield 1 square cm	High.
Q4161	NuShield 1 square cm	Low.
Q4162	Amnio bio and woundex flow	Low.
Q4163	Amnion bio and woundex sq cm	High.
Q4164	Helicoll, per square cm	High.
Q4165	Keramatrix, per square cm	Low.
Q4166	Cytal, per square cm	Low.
Q4167	Truskin, per square cm	Low.
Q4168	Amnioband, 1 mg	Low.
Q4169	Artacent wound, per square cm	Low.
Q4170	Cygnus, per square cm	Low.
Q4171	Interfyl, 1 mg	Low.
Q4172*	PuraPly, PuraPly antimic	High.
Q4173	Palingen or palingen xplus, per sq cm	Low.
Q4175	Miroderm, per square cm	Low.

* Pass-through payment status in CY 2017.

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 packaging status, are listed in Table 38 of the final rule.

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

For 2017, CMS finalized as proposed its policy to continue to pay separately payable drugs and biologicals at ASP+6 percent. The payment rates shown for drugs and biologicals in Addenda A and B of the final rule will be updated through the quarterly update process to reflect the actual payment rates that will be used beginning January 1, 2017. Payment rates effective January 2017 will be released near the end of December 2016 and will be based on ASP data submitted by manufacturers for the third quarter of 2016 (July 1, 2016 through September 30, 2016). Payment rates for drugs and biologicals in Addenda A and B to this final rule for which there was no ASP information available for October 2016 are based on mean unit cost in the available 2015 claims data. If ASP information becomes available for payment for the quarter beginning in January 2017, CMS will price payment for these drugs and biologicals based on the newly available ASP information. For drugs and biologicals that have ASP information available for this final rule (reflecting October 2016 ASP data) that do not have ASP information available for the quarter beginning in January 2017, payment will be paid based on mean unit cost data derived from 2015 hospital claims.

Biosimilar Biological Products

For 2017, CMS is continuing its established policies for biosimilar biological products without change. For 2016, CMS established 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 non-pass-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.

3. Payment Policy for Therapeutic Radiopharmaceuticals

As proposed for 2017, CMS is continuing to pay for all non-pass-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). CMS indicated that it would evaluate annually the continuing need and amount of this transitional payment. For the 2017 proposed and now final rule, CMS reassessed the $10 additional payment amount and did not identify any new information to cause a payment change. Thus, CMS will continue to provide an additional $10 payment for radioisotopes produced by non-HEU sources.

5. Payment for Blood Clotting Factors

As proposed for 2017, CMS is continuing to pay for blood clotting factors using the same methodology that it uses to pay other non-pass-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. Because this information was not available in the final rule, CMS will announce the actual fee through program instructions and will post the updated rate on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/ClotFactorFurnishFee.html.

When blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee also is applied to the payment.

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

As proposed for 2017, CMS is continuing to use the same payment policy as in 2016 for non-pass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data. The 2017 payment status of each of the non-pass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data is listed in Addendum B to the final rule, which is available on the CMS website.

VI. Payment for Partial Hospitalization Program (PHP) Services

A. PHP APC Update for 2017

For 2017, CMS finalizes its proposals for the calculation of the partial hospitalization program (PHP) APC per diem payment rates for Community Mental Health Centers (CMHCs) and for hospital-based PHPs. Specifically, for PHP services furnished in 2017, CMS combines the Level 1 and Level 2 PHP APCs for CMHCs and the Level 1 and Level 2 APCs for hospital-based PHPs. For CMHCs, APC 5853 replaces APCs 5851 and 5852, and for hospital-based PHPs, APC 5863 replaces APCs 5861 and 5862. Thus, the payment rate by provider type will be the same whether the provider furnishes 3 or 4 or more PHP services per day.

The final costs are contained in Table 41 of the final rule (reproduced below).

TABLE 41. 2017 PHP APC GEOMETRIC MEAN PER DIEM COSTS

2017 APC	Group Title	PHP APC Geometric Mean Per Diem Costs
5853	Partial Hospitalization (3 or more services per day) for CMHCs	$124.92
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	$213.14

Note: The final CMHC geometric mean per diem cost is lower than that calculated for the proposed rule ($135.30), but the final hospital-based geometric mean per diem cost is higher than that calculated for the proposed rule ($192.57).

For 2017, the outpatient mental health treatment cap will equal the combined hospital-based PHP rate under APC 5863. The outpatient mental health treatment cap limits the maximum payment for a day of individually billed outpatient mental health services.

B. Outlier Policy for CMHCs

CMS did not receive any comments on its proposals for its CMHC outlier policy and outlier cap, and it finalizes them without modification.

1. Estimated Outlier Threshold

For 2017, CMS designates 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 will set the outlier threshold for CMHCs for 2017 at 3.4 times the highest CMHC PHP APC payment rate (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 set a dollar threshold for CHMC outlier payments as it applies to other OPPS outlier payments.

2. CMHC Outlier Cap

CMS finalizes its proposal to implement a CMHC outlier payment cap to be applied at the provider level, such that in any given year, an individual CMHC will receive no more than a set percentage of its CMHC total per diem payments in outlier payments. The CMHC outlier payment cap will be set at 8 percent of the CMHC's total per diem payments for that same calendar year. CMS simulated the effect of varying outlier cap percentage options (see Table 42 in final rule) and found that 8 percent would have the intended effect of reducing outlier payments to those CMHCs with excessive outlier payments, while not harming those CMHCs with more reasonable outlier payment amounts.

C. Regulatory Impact

CMS estimates that payments to CMHCs will decrease by 13.7 percent in 2017. Almost all of the decrease is attributable to the CMS policy to combine APCs 5851 and 5852 into new APC 5853 (Partial Hospitalization (3 or more services) for CMHCs). CMS' estimates also include the trimming

VII. Procedures That Would Be Paid Only as Inpatient Procedures

A. Changes to the Inpatient Only (IPO) List

CMS is continuing to use the same methodology to review the inpatient-only list. Under that methodology, CMS proposed to remove the six procedures (four spine procedures and two laryngoplasty codes) from the inpatient-only list for 2017. CMS received comments both in support of and opposed to removing these procedures from inpatient-only list. In response to comment, CMS is removing one additional code from the inpatient-only list:

CPT Code	Code Descriptor	CY 2017 APC Assignment	CY 2017 Status Indicator
22585*	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy, and decompression of spinal cord and/or nerve roots; each additional interspace (List separately in addition to code for primary procedure	N/A	N
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

*Not included in the proposed rule. Added to list of codes removed from the inpatient only list in the final rule.

Other than the last two codes, each of the codes being removed from the inpatient only list are add-ons that are not paid separately. Addendum E of the final rule contains the complete list of codes that will be paid only as inpatient procedures for 2017.

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 (Public Law 114–74) excludes from the

definition of covered OPD services "applicable items and services" furnished on or after January 1, 2017 by certain off-campus outpatient departments of a provider (generally those that did not furnish 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 clarifies that section 603 applies to any entity that is paid under section 1833(t) (which includes a provider-based FQHC but excludes a hospital operated by the Indian Health Service, or by a tribe or tribal organization since the latter are paid pursuant to section 1880 of the Act).

Generally, CMS implements section 603 as follows:

(1) It creates and defines 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) It defines off-campus PBDs and establishes requirements for those off-campus PBDs to maintain excepted status (both for the facility and for the items and services it furnishes).
(3) It establishes payment policies for nonexcepted items and services (that are substantially revised from those policies in the proposed rule) through an IFC.

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

CMS reiterates that while there is no legislative history to guide its implementation of section 603, the Congressional Budget Office scored the provision as saving $9.3 billion over a 10-year budget period. Please note, however, that CMS estimates a net reduction in Part B spending of roughly $50 million in 2017 in the final rule which is a significant reduction from its proposed estimated savings of $330 million for 2017. This figure is explained in more detail below.

Definition of Excepted Items and Services (§419.48(a))

CMS finalizes the definition of excepted items and services to mean those items and services furnished on or after January 1, 2017 that are furnished by:

(a) A dedicated emergency department (as defined in §489.24(b) of the regulations[6]), or

[6] §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

(b) An excepted off-campus provider-based department (as defined in §419.48(b) of the regulations) that has not impermissibly relocated or changed ownership.

CMS clarifies that all items and services (emergency and nonemergency) that are furnished in a dedicated ED will continue to be paid under the OPPS.

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

CMS finalizes its definition of an excepted off-campus provider-based department with modifications. An excepted off-campus PBD means a "department of a provider" that as of November 2, 2015 was located on the or within the distance described in such definition from a "remote location of a hospital" that meets the requirements for provider-based status. The definition also includes a department of a provider that was billing under the OPPS with respect to covered OPD services furnished prior to November 2, 2015.

On-Campus Locations. Under this definition, on-campus PBDs and the items and services furnished by them will 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 did not propose to modify existing provider-based regulations or to change the definition of campus and believes hospitals may adequately determine whether departments are on campus, including through the voluntary provider-based attestation process. CMS believes the current definition of campus and the flexibility afforded to CMS Regional Offices to exercise discretion on a case-by-case basis is appropriate. However, CMS notes that as it gains experience with section 603 implementation, it may make revisions through future rulemaking.

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). CMS finalizes its proposal to except those off-campus PBDs located at or within 250 yards from a remote location of a hospital facility. CMS interprets this to mean that a hospital may measure 250 yards from any point of the physical facility that serves as the site of services of the remote location to any point in the PBD. CMS noted 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.

Exception at Section 1833(t)(21)(B)(ii) of the Act. Section 603 provides that an off-campus PBD that was billing for a covered OPD service furnished before November 2, 2015 will continue to be paid under the OPPS. CMS states that its major concern with implementing the scope of the exception was with respect to relocation of, or expansion of services lines of, an excepted off-campus PBD.

(i) Relocation

The statute does not address the issue of relocation.

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requiring a previously scheduled appointment.

CMS finalizes its relocation policy (i.e., relocation of an excepted off-campus PBD will generally result in loss of excepted status), but it will establish an extraordinary exceptions process through subregulatory guidance under which exceptions to the relocation policy will be evaluated on a case-by-case basis by the appropriate CMS Regional Office. CMS intends that exceptions will be both limited and rare. Relocation of an on-campus PBD to an off-campus location will result in the loss of the excepted status of that PBD.

(ii) 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 had proposed a clarification that services furnished that are not part of the clinical family of services (established by CMS) furnished and billed before November 2, 2015, would not be payable under the OPPS. CMS had proposed to define service types by 19 clinical families of hospital outpatient service types described in Table 21 of the proposed rule. Under the proposal, 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.

CMS does not finalize this proposal at this time. It will monitor service line growth and may propose limitations on expansions of services or service lines in the future. Thus, an excepted off-campus PBD may be paid under the OPPS for items and services furnished regardless of whether the facility furnished those items and services before November 2, 2015.

(iii) Facilities Under Development

CMS notes it did not propose a policy that would exempt mid-build off-campus PBDs or those under development at the time of the enactment of section 603 under section 1833(t)(21)(B)(ii) of the Act. Those facilities will be considered nonexempt off-campus PBDs that will be reimbursed under the applicable payment system described below for nonexcepted items and services.

(iv) Bill submission before November 2, 2015

For purposes of qualifying for the exception, in the proposed rule, CMS had interpreted the statute to require that an off-campus PBD must have actually submitted a bill before the enactment date of section 603. Some commenters believed that CMS misinterpreted the law, and others requested a more flexible interpretation that would provide exceptions for those facilities that were operational on the date of enactment but either had not treated patients before November 2, 2015 or had treated patients before that date but had not billed for the services until after November 2, 2015. CMS finalizes its proposed interpretation with a modification; an off-campus PBD that furnished a covered OPD service before November 2, 2015 and billed for the service under the OPPS after that date under the timely filing limits will qualify for an exception.

Change in Ownership. CMS reiterates 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 finalizes its proposal that the excepted status of an off-campus PBD will 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. Additionally, an individual excepted off-campus PBD that is transferred from one hospital to another will lose its excepted status.

Data Collection. CMS notes it is, and will continue, monitoring claims data that include the "PO" modifier; it is also establishing a new "PN" modifier to be used to bill for nonexcepted items and services (described further below).

Payment for Nonexcepted Off-Campus PBDs

Applicable Payment System

CMS finalizes its proposal to use the MPFS.

However, the final policy is substantially revised from the proposed policy which provided that for 2017, physicians furnishing services in off-campus PBDs would be paid based on the professional claim and at the nonfacility rate to the physician (unless the hospital separately enrolls as a non-hospital provider type) for services for which they are permitted to bill and no separate facility payment would be made to the hospital. Commenters strongly objected to the proposed policy for a number of reasons, including the absence of payment for the costs facilities would incur (e.g., nursing, lab, imaging, chemotherapy, surgical services etc.), the impact of fraud and abuse laws on financial arrangements that would be required of hospitals and referring physicians, the impact on State corporate practice of medicine and fee-splitting laws, and the impact on rural providers. CMS agrees its proposals raised many of these concerns, and it does not finalize its 2017 physician and facility payment as proposed.

Instead, CMS issued an IFC to establish rates under the MPFS for nonexcepted items and services furnished by off-campus PBDs on or after January 1, 2017 (described in more detail below). Under the final policy, payment will be made to physicians at the MPFS facility rate and to the off-campus PBD under new MPFS rates that are based on the OPPS rates for most nonexcepted items and services. CMS considers these rates to be site-of-service specific for the technical component of MPFS. Several OPPS payment policies (e.g., C-APCs and OPPS packaging logic) are adopted under the new site-of-service MPFS rates; CMS sets the rates at 50 percent of the OPPS rates for each nonexcepted item or service (with some exceptions) as the interim technical component payment rate. Providers will use an institutional claim to bill for these services using a new claim line modifier "PN" to indicate that the item or service was nonexcepted. **CMS seeks comment on the new payment rates and mechanisms, and will make adjustments as necessary based on that input as early as 2017.**

CMS notes that payments under the IFC policy may not equal payments under the technical component of the MPFS for any specific item or service. CMS will continue to pay for therapy services, preventive services, and separately payable drugs at the MPFS rate.

Additionally, commenters were concerned that the proposed payment policy might impact a off-campus PBD's eligibility as a covered entity under the 340B program because nonexcepted items and services would not be billed on the institutional claim and thus would not be automatically recorded as a reimbursable cost center on the cost report. Under the IFC payment policies, off-campus PBDs will continue to bill using the institutional claim, and services will continue to be reported on the hospital cost report. CMS directs interested parties to HRSA for questions relating to 340B eligibility, and it notes that if the final CMS payment policies require a change for hospital cost reporting, it will issue subregulatory guidance.

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.

CMS will likely make available a table showing the full range of exceptions and adjustments to the otherwise applicable OPPS payment rates; table X.B.2 identified in the preamble was not included in the display copy of the final rule.

Geographic Adjustments. CMS adopts hospital area wage index areas, as well as the actual hospital wage index values, for nonexcepted off-campus PBDs furnishing nonexcepted items and services to adjust the technical component rates in lieu of the MPFS geographic practice cost indices.

Coding Consistency. CMS notes that the same HCPCS codes are used to describe services paid under both the MPFS and the OPPS for most services. However, E&M services are reported under the OPPS using the single HCPCS code G0463 while 10 CPT codes are used to describe these services under the MPFS. The MPFS payment rate for nonexcepted off-campus PBDs furnishing nonexcepted E&M services in 2017 will be based on the rate for HCPCS code G0463 reduced by the 50-percent MPFS relativity adjuster.

CMS established HCPCS Level II "G" codes for radiation treatment delivery services furnished in a physician's office; under the OPPS, CPT codes are used to described these services furnished in the hospital outpatient department. CMS will require off-campus PBDs to bill for nonexcepted items and services using the HCPCS "G" codes under the MPFS to describe radiation treatment delivery services; the off-campus PBD must append modifier "PN" to each applicable claim line for nonexcepted items and services.

OPPS Payment Adjustments. CMS adopts the packaging payment rates and multiple procedure payment reduction percentage that apply under the OPPS to establish the MPFS payment rates for nonexcepted off-campus PBDs furnishing nonexcepted items and services that are billed by hospitals. The claims processing logic that is used for OPPS payment for comprehensive APCs, conditionally and unconditionally packaged items and services, and major procedures will all be incorporated into the newly established MPFS rates.

CMS notes that it is not adopting a number of OPPS payment adjustments under the IFC. These adjustments include outlier payments, the rural sole community hospital adjustment, the cancer hospital adjustments, transitional outpatient payments, the hospital outpatient quality reporting

payment adjustment, and the inpatient hospital deductible cap to the cost-sharing liability for a single hospital outpatient service.

Partial Hospitalization Programs (PHPs). Under the proposed payment policy, off-campus PBDs would not have been paid for PHP services furnished at their facilities unless the entity enrolled and billed as a CMHC for payment under the OPPS and it met all Medicare requirements and conditions of participation for CMHCs. Commenters clarified that this was not a viable option and noted that access to PHP services could be limited under the policy; they requested that CMS develop a policy for payment for PHP services furnished by nonexcepted off-campus PBDs. Under the IFC, PHP services will be paid at the CMHC rate for APC 5853 for providing 3 or more PHP services per day. CMS believes that adopting the CMHC rate is appropriate since CMHCs are freestanding entities that are not part of a hospital but provide the same services as hospital-based PHPs. CMS reiterates that an off-campus PBD may still enroll as a CMHC if it chooses to do so.

Supervision Rules. CMS notes that the amendments made by section 603 did not change the status of off-campus PBDs as provider-based departments; the amendments only changed the manner in which these provider-based departments are reimbursed for their nonexcepted items and services. Thus, the supervision rules under 42 CFR 410.27 continue to apply to off-campus PBDs that furnish nonexcepted items and services.

Beneficiary Cost-Sharing. CMS specifies that all beneficiary cost-sharing rules that apply under the MPFS pursuant to sections 1848(g) and 1866(a)(2)(A) of the Act will continue to apply for all nonexcepted items and services furnished by off-campus OPDs, regardless of the cost-sharing obligation under the OPPS.

Audits. CMS notes that audits of hospital billing will examine whether off-campus PBDs are billing correctly for nonexcepted items and services. CMS expect hospitals to maintain proper documentation showing which off-campus PBDs were billing Medicare 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 roughly $50 million in 2017; this represents a significant reduction from its proposed estimated savings of $330 million for 2017.

B. Changes in Payment for Film X-Ray

Payment under the OPPS is reduced 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 finalizes its proposal to establish a new modifier "FX" to be used on claims for these imaging services. Beginning in 2017, hospitals must use the "FX" modifier for these claims. CMS notes that when payment for an X-ray service taken using film is packaged into the payment for another item or service under the OPPS, no separate payment for the X-ray service taken using film is made, and the associated payment reduction would be 0 percent (or 20% of $0) in this circumstance.

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. 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. 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 final rule includes 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 final rule also includes specific clinical priority areas and exceptions to the AUC consultation and reporting requirements. Please see the 2017 MPFS final rule, or the HFMA summary of that rule, for further details, at https://www.hfma.org/Content.aspx?id=51101.

IX. CY 2017 OPPS Payment Status and Comment Indicators

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

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

CMS will assign edit 13 to status indicator "E2" items and services which will result in a line item rejection. CMS explains that a line item rejection is when a line has reached a final disposition with no payment for a reason other than medical necessity under section 1862(a)(1) of the Act.

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

Comment Indicator Definitions. CMS finalizes its proposal to use four comment indicators for 2017. It will continue to use the same three comment indicators that are in effect for the 2016 OPPS ("CH", "NI", and "NP"), and creates a new comment indicator "NC." Comment indicator "NC" is used in the final rule to indicate the HCPCS codes that were assigned to comment indicator "NP" in the proposed rule. Codes assigned the comment indicator "NC" in the final rule will not be subject to comment in the final rule. The four comment indicators and their descriptions are as follows:

- "CH" – Active HCPCS code in current and next calendar year; status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.
- "NI" – New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year interim APC assignment; comments will be accepted on the interim APC assignment for the new code.
- "NP" – New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.
- "NC" – New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year for which CMS requested in the proposed rule, final APC assignment; comments will be not be accepted on the final APC assignment for the new code.

The definitions of the OPPS comment indicators for 2017 are listed in Addendum D2 to the final rule and are available at the CMS website hyperlink on page 42.

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

Summary of selected key elements of proposed and final ASC payment rates for 2017				
	Proposed Rule		**Final Rule**	
	ASCs reporting quality data	ASCs not reporting quality data	ASCs reporting quality data	ASCs not reporting quality data
2016 ASC Conversion Factor	$44.190			
2017 Update				
CPI-U update	1.7%		2.2%	
Multi-factor productivity adjustment (MFP)	-0.5%		-0.3%	
Net MFP adjusted update	1.2%		1.9%	
Penalty for not reporting quality data	0.0%	-2.0%	0.0%	-2.0%

Summary of selected key elements of proposed and final ASC payment rates for 2017				
Net MFP and quality adjusted update	1.2%	-0.8%	1.9%	-0.1%
Wage index budget neutrality adjustment	0.9992		0.9996	
2017 ASC Conversion Factor	$44.684	$43.801	$45.030*	$44.330*

*These are the published numbers in the final rule, but the 2017 ASC conversion factors listed are not the product of the CY 2016 conversion factor multiplied by the wage index budget neutrality adjustments and the MFP-adjusted CPI-U payment update. Using the numbers CMS provided in the final rule, the 2017 conversion factor for ASCs reporting quality data would be $45.012; for ACSs not reporting quality data would be $44.128.

CMS estimates that under the final rule, total ambulatory surgical center (ASC) payments for 2017 will increase by $177 million over 2016 levels.

As with the rest of the OPPS final 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-FC.html.

A. Treatment of New and Revised Codes

CMS continues to recognize the following codes on ASC claims:

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

CMS finalizes proposals for new codes in two categories:

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

CMS clarifies that it considers revised codes to be new when they have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator.
Treatment of New and Revised Level II HCPCS Codes and Category III CPT Codes Implemented in April and July of 2016 for Which CMS Solicited Public Comments in the Proposed Rule

CMS did not receive any public comments regarding the proposed ASC payment indicators and payments rates. CMS adopts as final the new Level II HCPCS codes. Tables 44, 45, and 46 in the final rule, reproduced below, identify the codes.

The final 2017 payments rates for these codes can be found in Addendum AA and BB of the final rule at the CMS website referenced above.

New Level II HCPCS Codes for Covered Surgical Procedures for Covered Ancillary Services Implemented in April 2016 (Table 44)			
2016 HCPCS Code	**2017 HCPCS Code**	**2017 Long Descriptor**	**Final 2017 Payment Indicator**
C9137	J7207	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U.	K2
C9138	J7209	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), 1 I.U.	K2
C9461	A9515	Choline C 11, diagnostic, per study dose	K2
C9470	J1942	Injection, aripiprazole lauroxil, 1 mg	K2
C9471	J7322	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg	K2
C9472	J9325	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)	K2
C9473	J2182	Injection, mepolizumab, 1 mg	K2
C9474	J9205	Injection, irinotecan liposome,1 mg	K2
C9475	J9295	Injection, necitumumab, 1 mg	K2
J7503	J7503	Tacrolimus, extended release, (Envarsus XR), oral, 0.25 mg	K2
New Level II HCPCS Codes for Covered Ancillary Services Implemented in July 2016 (Table 45)			
C9476	J9145	Injection, daratumumab, 10 mg	K2
C9477	J9176	Injection, elotuzumab, 1 mg	K2
C9478	J2840	Injection, sebelipase alfa, 1 mg	K2
C9479	C9479	Instillation, ciprofloxacin otic suspension, 6 mg	K2
C9480	J9352	Injection, trabectedin, 0.1 mg	K2
Q9981	J8670	Rolapitant, oral, 1 mg	K2
Q5102	Q5102	Injection, infliximab, biosimilar, 10 mg	K2
Q9982*	Q9982	Flutemetamol F 18, diagnostic, per study dose, up to 5 millicuries	K2
Q9983**	Q9983	Florbetaben f18, diagnostic, per study dose, up to 8.1 millicuries	K2
*HCPCS Code C9459 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 46)			
2016 CPT Code	**2017 HCPCS Code**	**2016 Long Descriptor**	**2017 Payment Indicator**

0437T	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*	0438T	Transperineal placement of biodegradable material, periprostatic (via needle), single or multiple, includes image guidance	G2
0439T	0439T	Myocardial contrast perfusion echocardiography; at rest or with stress, for assessment of myocardial ischemia or viability (List separately in addition to primary procedure)	N1
0440T	0440T	Ablation, percutaneous, cryoablation, includes imaging guidance; upper extremity distal/peripheral nerve	G2
0441T	0441T	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve	G2
0442T	0442T	Ablation, percutaneous, cryoablation, includes imaging guidance; nerve plexus or other truncal nerve (eg, brachial plexus, pudendal nerve)	G2
0443T	0443T	Real time spectral analysis of prostate tissue by fluorescence spectroscopy	G2
0444T	0444T	Initial placement of a drug-eluting ocular insert under one or more eyelids, including fitting, training, and insertion, unilateral or bilateral	N1
0445T	0445T	Subsequent placement of a drug-eluting ocular insert under one or more eyelids, including re-training, and removal of existing insert, unilateral or bilateral	N1
*HCPCS Code C9743 was deleted on June 30, 2016 and replaced with CPT code 0438T effective July 1, 2016.			

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 finalizes its proposal to permanently designate one additional procedure as office-based: CPT Code 0377T (Anoscopy with directed submucosal injection of bulking agent for fecal incontinence), with payment indicator of "R2" in 2017. CMS did not receive any public comments on this proposal.

CMS also reviews 2015 volume and utilization data for the eight procedures finalized for temporary office-based status in last year's final rule. CMS found that there were very few or no

claims data for these procedures, and finalizes its proposal to maintain the temporary office-based designations for these eight codes for 2017. Table 48 in the final rule (reproduced below) lists the procedures and CMS' payment indicators for 2017.

2017 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARY OFFICE-BASED IN THE CY 2016 OPPS/ASC FINAL RULE WITH COMMENT PERIOD (Table 48)			
2017 CPT Code	**2017 Long Descriptor**	**2016 ASC Payment Indicator***	**Final 2017ASC Payment Indicator****
0299T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care;	R2*	R2**
0402T	Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when	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),	P2*	P2**
64461	Paravertebral block (PVB) (paraspinous block), thoracic; single injection site (includes	P3*	P3**
64463	Continuous infusion by catheter (includes imaging guidance, when performed)	P3*	P3**
65785	Implantation of intrastromal corneal ring segments	R2*	P2**
67229	Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (e.g., retinopathy of prematurity), photocoagulation or cryotherapy	R2*	R2**
G0429***	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies	R2*	R2**

* If designation is temporary.
** Final payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the MPFS final rates.
***HCPCS code G0429 replaces HCPCS code C9800, effective January 1, 2017.

CMS finalizes its proposal to designate two new 2017 codes (CPT codes 36901 and 36473) for ASC covered surgical procedures as temporarily office-based. Because CMS has no utilization data, CMS makes the office-based designations temporary. Table 49 lists the procedures and

CMS' payment indicators for 2019.

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

CMS finalizes its proposal for 2017, without modification, 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.

In addition, CMS finalizes its proposal, without modification, 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. CMS notes that in certain rare instances, such as for a very expensive implantable device, it may apply a higher offset percentage if warranted by additional information provided by a manufacturer.

For 2017, CMS finalizes its proposal to update the ASC list of covered surgical procedures that are eligible for payment according to the device-intensive payment methodology, consistent with its revised definition of device-intensive procedures. Addendum AA at the CMS ACS website lists the procedures, including the CPT code and short-descriptor, the 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 finalizes its proposal 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 will 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 will 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, the contractor will reduce payments to the ASC by 50 percent of the device offset amount. In order to report a partial credit, the ASC will 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 will 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.

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 finalizes its proposal with respect to seven of the eight procedures it proposed to add 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.

Table 51 in the final rule (reproduced below) displays the 11 procedures that CMS is adding to the ASC list of covered surgical procedures.

ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR 2017 (Table 51)		
2017 CPT Code	**2017 Long Descriptor**	**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

22853*	Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)	N1
22854*	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)	N1
22859*	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)	N1
* Effective January 1 2017, CPT codes 22853, 22854, and 22859 replaced CPT code 22851, which was deleted April 13, 2016 by the AMA Editorial Panel.		

Covered Ancillary Services:

CMS finalizes its proposal, without modification, to update the ASC list of covered ancillary services to reflect the payment status for the services under the OPPS. ASC covered ancillary services and their payment indicators for 2017 are included in Addendum BB at the ASC website.

C. ASC Payment and Comment Indicators

CMS finalizes its proposal to continue using the current comment indicators "NP" and "CH." CMS also finalizes its proposal that Category I and III CPT codes that are new and revised for 2017 and any new and existing Level II HCPCS codes with substantial revisions will be labeled with the new comment indicator 'NP" to indicate that these codes were open for comment as part of the 2017 proposed rule.

Addenda DD1 and DD2 provide a complete list of the ASC payment and comment indicators for 2017. CMS did not receive any public comments on the ASC payment and comment indicators.

D. Calculation of the ASC Conversion Factor and the ASC Payment Rates

Updating the ASC Relative Payment Rates for 2017 and Future Years

The 2017 ASC conversion factor published by CMS is $45.030 for ASCs reporting quality data, and $44.330 for those that do not, computed as follows:

	ASC reporting quality data	ASC not reporting quality data
2016 ASC conversion factor:	$44.190	
Wage adjustment for budget neutrality	x 0.9996	
Net MFP-adjusted update	x 1.019	x 0.999
2017 ASC conversion factor	$45.030*	$44.330*

*These are the published numbers in the final rule, but the 2017 ASC conversion factors listed are not the product of the CY 2016 conversion factor multiplied by the wage index budget neutrality adjustments and the MFP-adjusted CPI-U payment update. Using the numbers CMS provided in the final rule, the 2017 conversion factor for ASCs reporting quality data would be $45.012; for ACSs not reporting quality data would be $44.128.

E. 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 53 of the final 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 2 percent increase attributable to the payment changes in 2017. The second largest group, digestive system, is estimated to see a 1 increase. The Musculoskeletal group is estimated to receive the largest increase of 8 percent.

Summary of Table 53: Aggregate 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	**$3,993**	**2%**
Eye and ocular adnexa	$1,556	2%
Digestive system	$813	1%
Nervous system	$687	0%
Musculoskeletal system	$466	8%
Genitourinary system	$178	-1%
Integumentary system	$132	-3%

Notes: The six items total $3,832 million, $161 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 $31 million for 2017.

CMS sets out estimated increases for 30 selected procedures in Table 54 in the final 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 increase.

Excerpt from Table 54: Estimated Impact of the 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	$1,108	1%
43239	Egd biopsy single/multiple	$185	-9%
45380	Colonoscopy and biopsy	$180	13%
45385	Colonoscopy w/lesion removal	$118	13%
66982	Cataract surgery, complex	$96	1%
64483	Inj foramen epidural l/s	$87	6%
63685	Insert redo spine n generator	$82	10%
64493	Inj paravert f jnt 1/s 1 lev	$71	-24%
63650	Implant neuroelectrodes	$66	12%
66821	After cataract laser surgery	$65	4%
See Table 54 for full list of 30 procedures.			

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

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

XI. Hospital Outpatient Quality Reporting Program Updates

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

A. Background

No measures are removed under this rule. 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 adopts all seven of the proposed new OQR Program measures to begin with the 2020 payment determination.

1. Admissions and Emergency Department Visits for Patients 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 counts only in the inpatient admission score.
The performance period for this measure is one year; claims data for patients receiving OPD chemotherapy during calendar year 2018 will be used for the 2020 payment determination.

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

The second new 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. \

The performance period for this measure is one year; claims data for patients receiving same-day surgeries in the OPD during calendar year 2018 will be used for the 2020 payment determination.

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. Voluntary implementation of the OAS CAHPS Survey began in January 2016.

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

measures, including the survey cohort and risk adjustment, can be found at the OAS CAHPS Survey website noted above.

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

Administering and Scoring the OAS CAHPS Survey

Hospitals will be required to contract with a CMS-approved vendor to collect survey data on a monthly basis for quarterly reporting to CMS. For the 2020 payment determination, data will be collected during calendar year 2018; in general, the performance period is 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 apply.

Hospital eligibility to perform the OAS CAHPS Survey will be determined at the individual Medicare participating hospital level. All data collection and submission, and also public reporting, for these measures will be at the Medicare participating hospital level as identified by the hospital's CCN. Therefore, the reporting for a CCN would include all eligible patients from all eligible hospital locations of the Medicare participating hospital that is identified by the CCN.

Hospitals will be required to survey eligible patients each month. In general, over each 12-month reporting period, hospitals must collect at least 300 completed surveys (an average of 25 per month). As discussed below, certain low-volume hospitals may apply for an exemption but absent an exemption, smaller hospitals that cannot collect 300 completed surveys over a 12-month reporting period are required to survey all eligible patients.

CMS clarifies that hospitals will fall into one of three categories:

- Hospitals receiving more than 300 completed surveys during the reporting period must either randomly sample their eligible patient population or survey the entire population. That is, random sampling of 300 surveys is optional. The OAS CAHPS Survey Protocols and Guidelines Manual lists acceptable sampling methods (https://oascahps.org/Survey-Materials).
- Hospitals that anticipate not receiving 300 completed surveys during the 12-month reporting period must survey all patients. There is no option for random sampling.
- Hospitals with relatively few survey-eligible patients may request an exemption from the OAS CAHPS survey administration. The exemption is available to 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

1. Data Submission Requirements for the OAS CAHPS Measures

For the new OAS CAHPS measures, hospitals must meet the following requirements:

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

2. Extension for Extraordinary Circumstances Exemption Request Deadline

CMS extends 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 will be effective with ECEs requested on or after January 1, 2017 for the 2019 payment determination.

3. Public Display of OQR Measures

CMS finalizes formal adoption of 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.

4. Clarification Regarding OQR Program Reconsideration and Appeals

The process by which participating hospitals may submit requests for reconsideration was previously codified at 42 CFR 419.46(f), and language at §419.46(f)(3) addresses appeals to the Provider Reimbursement Review Board. In this 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 2017 Payment Determination

CMS continues existing policies with respect to computing and applying the payment reduction for hospitals that fail to meet the Hospital OQR Program requirements for the 2017 update factor. 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 reduced conversion factor of $75.001 by the full conversion factor of $73.501.

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

E. Summary Table of OQR Program Measures

The table in the Appendix shows the final 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 OQR Program measures are available on the QualityNet website: https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1196289981244.

XII. 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 adopts seven new measures for addition to the ASCQR Program beginning in 2020; no changes are made to the previously adopted measures, which continue unless proposed for removal. The new measures include two web-based measures and five OAS CAHPS measures that are also added to the OQR Program in this rule.

1. Normothermia Outcome Measure

This 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 data collection period for this measure will be the calendar year two years prior to the payment determination year (e.g., 2018 for the 2020 payment determination). Data will 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 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 normothermia outcome measure, the data collection period for this measure will be the calendar year two years prior to the payment determination year (e.g., 2018 for the 2020 payment determination). Data will 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 adopts for the ASCQR Program the same five OAS CAHPS measures adopted 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 new measures are:

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

As is the case for hospitals, ASCs must 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 requirements to the OQR Program are made for the ASCQR Program with respect to the data collection period (e.g., 2018 for 2020 payment), target minimum number of surveys (300 surveys per 12-month reporting period, with random sampling an option for higher-volume ASCs and survey of all patients for those anticipating fewer patients) and an exemption process for ASCs with fewer than 60 survey-eligible patients in the prior year. Measure calculations and scoring (for purposes of public reporting) are also the same as those finalized 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

The deadline for data submitted via a QualityNet website tool is changed from August 15 of the year prior to the payment determination year to May 15 of that year. This change is effective beginning with the 2019 payment determination. Five existing measures are affected and beginning with the 2020 payment determination, the two new web-based measures are also affected (ASC-6, ASC-7, ASC-9 ASC-10 ASC-11, ASC-13, ASC-14). As proposed, a change is made to the regulatory text to reflect this policy.

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

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

3. Extension for Extraordinary Circumstances Exemption Request Deadline

CMS extends the extraordinary circumstances exemption (ECE) request deadline from 45 days following an event causing hardship to 90 days following an event causing hardship, effective beginning with the 2019 payment determination. This change parallels the ECE request deadlines for other programs as well as the newly finalized change for the OQR Program discussed in section XIII.D.3 above.

4. Public Reporting of ASCQR Program Data

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

- 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 made to the policies for determining the payment reduction for ASCs that fail to meet the ASCQR Program requirements. Medicare law requires that a 2.0 percentage point reduction to the ASC annual update is applied to ASCs that fail to meet the requirements. The reduction applies to services calculated using the ASC conversion factor with the payment indicators of A2, G2, P2, R2, Z2, and the service portion of device-intensive procedures identified by J8. The reduction does not apply to services that are assigned other status indicators

for which payments are not calculated using the conversion factor, including separately payable drugs and biologicals, pass through devices that are contractor-prices, brachytherapy sources that are paid based on OPPS payment rates, and others. When the 2.0 update reduction is applied to a facility's update, beneficiary copayments are based on the reduced payment rate.

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

D. Summary Table of ASCQR Program Measures

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

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

As part of the Medicare Conditions of Participation (CoP) for solid organ transport programs, the regulations specify certain thresholds that a program cannot exceed and still be in compliance.[7] Specifically, the regulations specify that a program is not in compliance with the CoPs for patient and graft survival if three thresholds are all crossed: (1) the observed to expected (O/E) ratio exceeds 1.5; (2) the results are statistically significant ($p<.05$); and (3) the results are numerically meaningful (that is, the number of observed events minus the expected number is greater than 3). If all three thresholds are exceeded, the program is not in compliance with the CMS standard. CMS finalizes without modification its proposals 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 and to apply that same threshold to all organ types for both graft and patient survivals. 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.[8]

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

CMS proposed 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 policies in the proposed rule related 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 were proposed with respect to measure calculations for actions occurring outside the EHR reporting period.

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7 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.

8 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 adopts final policies based on its proposals, most without modification.

- It adopts the proposed changes to the objectives and measures for 2017 and 2018 for all eligible hospitals and CAHs that submit an attestation to CMS, including dual-eligible hospitals (described below).
- It provides for a 90-day EHR reporting period in both CYs 2016 and 2017 for all returning participants.
- It requires EPs, eligible hospitals and CAHs that have not successfully demonstrated meaningful use in a prior year and that are seeking to demonstrate meaningful use for the first time in 2017 to avoid the 2018 payment adjustment by attesting by October 1, 2017 to the Modified Stage 2 objectives and measures.
- It provides a one-time significant hardship exception from the 2018 payment adjustment for certain EPs who are new participants in the EHR Incentive Program in 2017 and are transitioning to MIPS in 2017.
- Beginning in CY 2017, it requires for measure calculations for actions outside the EHR reporting period, for all meaningful use measures, unless otherwise specified, that actions included in the numerator must occur within the EHR reporting period if that period is a full calendar year, or if it is less than a full calendar year, within the calendar year in which the EHR reporting period occurs.

Dual-eligible hospitals may submit one attestation for both the Medicare and Medicaid EHR Incentive Programs to CMS, and the attestation data will be shared with the appropriate State Medicaid agency to process the Medicaid incentive payment. State Medicaid agencies will be able to rely on these Medicare attestations to determine whether these hospitals qualify for incentive payments under the Medicaid EHR Incentive Program. Medicaid-only hospitals and dual-eligible hospitals that choose to attest directly to a State for the State's Medicaid EHR Incentive Program will continue to attest to the measures and objectives as finalized in the 2015 EHR Incentive Programs.

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

Responding to concerns about reporting burden, CMS adopts the set of changes it proposed 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 are reduced.

The changes relate only to the Medicare EHR Incentive Program; they do not affect requirements for an eligible hospital or CAH attesting under a State Medicaid EHR Incentive Program.

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

CMS determined that, based on 2015 attestation data, performance on the CPOE objective and measures meets the criteria as "topped out," and removes 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.

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

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

CMS adopts its proposals without modification to reduce the required reporting thresholds for a subset of measures. CMS believes this will 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 changes replace Stage 3 thresholds with Modified Stage 2 levels.

The revised specific threshold changes follow.

Modified Stage 2 in 2017

Objective: Patient Electronic Access

- View Download Transmit (VDT) Measure: At least ***1 patient*** (or patient authorized representative) [previously 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.

CMS notes that the reduced threshold does not apply to eligible hospitals and CAHs attesting to a state for the Medicaid EHR Incentive Program.

Stage 3 in 2017 and 2018

CMS retains the threshold for Stage 3 (i.e., greater than 25 percent), and clarifies that providers do have the flexibility to include or exclude controlled substances in the denominator for the Stage 3 electronic prescribing objective and measure.

Objective: Patient Electronic Access to Health Information Objective

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

CMS clarifies that for a health care provider to implement an API under the patient access measure, it must fully enable the API functionality in such a way that any application chosen by patients would enable them to gain access to their individual health information. The information provided in the application should be configured to meet the technical specifications of the API.

Objective: Coordination of Care Through Patient Engagement

- VDT Measure (same as Modified Stage 2 above): At least ***1 patient*** (or patient authorized representative) [previously 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*** [previously 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*** [previously 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*** [previously 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*** [previously 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.

Objective: Public Health and Clinical Data Registry Reporting

- Eligible hospitals/CAHs must successfully attest to reporting any combination of ***three*** measures [previously six]. (The six measures from which providers may 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 final rule includes tables that summarize the Modified Stage 2 and Stage 3 objectives and measures. These tables are reproduced here.

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	Yes/No attestation
*CDS (Clinical Decision Support)	Measure 1	Clinical Decision Support Interventions	Five CDS
	Measure 2	Drug Interaction and Drug-Allergy Checks	Yes/No
*CPOE (Computerized Provider Order Entry)	Measure 1	Medication Orders	>60%
	Measure 2	Laboratory Orders	>30%
	Measure 3	Radiology Orders	>30%
Electronic Prescribing	Measure	e-Prescribing	>10%
Health Information Exchange	Measure	Health Information Exchange	>10%
Patient Specific Education	Eligible Hospital/CAH Measure	Patient- Specific Education	>10%
Medication Reconciliation	Measure	Medication Reconciliation	>50%
Patient Electronic Access	Eligible Hospital/CAH Measure 1	Patient Access Measure	>50%
	Eligible Hospital/CAH Measure 2	View, Download or Transmit (VDT)	At least 1 patient
Public Health and Reporting	Immunization Reporting	Immunization Registry Reporting	Public Health Reporting to 3 Registries
	Syndromic Surveillance Reporting	Syndromic Surveillance Reporting	
	Specialized Registry Reporting	Specialized Registry Reporting	
	Electronic Reportable Laboratory Result Reporting	Electronic Reportable Laboratory Result Measure	
*Objective is removed.			

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	Yes/No attestation
Electronic Prescribing	Eligible hospital/CAH Measure	e-Prescribing	>25%
*CDS (Clinical Decision Support)	Measure 1	Clinical Decision Support Interventions	Five CDS
	Measure 2	Drug Interaction and Drug-Allergy Checks	Yes/No
*CPOE (Computerized Provider Order Entry	Measure 1	Medication Orders	>60%
	Measure 2	Laboratory Orders	>60%
	Measure 3	Diagnostic Imaging Orders	>60%
Patient Electronic Access to Health Information	Measure 1	Provide Patient Access	>50%
	Measure 2	Patient-Specific Education	>10%
Coordination of Care through Patient Engagement	Measure 1	View, Download or Transmit (VDT)	At least 1 patient
	Measure 2	Secure Messaging	>5%
	Measure 3	Patient Generated Health Data	>5%
Health Information Exchange	Measure 1	Send a Summary of Care	>10%
	Measure 2	Request/Accept Summary of Care	>10%
	Measure 3	Clinical Information Reconciliation	>50%
Public Health and Clinical Data Registry Reporting	Immunization Registry Reporting	Immunization Registry Reporting	Report to 3 Registries or claim exclusions
	Syndromic Surveillance Reporting	Syndromic Surveillance Reporting	
	Case Reporting	Case Reporting	
	Public Health Registry Reporting	Public Health Registry Reporting	
	Clinical Data Registry Reporting	Clinical Data Registry Reporting	
	Electronic Reportable Laboratory Result Reporting	Electronic Reportable Laboratory Result Reporting	
*Objective is removed.			

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 finalizes the reporting period for the 2016 and 2017 EHR reporting periods for returning participants as any continuous 90-day period within calendar year 2016 and 2017, respectively. CMS declines to make a 90-day reporting period a permanent feature of the programs citing its belief that a full year EHR reporting period is the most effective way to ensure that all actions related to patient safety that leverage CEHRT are fully enabled throughout the year. The applicable incentive payment year and payment adjustment years for the EHR reporting periods in 2016 and 2017, as well as the deadlines for attestation and other related program requirements, remain the same.

CMS also finalizes a continuous 90-day reporting period for reporting clinical quality measures (CQMs) for all EPs, eligible hospitals and CAHs that choose to report CQMs by attestation in 2016. This does not affect previously adopted requirements for electronic reporting of CQM data. The 90-day reporting 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. CMS intends to permit states to determine the form and manner of reporting CQMs for their State Medicaid EHR Incentive Programs, subject to CMS approval.

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

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

- A provider that has technology certified to the 2015 Edition may attest to Stage 3 or to the Modified Stage 2 requirements.
- A provider that has technology certified to a combination of 2015 Edition and 2014 Edition may attest to: (1) the Modified Stage 2 requirements; or (2) potentially to the Stage 3 requirements if the mix of certified technologies would not prohibit them from meeting the Stage 3 measures.
- A provider that has technology certified to the 2014 Edition only may attest to the Modified Stage 2 requirements and may not attest to Stage 3.

CMS has subsequently determined that it is not technically feasible for EPs, eligible hospitals, and CAHs that have not successfully demonstrated meaningful use in a prior year (new participants) to attest to the Stage 3 objectives and measures in 2017 in the EHR Incentive Program Registration and Attestation System. Therefore, CMS proposed that any EP or eligible hospital new participant seeking to avoid the 2018 payment adjustment by attesting for an EHR reporting period in 2017 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 states that providers using 2014 Edition, 2015

Edition, or any combination of 2014 and 2015 Edition certified EHR technology in 2017 will have the necessary technical capabilities to attest to the Modified Stage 2 objectives and measures. CMS finalizes its proposal, emphasizing that it will not permit these providers to attest to Stage 3 objectives and measures. CMS also notes that this policy applies for all new providers, including those who participate in the Medicaid EHR Incentive Program. The attestation date for these providers is October 1, 2017; CMS declines to push that date back. CMS will post guidance materials on its Web site at: https://www.cms.gov/EHRIncentivePrograms/.

This policy 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 will 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 had proposed to allow certain EPs to apply for a significant hardship exception from the 2018 payment adjustment; CMS finalizes this proposal. This application for a significant hardship exception is limited to EPs who have not previously demonstrated meaningful use in a prior year; who 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.

An EP must apply by October 1, 2017. The application must 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 must maintain documentation of the hardship application for six years.

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

For purposes of consistency, CMS finalizes a policy that, for all meaningful use measures, unless otherwise specified, actions included in the numerator must occur within the EHR reporting period if that period is a full calendar year, or if that period 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 reduced thresholds will significantly reduce the impact that these actions will have on performance. In addition, actions occurring after December 31 of the reporting year will count toward the next calendar year's EHR reporting period; CMS also wishes to avoid counting the same action in two different years. CMS notes this policy applies to both Modified Stage 2 and Stage 3 objectives and measures. It will update FAQ 8231 to explain the new policy.

XV. Additional Hospital Value-Based Purchasing Program Policies

CMS finalizes its proposal to remove the HCAHPS pain management dimension from the inpatient hospital VBP Program beginning with the 2018 payment determination year (calendar year 2016 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 necessitates changes in VBP scoring. For purposes of scoring the HCAHPS measure beginning in 2018 CMS will 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 have been 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 final 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.

CMS disagrees with commenters who recommended that CMS also remove or exclude the pain management questions from the IQR Program and from public reporting on *Hospital Compare*, including the HCAHPS star ratings and overall ratings, until alternative questions are developed. Noting that public reporting is not tied to payment, CMS believes that continuing to collect and report on these questions will help ensure that hospitals continue to appropriately manage patients' pain and engage in quality improvement related to pain management and communication. It does not believe there is empirical evidence that failing to prescribe opioids lowers a hospital's HCAHPS rate.

XVI. Files Available to the Public via the Internet

Addenda for this 2017 OPPS/ASC final rule are available on the following CMS website:

https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1656-FC-2017-OPPS-FR-Addenda.zip.

Accept the licensing agreement related to CPT and a listing of the Addenda as zip files will appear.

For addenda related to 2017 ASC payments, please see:
https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1656-FC.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending.

Scroll to the "Related Links" sections to find ASC Addenda Addendum AA, BB, DD1, DD2, and EE.

APPENDIX

Final measures for the 2020 Payment Determination with Previously Adopted OQR Measures for Payment Determinations from 2014 through 2019

NQF		2014	2015	2016	2017	2018	2019	2020
0287+	OP-1: Median Time to Fibrinolysis	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
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

NQF		2014	2015	2016	2017	2018	2019	2020
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 (see note below)
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							X
2687	OP-36 Hospital Visits After Hospital Outpatient Surgery							X
	OP 37a OAS CAHPS – About Facilities and Staff							X
	OP-37b: OAS CAHPS – Communication About Procedure							X
	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery							X
	OP-37d: OAS CAHPS – Overall Rating of Facility							X
	OP-37e: OAS CAHPS – Recommendation of Facility							X

[+] 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 final rule table of measures for 2020 incorrectly flags OP-30 as a voluntary measure.

ASCQR Program Measures with Previously Adopted Measures

ASCQR Program Measures 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 7-Day Risk Standardized Hospital Visit Rate after Outpatient Colonoscopy					X	X
ASC-13 Normothermia Outcome						X
ASC-14 Unplanned Anterior Vitrectomy						X
ASC 15a OAS CAHPS – About Facilities and Staff						X
ASC 15b: OAS CAHPS – Communication About Procedure						X
ASC 15c: OAS CAHPS – Preparation for Discharge and Recovery						X
ASC 15d: OAS CAHPS – Overall Rating of Facility						X
ASC 15e: OAS CAHPS – Recommendation of Facility						X
+CMS notes that NQF endorsement of these measures has been removed. 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.						

TABLE 52—ESTIMATED IMPACT OF THE CY 2017 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

		(1)	(2)	(3)	(4)	(5)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2,3) with Market Basket Update**	**All Changes**
ALL FACILITIES *		3,906	0.0	0.0	1.7	1.7
ALL HOSPITALS		3,789	0.0	0.0	1.8	1.8
(excludes hospitals permanently held harmless and CMHCs)						
URBAN HOSPITALS		2,958	0.0	0.0	1.7	1.8
	LARGE URBAN	1,616	0.0	-0.1	1.6	1.7
	(GT 1 MILL.)					
	OTHER URBAN	1,342	0.1	0.1	1.8	1.8
	(LE 1 MILL.)					
RURAL HOSPITALS		831	0.2	0.3	2.2	2.2
	SOLE COMMUNITY	376	0.2	0.4	2.3	2.2
	OTHER RURAL	455	0.2	0.2	2.1	2.1
BEDS (URBAN)						
	0 - 99 BEDS	1,045	-0.3	0.2	1.6	1.7
	100-199 BEDS	834	0.2	-0.1	1.8	1.8
	200-299 BEDS	465	0.2	0.0	1.9	1.9
	300-499 BEDS	405	0.1	0.0	1.8	1.9
	500 + BEDS	209	-0.2	0.0	1.5	1.5
BEDS (RURAL)						
	0 - 49 BEDS	340	0.3	0.5	2.5	2.5
	50- 100 BEDS	299	0.2	0.4	2.4	2.3
	101- 149 BEDS	108	0.1	-0.2	1.6	1.7
	150- 199 BEDS	45	0.1	0.5	2.3	2.2
	200 + BEDS	39	0.2	0.2	2.1	2.1
REGION (URBAN)						
	NEW ENGLAND	146	0.0	-1.1	0.6	0.6
	MIDDLE ATLANTIC	350	0.0	0.1	1.7	1.7
	SOUTH ATLANTIC	465	0.0	0.0	1.7	1.8
		(1)	(2)	(3)	(4)	(5)

		Number of Hospitals	APC Recalibration (all changes)	New Wage Index and Provider Adjustments	All Budget Neutral Changes (combined cols 2,3) with Market Basket Update	All Changes
	EAST NORTH CENT.	473	0.1	0.1	1.8	1.9
	EAST SOUTH CENT.	177	-0.3	0.3	1.7	1.7
	WEST NORTH CENT.	182	-0.1	0.0	1.6	1.5
	WEST SOUTH CENT.	527	-0.2	0.3	1.8	1.9
	MOUNTAIN	206	0.2	1.0	2.9	3.0
	PACIFIC	383	0.4	-0.3	1.7	1.8
	PUERTO RICO	49	0.4	-0.3	1.8	1.8
REGION (RURAL)						
	NEW ENGLAND	21	0.9	0.5	3.0	2.9
	MIDDLE ATLANTIC	55	0.1	1.2	3.0	3.0
	SOUTH ATLANTIC	126	0.3	-0.3	1.7	1.7
	EAST NORTH CENT.	121	0.2	0.4	2.3	2.3
	EAST SOUTH CENT.	158	0.0	0.2	1.9	1.9
	WEST NORTH CENT.	100	0.0	0.4	2.2	2.0
	WEST SOUTH CENT.	168	0.1	0.7	2.6	2.6
	MOUNTAIN	58	0.3	-0.1	1.9	1.8
	PACIFIC	24	0.3	-0.3	1.7	1.7
TEACHING STATUS						
	NON-TEACHING	2,712	0.1	0.1	1.9	2.0
	MINOR	731	0.1	0.0	1.9	1.9
	MAJOR	346	-0.2	-0.1	1.4	1.5
DSH PATIENT PERCENT						
	0	10	-1.7	-0.2	-0.3	-0.2
	GT 0 - 0.10	305	-0.4	0.0	1.2	1.3
	0.10 - 0.16	270	0.0	0.1	1.8	1.8
	0.16 - 0.23	600	0.1	0.1	1.9	2.0
	0.23 - 0.35	1,135	0.1	0.1	1.9	1.9
	GE 0.35	895	0.1	-0.1	1.7	1.8
	DSH NOT AVAILABLE **	574	-1.4	-0.2	0.1	0.1
URBAN TEACHING/DSH						
	TEACHING & DSH	975	0.0	0.0	1.6	1.7
	NO TEACHING/DSH	1,425	0.1	0.1	1.9	1.9
	NO TEACHING/NO	10	-1.7	-0.2	-0.3	-0.2

		(1)	(2)	(3)	(4)	(5)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2,3) with Market Basket Update**	**All Changes**
	DSH					
	DSH NOT AVAILABLE**	548	-1.4	-0.3	0.0	0.1
TYPE OF OWNERSHIP						
	VOLUNTARY	1,983	0.1	0.1	1.8	1.9
	PROPRIETARY	1,306	0.0	0.1	1.7	1.8
	GOVERNMENT	500	-0.1	-0.1	1.5	1.6
CMHCs		50	-15.1	-0.4	-13.9	-13.7

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all CY 2017 OPPS policies and compares those to the CY 2016 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the final FY 2017 hospital inpatient wage index, including all hold harmless policies and transitional wages. The rural adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the cancer hospital adjustment is 1.0003 because the target payment-to-cost ratio target changes from 0.92 in CY 2016 to 0.91 in CY 2017 (80 FR 70362 through 70364).

Column (4) shows the impact of all budget neutrality adjustments and the addition of the final 1.65 percent OPD fee schedule update factor. It also includes the impact of the additional adjustment of 1.0004 for laboratory services with "L1" modifiers packaged into the OPPS.

Column (5) shows the additional adjustments to the conversion factor resulting from the frontier adjustment, a change in the pass-through payment estimate, and adding estimated outlier payments.

* These 3,906 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.

** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.