Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs
SUMMARY

The Centers for Medicare & Medicaid Services (CMS) released the calendar year 2018[1] proposed rule for Medicare's hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system on July 13, 2017; policies in the proposed rule are generally proposed to go into effect on January 1, 2018. The rule was published in the July 20th issue of the *Federal Register* (82 FR 33558). **The 60-day public comment period ends at 5:00 PM EST on September 11, 2017.**

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-1678-P.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending

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

I. Overview

A. Estimated Impact on Hospitals

CMS estimates that, compared to 2017, its proposed policies will increase total payments under the OPPS by $897 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, CMS estimates that OPPS expenditures for 2018 will be $70 billion; an increase of approximately $5.7 billion compared to 2017 OPPS payments.

CMS proposes a conversion factor increase of 1.75 percent, based on the hospital inpatient market basket percentage increase of 2.9 percent for inpatient services paid under the IPPS[2], minus the multifactor productivity adjustment of 0.4 percentage points minus an additional 0.75 percentage point adjustment required by the Affordable Care Act (ACA). Hospitals that satisfactorily report quality data will qualify for the full update of 1.75 percent, while hospitals that do not will be subject to a statutory reduction of 2.0 percentage points in the update factor. The conversion factor decrease for hospitals not meeting the quality reporting requirements is -0.25 percent. All other adjustments are the same between the two sets of hospitals.

Table 38 in the proposed rule (reproduced in the Appendix to this summary) includes the estimated impact of the proposed rule by provider type. It shows a projected increase of 1.9 percent for all facilities and 2.0 percent for all hospitals (all facilities except cancer and children's hospitals, which are held permanently harmless, and CMHCs). The following table shows components of the 1.9 percent total:

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

	% Change All Facilities
All changes	+1.93
Fee schedule increase factor	+1.75
Difference in pass through estimates for 2017 and 2018	+0.22
Difference from 2017 outlier payments (1.04% vs. 1.0%)	-0.04

Pass-through spending for drugs, biologicals and devices for 2018 are estimated to be $26.2 million, or 0.04 percent of projected OPPS spending. The adjustment to the rates of +0.22 percent reflects the difference between this projection and the 0.26 percent estimate for 2017. The +0.22 percent adjustment is designed to ensure that pass-through spending remains budget neutral from one year to the next.[3] In addition, CMS estimates that actual outlier payments in 2017 will represent 1.04 percent of total OPPS payments compared to the 1.0 percent set aside, for an estimated decrease in 2018 payments of 0.04 percentage points.

Although CMS projects an overall increase of 1.9 percent for all facilities, the proposed rule impacts vary depending on the type of facility. Impacts will differ for each hospital category based on the mix of services provided, location and other factors. As shown in the table below and in the full impact analysis included in the appendix to this summary, the payment impacts are largely consistent among the major categories of hospitals. Major teaching hospitals have a modestly lower estimated increase in payment than average due to APC recalibration (-0.1 percent) and the wage index (-0.1). Proprietary hospitals have a larger estimated increase than average due to APC recalibration (+0.2) and the wage index (+0.1).

	Projected 2018 Impact
All Hospitals	+2.0%
All Facilities (includes CMHCs and cancer and children's hospitals)	+1.9%
Urban	+2.0%
Large Urban	+1.9%
Other Urban	+2.0%
Rural	+2.0%
Major Teaching	+1.7%
Type of ownership:	
Voluntary	+1.9%
Proprietary	+2.3%
Government	+1.9%
CMHCs	+2.1%

[3] In a communication with CMS, the agency indicated that the correct 2017 pass-through amount is 0.24 percent as noted in the 2017 OPPS/ASC Final Rule (81 FR 79678). The 2018 OPPS/ASC proposed rule incorrectly states 0.26 percent. This implies the 2018 adjustment would be 0.20 percent, not 0.22 percent as described in the proposed rule.

II. Proposed Updates Affecting OPPS Payments

A. Proposed Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

CMS is proposing to recalibrate the APC relative payment weights for 2018 using the same basic methodology used for many years. As discussed in succeeding sections of this summary, CMS proposes changes for: 1) pathogen reduced platelets and rapid bacterial testing of platelets, 2) brachytherapy insertion procedures, 3) blue light cystoscopy and 4) packaging low cost drug administration services.

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

In the 2014 OPPS/ASC final rule with comment period (78 FR 74840 through 74847), CMS created distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. However, in response to public comment, CMS removed claims from providers that use a cost allocation method of "square feet" to calculate CCRs used to estimate costs associated with the CT and MRI APCs (78 FR 74847) because of concerns about the accuracy of this cost allocation method. CMS indicated that it would provide hospitals with 4 years to transition to a more accurate cost allocation method and would use cost data from all providers, regardless of the cost allocation statistic employed, beginning in 2018.

Table 2 of the proposed rule shows the relative effect on imaging APC payments after removing cost data for providers that report CT and MRI standard cost centers using "square feet" as the cost allocation method. Table 3 of the proposed rule provides statistical values based on the CT and MRI standard cost center CCRs using the different cost allocation methods. Table 2 and Table 3 are reprinted below.

Table 2—Percentage Change in Estimate Cost for CT and MRI APCs when Excluding Claims from Provider Using "Square Feet" as the Cost Allocation Method

APC	APC Descriptor	Percentage Change
5521	Level 1 Imaging without Contrast	-4.3%
5522	Level 2 Imaging without Contrast	6.1%
5523	Level 3 Imaging without Contrast	1.1%
5524	Level 4 Imaging without Contrast	7.3%
5525	Level 5 Imaging without Contrast	4.5%
5571	Level 1 Imaging with Contrast	10.1%
5572	Level 2 Imaging with Contrast	9.4%
5573	Level 3 Imaging with Contrast	6.0%
8005	CT and CTA without Contrast Composite	13.5%

8006	CT and CTA with Contrast Composite	10.5%
8007	MRI and MRA without Contrast Composite	6.8%
8008	MRI and MRA with Contrast Composite	7.2%

Table 3—CCR Statistical Values Based on Use of Different Cost Allocation Methods

Cost Allocation Method	CT		MRI	
	Median CCR	Mean CCR	Median CCR	Mean CCR
All Providers	0.0397	0.0559	0.0828	0.1072
Square Feet Only	0.0332	0.0493	0.0726	0.0972
Direct Assign	0.0591	0.0680	0.1039	0.1247
Dollar Value	0.0485	0.0644	0.0941	0.1203
Direct Assign and Dollar Value	0.0485	0.0644	0.0949	0.1200

The proposed rule indicates that the number of valid MRI CCRs has increased by 15.6 percent to 2,142 providers and the number of valid CT CCRs has increased by 13.4 percent to 2,219 providers since CMS adopted its policy in 2014 of excluding providers that use the square foot cost allocation method. As shown in Table 2, eliminating these hospitals from the OPPS rate setting methodology increases the payment for all but one of the imaging APCs because hospitals that use the square foot allocation have lower CCRs for the imaging cost centers. Even though the proposed rule indicates that CMS believes it has appropriate imaging CCRs to use for determining payment, it is extending its policy of not using providers that use the square foot cost allocation methodology in calculating the OPPS relative weights for one additional year until 2019.

c. Calculation of single procedure APC criteria-based costs

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

Blood and blood products

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

CMS notes that the HCPCS codes and their associated APC is identified with a status indicator of "R" in Addendum B of the proposed rule. Status code "R" signifies the code is for a blood or blood product and paid under the methodology described above.

Pathogen-Reduced Platelets and Rapid Bacterial Testing for Platelets

In March 2016, the Food and Drug Administration recommended the use of rapid bacterial testing devices secondary to testing using a culture-based bacterial detection device or pathogen-reduction technology for platelets to adequately control the risk of bacterial contamination of platelets. In the 2016 OPPS/ASC final rule with comment period (80 FR 70322), CMS established HCPCS code P9072 (Platelets, pheresis, pathogen reduced, each unit). The CMS HCPCS Workgroup later revised HCPCS code P9072 to include the use of pathogen-reduction technology or rapid bacterial testing.

After the release of the 2017 OPPS/ASC final rule with comment period, several blood and blood product stakeholders stated that separate coding and payment are needed to distinguish bacterial testing from pathogen reduction because each service is distinct and pathogen reduction is much more costly than bacterial testing alone. After review of these concerns, the CMS HCPCS Workgroup deactivated HCPCS code P9072 for Medicare reporting and replaced the code with two new HCPCS codes effective July 1, 2017:

- Q9987 (Pathogen(s) test for platelets) for rapid bacterial testing or other pathogen tests for platelets is assigned to New Technology APC 1493, with a payment rate of $25.50; and
- Q9988 is assigned to APC 9536 (Pathogen Reduced Platelets), with a payment rate of $647.12.

The proposed rule indicates that CMS intends to price these new codes using the blood and blood-specific CCR methodology when it has hospital cost and charge data to set the relative weights for the APCs that include these codes. When CMS does not have data for new codes, it sets the rates based on a crosswalk to a code that CMS believes has similar costs. In this case, that would be HCPCS code P9072 for Q9988 as P9072 was originally developed solely for pathogen reduced platelets and was in use and active for all of 2016.

However, CMS is concerned that the 2016 data for HCPCS code P9072 may reflect confusion as to whether the code could be used just for rapid bacterial testing or both rapid bacterial testing and the more expensive pathogen reduction process as there were changes being contemplated and later adopted for this code during 2016 to have P9072 be used for both services. The geometric mean costs based on submitted claims for HCPCS code P9072 from 2016 is $491.53, which is a 24-percent reduction from the 2017 payment rate of $647.12. In response to the potential confusion in 2016 regarding use of HCPCS code P9072, CMS is proposing to crosswalk HCPCS code Q9988 to HCPCS code P9037 which has a geometric mean cost of $647.12.

Brachytherapy sources

The proposed rule for 2018 continues without change the policies used to set payment rates for brachytherapy sources; costs derived from the 2016 claims data were used to set proposed 2018 payment rates. The proposed payment rates appear in Addendum B to the proposed rule and are identified with status indicator "U" (Paid under OPPS; separate APC payment).

CMS is proposing to assign status indicator "E2" (Items and Services for Which Pricing Information and Claims Data Are Not Available) to HCPCS code C2645 (Brachytherapy planar, p-103). Even though this code was active in 2016, CMS did receive any claims for it and therefore has no information upon which to develop pricing. CMS previously assigned status indicator "E2" to HCPCS code C2644. However, it received one claim for HCPCS code C2644 in 2016 so CMS is proposing to assign the code status indicator "U" and basing its OPPS price on that one claim. CMS invites comment on its proposals.

d. Proposed Comprehensive APCs (C-APCs) for 2018

Proposed Additional C-APCs for 2018

CMS is not proposing any additional C-APCs to be paid under the existing C-APC payment policy beginning in CY 2018. Addendum J of the proposed rule contains all of C-APCs as well as all of the data related to the C-APC payment policy methodology, including the list of proposed complexity adjustments and other information.

Brachytherapy Insertion Procedures

Some of the HCPCS codes assigned to the C-APCs established for 2017 described surgical procedures for inserting brachytherapy catheters/needles and other related brachytherapy procedures such as the insertion of vaginal ovoids and/or the insertion of Heyman capsules. Commenters indicated that claims that included several insertion codes for brachytherapy devices often did not also contain a brachytherapy treatment delivery code (CPT codes 77750 through 77799) with the result that the brachytherapy delivery charges are being underrepresented in rate setting under the C–APC methodology. CMS is establishing a code edit that requires a brachytherapy treatment code when a brachytherapy insertion code is billed. The brachytherapy insertion codes that will be required to be billed with a brachytherapy treatment code are listed in Table 5 below.

Table 5—Proposed Brachytherapy Insertion Procedures Assigned Status Indicator "J1"

HCPCS Code	Long Descriptor
19296	Placement of radiotherapy after loading expandable catheter (single or multichannel) into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy

19298	Placement of radiotherapy after loading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance
19499	Unlisted procedure, breast
20555	Placement of needles or catheters into muscle and/or soft tissue for subsequent interstitial radioelement application (at the time of or subsequent to the procedure)
31643	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of catheter(s) for intracavitary radioelement application
41019	Placement of needles, catheters, or other device(s) into the head and/or neck region (percutaneous, transoral, or transnasal) for subsequent interstitial radioelement application
43241	Esophagogastroduodenoscopy, flexible, transoral; with insertion of intraluminal tube catheter
55875*	Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy
55920	Placement of needles or catheters into pelvic organs and/or genitalia (except prostate) for subsequent interstitial radioelement application
57155	Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy
53846	Insertion of Heyman capsules for clinical brachytherapy

*CMS is proposing to delete the current composite APC 8001 (LDR Prostate Brachytherapy Composite) assign HCPCS code 55875 to C-APC 5375 (Level 5 Urology and Related Services).

C-APC 5627 (Level 7 Radiation Therapy) Stereotactic Radiosurgery (SRS)

Section 634 of the American Taxpayer Relief Act of 2012 (Pub. L. 112–240) requires that OPPS payments for Cobalt-60-based SRS be reduced to equal that of payments for LINAC-based SRS for covered OPD services furnished on or after April 1, 2013.

CMS complied with the statutory requirement by assigning SRS using both technologies to C-APC (C-APC 5627 Level 7 Radiation Therapy). However, CMS identified differences in the billing patterns for SRS procedures delivered using Cobalt-60-based and LINAC-based technologies. SRS delivered using Cobalt-60 (as described by HCPCS code 77371) typically included SRS treatment delivery and planning services (for example, imaging studies, radiation treatment aids, and treatment planning) on the same day and a single claim. SRS delivered using LINAC (as described by HCPCS code 77372) frequently provided these services on separate days and multiple claims.

To address this issue, CMS established modifier "CP" to be used for 2016 and 2017 to identify services that are adjunctive to the primary SRS treatment described by HCPCS codes 77371 and 77372, but reported on a different claim within one month of furnishing the radiation treatment delivery service. Once CMS has these data, it planned to package these services into C-APC 5627. In the interim, CMS removed any costs associated with HCPCS codes 70551, 70552, 70553, 77011, 77014, 77280, 77285, 77290, 77295, and 77336) from C-APC 5627 and allowed these codes to be paid separately when furnished within 1-month of the radiation treatment delivery.

The data collection period for SRS claims with modifier "CP" began on January 1, 2016 and concludes on December 31, 2017. CMS' analysis of preliminary data collected with modifier "CP" identified some additional services that are adjunctive to the primary SRS treatment and reported on a different claim outside of the 10 SRS planning and preparation codes that were removed from the SRS C-APC costs calculations and paid separately. However, the proposed rule indicates the "CP" modifier has been used by a small number of providers since its establishment and is often used incorrectly.

Consistent with its original plan, CMS is deleting modifier "CP" after December 31, 2017. For CY 2018, CMS is proposing to continue making separate payments for the 10 planning and preparation services adjunctive to the delivery of the SRS treatment using either the Cobalt-60-based or LINAC-based technology. CMS indicates that the continued separate payment of these services will allow it to complete its analysis of the claims data including modifier "CP" from both 2016 and 2017 claims. CMS will consider in the future whether repackaging all adjunctive services (planning, preparation, and imaging, among others) back into cranial single session SRS is appropriate.

Proposed Complexity Adjustment for Blue Light Cystoscopy Procedures

Drugs that function as supplies in a diagnostic test are always packaged and not separately paid. Cysview® (hexaminolevulinate Hell) (described by HCPCS code C9275) is one such drug that is used in conjunction with blue light cystoscopy. Enhanced bladder cancer diagnostics, such as narrow band imaging or blue light cystoscopy, increase tumor detection in non-muscle invasive bladder cancer over white light cystoscopy alone, thus enabling more precise tumor removal by the urologist. Blue light cystoscopy can only be performed after white light cystoscopy.

In response to public comments concerned about barriers to access for this technology, CMS evaluated whether blue light cystoscopy following white light cystoscopy should be eligible for a C-APC complexity adjustment. To evaluate whether blue light cystoscopy following white light cystoscopy should be eligible for a complexity adjustment when assigned to a C-APC, CMS crosswalked the costs of HCPCS code C9275 (Hexaminolevulinate hcl) to the proposed new HCPCS code C97XX. CMS then evaluated the costs of HCPCS code C97XX in combination with the following APCs and HCPCS codes used for white light cystoscopy of the bladder:

- APC 5372 (Level 2 Urology and Related Services)
    - CPT code 52000
- APC 5373 (Level 3 Urology and Related Services
    - CPT code 52204
    - CPT code 52214
    - CPT code 52224
- APC 5374 (Level 4 Urology and Related Services)
    - CPT code 52234
    - CPT code 52235
- APC 5375 (Level 5 Urology and Related Services)
    - CPT code 52240

APC 5372 is not a C-APC and is not eligible for a complexity adjustment. CMS determined that HCPCS code C97XX in combination with the above HCPCS codes would be eligible for a complexity adjustment in APC 5373 but not APC 5374 or APC 5375. Under the C-APC policy, blue light cystoscopy would be packaged, but CMS proposes to assign the combination of HCPCS code C97XX with the cystoscopy procedures currently assigned to APC 5373 to APC 5374, resulting in a higher payment than for the white light cystoscopy procedure alone.

e. Proposed 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 continuing composite policies for mental health services *(APC 8010)* and multiple imaging services *(APCs 8004, 8005, 8006, 8007, and 8008).* CMS is proposing to delete the low dose rate (LDR) prostate composite APC and assign CPT code 55875 (Transperineal placement of needs or catheters into prostate for interstitial radioelement application, with or without cystoscopy) to a C-APC.

2. Proposed Changes to Packaged Items and Services

For 2018, CMS is proposing to conditionally package Level 1 and Level 2 Drug Administration Services and is requesting comment on whether to unconditionally package drug administration add-on codes.

CY 2018 Drug Administration Packaging Proposal

CMS is proposing to conditionally package payment for HCPCS codes describing drug administration services in APC 5691 and APC 5692 except for add-on codes and preventive services, when these services are performed with another service.

CMS is continuing to exclude preventive services from packaging policies and is, therefore, proposing to continue to pay separately for Medicare Part B vaccine administration services. CMS is not proposing to package any drug administration services in APC 5693 (Level 3 Drug Administration) or APC 5694 (Level Drug Administration). The proposed status indicators for drug administration services in APC 5691 and APC 5692 are listed in Table 7 below.

Table 7—Proposed Cy 2018 Status Indicators for Drug Administration Services in Level 1 and Level 2 Drug Administration APCS

HCPCS Code	Short Descriptor	Proposed CY 2018 Status Indicator
APC 5691--Level 1 Drug Administration		
95115	Immunotherapy one injection	Q1
95117	Immunotherapy injections	Q1
95144	Antigen therapy services	Q1
95145	Antigen therapy services	Q1

HCPCS Code	Short Descriptor	Proposed CY 2018 Status Indicator
95146	Antigen therapy services	Q1
95165	Antigen therapy services	Q1
95170	Antigen therapy services	Q1
96361	Hydrate iv infusion add-on	S
96366	Ther/proph/diag iv inf addon	S
96370	Sc ther infusion addl hr	S
96375	Tx/pro/dx inj new drug addon	S
96377	Application on-body injector	Q1
96379	Ther/prop/diag inj/inf proc	Q1
96423	Chemo ia infuse each addl hr	S
96549	Chemotherapy unspecified	Q1
G0008	Admin influenza virus vac	S
G0009	Admin pneumococcal vaccine	S
G0010	Admin hepatitis b vaccine	S

APC 5692--Level 2 Drug Administration		
90471	Immunization admin	Q1
90473	Immune admin oral/nasal	Q1
95147	Antigen therapy services	Q1
95148	Antigen therapy services	Q1
95149	Antigen therapy services	Q1
96367	Tx/proph/dg addl seq iv inf	S
96371	Sc ther infusion reset pump	Q1
96372	Ther/proph/diag inj sc/im	Q1
96401	Chemo anti-neopl sq/im	Q1
96402	Chemo hormon antineopl sq/im	Q1
96405	Chemo intralesional up to 7	Q1
96411	Chemo iv push addl drug	S
96415	Chemo iv infusion addl hr	S
96417	Chemo iv infused each addl seq	S

3. Proposed Calculation of OPPS Scaled Payment Weights

CMS proposes to continue its policy adopted in 2013 of calculating the relative payment weights for each APC using geometric mean-based APC costs. As in past years, CMS proposes to standardize the relative weights based on APC 5012 (Level 2 Examinations and Related Services) because that is the APC where HCPC code G0463 is assigned. G0463 (Hospital outpatient clinic visit for assessment and management of a patient) is the most commonly billed OPPS service. CMS is giving APC 5012 a relative weight of 1.0 and dividing the geometric mean costs of all other APCs by the geometric mean cost for APC 5012 to determine its associated relative payment weight.

CMS proposes to follow its past practice with respect to applying budget neutrality for changes in the OPPS relative weights. Holding all other variables constant, CMS multiplies the 2017 and 2018 relative weights respectively for each APC by its associated volume from 2016. It sums the 2017 and 2018 relative weights respectively, and then divides the 2017 aggregate relative weights by the 2018 aggregate relative weights to determine the weight scaler. Using this process, CMS is proposing a weight scaler of 1.328. The unscaled 2018 relative payments are multiplied by 1.328 to determine the proposed 2018 scaled relative weights that are shown in Addendum A and B.

B. Proposed Conversion Factor Update

CMS proposes an OPPS conversion factor for 2018 of $76.483. For hospitals that do not meet OQR requirements, CMS indicates that substituting a fee schedule increase factor of -0.25 percent for the 1.75 fee schedule increase factor for other hospitals produced a CF of $74.953.[4]

C. Proposed Wage Index Changes

The 2018 OPPS proposed rule wage index is based on the FY 2018 IPPS proposed post-classified wage index. The wage index tables are available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2018-Wage-Index-Home-Page.html.

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

The proposed rule would retain the OPPS labor-related share of 60 percent for purposes of applying the wage index for 2018 and notes that the wage index adjustment is made in a budget neutral manner.

As CMS did in the FY 2018 IPPS/LTCH PPS proposed rule, the agency proposes to transition to using only FIPS codes for 2018 and subsequent years, and to use the Census Bureau update changes listed below to calculate area wage indexes consistent with the CBSA-based methodologies finalized in the FY 2015 IPPS/LTCH PPS final rule.

- Petersburg Borough, AK (FIPS State County Code 02-195), CBSA 02, was created from part of former Petersburg Census Area (02-195) and part of Hoonah-Angoon Census Area (02-105). The CBSA code remains 02.
- The name of La Salle Parish, LA (FIPS State County Code 22-059), CBSA 14, is now LaSalle Parish, LA (FIPS State County Code 22-059). The CBSA code remains as 14.

[4] HPA calculations are also different with respect to the conversion factor for hospitals that fail to meet the quality reporting requirements. ($75.001 X 1.0002 X 0.9999 X 1.0003 X 0.9975 = $74.978). This section of the proposed rule indicates that the CF for hospitals that fail to meet the quality reporting requirements is determined by substituting an update of -0.25 percent for the 1.75 percent update that applies for other hospitals. However, in several other places, CMS indicates it determines the reduced payment for hospitals that fail to meet the quality reporting requirements by multiplying the fully updated CF by 0.98. (See pages 33564, 33598, 33599, 33600 and 33685). CMS' CF for hospitals that do not meet quality data reporting requirements ($74.953) is 98 percent of its CF for hospitals that do meet quality data reporting requirements ($76.483).

- The name of Shannon County, SD (FIPS State County Code 46-113), CBSA 43, is now Oglala Lakota County, SD (FIPS State County Code 46-102). The CBSA code remains as 43.

CMS states that hospitals located in these counties will not be impacted by these changes; they will continue to be considered rural for the hospital wage index. CMS proposes to implement the revisions effective January 1, 2018, beginning with the 2018 OPPS wages indexes.

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

In the FY 2018 IPPS/LTCH PPS proposed rule, CMS proposed to discontinue the imputed floor policy for fiscal year 2018 and subsequent fiscal years. Thus, for purposes of the OPPS for 2018 and subsequent years, CMS proposes in this rule to discontinue the application of the imputed floor policy to hospitals paid under the OPPS but not under the IPPS.

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

In the 2015 final OPPS rule, CMS adopted a 3-year transition period for hospitals paid under the OPPS but not under the IPPS that are currently located in urban counties that would become rural under the new OMB delineations. During the transition, those hospitals maintain the wage index of the CBSA in which they were physically located in FY 2014 for three years. The final year of the transition is 2017, and it will not be applied in 2018.

D. Proposed Statewide Average Default CCRs

CMS uses overall hospital-specific CCRs calculated from the hospital's most recent cost report to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS during the OPPS year. Default CCRs are used for hospitals for which the MACs cannot calculate a valid CCR.Table 10 in the proposed rule sets out the statewide default CCRs for urban and rural areas in each state for 2018 and the comparable default CCRs for 2017.

E. Adjustment for Rural Sole Community Hospitals (SCH) and Essential Access Community Hospitals (EACH) for 2018

For 2018, CMS is continuing to apply a 7.1 percent payment adjustment under section 1833(t)(13)(B) of the Act for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs. The adjustment is budget neutral and is applied before calculating outliers and copayments.

F. Proposed Payment Adjustment for Certain Cancer Hospitals

Medicare law exempts 11 cancer hospitals meeting statutory classification criteria for exclusion from payment under the IPPS. Since the inception of the OPPS, Medicare has paid these hospitals under the OPPS for covered outpatient hospital services. The ACA requires a budget neutrality adjustment to the extent that the Secretary determines that the 11 cancer hospitals' OPPS costs are greater than other OPPS hospitals' costs, including consideration of the cost of drugs and biologicals.

With one change for 2018, CMS is continuing the cancer adjustment policy used since 2012 to make additional payments to the 11 cancer hospitals. Prior to enactment of the 21st Century Cures Act in 2016, the law required CMS to make an adjustment to cancer hospital payments sufficient to bring each hospital's payment-to-cost ratio (PCR) up to the level of the PCR for all other hospitals. The 21st Century Cures Act requires the target PCR be reduced from the amount it would otherwise be by 1.0 percentage point. The law further excluded this additional 1.0 percentage point reduction from OPPS budget neutrality.

Table 11 in the proposed rule, copied below, shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals, with increases in OPPS payments for 2017 ranging from 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 2018 payments and costs.

Table 11—Proposed Estimated 2018 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	32.9%
050660	USC Norris Cancer Hospital	11.5%
100079	Sylvester Comprehensive Cancer Center	24.3%
100271	H. Lee Moffitt Cancer Center & Research Institute	23.1%
220162	Dana-Farber Cancer Institute	45.8%
330154	Memorial Sloan-Kettering Cancer Center	47.1%

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for 2017
330354	Roswell Park Cancer Institute	21.4%
360242	James Cancer Hospital & Solove Research Institute	28.9%
390196	Fox Chase Cancer Center	8.8%
450076	M.D. Anderson Cancer Center	76.9%
500138	Seattle Cancer Care Alliance	53.9%

G. Proposed Hospital Outpatient Outlier Payments

For 2018, CMS is proposing to continue to set aside 1.0 percent of the estimated aggregate total payments under the OPPS for outlier payments. It calculates the fixed-dollar threshold using the same methodology that was used to set the threshold for 2017 and previous years.

For the 2018 proposed rule, CMS provides that the outlier threshold would be met when a hospital's cost of furnishing a service or procedure exceeds 1.75 times the APC payment amount and also exceeds the APC payment rate plus a $4,325 fixed-dollar threshold (compared to $3,825 in 2017). 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 ($4,325) are met.

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.

III. OPPS Ambulatory Payment Classification (APC) Group Policies

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

1. Proposed Treatment of New HCPCS Codes That Were Effective April 1, 2017

Through the April 2017 OPPS quarterly update, CMS made effective six new Level II HCPCS codes and assigned them to interim OPPS status indicators and APCs (see Table 13 of the proposed rule). The payment rates, where applicable, can be found in Addendum B to the proposed rule.

Table 13—New Level II HCPCS Codes Effective April 1, 2017

CY 2017 HCPCS Code	CY 2017 Long Descriptor	Proposed CY 2018 SI	Proposed CY 2018 APC
C9484	Injection, eteplirsen, 10 mg	G	9484
C9485	Injection, olaratumab, 10 mg	G	9485
C9486	Injection, granisetron extended release, 0.1 mg	G	9486
C9487*	Ustekinumab, for intravenous injection, 1 mg	G	9487
C9488	Injection, conivaptan hydrochloride, 1 mg	G	9488

*HCPCS code C9487, which was effective April 1, 2017, was deleted June 30, 2017 and replaced with HCPCS code Q9989 (Ustekinumab, for intravenous injection, 1 mg) effective July 1, 2017.

2. Proposed Treatment of New HCPCS Codes That Were Effective July 1, 2017

Through the July 2017 OPPS quarterly update CR, CMS made 10 new Category III CPT codes and 13 Level II HCPCS codes effective July 1, 2017 and assigned them interim OPPS status indicators and to APCs. Three HCPCS codes are no longer payable under the OPPS because they have been replaced with more specific or different codes effective July 1, 2017. **CMS is soliciting public comments on the proposed APC and status indicator assignments for 2018 for the CPT and Level II HCPCS codes implemented on July 1, 2017**, all of which are listed in Table 14 below.

Table 14—New Category III CPT and Level II HCPCS Codes Effective July 1, 2017

2017 HCPCS Code	CY 2017 Long Descriptor	Proposed CY 2018 SI	Proposed CY 2018 APC
C9489	Injection, nusinersen, 0.1 mg	G	9489
C9490	Injection, bezlotoxumab, 10 mg	G	9490
C9745	Nasal endoscopy, surgical; balloon dilation of eustachian tube	J1	5165
C9746	Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed and/or fluoroscopy, when performed	J1	5377
C9747	Ablation of prostate, transrectal, high intensity focused ultrasound (HIFU), including imaging guidance	J1	5376
K0553	Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 Unit Of Service	Y	N/A

2017 HCPCS Code	CY 2017 Long Descriptor	Proposed CY 2018 SI	Proposed CY 2018 APC
K0554	Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system	Y	N/A
Q9984	Levonorgestrel-releasing intrauterine contraceptive system (Kyleena), 19.5 mg	E1	N/A
Q9985	Injection, hydroxyprogesterone caproate, not otherwise specified, 10 mg	N	N/A
Q9986*	Injection, hydroxyprogesterone caproate (Makena), 10 mg	K	9074
Q9987	Pathogen(s) test for platelets	S	1493
Q9988	Platelets, pheresis, pathogen reduced, each unit	R	9536
Q9989#	Ustekinumab, for intravenous injection, 1 mg	G	9487
0469T	Retinal polarization scan, ocular screening with on-site automated results, bilateral	E1	N/A
0470T	Optical coherence tomography (OCT) for microstructural and morphological imaging of skin, image acquisition, interpretation, and report; first lesion	M	N/A
0471T	Optical coherence tomography (OCT) for microstructural and morphological imaging of skin, image acquisition, interpretation, and report; each additional lesion (List separately in addition to code for primary procedure)	N	N/A
0472T	Device evaluation, interrogation, and initial programming of intra- ocular retinal electrode array (e.g., retinal prosthesis), in person, with iterative adjustment of the implantable device to test functionality, select optimal permanent programmed values with analysis, including visual training, with review and report by a qualified health care professional	Q1	5743
0473T	Device evaluation and interrogation of intra-ocular retinal electrode array (e.g. retinal prosthesis), in person, including reprogramming and visual training, when performed, with review and report by a qualified health care professional	Q1	5742
0474T	Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space	J1	5492

2017 HCPCS Code	CY 2017 Long Descriptor	Proposed CY 2018 SI	Proposed CY 2018 APC
0475T	Recording of fetal magnetic cardiac signal using at least 3 channels; patient recording and storage, data scanning with signal extraction, technical analysis and result, as well as supervision, review, and interpretation of report by a physician or other qualified health care professional	M	N/A
0476T	Recording of fetal magnetic cardiac signal using at least 3 channels; patient recording, data scanning, with raw electronic signal transfer of data and storage	Q1	5734
0477T	Recording of fetal magnetic cardiac signal using at least 3 channels; signal extraction, technical analysis, and result	Q1	5734
0478T	Recording of fetal magnetic cardiac signal using at least 3 channels; review, interpretation, report by physician or other qualified health care professional	M	N/A

HCPCS code J1725 (Injection, hydroxyprogesterone caproate, 1 mg) was replaced with HCPCS code Q9986 effective July 1, 2017.

[#] HCPCS code C9487, which was effective April 1, 2017, was replaced with HCPCS code Q9989 (Ustekinumab, for intravenous injection, 1 mg) effective July 1, 2017.

3. Proposed Care Management Coding Changes Effective January 1, 2018 (APCs 5821 and 5822)

CMS indicates that it is interested in the ongoing work of the medical community to refine the set of codes used to describe care management services, including chronic care management and is proposing to adopt CPT replacement codes for 2018 for several of the care management services finalized last year and is seeking public comment on ways it might further reduce burden on reporting providers, including through stronger alignment between CMS requirements and CPT guidance for existing and potential new codes. Table 15 below details the proposed care management coding change. Addendum B of the proposed rule includes the proposed 2018 payment rates for the replacement codes.

Table 15—Proposed Care Management Coding Changes Effective January 1, 2018

CY 2017 HCPCS Code	CY 2017 HCPCS Short Descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	Proposed CY 2018 Replacement CPT Code*	Proposed CY 2018 Replacement HCPCS Short Descriptor*	Proposed CY 2018 OPPS SI	Proposed CY 2018 OPPS APC
G0502	Init psych care Manag, 70min	S	5822	994X1	1st psyc collab care mgmt	S	5822

G0503	Subseq psych care man, 60mi	S	5822	994X2	Sbsg psyc collab care mgmt	S	5822
G0504	Init/sub psych Care add 30 m	N	N/A	994X3	1st/sbsq psyc collab care	N	N/A
G0505	Cog/func assessment outpt	S	5822	994X4	Assmt & care pln pt cog imp	S	5822
G0507	Care manage serv minimum 20	S	5821	994X5	Care mgmt. svc bhvl hlth cond	S	5821

*These are the 5-digit placeholder CPT codes. The final CPT code numbers will be included in the CY 2018 OPPS/ASC final rule with comment period. The long descriptors for the codes can be found in Addendum O (New Category I and Category III CPT Codes Effective January 1, 2018) of the proposed rule, which is available via the Internet on the CMS website.

B. OPPS Changes – Variations within APCs

1. APC Exceptions to the 2 Times Rule

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

Table 16 in the proposed rule, and below, lists 12 APCs that CMS proposed to except from the 2 times rule for 2018 based on established criteria and 2016 claims data.

TABLE 16—PROPOSED APC EXCEPTIONS TO THE TWO TIMES RULE FOR CY 2018

Proposed CY 2018 APC	Proposed CY 2018 APC title
5112	Level 2 Musculoskeletal Procedures.
5161	Level 1 ENT Procedures.
5311	Level 1 Lower GI Procedures.
5461	Level 1 Neurostimulator and Related Procedures.
5521	Level 1 Imaging without Contrast.
5573	Level 3 Imaging with Contrast.
5611	Level 1 Therapeutic Radiation Treatment Preparation.
5691	Level 1 Drug Administration.
5731	Level 1 Minor Procedures.
5735	Level 5 Minor Procedures.
5771	Cardiac Rehabilitation.
5823	Level 3 Health and Behavior Services.

C. New Technology APCs

1. Proposed and Revised and Additional New Technology APC Groups

Currently, there are 51 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 1906 (New Technology – Level 48 ($140,001 - $160,000)). Payment for each APC is made at the mid-point of the APC's assigned cost band.

For 2018, CMS is proposing to narrow the increments for New Technology APCs 1901 – 1906 from $19,999 cost bands to $14,999 cost bands. It is also proposing to add New Technology APCs 1907 and 1908 (New Technology Level 52 ($145,001-$160,000), which would allow for an appropriate payment of retinal prosthesis implantation procedures, which is discussed further below. Table 17 of the proposed rule (below), includes the new Technology APC numbers, titles and cost bands.

TABLE 17—PROPOSED CY 2018 ADDITIONAL NEW TECHNOLOGY APC GROUPS

Proposed CY 2018 APC	Proposed CY 2018 APC Title	Proposed CY 2018 SI	Updated or new APC
1901	New Technology—Level 49 ($100,001–$115,000)	S	Updated.
1902	New Technology—Level 49 ($100,001–$115,000)	T	Updated.
1903	New Technology—Level 50 ($115,001–$130,000)	S	Updated.
1904	New Technology—Level 50 ($115,001–$130,000)	T	Updated.
1905	New Technology—Level 51 ($130,001–$145,000)	S	Updated.
1906	New Technology—Level 51 ($130,001–$145,000)	T	Updated.
1907	New Technology—Level 52 ($145,001–$160,000)	S	New.
1908	New Technology—Level 52 ($145,001–$160,000)	T	New.

2. Proposed Procedures Assigned to New Technology APC Groups for 2018

Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (APCs 1537, 5114, and 5414)

Currently, four CPT/HCPCS codes describe magnetic resonance image guided high intensity focused ultrasound (MRgFUS) procedures. CMS is continuing the current APC assignment for CPT codes 0071T, 0072T that are used for the treatment of uterine fibroids, and HCPCS code C9734 that is used for pain palliation for metastatic bone cancer. CMS received only one claim for CPT code 0398T used to treat essential tremor that it is continuing to assign to APC 1537 (New Technology - Level 37 ($9501-$10000)), with a proposed payment rate of approximately $9,751 for CY 2018.

Retinal Prosthesis Implant Procedure

CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy) describes the

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

For 2017, CMS reassigned the procedure described by CPT code 0100T from APC 1599 to APC 1906 (New Technology – Level 51 ($140,001 - $160,000) which has a payment rate of approximately $150,000. In 2016, CMS received three claims for CPT code 0100T with a geometric mean cost of $116,239. For 2018, CMS proposed to assign CPT code 0100T to APC 1904 ((New Technology - Level 50 $115,001-$130,000)), with a proposed payment of $122,000, which is the new technology payment band consistent with the costs of this procedure. CMS invites comment on this proposal.

Pathogen Test for Platelets

The CMS HCPCS Workgroup has established HCPCS code Q9987 (Pathogen(s) test for platelets) effective July 1, 2017. HCPCS code Q9987 will be used to report any test used to identify bacterial or other pathogen contamination in blood platelets. HCPCS code Q9987 was established after concerns that the previous CPT code describing pathogen tests for platelets, CPT code P9072, inappropriately described rapid bacterial testing by combining the test with the pathogen reduction of platelets. CPT code P9072 is inactive effective July 1, 2017.

CMS assigned HCPCS code Q9987 to New Technology APC 1493 (New Technology - Level 1C ($21-$30)), with a payment rate of $25.50 effective July 1, 2017. CMS is proposing to continue to assign HCPCS code Q9987 to New Technology APC 1493 until claims data are available to support assignment to a clinical APC.

D. OPPS APC-Specific Policies

Addendum B to the proposed 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 2018 are related to changes in costs of services that were observed in the 2016 claims data used for 2018 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. Blood-Derived Hematopoietic Cell Harvesting

HCPCS code 38205 represents a donor acquisition cost for an allogeneic hematopoietic stem cell transplant (HSCT). Since 2010, CMS has packaged payment for donor acquisition costs with the

procedure. However, donor acquisition costs for HCPCS code 38230 (Bone marrow harvesting for transplantation; allogeneic) is separately paid. For consistency and to ensure that the donor acquisition costs are captured accurately, for 2018, CMS is proposing to change the status indicator assignment for the procedure described by HCPCS code 38205 from "B" to "S", which indicates that the procedure is paid under the OPPS and receives separate payment.

CMS indicates that it is proposing to assign HCPCS code 38205 to APC 5242 (Level 2 Blood Product Exchange and Related Services) because that is the APC that is the most clinically similar and has comparable resources.

2. Radiology and Imaging Procedures and Services

Imaging APCs

CMS is proposing to create a Level 5 Imaging without Contrast APC to more appropriately group certain imaging services with higher resource costs. CMS indicates that the data support splitting the current Level 4 Imaging without Contrast APC into two APCs such that the Level 4 Imaging without Contrast APC would include high frequency low cost services and the proposed Level 5 Imaging without Contrast APC would include low frequency high cost services. This proposal would increase the imaging APCs from 7 APCs in 2017 to 8 in 2018. Table 20 of the proposed rule lists the imaging APCs being proposed for 2018.

Non-Ophthalmic Fluorescent Vascular Angiography (APC 5524)

For the 2018 OPPS update, CMS is proposing to reassign HCPCS code C9733 (Non-ophthalmic fluorescent vascular angiography) from APC 5523 (Level 3 Imaging without Contrast) to APC 5524 (Level 4 Imaging without Contrast) based on its geometric mean costs in the 2016 claims data. CMS' 2016 claims data show a geometric mean cost of approximately $236 for HCPCS code C9733 based on 216 single claims (out of 953 total claims), which is closely aligned with the geometric mean cost of approximately $275 for APC 5524.

CMS is proposing to continue "conditionally packaging" meaning that the service is conditionally packaged when performed in conjunction with other procedures on the same day but paid separately when performed as a stand-alone service.

IV. Proposed OPPS Payment for Devices

A. Pass-Through Payments for Devices

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

CMS follows the statutory requirements that a category of devices is eligible for transitional pass-through payments for at least 2, but not more than 3 years. CMS' policy is to begin the pass-through payment period on the first date the pass-through payment may be made.

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

- 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.

The pass-through payment status of these three device categories ends on December 31, 2017. Because all the devices in these device categories were approved prior to 2017, CMS applied its policy to expired device categories at the end of the year when at least 2 years of pass-through payments have been made. CMS proposes, beginning in 2018 to package the costs of the device described by HCPCS codes C2623, C2613, and C1822 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 2018

CMS received five applications by the March 1, 2017 quarterly deadline, the last quarterly deadline in time for this proposed rule. The summary below provides a high-level discussion of each application; readers are advised to review the proposed rule for more detailed information. **CMS invites public comment on whether the three technologies in question meet the newness, cost, and substantial clinical improvement criteria.**
CMS notes that applications received for the remaining 2017 quarters (June1, September 1, and December 1) will be discussed in the 2019 OPPS/ASC proposed rule.

1. Architect® Px

Harbor MedTech, Inc submitted an application for Architect® Px, a collagen biomatrix comprised of a stabilized extracellular matrix derived from equine pericardium. The equine pericardium is stabilized to become a catalyst and scaffold for use by autologous tissue regeneration factors.

- With respect to the newness criterion,CMS is concerned that UniteBioMatrix, cleared by the FDA on June 20, 2007, is cited in the application as a predicate of Architect® Px. **CMS notes that if the date for FDA clearance for Unite BioMatrix is used to evaluate the newness criterion, Architect® Px may not meet this criterion and invites comments.**
- With respect to the eligibility criterion, CMS has not identified an existing pass-through payment device category for this product.
- With respect to the substantial clinical improvement criterion, CMS is concerned that the evidence is insufficient to determine that Architect® Px meets the substantial clinical improvement criterion.
- With respect to the cost criterion, Architect® Px meets all the three cost significance tests and satisfies the cost significance criterion.

2. Dermavest and Purists Human Placental Connective Tissue Matrix (HPCTM)

Aedicell, Inc. submitted an application for Dermavest and Plurivest products. These products replace or supplement damaged tissue or inadequate integumental tissue by providing a scaffold to entrap migrating cells for population.

- CMS is uncertain if the newness criterion is met.
- With respect to the eligibility criterion, CMS has not identified an existing pass-through payment device category for this product.
- With respect to the substantial clinical improvement criterion, CMS is concerned that the research included in the application did not clinically demonstrate that Dermavest and Plurivest provide a substantial clinical improvement over other treatments for wound care.
- With respect to the cost criterion, Dermavest and Plurivest meet all the three cost significance tests and satisfies the cost significance criterion.

3. FlōGraft®/Flōgragt Neogenesis®

Applied Biologics, LLS submitted an application for FlōGraft®/Flōgragt Neogenesis®, an injectable human placental amniotic fluid that is used as an allograft to segment tissue to bone and tissue-to-tissue repairs. The applicant stated the product helps healing.

- With respect to the newness criterion, CMS is not certain if the newness criterion is met.
- With respect to the eligibility criterion, CMS has not identified an existing pass-through payment device category for this product.
- With respect to the substantial clinical improvement criterion, CMS is concerned that the data included in the application is insufficient to demonstrate these products offer a substantial clinical improvement over other treatments for wound care.
- With respect to the cost criterion, FlōGraft®/Flōgragt Neogenesis® meets all the three cost significance tests and satisfies the cost significance criterion.

4. Kerecis™ Omega3 Wound (Skin Substitute)

Kerecis, LLS submitted an application for Kerecis™ Omega3 Wound, a skin substitute product made from acellular fish skin from wild Atlantic cod (Gadus morhua) that is used to regenerate damaged human tissue in chronic wounds. The product is supplied as a sterile, single use sheet in peel-open pouches.

- With respect to the newness criterion, the applicant received FDA clearance for Kerecis™ Omega3 Wound through the premarket notification section 510(k) process on October 20, 2013 and its application on June 1, 2016 was within 3 years of FDA clearance.
- With respect to the eligibility criterion, CMS has not identified an existing pass-through payment device category for this product.

- With respect to the substantial clinical improvement criterion, CMS concludes there is no clinical data to suggest that Kerecis™ Omega3 Wound provides a substantial clinical improvement over other similar skin substitute products.
- With respect to the cost criterion, Kerecis™ Omega3 Wound meets all the three cost significance tests and satisfies the cost significance criterion.

5. X-WRAP®

Applied Biologics, LLC submitted an application for X-WRAP®, a chorion-free, amnion membrane allograft that can be used as a biological wrap or patch at any surgical site. It is used as a treatment for surgical or traumatic injury to bone or soft tissue.

- With respect to the newness criterion, CMS is not certain if the newness criterion is met.
- With respect to the eligibility criterion, CMS has not identified an existing pass-through payment device category for this product.
- With respect to the substantial clinical improvement criterion, CMS is concerned that the data is insufficient to demonstrate these products offer a substantial clinical improvement over other treatments for wound care.
- With respect to the cost criterion, X-WRAP® meets all the three cost significance tests and satisfies the cost significance criterion.

B. Proposed Device-Intensive Procedures

Prior to 2017, device-intensive APCs were defined as APCs with a device offset greater than 40 percent (79 FR 66795); the device costs of all procedures within the APC were calculated as well as their geometric mean device offset, which had to exceed 40 percent. The no cost/full credit and partial credit device policy (79 FR 66872 through 66873) applied to device-intensive APCs (see discussion below). CMS required that procedures assigned to certain APCs require the reporting of a device code on the claim.

1. HCPCS Code-Level Device-Intensive Determination

The full listing of proposed device-intensive procedures for 2018 is available in Addendum P of this proposed rule. This list can also be found in the Appendix of this document.

2. Changes to Device Edit Policy for 2017 and Subsequent Years

In the 2017 OPPS final rule, CMS finalizes 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.

In addition, CMS created 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.

For 2018, CMS is not proposing any changes to the device edit policy.

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

For 2018, CMS is not proposing any changes to the No Cost/Full Credit and Partial Credit Devices policy.

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

In the 2017 OPPS final rule, CMS finalized that the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC be calculated using the median cost instead of the geometric mean cost. CMS proposes to continue this policy for low-volume device-intensive procedures for 2018.

For 2018, CMS this policy would continue to apply only to the procedure described by CPT code 0308T in APC 5495 (Level 5 Intraocular Procedures). The proposed 2018 payment rate, calculated using the median cost, is approximately $16,963.69.

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

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

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

CMS is proposing that the pass-through payment status of 19 drugs and biologicals that were approved for pass-through status on or before January 1, 2016 would expire on December 31, 2017. Table 21 of the proposed rule, also found in the Appendix of this document, lists the drugs with expiring pass-through status. All of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2017.

Once pass-through payment expires, drugs are either policy packaged[5] or paid separately if they have per day costs above the packaging threshold of $120 for 2018. Following past practice, CMS proposes to either policy package payment for these drugs or pay for them separately if they have costs per day above $120 in 2018. If paid separately, CMS proposes to pay these drugs at ASP + 6 percent.

[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).

2. Proposed Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Payment Status in 2018

CMS is proposing to continue pass-through payment status in 2018 for 38 drugs and biologicals. None of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2017. These drugs and biologicals, which were approved for pass-through status between January 1, 2016, and July 1, 2017, are listed in Table 22 of the proposed rule, and also in the Appendix of this document. The APCs and HCPCS codes for these drugs and biologicals approved for pass-through payment status through July 1, 2017 are assigned status indicator "G" in Addenda A and B of the proposed rule.

CMS proposes to pay at ASP + 6 percent for these pass-through drugs and biologicals including those drugs, biologicals and radiopharmaceuticals that would otherwise be policy packaged were it not for their pass-through status. CMS proposes to update the ASP on a quarterly basis. If ASP data are not available for a radiopharmaceutical, CMS is proposing to provide pass-through payment at wholesale acquisition cost (WAC) + 6 percent, the equivalent payment provided to pass-through drugs and biologicals without ASP information. If WAC information also is not available, CMS proposes to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent average wholesale price (AWP).

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

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

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

For 2018, CMS proposes to continue to apply the current offset policies for all of the policy-packaged drugs, biologicals, and radiopharmaceuticals. 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/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files-Items/2018-Annual-Policy-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending.

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

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

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.

Proposed Cost Threshold for Packaging of "Threshold-Packaged Drugs"

"Threshold-packaged drugs" under the OPPS are drugs, non-implantable biologicals and therapeutic radiopharmaceuticals whose packaging status is determined by the packaging threshold. CMS is proposing a packaging threshold for 2018 of $120.

High/Low Cost Threshold for Packaged Skin Substitutes

There are no skin substitutes that are proposed to have pass-through payment status for 2018. CMS is proposing that a skin substitute that was assigned to the high cost group for 2017 would be assigned to the high cost group for 2018, even if it does not exceed the CY 2018 MUC or PDC thresholds. Table 24 in the 2018 proposed rule shows the high/low cost status for each skin substitute product in 2018. The skin substitute products affected by this proposed policy are identified with an "*" in Table 24 of the proposed rule.

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

For 2018, CMS proposes to continue 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 25 of the proposed rule.

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

Except for separately payable, non-pass-through drugs acquired with a 340B discount, CMS proposes to continue paying separately payable drugs and biologicals at ASP+6 percent in 2018. As explained in more detail below, CMS proposes to pay for drugs acquired with a 340B discount at ASP minus 22.5 percent. Medicare's payment represents the combined acquisition and pharmacy overhead payment for drugs and biologicals.

The payment rates shown for drugs and biologicals in Addenda A and B of the proposed rule are not the payment rates that Medicare will pay on January 1, 2018. These rates will be updated through the quarterly update process to reflect the actual payment rates that will be used beginning January 1, 2018. Payment rates effective January 2018 will be released near the end of December 2017 and will be based on ASP data submitted by manufacturers for the third quarter of 2017 (July 1, 2017 through September 30, 2017).

Biosimilar Biological Products

For 2016 and 2017, CMS finalized a policy to pay for non-pass-through biosimilar biological products based on ASP + 6 percent subject to the annual packaging threshold. For 2018, CMS is proposing to continue this same payment policy.

3. Payment Policy for Therapeutic Radiopharmaceuticals

For 2018, CMS is proposing to continue the payment policy for therapeutic radiopharmaceuticals that it began in 2010. 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

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

5. Payment for Blood Clotting Factors

For 2018, CMS proposes to continue paying 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 2017 furnishing fee ($0.209 per unit) based on the percentage increase in the Consumer Price Index (CPI) for medical care following the same methodology it has used since 2008. For 2018, CMS proposes to update the furnishing fee based on the percentage increase in the CPI for medical care for the 12-month period ending

in June 2017. This information is not available currently and won't be available for the final rule.

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

CMS is proposing to continue the same payment policy as in 2017 for non-pass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data. In priority order, CMS will pay for these products using ASP + 6 percent if ASP is reported, WAC + 6 percent[6] if a WAC is available and at 95 percent of AWP if ASP and WAC are unavailable. The 2018 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 of the proposed rule, which is available on the CMS website.

7. Alternative Payment Methodology for Drugs Purchased Under the 340B Drug Discount Program

CMS intends to establish a modifier, to be effective January 1, 2018, for hospitals to report with separately payable drugs that were not acquired under the 340B program. Because a significant portion of hospitals paid under the OPPS participate in the 340B program, CMS believes it is appropriate to presume that a separately payable drug reported on an OPPS claim was purchased under the 340B program. Further details regarding this modifier will be in the final rule and sub-regulatory guidance, including guidance related to billing for dually eligible beneficiaries for whom covered entities do not receive a discount under the 340B program.

Confidentiality limits CMS' ability to precisely calculate the price paid by 340B hospitals for a particular covered outpatient drug, so it is proposing an average discounted price of 22.5 percent of the ASP for non-pass-through separately payable drugs purchased under the 340B program.

CMS is also proposing that the reduced payments for separately payable drugs and biologicals purchased under the 340B program are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act, and that the budget neutral weight scaler is not applied in determining payments for these separately paid drugs and biologicals purchased under the 340B program. The proposed rule indicates that CMS is further soliciting public comments on whether to apply all or part of the savings generated by the payment reduction to:

- Increase payments for specific services paid under the OPPS;
- Increase payments generally under Part B (that is, other than services paid under the OPPS);
- Whether and how the offsetting increase could be targeted to hospitals that treat a large share of indigent patients, especially those patients who are uninsured; and

[6] The + 6 percent for WAC is not specifically stated in the 2016 rulemaking cited by CMS as the source of its policy but would be consistent with "ensur[ing] that new non-pass-through drugs, biologicals, and therapeutic radiopharmaceuticals would be treated like other drugs, biologicals, and therapeutic radiopharmaceuticals under the OPPS."

- Whether the redistribution of savings associated with this proposal would result in unnecessary increases in the volume of covered services paid under the OPPS which should be adjusted in accordance with section 1833(t)(2)(F) of the Act.

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

The proposed rule estimate for total pass-through spending for drug and device pass-through payments during 2018 is approximately $26.2 million, or 0.04 percent of total OPPS projected payments for 2018, which is less than the applicable pass-through payment percentage statutory limit of 2.0 percent.

A. Devices

Using its established methodology, CMS projects $10 million in pass-through spending attributable to device categories in 2018. CMS indicates that there will be no active device pass-through categories that were recently made eligible for pass-through payment that will continue to be eligible for pass-through payment in 2018. CMS estimates $10 million for device categories CMS knows or projects may be approved for pass-through status in 2018, and includes contingent projections for new device categories in 2018. CMS includes implantable biologicals newly eligible for pass-through payment in the estimate for this group.

B. Drugs and Biologicals

For the proposed rule, CMS calculates a pass-through spending estimate of $16.2 million in 2018 attributable to drugs and non-implantable biologicals and radiopharmaceuticals.

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

CMS proposes no changes to the current clinic and emergency department hospital outpatient visits payment policies or to the payment policy for critical care services.

VIII. Proposed Payment for Partial Hospitalization Program (PHP) Services

A. Proposed PHP APC Update for 2018

The proposed 2018 geometric mean per diem costs and payment rates are as follows:

2018 APC	Group Title	Proposed PHP APC Geometric Mean Per Diem Costs*	Proposed Payment Rates**
5853	Partial Hospitalization (3 or more services per day) for CMHCs	$128.81	$123.84
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	$213.60	$205.36

* Table 26 of the proposed rule shows the proposed PHP APC geometric mean per diem costs.

** The proposed payment rates are included in Addendum A to the proposed rule.

B. PHP Service Utilization

Updates. CMS has previously expressed concern about the low frequency of individual therapy in PHP services. CMS believes that appropriate treatment for PHP patients includes individual therapy, and its analysis of 2016 claims data shows a slight increase in the provision of individual therapy on days with only three services provided. Because of its single-tier payment policy, CMS is concerned that PHP providers may provide only 3 services per day when payment is heavily weighted to providing 4 or more services. Based on its review of 2016 claims, CMS believes that PHPs maintained an appropriately low utilization of 3 service days as compared to the preceding year, but the agency will continue to monitor utilization of days with only 3 PHP services. CMS reiterates its expectation that days with only 3 services should be the exception and not the typical PHP day.

Minimum Service Requirement: 20 Hours per Week. As it did in the 2017 OPPS rulemaking cycle, CMS notes that the eligibility requirements under §§410.43(a)(3) and (c)(1) state that PHP beneficiaries require a minimum of 20 hours per week in services as evidenced in the plan of care. CMS has stated in several earlier regulations that a typical PHP includes 5 to 6 hours per day (e.g., 70 FR 68548, 71 FR 67999, 72 FR 66671, and 73 FR 68687). CMS analyzed 2015 PHP claims data and determined that a majority of PHP patients did not receive at least 20 hours per week in partial hospitalization services, and just over half of PHP beneficiaries received 20 or more hours of services in 50 percent or more of non-transitional weeks.[7] Based on 2016 claims data, only 16.4 percent of beneficiaries in CMHCs and 34.8 percent in hospital-based PHPs received at least 20 hours of PHP services in 100 percent of non-transitional weeks which leads CMS to suggest that some PHPs may not provide the intensive services that beneficiaries need. CMS will continue to monitor the intensity of services provided on a weekly basis.

CMS seeks comment on the advisability of applying a payment requirement conditioned on the beneficiary's receipt of a minimum 20 hours of therapeutic services per week and on exceptions to the policy (i.e., circumstances that would cause a PHP patient to receive less than 20 hours of PHP services per week).

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

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

CMS is proposing to remove the procedures described by the following codes from the IPO list for 2018: CPT code 27447 (Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)) and CPT code 55866 (Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed):

[7] Generally, CMS considers the week during which a PHP patient is admitted or discharged to be transitional and the remaining weeks of the PHP to be non-transitional.

CPT Code	Code Descriptor	Proposed 2018 OPPS APC assignment	Proposed 2018 OPPS status indicator
27447	Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty	5115	J1
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed	5362	J1

Addendum E of the proposed rule contains the complete list of codes that are proposed to be paid only as inpatient procedures for 2018.

Total Knee Replacement

CMS proposes that CPT code 27447 would be assigned to C–APC 5115 (Level 5 Musculoskeletal Procedures) with status indicator ‘‘J1.” The proposed rule further notes that the decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician based on the beneficiary’s individual clinical needs and preferences and on the general coverage rules requiring that any procedure be reasonable and necessary. Therefore, if CMS finalizes its proposal, it would prohibit Recovery Audit Contractor (RAC) review for patient status for TKA procedures performed in the inpatient setting for a period of 2 years to allow time and experience for these procedures under this setting. CMS would not want hospitals to err on the side of inappropriately performing the procedure on an outpatient basis due to concerns about the possibility of an inpatient TKA claim being denied for patient status. Contractor reviews for issues other than patient status would continue to be permitted, including those for underlying medical necessity.

Laparoscopy, surgical prostatectomy

CMS is proposing to remove CPT code 55866 from IPO list. The proposed APC assignment is to C–APC 5362 (Level 2 Laparoscopy & Related Services) with status indicator ‘‘J1.”

B. Solicitation of Public Comments on the Possible Removal of Partial Hip Arthroplasty (PHA) and Total Hip Arthroplasty (THA) Procedures from the IPO List

Topics and Questions for Public Comments

CMS is seeking public comments on whether to remove CPT codes 27125 and 27130 from the IPO list from all interested parties, including: Medicare beneficiaries and advocate associations for Medicare beneficiaries; orthopedic surgeons and physician specialty societies that represent orthopedic surgeons who perform PHA and/or THA procedures; hospitals and hospital trade associations; and any other interested stakeholders.

CMS requests comment on the following questions:

- Are most outpatient departments equipped to provide PHA and/or THA to some Medicare beneficiaries?
- Can the simplest procedure described by CPT codes 27125 and 27130 be performed in most outpatient departments?
- Are the procedures described by CPT codes 27125 and 27130 sufficiently related to or similar to other procedures CMS has removed from the IPO list?
- How often is the procedure described by CPT codes 27125 and 27130 being performed on an outpatient basis (either in an HOPD or ASC) on non-Medicare patients?
- Would it be clinically appropriate for some Medicare beneficiaries in consultation with his or her surgeon and other members of the medical team to have the option of either a PHA or THA procedure as a hospital outpatient, which may or may not include a 24-hour period of recovery in the hospital after the operation?
- Do PHA and THA procedures meet the criteria to be added to the ASC Covered Procedures List?
- What would the effect be of removing PHA and THA from the IPO list on the CJR and BPCI Models?

X. Nonrecurring Policy Changes

A. Payment for Certain Items and Services Furnished by Certain Off-Campus Departments of a Provider

Service Line Expansion

For 2018, CMS does not make any proposals to limit clinical service line expansion or volume increases at excepted off-campus PBDs of a hospital. CMS states that it will continue to monitor claims data for changes in billing patterns and utilization and **invites comment on the issue**. The proposed payment rates under the Medicare Physician Fee Schedule for nonexcepted items and services furnished by nonexcepted off-campus PBDs of a hospital are available in the 2018 Medicare Physician Fee Schedule proposed rule.

Implementation of Section 16002 of the 21st Century Cures Act (Cures Act).

CMS has provided operational guidance to MACs on the implementation of section 16002 of the Cures Act. Section 16002 exempts an off-campus PBD of the eleven dedicated cancer hospitals from section 603 if the cancer hospital provided an attestation by certain deadlines. Specifically, the attestation would have to be provided to CMS not later than February 10, 2017 (i.e., 60 days from date of enactment of the Cures Act) that the off-campus PBD met the provider-based rule requirements (42 CFR §413.65) after November 1, 2015, and before the date of the enactment of the Cures Act on December 13, 2016. If an off-campus PBD of a cancer hospital first meets the provider-based rule requirements after December 13, 2016, it must provide an attestation to meeting the provider-based rules within 60 days of first meeting the provider-based rule requirements to be exempt from the application of section 603.

Section 1833(t)(18) of the Act includes special OPPS payment provisions for cancer hospitals. These provisions provide supplemental payments to cancer hospitals at cost report settlement such that the target OPPS payment-to-cost ratio for the cancer hospital equals the average payment-to-cost ratio for all other OPPS hospitals. Section 16002 of the Cures Act requires the Secretary to reduce the target payment-to-cost ratio that would otherwise apply by 1 percentage point and permits the Secretary to consider an additional percentage point reduction that takes into account payment rates under the section 603 applicable payment system for non-cancer hospitals.

B. Medicare Site-of-Service Price Transparency (Section 4011 of the 21st Century Cures Act)

Section 4011 of the 21st Century Cures Act (Pub. L. 114–255), enacted on December 13, 2016, adds new subsection 1834(t) requiring the Secretary to make available to the public via a searchable Web site the estimated payment amount and beneficiary liability for an item or service payable under the OPPS and ASC payment systems. CMS is not required to make this information available for all services but for an "appropriate number of items and services." CMS is announcing its plan to establish the searchable Web site required by section 1834(t) of the Act. Details regarding the Web site will be issued through a sub-regulatory process. CMS anticipates the Web site will be made available in early 2018.

C. Enforcement Instruction for the Supervision of Outpatient Therapeutic Services in Critical Access Hospitals (CAHs) and Certain Small Rural Hospitals

CMS is proposing to reinstate the nonenforcement of the direct supervision requirements for outpatient therapeutic services for CAHs and small rural hospitals having 100 or fewer beds for 2018 and 2019. The proposed rule indicates that this enforcement moratorium will give CAHs and small rural hospitals with 100 or fewer beds more time to comply with the supervision requirements for outpatient therapeutic services and to give all parties time to submit specific services to be evaluated by the HOP Panel for a recommended change in the supervision level. These hospitals would continue to be subject to conditions of participation for hospitals and other Medicare rules regarding supervision.

D. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

1. Background

Section 218(b) of the PAMA amended Title XVIII of the Act to add section 1834(q) directing CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. There are four major components of the AUC program under section 1834(q) of the Act, each with its own implementation date:

(1) establishment of AUC by November 15, 2015;
(2) mechanisms for consultation with AUC by April 1, 2016;
(3) AUC consultation by ordering professionals and reporting on AUC consultation by furnishing professionals by January 1, 2017; and

(4) annual identification of outlier ordering professionals for services furnished after January 1, 2017.

CMS notes it did not identify mechanisms for consultation by April 1, 2016 and will not have specified or published the list of qualified clinical decision support mechanisms (CDSMs) by January 1, 2017; therefore ordering professionals will not be required to consult CDSMs and furnishing professionals will not be able to report information on the consultation by January 1, 2017.

In the 2016 PFS final rule, CMS primarily addressed the first major component – the process for establishment of AUC. CMS finalized that an "applicable imaging service" must be an advanced imaging service (includes diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography); and other diagnostic imaging services CMS may specify in consultation with physician specialty organizations and other stakeholders, but excluding x-ray, ultrasound and fluoroscopy services).

CMS defined the term provider-led entities (PLE) to include national professional medical societies, health systems, hospitals, clinical practices and collaborations of such entities such as the National Comprehensive Cancer Network. Qualified PLEs may also collaborate with third parties. In June 2016, CMS identified 11 qualified PLEs.[8]

In the 2017 PFS final rule, CMS primarily addressed the second major component of the AUC program - the identification of qualified CDSMs that could be used by ordering professionals for consultation with applicable AUC. CMS defined CDSM as an interactive, electronic tool for use by clinicians that communicates AUC information to the user and assists them in making the most appropriate treatment decision for a patient's specific condition. In June 2017, CMS identified 6 qualified CDSMs and 9 CDSMs with preliminary qualifications.9

The third major component of the AUC program is Consultation with Applicable Appropriate Use Criteria. This section establishes, beginning January 1, 2017, the requirement for an ordering professional to consult with a listed qualified CDS mechanism when ordering an applicable imaging service that would be furnished in an applicable setting and paid for under an applicable payment system, and for the furnishing professional to include on the Medicare claim information about the ordering professional's consultation with a qualified CDS mechanism. The Act provides for certain exceptions to the AUC consultation and reporting requirements including in the case of certain emergency services, inpatient services paid under Medicare Part A, and ordering professionals who obtain an exception due to significant hardship. The Act specifies that the applicable payment systems for the AUC consultation and reporting are the PFS, hospital OPPS and ASC payment systems. Since a list of qualified CDSMs will not be available by January 1, 2017, CMS states it will not require ordering professionals to meet this requirement by that date.

8 The list of qualified PLEs can be accessed at https://www.cms.gov/Medicare/Quality-Initiative-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html.
9 The list of qualified CDSMs can be accessed at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/CDSM.html.

The fourth component of the AUC program is Identification of Outlier Ordering Professionals. This section facilitates a prior authorization requirement for outlier professionals beginning January 1, 2020. In the 2017 PFS final rule, CMS finalized the first list of priority clinical areas,10 which may serve as part of the basis for identifying outlier ordering professionals.

2. Proposals for Implementation

CMS proposes to amend §414.94, "Appropriate Use Criteria for Certain Imaging Services" to reflect the following proposals:

a. Consultation by Ordering Professional and Reporting by Furnishing Professional

Ordering Professional. CMS proposes that ordering professionals must consult specified applicable AUC through qualified CDSMs for applicable imaging services furnished in an applicable setting, paid for under an applicable payment system and ordered on or after January 1, 2019. CMS states it is establishing this date through rulemaking this year to allow impacted parties to have sufficient time to prepare to meet all the requirements. In response to commenters' recommendations, CMS believes it is allowing sufficient time for education and outreach efforts, time for practitioners and stakeholders to prepare, and time for CDSMs to continue to evolve and become more "user-friendly and less burdensome." The proposed date lags the statutory requirement of January 1, 2017 but CMS states this delay is necessary to maximize the opportunity for public comment and stakeholder engagement, also a statutory requirement, and allows for adequate advance notice for all stakeholders.

Furnishing Professional. CMS proposes that furnishing professionals report the following information on Medicare claims for applicable imaging service, furnished in an applicable setting, paid for under an applicable payment system, and ordered on or after January 1, 2019:

- Which qualified CDSM was consulted by the ordering professional;
- Whether the service ordered would adhere to specified applicable AUC, would not adhere to specified applicable AUC, or whether specified applicable AUC were not applicable to the service ordered; and
- The NPI of the ordering professional (if different from the furnishing professional).

CMS states that unless a statutory exception applies, an AUC consultation must take place for every order for an applicable imaging service furnished in an applicable setting and under an applicable payment system. CMS notes that qualified CDSMs must make available, at a minimum, AUC that reasonably address common and important clinical scenarios within all clinical areas and that the current list of priority clinical areas represent about 40 percent of advanced diagnostic imaging services paid for by Medicare in 2014. CMS expects CDSMs to have limited situations where the CDSM does not have specified applicable AUC for the service ordered and expects these responses to decrease with time.

10 The first list of priority clinical areas includes coronary artery disease (suspected or diagnosed, suspected pulmonary embolism, headache (traumatic and non-traumatic), hip pain, low back pain, shoulder pain (includes suspected rotator cuff injury), cancer of the lung (primary or metastatic, suspected or diagnosed), and cervical or neck pain.

Section 1834(q)(4)(B) requires that payment may only be made if the claim for the service includes the proposed information required by furnishing professionals. This information is required across claims types (both the furnishing and facility claims) and across all three applicable payment systems (PFS, hospital outpatient, and ambulatory surgery center). CMS states this information would need to be included on the practitioner claim that includes the PC of the imaging service and on the hospital outpatient claim for the TC of the imaging service. Claims not paid under the PFS, hospital outpatient or ambulatory surgery center payment system would not need to include the information.
CMS proposes to establish a series of HCPCS level 3 codes to implement the reporting requirements. CMS eventually intends to have one G-code for every qualified CDSM with the code description including the name of the CDSM. To ensure that there is a code available to immediately describe newly qualified CDSMs, CMS proposes to establish a generic G-code that would indicate a qualified CDSM was consulted, but would not identity a specific qualified CDSM. This generic code would be used until a specific G-code was available. CMS also proposes to establish a G-code that indicates a qualified CDSM was not consulted by the ordering professional. CMS states that G-codes would be a line-item on both practitioner and facility claims. For example, if there are two codes billed for advanced diagnostic imaging on the claim, CMS would expect two G-codes.

CMS also proposes to develop a series of modifiers to provide information as to whether the ordered service adheres to the AUC:

- The imaging service would adhere to the applicable AUC;
- The imaging service would not adhere to the applicable AUC; or
- AUC were not applicable to the imaging service ordered.

CMS also proposes to create additional modifiers to describe situations where an exception applies and a qualified CDSM was not used. A modifier would indicate the imaging service was ordered for a patient with an emergency medical condition and another modifier would indicate the ordering professional has a significant hardship exception. **CMS seeks comments on any additional HCPCS modifiers that might be needed to separately identify allowable scenarios for which a qualified CDSM was not consulted by the ordering professional**.

CMS expects voluntary reporting to be available beginning July 2018. CMS expects the January 1, 2019 proposed start date provides adequate time for it to develop the claims-based procedures and system changes necessary to process claims with the AUC information. It also believes this time will allow development of processes for the transfer of the AUC consultation information from the ordering to the furnishing professional and facility and development of billing system to translate the AUC consultation information into Medicare claims in the form of G codes and HCPCS modifiers. CMS notes that all these issues contribute to the need for an educational and operations testing program during the first year. CMS would continue to pay claims whether or not the claims correctly included the required information during this period but it does not expect to continue the educational and operational testing period beyond the first year of the AUC program.

E. Payment Changes for Film X-Ray Services and Proposed Payment Changes for X-rays Taken Using Computed Radiography Technology

Section 502(b) of the Consolidated Appropriations Act, 2016 (Pub. L. 114-113) enacted on December 18, 2015 requires that the OPPS payment be reduced by 20 percent from the amount that would otherwise be made if the hospital furnishes an X-ray service taken using film or computed radiography that uses cassette-based imaging with an imaging plate to create an image.

CMS implemented the X-ray provision by establishing the modifier ‘‘FX’’ (X-ray taken using film), effective January 1, 2017. The payment for X-rays taken using film and furnished during 2017 or a subsequent year will be reduced by 20 percent when modifier ‘‘FX’’ (X-ray taken using film) is reported with the appropriate HCPCS codes.

Payments for computed radiography technology services furnished during 2018, 2019, 2020, 2021, or 2022, that use cassette-based imaging with an imaging plate to create an image are reduced by 7 percent from the otherwise applicable OPPS payment. If such services are furnished during 2023 or a subsequent year, the reduction is 10 percent. To implement this provision, CMS is establishing a new modifier “XX” that would be reported on claims to identify those HCPCS codes that describe X-rays taken using computed radiography technology with an imaging plate. When this modifier is used, CMS proposes to apply the reduction required by the statute. (Modifier ‘‘XX’’ is a placeholder. The actual 2-digit modifier and long descriptor will be described in the 2018 OPPS/ASC final rule with comment period).

F. Potential Revisions to the Laboratory Date of Service Policy

The date of service (DOS) is a required data field on all Medicare claims for laboratory services. CMS policy requires that the DOS for a laboratory service is the date the specimen is collected. For “archived specimens,” the DOS is the date the specimen is obtained from storage. An “archived” specimen is as a specimen that is stored for more than 30 calendar days before testing.

The “14- Day Rule”

The DOS of a test may affect payment for the test, especially in situations in which a specimen that is collected while the patient is being treated in a hospital setting (for example, during a surgical procedure), is later used for testing after the patient has been discharged from the hospital. Payment for the test is usually bundled with payment for the hospital service, even where the results of the test did not guide treatment during the hospital stay. To address concerns raised for tests related to cancer recurrence and therapeutic interventions, CMS finalized modifications to the DOS policy for a test performed on a specimen stored less than or equal to 30 calendar days from the date it was collected (a non-archived specimen), so that the DOS is the date the test is performed (instead of the date of collection) if the following conditions are met:

- The test is ordered by the patient’s physician at least 14 days following the date of the patient’s discharge from the hospital;

- The specimen was collected while the patient was undergoing a hospital surgical procedure;
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- The results of the test do not guide treatment provided during the hospital stay; and
- The test was reasonable and medically necessary for the treatment of an illness.

When the 14-day rule applies, laboratory tests are not bundled into the hospital stay, but are instead paid separately under Medicare Part B.

Chemotherapy sensitivity tests are primarily used to determine post-hospital chemotherapy care for patients. The DOS for chemotherapy sensitivity tests is the date the test is performed if the following conditions are met:

- The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge;
- The specimen was collected while the patient was undergoing a hospital surgical procedure;
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- The results of the test do not guide treatment provided during the hospital stay; and
- The test was reasonable and medically necessary for the treatment of an illness.

For chemotherapy sensitivity tests that meet this DOS policy, Medicare would allow separate payment under Medicare Part B, that is, separate from the payment for hospital services.

Potential Revisions to the Laboratory DOS Policy

CMS is considering potential modifications to the DOS policy that would allow laboratories to bill Medicare directly for certain laboratory tests excluded from the OPPS packaging policy. One approach under consideration would create a new exception to the DOS policy for molecular pathology tests and tests that have been granted ADLT status by CMS. CMS believes these tests are relatively new and may have a different pattern of clinical use than more conventional laboratory tests, which may make them generally less tied to a primary service in the hospital outpatient setting than more common and routine laboratory tests that are packaged. CMS is seeking public comment on whether these tests, by their nature, are appropriately separable from the hospital stay that preceded the test and therefore should have a DOS that is the date of performance rather than the date of collection.

CMS is not specifically proposing but says that it is considering modifying §414.510(b) by adding a new paragraph (5) to establish that in the case of a molecular pathology test or an ADLT, the DOS must be the date the test was performed only if:

- The physician orders the test following the date of a hospital outpatient's discharge from the hospital outpatient department;
- The specimen was collected from a hospital outpatient during an encounter (as both are defined 42 CFR 410.2);

- It would be medically inappropriate to have collected the sample from the hospital outpatient other than during the hospital outpatient encounter;
- The results of the test do not guide treatment provided during the hospital outpatient encounter; and
- The test was reasonable and medically necessary for the treatment of an illness.

Limiting the DOS Rule Exception to ADLTs

CMS is also considering whether to potentially revise the DOS rule only for ADLTs and not molecular pathology tests. Among other criteria, a test can only qualify to be an ADLT if it is performed by one laboratory in a single location. The proposed rule indicates that CMS is considering limiting its policy change to ADLTs for this reason. There may be additional beneficiary access concerns for ADLTs that do not apply to molecular pathology tests as hospitals may not have arrangements with the only laboratory that furnishes a particular ADLT. With the hospital unable to furnish the test under arrangement, performance of the test may be delayed until 14 days after the patient's release from the hospital to avoid financial risk of no payment and thus potentially delay medically necessary care for the beneficiary.

CMS is also requesting public comments on how the current laboratory DOS policy may affect billing for other separately payable laboratory test codes that are not packaged under the OPPS, such as a laboratory test that is the only service provided to a beneficiary on a claim or molecular pathology tests.

XI. Proposed 2018 OPPS Payment Status and Comment Indicators

A. Proposed 2018 OPPS Payment Status Indicator Definitions

For CY 2018, CMS is not proposing any changes to status indicators. Status indicators and their definitions can be found in Addendum D1 of the proposed rule.

B. Proposed 2018 Comment Indicator Definitions

For 2018, CMS proposing to continue using the following comment indicators that are in effect for CY 2017:

- ''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.
- ''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 is requesting comments in the proposed rule, final APC assignment; comments will not be accepted on the final APC assignment for the new code.
- ''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.

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

Summary of Selected Key Elements of Proposed ASC Payment Rates for 2018		
	ASCs reporting quality data	**ASCs not reporting quality data**
2017 ASC Conversion Factor	$45.003	
Wage index budget neutrality adjustment	1.0004	
Proposed 2018 Update		
CPI-U update	2.3%	
Multi-factor productivity adjustment (MFP)	-0.4%	
Net MFP adjusted update	1.9%	
Penalty for not reporting quality data	0.0%	-2.0%
Net MFP and quality adjusted update	1.9%	-0.1%
Proposed 2018 ASC Conversion Factor	$45.876	$44.976

CMS notes that the projections may be updated in the final rule based on more recent data. As with the rest of the OPPS proposed rule and other CMS rules, addenda related to the ASC section (and referenced in this summary) are available only on the CMS website, at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html; select “1678-P” from the list of regulations. All ASC Addenda to the proposed rule are contained in the zipped folders entitled Addendum AA, BB, DD1, DD2, and EE.

A. Proposed Treatment of New and Revised Codes

Proposed Treatment of New and Revised Level II HCPCS Codes and Category III CPT Codes Implemented in April and July of 2017 for Which CMS is Soliciting Public Comments in this Proposed Rule

CMS, in April and July of 2017 change requests (CRs), made effective 13 new Level II HCPCS codes and 1 new Category III CPT Code describing covered ASC services that were not included in the 2017 OPPS final rule. Tables 31-33 copied below set out the codes, descriptors, and proposed 2018 payment indicators.

New Level II HCPCS Codes for Covered Ancillary Services Effective on April 1, 2017 (Table 31)		
C9484	Injection, eteplirsen, 10 mg	K2
C9485	Injection, olaratumab, 10 mg	K2
C9486	Injection, granisetron extended release, 0.1 mg	K2

C9487*	Ustekinumab, for intravenous injection, 1 mg	K2
C9488	Injection, conivaptan hydrochloride, 1 mg	K2
J7328	Hyaluronan or derivative, gel-syn, for intra-articular injection, 0.1 mg	K2
*HCPCS Code C9487, which was effective April 1, 2017, was deleted on June 30, 2017 and replaced with HCPCS Code Q9989 (Ustekinumab, for intravenous injection, 1 mg) effective July 1, 2017		

New Level II HCPCS Codes for Covered Surgical Procedures and Ancillary Services Effective on July 1, 2017 (Table 32)		
2017 HCPCS Code	**2017 Long Descriptor**	**Proposed 2018 Payment Indicator**
C9489	Injection, nusinersen, 0.1 mg	K2
C9490	Injection, bezlotoxumab, 10 mg	K2
C9745	Nasal endoscopy, surgical; balloon dilation of eustachian tube	J8
C9746	Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed and/or fluoroscopy, when performed	J8
C9747	Ablation of prostate, transrectal, high intensity focused ultrasound (HIFU), including imaging guidance	G2
Q9986	Injection, hydroxyprogesterone caproate (Makena), 10 mg	K2
Q9989*	Ustekinumab, for Intravenous Injection, 1 mg	K2
*HCPCS Code C9487, which was effective April 1, 2017, was replaced with HCPCS Code Q9989 (Ustekinumab, for intravenous injection, 1 mg) effective July 1, 2017		

New Category III CPT Code For Covered Surgical Procedure Effective on July 1, 2017 (CMS Table 33)		
2017 CPT Code	**2017 Long Descriptor**	**Proposed 2018 Payment Indicator**
0474T	Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space	J8

CMS notes that the proposed payment rates, where applicable, can be found in Addendum BB to the proposed rule for the Level II HCPCS codes and in Addendum AA to the proposed rule for the new Category III code at the CMS website referenced above. **CMS invites comments on these proposals.**

Proposed Process for New and Revised Level II HCPCS Codes That Will Be Effective October 1, 2017 and January 1, 2018 for Which CMS Will Solicit Comments in the 2018 OPPS/ASC Final Rule

CMS proposes to continue to assign comment indicator "NI" in Addendum B to the 2018 OPPS/ASC final rule for those new and revised Level II HCPCS codes that are effective October 1, 2017 and January 1, 2018. This indicates that CMS has assigned the codes an interim OPPS

payment status for 2018. CMS will invite public comments in that 2018 final rule on the interim status indicators, APC assignments and payment rates that will be finalized in the 2019 OPPS/ASC final rule.

Proposed Process for Recognizing New and Revised Category I and Category III CPT Codes That Will Be Effective January 1, 2018 for Which CMS Will Solicit Comments in the 2018 OPPS/ASC Final Rule

For new and revised Category I and III CPT codes effective January 1, 2018 that are received in time to be included in the proposed rule, CMS proposes Ambulatory Payment Classification (APC) and status indicator assignments, as well as proposed payment rates. Such codes are assigned new comment indicator "NP". Those new and revised codes are listed in Addendums AA and BB, and the long descriptors are in Addendum O at the ACS website.

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

Covered Surgical Procedures Designated as Office-Based

Based on its review of 2016 volume and utilization data, CMS proposes to permanently designate two additional procedures as office-based:

- CPT Code 37241 (Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural road mapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (e.g. congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles)), with proposed ASC payment indicator of "P2/P3" in 2018.
- CPT Code 67227 (Destruction of extensive or progressive retinopathy (e.g. diabetic retinopathy), cryotherapy, diathermy), with proposed ASC payment indicator of "P2/P3" in 2018.

Additionally, CMS proposes to permanently designate HCPCS code G0429 (Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies) as office-based and to assign payment indicator "P2/P3" in 2018. CMS notes that HCPCS code 0299T (Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound) was finalized for temporary office-based status in the CY 2017 OPPS/ASC final rule. However, this code will be deleted by the AMA, effective December 31, 2017.

CMS proposes to designate one new 2018 CPT code for ASC covered surgical procedures as temporary office-based, using a 5-digit CMS placeholder code as follows: 382X3 (Diagnostic bone marrow; biopsy(ies) and aspiration(s) with the 2018 payment indicator "P2/P3".

Proposed ASC Covered Surgical Procedures to Be Designated as Device-Intensive

For 2018, CMS proposes to update the ASC list of covered surgical procedures that are eligible for payment according to the device-intensive payment methodology, reflecting the proposed

individual HCPCS code device offset percentages based on 2016 OPPS claims and cost report data. The procedures are assigned the payment indicator "J8" and are included in Addendum AA (at the CMS ACS website) which lists the procedures, the CPT code and short-descriptor, the device offset percentage, and an indication of the full credit/partial credit device adjustment policy that would apply.

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

CMS finalized a modification in payment for devices furnished with full or partial credit under the OPPS in the 2014 final rule, but there is no mechanism in the ASC claims processing system for ASCs to submit the actual amount received when furnishing a device without cost or with full or partial credit. CMS proposes to continue its policy for ASCs for 2018:

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

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

CMS proposes to update the list of ASC covered device-intensive procedures which would be subject to the full credit/partial credit policy to all device-intensive procedures in 2018.

Proposed Additions to the List of ASC Covered Surgical Procedures

CMS proposes to add three procedures to the list of covered surgical procedures that could meet the standards for inclusion – that is, they could be safely performed in the ASC setting and would not require an overnight stay. The three proposed additions are as follows:

Proposed Additions to the List of ASC Covered Surgical Procedures for 2018 (CMS Table 37)		
2018 CPT Code	**2018 Long Descriptor**	**Proposed 2018 ASC Payment Indicator**
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical	J8

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)	N1
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250g	G2

CMS notes that, as in prior years, this update includes review of procedures being proposed for removal from the OPPS inpatient list for possible inclusion on the ASC list of covered surgical procedures. While CMS proposes to remove from the OPPS inpatient list the two procedures described by CPT codes 27447 and 55866,[11] it proposes to exclude the procedures from the ASC covered procedures list because they typically require more than 24 hours of active medical care following the procedure.

CMS also seeks comment on whether the following procedures meet the criteria to be added to the ASC covered surgical procedure list:

- CPT code 27125 (Hemiarthroplasty, hip, partial (e.g. femoral stem prosthesis, bipolar arthroplasty)), and
- CPT code 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft)

Covered Ancillary Services

CMS proposes to update the ASC list of covered ancillary services to reflect the payment status for the services under the OPPS. CMS notes that this may result in packaged status under the ASC payment system for covered ancillary services that were separately payable in a preceding year if the covered ancillary service is proposed for packaged status under the OPPS. CMS proposes to continue this reconciliation of packaged status for subsequent years. All ASC covered ancillary services and their proposed payment indicators for 2018 are included in Addendum BB at the ASC website. **CMS invites comments.**

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

Payment for Covered Surgical Procedures; Proposed Update to ASC Covered Surgical Procedure Payment Rates for 2018

CMS would make payment for office-based procedures at the lesser of the proposed 2018 Medicare Physician Fee Schedule non-facility PE RVU-based amount, or the proposed 2018 ASC payment amount calculated according to the standard methodology. CMS proposes to continue its policy for device removal procedures – such procedures that are conditionally packaged in the OPPS would be assigned the current ASC payment indicators and continue to be paid separately under the ASC payment system.

[11] CPT codes 27447 (Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)) and 55866 (Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed).

Payment for Covered Ancillary Services

CMS proposes to update payments and make changes necessary to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services. CMS also proposes to continue to set payment methodologies for brachytherapy services and separately payable drugs and biologicals equal to the proposed 2018 OPPS rates.

CMS proposes to continue to base payment for separately payable covered radiology services based on the lower of the 2018 Medicare Physician Fee Schedule non-facility PE RVU-based amounts and the proposed 2018 ASC rate calculated under standard rate-setting methodology (except in the case of nuclear medicine procedures and services that use contrast agents). If the radiology service is packaged or conditionally packaged under the OPPS, payment for the radiology service would be packaged into the payment for the ASC. Addendum BB indicates the payment status for each radiology service.

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

CMS proposes to continue to not make separate payment for procurement of corneal tissue when used in any noncorneal transplant procedure.
With regards to contractor-priced codes, CMS proposes to continue to designate hepatitis B vaccines as contractor-priced based on the invoiced costs for the vaccine, and corneal tissue acquisition as contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplant. In addition, consistent with its established ASC payment policy, CMS proposes that the 2018 payment for devices that are eligible for pass-through payment under the OPPS would be separately paid under the ASC payment system and contractor-priced.

Consistent with its current policy, CMS proposes that certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS be covered ancillary services when they are integral to an ASC covered surgical procedure. CMS proposes to pay for the tests at the lower of the Medicare Physician Fee Schedule non-facility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard rate-setting methodology. CMS identifies no new codes that meet this criterion for 2018.

D. New Technology Intraocular Lenses (NTIOL)

CMS is not proposing any change to its payment adjustment of $50 per lens for a 5-year period from the implementation date of a new NTIOL class.

E. Proposed ASC Payment and Comment Indicators

CMS proposes to continue using the current comment indicators “NP” and “CH.” CMS

proposes that Category I and III CPT codes that are new and revised for 2018 and any new and existing Level II HCPCS codes with substantial revisions would be labeled with the proposed new comment indicator 'NP" to indicate that these codes are open for comment as part of this 2018 proposed rule.
Addenda DD1 and DD2 provide a complete list of the ASC payment and comment indicators proposed for 2017. CMS will respond to public comment on the proposed payment and comment indicators and finalize their ASC assignment in the final rule.

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

Updating the ASC Conversion Factor

CMS proposes to continue its policy of updating the conversion factor by the CPI-U estimated for the 12-month period ending with the mid-point of 2018. CMS uses the IHS Global Insight (IGI) 2017 first quarter forecast, which projected a CPI-U update of 2.3 percent and a multifactor productivity adjustment of -0.4 percent. This yields a proposed update of 1.9 percent for ASCs meeting quality reporting requirements.

CMS proposes to continue its policy of reducing the update by 2.0 percentage points for ASCs not meeting the quality reporting requirements, yielding an update of -0.1 percent (a 0.999 update factor) for such ASCs. CMS notes that, as in prior years, it proposes to revise the updates if more current CPI-U or MFP data are available when the final rule is issued.
The resulting 2018 ASC conversion factor proposed by CMS is $45.876 for ASCs reporting quality data, and $44.976 for those that do not, computed as follows:

	ASCs reporting quality data	**ASCs not reporting quality data**
2017 ASC conversion factor	$45.003	
Wage adjustment for budget neutrality	x 1.0004	
Net MFP-adjusted update	x 1.019	x 0.999
Proposed 2018 ASC conversion factor	$45.876	$44.976

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 39 of the proposed rule, replicated below, which assumes the same mix of services as reflected in 2016 claims data.

Summary of Table 39: Aggregate Proposed 2018 Medicare Program Payments by Surgical Specialty, for the six largest groups		
Surgical Specialty Group	Estimated 2017 ASC Payments (in Millions)	Estimated Proposed 2018 Percent Change
Total	**$4,460**	**2%**

Summary of Table 39: Aggregate Proposed 2018 Medicare Program Payments by Surgical Specialty, for the six largest groups		
Surgical Specialty Group	Estimated 2017 ASC Payments (in Millions)	Estimated Proposed 2018 Percent Change
Eye and ocular adnexa	$1,688	2%
Digestive system	$852	3%
Nervous system	$849	2%
Musculoskeletal system	$530	3%
Genitourinary system	$186	1%
Integumentary system	$141	5%
Ancillary items and services	$55	-43%

CMS sets out estimated increases for 30 selected procedures in Table 40 in the proposed rule; the top 10 procedures are replicated below. CPT code 66984 (Cataract surgery with intraocular lens, 1 stage) is the largest aggregate payment procedure by far, and is estimated to see a 1 percent decrease.

Excerpt from Table 40: Estimated Impact of the Proposed 2018 Update to the ASC Payment System on Aggregate Payments for the Top 10 Procedures			
CPT/ HCPS Code	Short Descriptor	Estimated 2017 ASC Payments (in Millions)	Estimate 2018 Percent Change Percent Change
66984	Cataract surg w/iol, 1 stage	$1,172	2%
45380	Colonoscopy and biopsy	$216	3%
43239	Egd biopsy single/multiple	$178	3%
63685	Insert/redo spine n generator	$151	-4%
45385	Colonoscopy w/lesion removal	$146	3%
63650	Implant neuroelectrodes	$118	3%
64483	Inj foramen epidural l/s	$99	3%
66982	Cataract surgery, complex	$94	2%
0191T	Insert ant segment drain int	$86	1%
66821	After cataract laser surgery	$69	1%

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-1678-P.html.

- AA -- Proposed List of ASC Covered Surgical Procedures for 2018 (Including surgical procedures for which payment is packaged)
- BB -- Proposed ASC Covered Ancillary Services Integral to Covered Surgical Procedures for 2018 (Including Ancillary Services for Which Payment is Packaged)
- DD1 -- Proposed ASC Payment Indicators for 2018
- DD2 -- Proposed ASC Comment Indicators for 2018
- EE -- Surgical Procedures Proposed to be Excluded from Payment in ASCs for 2018

XIII. Hospital Outpatient Quality Reporting Program Updates

CMS proposes changes to the Hospital Outpatient Quality Reporting (OQR) Program including the removal of six measures beginning with the 2020 payment determination. No measures are proposed for addition. Changes are proposed to public display of one measure and to data submission and data validation requirements. A summary table at the end of this section shows all adopted and proposed OQR Program measures for the 2015 through 2021 payment determinations.

A. Hospital OQR Program Quality Measures and Public Reporting

1. Accounting for Social Risk Factors

CMS seeks public comment on whether to account for social risk factors in the OQR Program, and if so, what combination of methods would be most appropriate (e.g., confidential reporting to providers of rates stratified by social risk factors; public reporting of stratified measure rates; and risk adjustment of measures as appropriate based on data and evidence).

2. Removal of Measures

A total of six measures are proposed for removal from the OQR Program. Two measures are proposed for removal beginning with the 2020 payment determination, and the remaining four beginning with the 2021 payment determination.

Proposed for removal beginning with the 2020 payment determination:

- OP-21: Median Time to Pain Management for Long Bone Fracture
- OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures

Proposed for removal beginning with the 2021 payment determination:

- OP-1: Median Time to Fibrinolysis
- OP-4: Aspirin at Arrival
- OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional
- OP-25: Safe Surgery Checklist

3. Delay of OAS CAHPS Measure

CMS proposes to delay indefinitely the implementation of the OAS CAHPS measures, currently scheduled for inclusion in the OQR Program measure set beginning with 2020 payment (2018 data collection). CMS has determined that it lacks operational and implementation data, and believes that national (voluntary) implementation of the survey during 2016 and 2017 will provide valuable information for the future. Particular issues identified are patient response rates, both aggregate and by survey administration method; reliability of the data; and administrative burden.

4. Possible Hospital OQR Program Measure Topics for Future Consideration

CMS is considering developing OP-2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival as an eCQM for future rulemaking. It believes that automatic extraction and reporting of clinical quality data would reduce reporting burden under the OQR Program.

5. Public Display of OP-18 Measure

CMS proposes to modify public display of the measure OP-18: Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients. The measure data are stratified into four separate calculations OP-18a is the overall rate; OP-18b is the reporting measure, which excludes psychiatric/mental health patients and transfer patients; OP-18c assesses psychiatric/mental health patients; and OP-18d assesses transfer patients.

Beginning as early as July 2018 CMS proposes that OP-18c also be publicly reported, using data from patient encounters during the third quarter of 2017. The Measure Information Form would be modified to rename OP-18b to make clear psychiatric and transfer patients are excluded. No new data collection would be required. Hospitals would be able to preview the data to be reported for OP-18c as part of the regular 30-day data preview process.

The proposal is made because OP-18c includes numerous substance abuse ICD-10 codes, and CMS believes that public reporting will address a behavioral health gap in the OQR Program measure set. CMS says it considered proposing to begin with data for the first quarter of 2018, but chose not to wait because the earliest public reporting would be July 2019.

B. Administrative and Data Submission Requirements

1. Continuation of Policies

CMS describes ongoing OQR Program policies for which it proposes no changes, which are related to the following: maintenance of technical specifications for measures; data submission requirements; data submission deadlines for 2020 payment; the QualityNet account and security administrator; requirements for reporting chart-abstracted measures; requirements for claims-based measures; requirements for measures submitted via a web-based tool; population and data sampling requirements; and reconsiderations and appeals.

2. Changes to the Notice of Participation Deadline

CMS proposes to extend the Notice of Participation deadline for hospitals participating in the OQR Program. CMS proposes that hospitals must submit the NOP any time prior to registering on the QualityNet website. For example, a hospital submitting data for Q1 2019 encounters would be required to submit the NOP prior to registering on the QualityNet website, which must be done prior to the data submission deadline of August 1, 2019. Conforming changes would be made in the regulatory text.

3. Data Submission Requirements for Newly Participating Hospitals

Hospitals that did not participate in the previous year's OQR Program would be required to submit data beginning with encounters occurring during the first calendar quarter of the year prior to the affected payment year. This proposal would replace the previously adopted policy under which the deadline depends upon whether the hospital's Medicare acceptance date is before or after January 1 of the year prior to the payment year. Conforming changes would be made to the regulatory text at 42 CFR 419.46(c)(3).

4. Data Validation Requirements

Under the previously adopted validation selection process, CMS will choose a random sample of 450 hospitals for validation purposes and select an additional 50 hospitals based on two criteria: (1) hospital failed validation in the previous year, or (2) hospital has an outlier value for a measure, defined as greater than 5 standard deviations for the mean value for the measure.

In this proposed rule, CMS clarifies that the outlier value criterion refers specifically to hospitals with a poor score on a measure.

CMS proposes to formalize its process for educational review and to specify that if the results of an educational review indicate that CMS incorrectly scored a hospital's medical records submitted for validation, the corrected quarterly validation score would be used to compute the hospital's confidence interval and final validation score for the year. Currently, if an error is identified, the results are not changed but are taken into account if the hospital submits a reconsideration request.

Specifically, for beginning with validation of 2018 data (for the 2020 payment determination) CMS formalizes its current educational review process under which a hospital can request informal educational reviews for each quarter it receives validation results. The hospital has 30 days after posting of the validation results on the QualityNet secure portal to make the request for review.

CMS proposes that during the educational review process, it would determine whether a quarterly validation score was correct using the same process adopted for reconsideration requests. Evaluation of the score would consist of reviewing data elements that were labeled as mismatched in the original validation results. CMS would take into consideration written justifications provided by hospitals in the educational review request.

Beginning with the 2020 payment determination, if an educational review requested for any of the first 3 quarters of validation yields incorrect validation results for chart-abstracted measures, any quarterly score that is recalculated and corrected during the educational review process would be used to compute the hospital's final validation confidence interval at the end of the year.

C. Payment Reduction for Hospitals That Fail to Meet the Hospital OQR Program Requirements for the 2018 Payment Determination

CMS proposes to continue existing policies with respect to computing and applying the payment reduction for hospitals that fail to meet the Hospital OQR Program requirements for the 2018 update factor. The reduction ratio for hospitals that fail to meet OQR Program requirements, called the "reporting ratio", is 0.98. Continuing previous policies, when applicable the reporting ratio is applied to all services calculated using the OPPS conversion factor and applied to all HCPCS codes to which CMS has assigned status indicators J1, J2, P, Q1, Q2, Q3, R, S, T, V, or U, excluding services paid under the New Technology APCs to which CMS has assigned status indicators S and T. The reporting ratio does not apply to codes with a status indicator of "Q4" because these services are either packaged or paid through the clinical laboratory fee schedule and are never paid under the OPPS.

D. Summary Table of OQR Program Measures

The table below shows proposed changes in measures for the 2020 and 2021 payment determinations along with OQR measures previously adopted for payment determinations beginning in 2015. (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

Summary Table—OQR Measures Previously Adopted for 2015-2020 and Proposals (*in italics)* for 2020 and 2021

NQF		2015	2016	2017	2018	2019	2020	2021
0287+	OP-1: Median Time to Fibrinolysis	X	X	X	X	X	X	*Remove*
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	*Remove*
0289+	OP-5: Median Time to ECG	X	X	X	X	X	X	X
	OP-6: Timing of Antibiotic Prophylaxis	X	X	Removed				
	OP-7: Prophylactic Antibiotic Selection for Surgical Patients	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

Summary Table—OQR Measures Previously Adopted for 2015-2020 and Proposals (*in italics)* for 2020 and 2021								
NQF		**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**
	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	*Remove*
0662	OP-21: ED- Median Time to Pain Management for Long Bone Fracture	X	X	X	X	X	*Remove*	
0499+	OP-22: ED- Left Without Being Seen	X	X	X	X	X	X	X
0661	OP-23: ED- Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival	X	X	X	X	X	X	X
	OP-25: Safe Surgery Checklist Use	X	X	X	X	X	X	*Remove*
	OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures	X	X	X	X	X	*Remove*	
0431	OP-27: Influenza Vaccination Coverage among Healthcare Personnel		X	X	X	X	X	X
0658	OP-29: Appropriate Follow- up Interval for Normal Colonoscopy in Average Risk Patients		X	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	X
1536	OP-31: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery		Adopted, then excluded	Voluntary				
2539	Op-32: Facility Seven Day Risk Standardized Hospital Visit Rate After Outpatient Colonoscopy				X	X	X	X

Summary Table—OQR Measures Previously Adopted for 2015-2020 and Proposals (*in italics)* for 2020 and 2021								
NQF		**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**
1822	OP-33: External Beam Radiotherapy for Bone Metastases				X	X	X	X
	OP-35 Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy						X	X
2687	OP-36 Hospital Visits After Hospital Outpatient Surgery						X	X
	OP 37a OAS CAHPS – About Facilities and Staff						*Delay*	
	OP-37b: OAS CAHPS – Communication About Procedure						*Delay*	
	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery						*Delay*	
	OP-37d: OAS CAHPS – Overall Rating of Facility						*Delay*	
	OP-37e: OAS CAHPS – Recommendation of Facility						*Delay*	
+ CMS notes that NQF endorsement for the measure has been removed.								

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

In the 2012 OPPS/ASC final rule, CMS finalized the implementation of the ASCQR Program beginning with the 2014 payment determination. That rule finalized measures for the 2014, 2015 and 2016 payment determinations. In several subsequent rules, additional program requirements were finalized and additional measures were adopted through 2020.

A. ASCQR Program Measures

In this rule, CMS proposes to: remove three measures from ASCQR Program beginning in 2019; delay implementation of the OAS CAHPS measure slated for 2020; add one new measure beginning in 2021; and add two more measures beginning in 2022. No other changes are proposed regarding to the previously adopted measures, which continue unless proposed for removal.

1. Accounting for Social Risk Factors

CMS seeks public comment on whether to account for social risk factors in the ASCQR Program, and if so, what combination of methods would be most appropriate (e.g., confidential reporting to providers of rates stratified by social risk factors; public reporting of stratified measure rates; and risk adjustment of measures as appropriate based on data and evidence).

2. Removal of Measures

Three measures are proposed for removal from the ASCQR Program beginning with the 2019 payment determination:

- ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing
- ASC-6: Safe Surgery Checklist Use
- ASC-7: ASC Facility Volume Data on Selected Procedures.

3. Delay of OAS CAHPS Measure

CMS proposes to delay indefinitely the implementation of the OAS CAHPS measures, currently scheduled for inclusion in the ASCQR Program measure set beginning with 2020 payment (2018 data collection). The rationale for this proposal is discussed above with respect to the OQR Program (XIII.B.3).

4. Proposed New Measure for 2021: ASC-16: Toxic Anterior Segment Syndrome

This measure assesses the number of ophthalmic anterior segment surgery patients diagnosed with Toxic Anterior Segment Syndrome (TASS) within two days of surgery. TASS is an acute, noninfectious inflammation of the anterior segment of the eye and is a complication of anterior segment eye surgery that typically develops within 24 hours after surgery. The numerator would be the number of ophthalmic anterior segment surgery patients diagnosed with TASS within 2 days of surgery; the denominator would be all ophthalmic anterior segment surgery patients. The measure would not be risk adjusted. CMS solicited comments on this measure as part of last year's rulemaking. More information on the measure can be found at: http://ascquality.org/documents/ASC-QC-Implementation-Guide-4.0-September-2016.pdf

5. Two New Measures for 2022

CMS proposes two new claims-based measures that for the ASCQR Program beginning with the 2022 payment determination. The measures are ASC-17: Hospital Visits after Orthopedic ASC Procedures and ASC-18: Hospital Visits after Urology ASC Procedures. Each is a risk-standardized measure that would assess all-cause unplanned hospital visits within seven days of the specified orthopedic or urology ASC procedures.

B. Administrative and Data Submission Requirements

Previously adopted ASCQR Program policies are proposed to continue unchanged regarding maintenance of technical specifications; public reporting; QualityNet account and administrator; participation status; data collection periods for claims-based measures; minimum threshold, case volume and data completeness requirements for claims based measures; and program reconsideration procedures.

1. Batch Submission Option

CMS proposes to expand its online tool to allow for "batch submission" for multiple ASCs beginning with data submitted in 2018 for the 2020 payment determination. Batch submission would permit submission of data for multiple facilities simultaneously using a single electronic file through one agent QualityNet account. An ASC agent (for example, a corporate representative for a corporate entity consisting of multiple ASC facilities with separate NPIs) would be assigned a vendor ID and an ASC's representative would submit the Security Administrator form with the assigned vendor ID for the agent to establish their own QualityNet account.

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

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

D. Summary Table of ASCQR Program Measures

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

ASCQR Program Measures by Payment Determination Year (*Proposed changes in italics*)									
	2014	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**
ASC-1: Patient Burn (NQF #0263)	X	X	X	X	X	X	X	X	X
ASC-2: Patient Fall (NQF #0266)	X	X	X	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	X	X	X
ASC-4: All-Cause Hospital Transfer/Admission (NQF #0265)+	X	X	X	X	X	X	X	X	X
ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing (NQF #0264)+	X	X	X	X	X	*Remove*			
ASC-6: Safe Surgery Checklist Use		X	X	X	X	*Remove*			
ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures (see below)		X	X	X	X	*Remove*			
ASC-8: Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)			X	X	X	X	X	X	X
ASC-9 Endoscopy/Poly Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF			X	X	X	X	X	X	X

ASCQR Program Measures by Payment Determination Year (*Proposed changes in italics)*									
	2014	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**
#0658)									
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	X	X	X
ASC-11 Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536)			Adopted then excluded	Voluntary					
ASC-12 Facility 7-Day Risk Standardized Hospital Visit Rate after Outpatient Colonoscopy					X	X	X	X	X
ASC-13 Normothermia Outcome							X	X	X
ASC-14 Unplanned Anterior Vitrectomy							X	X	X
ASC 15a OAS CAHPS – About Facilities and Staff							*Delay*		
ASC 15b: OAS CAHPS – Communication About Procedure							*Delay*		
ASC 15c: OAS CAHPS – Preparation for Discharge and Recovery							*Delay*		
ASC 15d: OAS CAHPS – Overall Rating of Facility							*Delay*		
ASC 15e: OAS CAHPS – Recommendation of Facility							*Delay*		
ASC-16: Toxis Anterior Segment Syndrome								*Proposed*	
ASC-17: Hospital Visits After Orthopedic ASC Procedure									*Proposed*
ASC-18: Hospitals Visits After Urology ASC Procedure									*Proposed*
+ CMS notes that NQF endorsement for the measure has been removed.									

XV. Request for Information and Public Comments

A. Eliminating Inappropriate Medicare Payment Differentials for Similar Services in the Inpatient and Outpatient Settings

CMS requests comments on eliminating payment differentials for similar services provided in inpatient and outpatient settings. CMS references MedPAC's June 2015 Report to Congress where MedPAC stated "the high profitability of one-day stays under the inpatient prospective payment system (IPPS) and the generally lower payment rates for similar care under the outpatient prospective payment system (OPPS) have heightened concern about the appropriateness of inpatient one-day stays." The proposed rule indicates that both hospitals and CMS have had the opportunity to gain experience under the various policy changes that have occurred with respect to short inpatient hospital stays since the last time CMS requested public comment on payment policy options for addressing differentials between inpatient and outpatient payment for the same services (in the CY 2016 OPPS/ASC final rulemaking (80 FR 70549)).

XVI. Files Available to the Public via the Internet

Addenda for this 2018 OPPS/ASC proposed rule are available on the following CMS website:

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1678-P.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending

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

For addenda related to 2018 ASC payments, please see:
https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1678-P.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: Table 38—OPPS Impact Table

	Number of hospitals (1)	APC recalibration (all proposed changes) (2)	Proposed new wage index and provider adjustments (3)	All proposed budget neutral changes (combined cols 2,3) with market basket update (4)	All proposed changes (5)
ALL FACILITIES *	3,828	0.0	0.0	1.8	1.9
ALL HOSPITALS (excludes hospitals permanently held harmless and CMHCs)	3,714	0.0	0.0	1.8	2.0
URBAN HOSPITALS	2,902	0.0	0.0	1.8	2.0
LARGE URBAN (GT 1 MILL.)	1,577	0.1	-0.1	1.8	1.9
OTHER URBAN (LE 1 MILL.)	1,325	0.0	0.1	1.9	2.0
RURAL HOSPITALS	812	0.0	0.0	1.8	2.0
SOLE COMMUNITY	371	0.0	0.2	1.9	2.1
OTHER RURAL	441	0.0	-0.2	1.6	1.8
BEDS (URBAN)					
0–99 BEDS	988	0.2	0.0	1.9	2.1
100–199 BEDS	841	0.2	0.0	1.9	2.1
200–299 BEDS	465	0.1	0.0	1.8	2.0
300–499 BEDS	395	0.0	0.0	1.8	2.0
500 + BEDS	213	-0.1	0.1	1.7	1.8
BEDS (RURAL)					
0–49 BEDS	337	0.0	-0.2	1.5	1.7
50–100 BEDS	289	0.1	-0.2	1.6	1.9
101–149 BEDS	101	0.0	0.1	1.9	2.1
150–199 BEDS	46	0.0	0.1	1.9	2.1
200 + BEDS	39	-0.1	0.3	2.0	2.1
REGION (URBAN)					
NEW ENGLAND	144	0.2	0.1	2.1	2.2
MIDDLE ATLANTIC	343	0.1	-0.3	1.5	1.7
SOUTH ATLANTIC	461	0.1	0.2	2.0	2.2
EAST NORTH CENT.	464	0.0	0.1	1.8	1.9
EAST SOUTH CENT.	172	-0.2	-0.1	1.5	1.7
WEST NORTH CENT.	185	-0.2	0.5	2.0	2.2
WEST SOUTH CENT.	501	0.1	0.2	2.0	2.2
MOUNTAIN	202	0.2	-0.9	1.0	1.3
PACIFIC	382	0.1	0.0	1.8	2.0
PUERTO RICO	48	-0.3	0.3	1.7	1.9
REGION (RURAL)					
NEW ENGLAND	21	0.0	1.6	3.4	3.5
MIDDLE ATLANTIC	53	0.1	-0.1	1.8	2.0
SOUTH ATLANTIC	123	0.0	-0.7	1.0	1.2
EAST NORTH CENT.	121	0.0	-0.1	1.7	1.9
EAST SOUTH CENT.	155	-0.1	-0.1	1.5	1.7
WEST NORTH CENT.	96	0.0	0.2	2.0	2.3
WEST SOUTH CENT.	162	0.1	0.3	2.1	2.3

	Number of hospitals	APC recalibration (all proposed changes)	Proposed new wage index and provider adjustments	All proposed budget neutral changes (combined cols 2,3) with market basket update	All proposed changes
	(1)	(2)	(3)	(4)	(5)
MOUNTAIN	57	0.0	-0.3	1.5	1.9
PACIFIC	24	0.1	0.1	1.9	2.1
TEACHING STATUS					
NON-TEACHING	2,624	0.1	0.1	2.0	2.1
MINOR	746	0.0	0.0	1.8	2.0
MAJOR	344	-0.1	-0.1	1.6	1.7
DSH PATIENT PERCENT					
0	11	0.0	-0.1	1.7	1.8
GT 0–0.10	277	0.2	0.0	2.0	2.1
0.10–0.16	269	0.2	-0.1	1.8	2.0
0.16–0.23	577	0.1	0.2	2.1	2.2
0.23–0.35	1,121	0.0	0.0	1.8	1.9
GE 0.35	920	0.0	-0.1	1.7	1.8
DSH NOT AVAILABLE	539	-1.5	0.1	0.3	0.5
URBAN TEACHING/DSH					
TEACHING & DSH	982	0.0	-0.1	1.7	1.8
NO TEACHING/DSH	1,394	0.2	0.2	2.1	2.2
NO TEACHING/NO DSH	11	0.0	-0.1	1.7	1.8
DSH NOT AVAILABLE **	515	-1.5	0.1	0.4	0.5
TYPE OF OWNERSHIP					
VOLUNTARY	1,970	0.0	0.0	1.8	1.9
PROPRIETARY	1,253	0.2	0.1	2.1	2.3
GOVERNMENT	491	-0.1	0.1	1.8	1.9
CMHCs	48	-0.1	0.2	1.9	2.1

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

Column (2) includes all proposed CY 2018 OPPS policies and compares those to the CY 2017 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2018 hospital inpatient wage index, including all hold harmless policies and transitional wages. The proposed rural adjustment continues CMS' current policy of 7.1 percent so the budget neutrality factor is 1. The proposed budget neutrality adjustment for the cancer hospital adjustment is 1.0003 because the target payment-to-cost ratio changes from 0.91 in CY 2017 to 0.90 in CY 2018 and is further reduced by one percentage point to 0.89 in accordance with the 21st Century Cures Act; however, this reduction does not affect the budget neutrality adjustment consistent with statute.

Column (4) shows the impact of all budget neutrality adjustments and the addition of the proposed 1.75 percent OPD fee schedule update factor (2.9 percent reduced by 0.4 percentage points for the proposed productivity adjustment and further reduced by 0.75 percentage point as required by law).

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

* These 3,828 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.

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

Addendum P - Proposed Device Intensive Procedures for 2018

HCPCS	Short Descriptor	SI	APC	Device Offset Percentage
19296	Place po breast cath for rad	J1	5093	41.82%
20692	Apply bone fixation device	J1	5115	42.51%
21243	Reconstruction of jaw joint	J1	5116	56.95%
21244	Reconstruction of lower jaw	J1	5165	48.01%
21811	Optx of rib fx w/fixj scope	J1	5113	49.76%
21812	Treatment of rib fracture	J1	5112	50.87%
22551	Neck spine fuse&remov bel c2	J1	5115	46.78%
22554	Neck spine fusion	J1	5115	44.79%
22856	Cerv artific diskectomy	J1	5116	54.85%
23406	Incise tendon(s) & muscle(s)	J1	5113	65.46%
23470	Reconstruct shoulder joint	J1	5115	52.95%
23473	Revis reconst shoulder joint	J1	5115	40.36%
23490	Reinforce clavicle	J1	5114	73.91%
23491	Reinforce shoulder bones	J1	5115	43.07%
23615	Treat humerus fracture	J1	5115	43.08%
23616	Treat humerus fracture	J1	5116	49.94%
24361	Reconstruct elbow joint	J1	5116	57.55%
24363	Replace elbow joint	J1	5116	60.72%
24366	Reconstruct head of radius	J1	5115	57.18%
24370	Revise reconst elbow joint	J1	5115	45.16%
24371	Revise reconst elbow joint	J1	5116	52.30%
24435	Repair humerus with graft	J1	5115	40.93%
24545	Treat humerus fracture	J1	5115	41.87%
24546	Treat humerus fracture	J1	5116	43.51%
24587	Treat elbow fracture	J1	5115	42.49%
24666	Treat radius fracture	J1	5115	55.41%
25350	Revision of radius	J1	5114	42.61%
25391	Lengthen radius or ulna	J1	5115	41.86%
25426	Repair/graft radius & ulna	J1	5113	41.00%
25441	Reconstruct wrist joint	J1	5115	62.75%
25442	Reconstruct wrist joint	J1	5116	63.62%
25443	Reconstruct wrist joint	J1	5114	47.90%
25444	Reconstruct wrist joint	J1	5115	79.81%
25446	Wrist replacement	J1	5116	68.84%
25574	Treat fracture radius & ulna	J1	5114	44.39%
25607	Treat fx rad extra-articul	J1	5114	42.56%
25608	Treat fx rad intra-articul	J1	5114	42.70%
25609	Treat fx radial 3+ frag	J1	5114	43.99%
25800	Fusion of wrist joint	J1	5114	41.04%
26531	Revise knuckle with implant	J1	5114	43.13%
27111	Transfer of iliopsoas muscle	J1	5113	41.00%
27179	Revise head/neck of femur	J1	5114	41.00%
27279	Arthrodesis sacroiliac joint	J1	5116	70.91%

27415	Osteochondral knee allograft	J1	5115	63.03%
27438	Revise kneecap with implant	J1	5115	42.42%
27440	Revision of knee joint	J1	5115	45.26%
27442	Revision of knee joint	J1	5115	47.12%
27446	Revision of knee joint	J1	5115	47.78%
27477	Surgery to stop leg growth	J1	5113	41.00%
27479	Surgery to stop leg growth	J1	5114	41.00%
27722	Repair/graft of tibia	J1	5114	45.20%
27740	Repair of leg epiphyses	J1	5113	41.00%
27758	Treatment of tibia fracture	J1	5115	40.46%
27870	Fusion of ankle joint open	J1	5115	45.13%
27871	Fusion of tibiofibular joint	J1	5115	41.54%
28305	Incise/graft midfoot bones	J1	5114	45.93%
28420	Treat/graft heel fracture	J1	5115	42.91%
28545	Treat foot dislocation	J1	5113	41.00%
28585	Repair foot dislocation	J1	5114	44.52%
28705	Fusion of foot bones	J1	5116	49.63%
28715	Fusion of foot bones	J1	5115	45.94%
28730	Fusion of foot bones	J1	5115	47.95%
28735	Fusion of foot bones	J1	5115	48.06%
28737	Revision of foot bones	J1	5115	48.20%
28740	Fusion of foot bones	J1	5114	42.77%
28750	Fusion of big toe joint	J1	5114	41.75%
29855	Tibial arthroscopy/surgery	J1	5114	48.69%
29856	Tibial arthroscopy/surgery	J1	5115	49.85%
29867	Allgrft implnt knee w/scope	J1	5115	47.13%
29907	Subtalar arthro w/fusion	J1	5115	41.57%
31636	Bronchoscopy bronch stents	J1	5155	42.83%
31660	Bronch thermoplsty 1 lobe	J1	5155	45.26%
31661	Bronch thermoplsty 2/> lobes	J1	5155	41.48%
33206	Insert heart pm atrial	J1	5223	58.94%
33207	Insert heart pm ventricular	J1	5223	61.07%
33208	Insrt heart pm atrial & vent	J1	5223	65.71%
33211	Insert card electrodes dual	J1	5222	42.48%
33212	Insert pulse gen sngl lead	J1	5222	61.90%
33213	Insert pulse gen dual leads	J1	5223	65.95%
33214	Upgrade of pacemaker system	J1	5223	62.92%
33216	Insert 1 electrode pm-defib	J1	5222	40.79%
33217	Insert 2 electrode pm-defib	J1	5222	50.45%
33221	Insert pulse gen mult leads	J1	5224	65.59%
33224	Insert pacing lead & connect	J1	5223	57.20%
33227	Remove&replace pm gen singl	J1	5222	61.87%
33228	Remv&replc pm gen dual lead	J1	5223	64.32%
33229	Remv&replc pm gen mult leads	J1	5224	68.30%

33230	Insrt pulse gen w/dual leads	J1	5231	76.71%
33231	Insrt pulse gen w/mult leads	J1	5232	77.15%
33240	Insrt pulse gen w/singl lead	J1	5231	78.76%
33249	Insj/rplcmt defib w/lead(s)	J1	5232	76.24%
33262	Rmvl& replc pulse gen 1 lead	J1	5231	74.35%
33263	Rmvl & rplcmt dfb gen 2 lead	J1	5231	75.41%
33264	Rmvl & rplcmt dfb gen mlt ld	J1	5232	77.86%
33270	Ins/rep subq defibrillator	J1	5232	76.90%
33271	Insj subq impltbl dfb elctrd	J1	5222	72.03%
33282	Implant pat-active ht record	J1	5222	76.80%
36260	Insertion of infusion pump	T	5184	41.00%
36261	Revision of infusion pump	T	5221	45.57%
36560	Insert tunneled cv cath T	5183	48.18%	
36563	Insert tunneled cv cath T	5184	71.96%	
36583	Replace tunneled cv cath	T	5184	83.56%
36800	Insertion of cannula T	5184	50.19%	
37191	Ins endovas vena cava filtr	T	5184	43.03%
37221	Iliac revasc w/stent J1	5193	40.04%	
37225	Fem/popl revas w/ather J1	5193	56.05%	
37226	Fem/popl revasc w/stent J1	5193	47.56%	
37227	Fem/popl revasc stnt & ather	J1	5194	55.17%
37229	Tib/per revasc w/ather J1	5194	46.94%	
37230	Tib/per revasc w/stent J1	5194	45.87%	
37231	Tib/per revasc stent & ather	J1	5194	49.41%
37238	Open/perq place stent same	J1	5193	46.86%
43212	Esophagoscop stent placement	J1	5331	51.53%
43266	Egd endoscopic stent place	J1	5331	55.52%
43770	Lap place gastr adj device	J1	5362	43.27%
44379	S bowel endoscope w/stent	J1	5331	40.11%
44402	Colonoscopy w/stent plcmt	J1	5331	58.81%
45347	Sigmoidoscopy w/plcmt stent	J1	5331	59.63%
45389	Colonoscopy w/stent plcmt	J1	5331	50.74%
46762	Implant artificial sphincter	J1	5331	75.62%
47538	Perq plmt bile duct stent	J1	5361	46.37%
47540	Perq plmt bile duct stent	J1	5361	42.88%
53440	Male sling procedure J1	5376	61.46%	
53444	Insert tandem cuff J1	5377	60.60%	
53445	Insert uro/ves nck sphincter	J1	5377	69.04%
53447	Remove/replace ur sphincter	J1	5377	63.76%
54400	Insert semi-rigid prosthesis	J1	5377	62.74%
54401	Insert self-contd prosthesis	J1	5377	70.14%
54405	Insert multi-comp penis pros	J1	5377	71.22%
54410	Remove/replace penis prosth	J1	5377	67.69%
54411	Remov/replc penis pros comp	J1	5377	60.98%

54416	Remv/repl penis contain pros	J1	5377	64.27%
54417	Remv/replc penis pros compl	J1	5377	56.46%
54660	Revision of testis	J1	5375	42.76%
55873	Cryoablate prostate	J1	5376	42.55%
61885	Insrt/redo neurostim 1 array	J1	5463	85.69%
61886	Implant neurostim arrays	J1	5464	86.80%
62360	Insert spine infusion device	J1	5471	75.47%
62361	Implant spine infusion pump	J1	5471	76.61%
62362	Implant spine infusion pump	J1	5471	75.64%
63650	Implant neuroelectrodes	J1	5462	51.78%
63655	Implant neuroelectrodes	J1	5463	68.96%
63664	Revise spine eltrd plate	J1	5463	56.26%
63685	Insrt/redo spine n generator	J1	5464	82.78%
63741	Install spinal shunt	J1	5432	40.54%
64446	N blk inj sciatic cont inf	T	5443	41.03%
64553	Implant neuroelectrodes	J1	5462	56.04%
64555	Implant neuroelectrodes	J1	5462	51.86%
64561	Implant neuroelectrodes	J1	5462	53.52%
64568	Inc for vagus n elect impl	J1	5464	87.43%
64569	Revise/repl vagus n eltrd	J1	5462	81.23%
64575	Implant neuroelectrodes	J1	5463	64.16%
64580	Implant neuroelectrodes	J1	5463	75.43%
64581	Implant neuroelectrodes	J1	5462	66.31%
64590	Insrt/redo pn/gastr stimul	J1	5463	84.84%
65770	Revise cornea with implant	J1	5493	54.73%
65785	Impltj ntrstrml crnl rng seg	J1	5492	41.85%
66183	Insert ant drainage device	J1	5492	41.33%
69714	Implant temple bone w/stimul	J1	5115	66.95%
69715	Temple bne implnt w/stimulat	J1	5116	64.16%
69717	Temple bone implant revision	J1	5114	56.69%
69930	Implant cochlear device	J1	5166	82.10%
75840	Vein x-ray adrenal gland	Q2	5183	41.00%
92924	Prq card angio/athrect 1 art	J1	5193	46.80%
92933	Prq card stent/ath/angio	J1	5194	53.25%
92943	Prq card revasc chronic 1vsl	J1	5193	41.67%
93580	Transcath closure of asd	J1	5194	63.32%
93581	Transcath closure of vsd	J1	5194	47.55%
93582	Perq transcath closure pda	J1	5194	49.95%
93610	Intra-atrial pacing	J1	5212	47.15%
93650	Ablate heart dysrhythm focus	J1	5212	40.04%
93656	Tx atrial fib pulm vein isol	J1	5213	44.39%
0100T	Prosth retina receive&gen	T	1904	92.69%
0101T	Extracorp shockwv tx hi enrg	J1	5113	41.00%
0191T	Insert ant segment drain int	J1	5492	51.71%

0221T	Plmt post facet implt lumb	J1	5114	55.98%	
0236T	Trluml perip athrc abd aorta	J1	5193	44.27%	
0238T	Trluml perip athrc iliac art	J1	5194	47.66%	
0268T	Implt/rpl crtd sns dev gen	J1	5463	89.50%	
0308T	Insj ocular telescope prosth	J1	5495	80.38%	
0316T	Replc vagus nerve pls gen	J1	5463	92.17%	
0317T	Elec alys vagus nrv pls gen	Q1	5741	77.59%	
0335T	Extraosseous joint stblztion	J1	5114	52.37%	
0387T	Leadless pm ins/rpl ventr	J1	5194	61.94%	
0408T	Insj/rplc cardiac modulj sys	J1	5231	65.07%	
0424T	Insj/rplc nstim apnea compl	J1	5464	79.92%	
0474T	Insj aqueous drg dev io rsvr	J1	5492	41.00%	
C9600	Perc drug-el cor stent sing	J1	5193	41.19%	
C9602	Perc d-e cor stent ather s	J1	5194	55.75%	
C9604	Perc d-e cor revasc t cabg s	J1	5193	42.08%	
C9607	Perc d-e cor revasc chro sin	J1	5194	55.76%	
C9739	Cystoscopy prostatic imp 1-3	J1	5375	61.30%	
C9740	Cysto impl 4 or more	J1	5376	71.56%	
C9741	Impl pressure sensor w/angio	J1	5200	92.77%	
C9745	Nasal endo balloon dil	J1	5165	41.00%	
C9746	Trans imp balloon cont	J1	5377	41.00%	

TABLE 21—PROPOSED DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS EXPIRES DECEMBER 31, 2017

CY 2017 HCPCS Code	CY 2017 Long descriptor	CY 2017 Status indicator	CY 2017 APC	Pass-through payment effective date
A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	1664	01/01/2015
C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	1663	01/01/2015
J0596	Injection, c-1 esterase inhibitor (human), Ruconest, 10 units	G	9445	04/01/2015
J0695	Injection, ceftolozane 50 mg and tazobactam 25 mg	G	9452	04/01/2015
J0875	Injection, dalbavancin, 5 mg	G	1823	01/01/2015
J1833	Injection, isavuconazonium sulfate, 1 mg	G	9456	10/01/2015
J2407	Injection, oritavancin, 10 mg	G	1660	01/01/2015
J2502	Injection, pasireotide long acting, 1 mg	G	9454	07/01/2015
J2547	Injection, peramivir, 1 mg	G	9451	04/01/2015
J2860	Injection, siltuximab, 10 mg	G	9455	07/01/2015
J3090	Injection, tedizolid phosphate, 1 mg	G	1662	01/01/2015
J7313	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg	G	9450	04/01/2015
J8655	Netupitant (300 mg) and palonosetron (0.5 mg)	G	9448	04/01/2015
J9032	Injection, belinostat, 10 mg	G	1658	01/01/2015
J9039	Injection, blinatumomab, 1 mcg	G	9449	04/01/2015
J9271	Injection, pembrolizumab, 1 mg	G	1490	01/01/2015
J9299	Injection, nivolumab, 1 mg	G	9453	07/01/2015
Q4172	PuraPly, and PuraPly Antimicrobial, any type, per square centimeter.	G	1657	01/01/2015
Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9457	10/01/2015

TABLE 22—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS IN CY 2018

CY 2017 HCPCS code	CY 2018 HCPCS code	CY 2018 long descriptor	Proposed CY 2018 status indicator	Proposed CY 2018 APC	Pass-through payment effective date
A9515	A9515	Choline C 11, diagnostic, per study dose	G	9461	04/01/2016
A9587	A9587	Gallium ga–68, dotatate, diagnostic, 0.1 millicurie	G	9056	01/01/2017
A9588	A9588	Fluciclovine f–18, diagnostic, 1 millicurie	G	9052	01/01/2017
C9140	C9140	Injection, Factor VIII (antihemophilic factor, recombinant) (Afstyla), 1 I.U..	G	9043	01/01/2017
C9460	C9460	Injection, cangrelor, 1 mg	G	9460	01/01/2016
C9482	C9482	Injection, sotalol hydrochloride, 1 mg	G	9482	10/01/2016
C9483	C9483	Injection, atezolizumab, 10 mg	G	9483	10/01/2016
C9484	C9484	Injection, eteplirsen, 10 mg	G	9484	04/01/2017
C9485	C9485	Injection, olaratumab, 10 mg	G	9485	04/01/2017
C9486	C9486	Injection, granisetron extended release, 0.1 mg	G	9486	04/01/2017
Q9989	Q9989	Ustekinumab, for Intravenous Injection, 1 mg	G	9487	04/01/2017
C9488	C9488	Injection, conivaptan hydrochloride, 1 mg	G	9488	04/01/2017
C9489	C9489	Injection, nusinersen, 0.1 mg	G	9489	07/01/2017
C9490	C9490	Injection, bezlotoxumab, 10 mg	G	9490	07/01/2017
J0570	J0570	Buprenorphine implant, 74.2 mg	G	9058	01/01/2017
J1942	J1942	Injection, aripiprazole lauroxil, 1 mg	G	9470	04/01/2016
J2182	J2182	Injection, mepolizumab, 1 mg	G	9473	04/01/2016
J2786	J2786	Injection, reslizumab, 1 mg	G	9481	10/01/2016
J2840	J2840	Injection, sebelipase alfa, 1 mg	G	9478	07/01/2016
J7179	J7179	Injection, von willebrand factor (recombinant), (Vonvendi), 1 i.u. vwf:rco.	G	9059	01/01/2017
J7202	J7202	Injection, Factor IX, albumin fusion protein (recombinant), Idelvion, 1 i.u..	G	9171	10/01/2016
J7207	J7207	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U..	G	1844	04/01/2016
J7209	J7209	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), per i.u..	G	1846	04/01/2016
J7322	J7322	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg.	G	9471	04/01/2016
J7328	J7328	Hyaluronan or derivative, gel-syn, for intra-articular injection, 0.1 mg.	G	1862	04/01/2017
J7342	J7342	Instillation, ciprofloxacin otic suspension, 6 mg	G	9479	07/01/2016
J7503	J7503	Tacrolimus, extended release, (envarsus xr), oral, 0.25 mg.	G	1845	04/01/2016

J9034	J9034	Injection, bendamustine hcl (Bendeka), 1 mg	G	1861	01/01/2017
J9145	J9145	Injection, daratumumab, 10 mg	G	9476	07/01/2016
J9176	J9176	Injection, elotuzumab, 1 mg	G	9477	07/01/2016
J9205	J9205	Injection, irinotecan liposome, 1 mg	G	9474	04/01/2016
J9295	J9295	Injection, necitumumab, 1 mg	G	9475	04/01/2016
J9325	J9325	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU).	G	9472	04/01/2016
J9352	J9352	Injection, trabectedin, 0.1 mg	G	9480	07/01/2016
Q5101	Q5101	Injection, Filgrastim (G–CSF), Biosimilar, 1 microgram	G	1822	01/01/2016
Q5102	Q5102	Injection, Infliximab, Biosimilar, 10 mg	G	1847	04/01/2017
Q9982	Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries.	G	9459	01/01/2016
Q9983	Q9983	Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries.	G	9458	01/01/2016