

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 2018¹ final rule for Medicare’s hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system on November 1, 2017; policies in the final rule are generally effective on January 1, 2018 unless otherwise indicated. The rule will be published in the November 13th issue of the *Federal Register*. **There is a 60-day public comment period that ends at 5:00 PM EST on December 31, 2017.** Comments are accepted on the payment classifications assigned to Healthcare Common Procedure Coding System (HCPCS) codes identified in Addenda B, AA, and BB with the comment indicator “NI” and on other areas specified throughout the final rule.

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

Addenda containing relative weights, payment rates, wage indices and other payment information are available only on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1678-FC.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.

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I. Overview

A. Estimated Impact on Hospitals

CMS estimates that, compared to 2017, its final rule policies will increase total payments under the OPPS by \$690 million, *including* beneficiary cost-sharing and *excluding* estimated changes in enrollment, utilization, and case-mix. Including all factors, CMS estimates that OPPS expenditures for 2018 will be \$69.9 billion; an increase of approximately \$5.8 billion compared to 2017 OPPS payments. The final rule impact table indicates that Medicare makes payments under the OPPS to 3,878 facilities, including general acute care hospitals, children’s hospitals, cancer hospitals, and community mental health centers (CMHCs).

For the final rule, CMS is adopting a conversion factor increase of 1.35 percent, based on the hospital inpatient market basket percentage increase of 2.7 percent for inpatient services paid under the inpatient prospective payment system (IPPS)², less the multifactor productivity adjustment of 0.6 percentage points, less 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 1.35 percent, while hospitals that do not will be subject to a statutory reduction of 2.0 percentage points in the update factor.

The reduction in payments for hospitals not meeting the quality reporting requirements is implemented by substituting a fee schedule increase factor of -0.65 percent (0.9935) for the 1.35 percent fee schedule increase factor that applies to hospitals meeting the quality reporting requirements. All other adjustments are the same between the two sets of hospitals. Of the 3,228 hospitals that met eligibility requirements to report quality data for 2017, CMS determined that 87 hospitals did not meet the requirements to receive the full outpatient department (OPD) fee schedule increase factor. Most of these hospitals (66 of the 87), chose not to participate in the Hospital OQR Program for the 2017 payment determination. CMS estimates that approximately 100 hospitals will not receive the full OPD fee schedule increase factor for the 2018 payment determination and subsequent years.

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

Table 88 in the final rule (reproduced in the Appendix to this summary) includes the estimated impact of the final rule by provider type. It shows a projected increase of 1.4 percent for all facilities and 1.5 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 1.4 percent total:

	% Change All Facilities
All changes	+1.4
Fee schedule increase factor	+1.35
Difference in pass through estimates for 2017 and 2018	+0.2
Difference from 2017 outlier payments (1.04% vs. 1.0%)	-0.11

Pass-through spending for drugs, biologicals and devices for 2018 are estimated to be \$28.06 million, or 0.04 percent of projected OPPS spending. The adjustment to the rates of +0.2 percent reflects the difference between this projection and the 0.24 percent estimate for 2017. The +0.2 percent adjustment is designed to ensure that pass-through spending remains budget neutral from one year to the next. In addition, CMS estimates that actual outlier payments in 2017 will represent 1.11 percent of total OPPS payments compared to the 1.0 percent set aside, for an estimated decrease in 2018 payments of 0.11 percentage points.

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

Although CMS projects an overall increase of 1.4 percent for all facilities, the final 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. The most significant variable explaining the differential impact of the rule by hospital category is CMS’ policy to pay for separately payable drugs furnished by 340B hospitals at ASP - 22.5 percent. This policy was adopted to be budget neutral among all hospitals through an increase in the OPPS conversion factor which will increase payment for all OPPS services paid through APCs (which excludes separately payable drugs). Generally, CMS’ policy will advantage small hospitals, rural hospitals, proprietary hospitals (which are ineligible for the 340B program) and hospitals with a low disproportionate share patient percentages (DPP) and disadvantage large hospitals, urban hospitals, teaching hospitals and hospitals with high DPPs. The large increase in the below table for CMHCs is largely due to APC recalibration (+12.5 percent) and the 340B policy (+3.2 percent).

	Projected 2018 Impact
All Hospitals	+1.5%
All Facilities (includes CMHCs and cancer and children’s hospitals)	+1.4%
Urban	+1.3%

	Projected 2018 Impact
Large Urban	+1.3%
Other Urban	+1.3%
Rural	+2.7%
Major Teaching	-0.9%
Type of ownership:	
Voluntary	+1.3%
Proprietary	+4.5%
Government	+0.0%
CMHCs	+17.2%

By geographic region, those in the impact table with the largest differences from the average are:

Urban East South Central	-0.3%
Puerto Rico	+4.4%
Rural New England	+4.2%

For Urban East South Central and Puerto Rico, the 340B policy explains the difference from the average increase for all hospitals. For rural New England, the difference is explained by the 340B policy (+1.2 percent) and new wage index data and provider adjustments (+1.5 percent).

B. Estimated Impact on Beneficiaries

CMS estimates that the aggregate beneficiary coinsurance percentage will be 18.5 percent for all services paid under the OPPS in 2018—the same percentage that the agency estimated for 2017. The coinsurance percentage reflects the requirement for beneficiaries to pay a 20 percent coinsurance after meeting the annual deductible. Coinsurance is the lesser of 20 percent of Medicare’s payment amount or the Part A inpatient deductible which accounts for the aggregate coinsurance percentage being less than 20 percent.

At the inception of the OPPS in 2000, many APCs had a coinsurance percentage above 20 percent. As explained in section II.I. below, CMS has been gradually transitioning all APCs to 20 percent coinsurance. Addendum A of the final rule shows that transition is at or nearly complete as the coinsurance percentages are at or round to 20 percent for all but a small number of APCs.

II. Updates Affecting OPPTS Payments

A. Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

CMS is recalibrating 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 is making 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.

For the 2018 final rule, CMS uses hospital final action claims for services furnished from January 1, 2016 through December 31, 2016 and processed on or before June 30, 2017. Cost data are from the most recent filed cost reports, in most cases for cost reporting periods beginning in 2015. Unless otherwise specified, in all circumstances, CMS uses these same data in the 2018 rate setting process. In a separate document available on the CMS website, CMS provides a detailed description of the claims preparation process and an accounting of claims used in the development of the final rule payment rates, including the number of claims available at each stage of the process. The claims accounting can be found at: “[2018 NFRM OPPTS Claims Accounting](#).”

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

For 2018, CMS bypasses the 167 HCPCS codes identified in Addendum N to the final rule. CMS indicates the list of bypass codes may include codes that were reported on claims in 2016 but were deleted for 2017. Addendum N is available from the CMS website at “[2018 NFRM OPPTS Addenda](#).”

Table 1 of the final rule lists 37 HCPCS codes that CMS is deleting from the 2018 bypass list. By comparison, CMS only deleted 6 HCPCS codes from the 2017 bypass list. While there are more codes removed from 2018 bypass list, many of these codes are not used for OPPTS payment (such as the CPT codes for Office/Outpatient Visits) or are not commonly paid under the OPPTS (psychotherapy, medication management and other psychiatric services).

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

To convert billed charges on the outpatient claims to estimated costs, CMS multiplies the charges by a hospital-specific CCR associated with each revenue code and cost center. To calculate CCRs for 2018, CMS is employing the same basic approach used for APC rate

construction used since 2007. CMS applies the relevant hospital-specific CCR to the hospital's charges at the most detailed level possible based on a revenue code-to-cost center crosswalk containing a hierarchy, for each revenue code, of CCRs for estimating costs from charges. The current crosswalk is available for review and continuous comment on the CMS website: "[2018 NFRM OPPTS Revenue Code-to-Cost Center Crosswalk](#)."

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

For 2018, CMS proposed to remove claims from providers that use the "square feet" cost allocation statistic to estimate costs for implantable devices, MRIs, CT scans, and cardiac catheterization. CMS is finalizing its proposal. In the 2014 OPPTS/ASC final rule with comment period (78 FR 74840 through 74847), CMS created distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. In response to public comment, CMS removed claims from providers that use a cost allocation method of square feet to calculate CCRs 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 final 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 final 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	-3.8%
5522	Level 2 Imaging without Contrast	5.3%
5523	Level 3 Imaging without Contrast	6.3%
5524	Level 4 Imaging without Contrast	5.0%
5571	Level 1 Imaging with Contrast	9.0%
5572	Level 2 Imaging with Contrast	7.0%
5573	Level 3 Imaging with Contrast	2.1%
8005	CT and CTA without Contrast Composite	14.4%
8006	CT and CTA with Contrast Composite	11.9%
8007	MRI and MRA without Contrast Composite	7.2%
8008	MRI and MRA with Contrast Composite	7.5%

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	0.0387	0.0538	0.0795	0.1059
Square Feet Only	0.0317	0.0488	0.0717	0.0968
Direct Assign	0.0557	0.0650	0.1032	0.1222
Dollar Value	0.0457	0.0603	0.0890	0.1178
Direct Assign and Dollar Value	0.0457	0.0603	0.0893	0.1175

The final rule indicates that the number of valid MRI CCRs has increased by 17.5 percent to 2,177 providers and the number of valid CT CCRs has increased by 15.1 percent to 2,251 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 OPPTS 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 final 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 OPPTS relative weights for one additional year until 2019.

Public comments supported CMS decision to extend the exclusion of provider CCRs that use the cost allocation methodology for 2018. Other public comments recommended that CMS discontinue use of the CT and MRI cost centers for developing CT and MRI CCRs. CMS rejected that suggestion indicating that it is not convinced that the change in CT and MRI CCRs is the result of costs not being reported accurately as these new cost centers have been in effect since May 1, 2010. Beginning in 2019, CMS plans to use claims from providers that use the square feet cost allocation statistic in determining the APC relative weights for CT and MRI.

2. Data Development Process and Calculation of Costs Used for Rate Setting

From the inception of the OPPTS through 2012, CMS calculated the APC relative weights based on median costs. Beginning with 2013, CMS has been determining the relative weights based on geometric mean costs. In short, CMS takes single procedure claims and adjusts charges to costs for each procedure within an APC and then calculates the APC's geometric mean cost. The relative weight is the geometric mean cost of the APC divided by the geometric mean cost across all APCs. As explained below in more detail, CMS standardizes the relative weights to the APC for G0463 which is an outpatient hospital visit—the most commonly furnished service billed under the OPPTS. CMS is continuing to follow this basic process for the 2018 OPPTS.

a. Calculation of single procedure APC criteria-based costs

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

Blood and blood products

For 2018, CMS is continuing, without change, to set payment rates for blood and blood products using the blood-specific CCR methodology that it has used since 2005. CMS calculated the procedure costs for setting the 2018 payment rates for blood and blood products using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and using a hospital-specific simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

CMS is also 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. Addendum B to the final rule is available on the CMS website and includes the 2018 payment rates for blood and blood products.

CMS notes that the HCPCS codes and their associated APC for blood and blood products is identified with a status indicator of “R” in Addendum B of the final rule.

CMS received a number of comments expressing concern about payment changes for specific APCs for blood and blood products. In response, CMS indicated that the payment changes are the result of normal cost variation in the claims data.

Other comments asked CMS to include the costs of newly implement Food and Drug Administration (FDA) blood safety measures prior to the new claims data containing those costs. CMS rejected this suggestion indicating that it is not possible to estimate the costs associated with complying with new FDA blood safety regulations outside of claims data.

CMS indicates that public commenters resubmitted prior comments suggesting that the HCPCS codes for blood and blood products be revised and updated and CMS establish a “not otherwise classified” code to bill for blood and blood products not described by a specific HCPCS P-code. CMS responded that the safety of the blood supply continues to be among the nation’s highest priorities and it will work with stakeholders to ensure that future updates to HCPCS P codes support that public safety goal.

Pathogen-Reduced Platelets and Rapid Bacterial Testing for Platelets

In March 2016, the FDA 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 OPPTS/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 OPPTS/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.

In the proposed rule, CMS indicated that it 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 was concerned in the proposed rule 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 was \$491.53 for the proposed rule, which would be 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 proposed to crosswalk HCPCS code Q9988 to HCPCS code P9037 which has a 2017 geometric mean cost of \$647.12.

Public comments supported CMS' proposal. One commenter asked that CMS add the word "secondary" to HCPCS code Q9987 to indicate that the code is only to be used for secondary bacterial testing of platelets. CMS rejected that comment indicating that it believes its guidance is sufficient for providers to understand how to appropriately report code Q9987.

CMS is finalizing its proposal but replacing HCPCS code Q9987 with HCPCS code P9100 and replacing HCPCS code Q9988 with HCPCS code P9073. The titles are unchanged. The final payment rates for 2018 are: P9100 = \$25.50; and P9073 = \$624.71.

Brachytherapy sources

The statute requires the Secretary to create additional groups of covered OPD services that classify devices of brachytherapy consisting of a seed or seeds (or radioactive source) – i.e.,

“brachytherapy sources” – separately from other services or groups of services, in order to reflect the number, isotope, and radioactive intensity of the brachytherapy sources furnished. In addition, separate groups are required for palladium-103 and iodine-125 sources, and for stranded and non-stranded devices. Since 2010, CMS has used the standard OPPTS payment methodology for brachytherapy sources, with payment rates based on source-specific costs as required by statute.

CMS is continuing without change the policies used to set payment rates for brachytherapy sources for 2018; costs derived from the 2016 claims data were used to set 2018 payment rates. The 2018 payment rates appear in Addendum B to the final rule and are identified with status indicator “U” (Paid under OPPTS; separate APC payment).

CMS proposed 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 not 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 proposed to assign the code status indicator “U” and base its OPPTS price on that one claim.

CMS received comments requesting that it set the APC payment rate for HCPCS code C2636 (Brachytherapy linear, non-stranded, palladium-103, per 1mm) at \$26.99 and continue to use external data to price HCPCS code C2645 at \$4.69 per mm². CMS rejected the comment for HCPCS code C2636 indicating that the code has been active since 2007 and that its pricing for 2018 is based on data from the eight claims that it received in 2016. CMS agreed with the comment on HCPCS code C2645 and finalizes a 2018 price at \$4.69 per mm².

CMS also invites hospitals and other parties to submit recommendations to CMS for new HCPCS codes that describe new brachytherapy sources. Recommendations should be directed to the Division of Outpatient Care, Mail Stop C4-01-26, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. CMS will continue to add new brachytherapy source codes and descriptors to its payment systems on a quarterly basis through program transmittals.

b. Comprehensive APCs (C-APCs) for 2018

Background. CMS established and implemented a new policy for comprehensive APCs (C-APCs) in 2015 based on policies finalized in the 2014 final OPPTS rule, with a delayed effective date of January 1, 2015. Prior to implementing, CMS made additional changes to the C-APC policy in the 2015 final rule. A C-APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. CMS established C-APCs as a category broadly for OPPTS payment and implemented 25 C-APCs beginning in 2015; 10 additional C-APCs were finalized for 2016. There are currently 62 C-APCs.

Current Policy for C-APCs

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

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

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

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

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

- Ambulance services
- Brachytherapy
- Diagnostic and mammography screenings
- Physical therapy, speech-language pathology and occupational therapy services reported on a separate facility claim for recurring services
- Pass-through drugs, biologicals, and devices
- Preventive services defined in 42 CFR §410.2

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

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

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

CMS packages all add-on codes and assigns them status indicator “N” (unconditionally packaged). A set of these codes are evaluated for purposes of determining whether a complexity adjustment is warranted. These are identified in Addendum J to the 2018 final rule.

Complexity adjustments

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

CMS is continuing to follow the criteria for determining which combinations of primary service codes reported in conjunction with an add-on code may qualify for a complexity adjustment:

- Frequency of 25 or more claims reporting the code combination (i.e., the frequency threshold); and
- Violation of the 2 times rule, that is, the comprehensive geometric mean cost of the complex code combination exceeds the comprehensive geometric mean cost of the lowest significant HCPCS code assigned to the comprehensive APC by more than 2 times (the cost threshold).³

For code combinations satisfying the complexity criteria, CMS does not apply the 2 times rule to the receiving APC when a code combination results in assignment to a higher cost C-APC. Currently, code combinations satisfying the complexity criteria are moved to the next higher cost C-APC within the clinical family, unless the primary service is already assigned to the highest cost APC within the C-APC clinical family. CMS does not create new APCs with a geometric mean cost that is higher than the highest cost C-APC in a clinical family just to accommodate potential complexity adjustments.

Changes for 2018. Addendum J to the 2018 final rule shows that 37,141 code combinations were evaluated for a complexity adjustment and that 456 code combinations qualified. The full Addendum J also includes cost statistics for all the code combinations which were evaluated for a complexity adjustment and the ranking of HCPCS codes within each C-APC based on the geometric mean cost of single J1 unit claims; this is the ranking used to determine the primary assignment of comprehensive HCPCS codes.

CMS received comments requesting exceptions to the current complexity adjustment criteria for specific services and changes to the complexity adjustment criteria themselves (such as using fewer than 25 claims to evaluate whether a code combination qualifies for the complexity adjustment, not applying the 2 times rule and allowing a code combination that qualifies for a complexity adjustment one year to continue qualifying the following year as long as it is within 5 percent of meeting the cost threshold). CMS declined to make any adjustments to the complexity adjustment criteria or make exceptions to them for specific codes.

Some commenters indicated that several vertebroplasty codes and one ablation therapy code (CPT codes 22510 and 22512; CPT codes 22511 and 22512; CPT codes 22511 and 20982) were not evaluated for a complexity adjustment. CMS responded that it inadvertently excluded these codes combinations for evaluation of a complexity adjustment and added them to Addendum J. These code combinations continue to qualify a complexity adjustment in 2018.

In response to another comment indicating that CMS did not evaluate a number of imaging add-on codes for a complexity adjustment, CMS indicated that it evaluated two of those codes (92978 and 93571) for a complexity adjustment. The other two codes (92979 and 93572) are not add-ons to the primary procedure and do not meet the criteria for being evaluated for a complexity adjustment.

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

Additional C-APCs for 2018

CMS did not propose any additional C-APCs to be paid under the existing C-APC payment policy beginning in 2018. CMS received a few comments on the C-APCs: one that asked it to pay separately for an expensive ocular drug (J7311) used in conjunction with an eye surgery; another asking CMS to remove Level 1 Intraocular Procedures (APC 5491) from the C-APC methodology; and one expressing concern about how payment for tests are affected by critical care services being included in the C-APC methodology when patients are treated in the intensive care unit (ICU). CMS rejected the first two comments noting the procedures and drugs referenced meet the criteria to be included in a C-APC and the higher costs of the drug would be reflected in the costs used to determine the C-APC. With respect to critical care, CMS notes that the case would likely be paid under the IPPS if the patient is moved to the ICU.

Addendum J of the final 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 complexity adjustments and other information.

Brachytherapy Insertion Procedures

Some of the HCPCS codes assigned to the C-APCs established for 2017 describes 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. Following established practice, CMS did not exclude claims from the 2017 rate setting calculation but said it would examine this issue further to determine whether to make any future adjustment to the methodology (or possibly code edits).

In the proposed rule, CMS indicated that it analyzed the claims that include brachytherapy insertion codes that received payment through a C-APC and determined that several of these codes are frequently billed without an associated brachytherapy treatment code. To address this issue, CMS proposed to establish a code edit that requires a brachytherapy treatment code when a brachytherapy insertion code is billed. In addition, CMS proposed 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).

Several commenters opposed CMS' proposed code edit indicating that the insertion procedure and the brachytherapy treatment may be reported on different days and would be on separate claims or that the brachytherapy insertion procedure and radiation treatment delivery could be performed by different facilities. These scenarios make the proposed coding edit inapplicable. CMS decided not to finalize its proposal in response to these comments.

Otherwise, CMS is finalizing its C-APC policies as proposed. Other commenters requested that CMS discontinue the C-APC payment policy for all brachytherapy insertion codes for similar

reasons as the comments that opposed the proposed code edit described above—that placement of needles and catheters may occur on different days or at different sites of service than the brachytherapy treatment delivery—and that these practices are inconsistent with the C-APC policy that packages items and services at the claims level.

Commenters also requested that CMS maintain the composite for APC 8001. CMS rejected the suggestions in these comments stating that it believes brachytherapy insertion procedures remains appropriate for the C-APC policy as it is the primary procedure for which the patient is treated in the outpatient department but that it would continue to monitor hospital billing practices for brachytherapy and brachytherapy insertion procedures.

Other comments requested that CMS exclude radiation oncology codes from the C-APC policy and make separate payment for these services like it does with stereotactic radiosurgery (SRS). CMS rejected this suggestion indicating that the policy suggested in the comment is inconsistent with the C-APC policy and that there are special circumstances regarding the payment policy for SRS that are intended to be temporary.

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

SRS is a type of radiation therapy that targets multiple beams of radiation to precisely deliver radiation to a brain tumor while sparing the surrounding normal tissue. SRS treatment can be delivered by Cobalt-60-based (also referred to as gamma knife) technology or robotic linear accelerator-based (LINAC)-based technology. Section 634 of the American Taxpayer Relief Act of 2012 (Pub. L. 112–240) requires that OPPTS 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.

Beginning in 2016, CMS complied with the statutory requirement by assigning SRS using either of the two 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 “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 2018, CMS is continuing to make 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.

Complexity Adjustment for Blue Light Cystoscopy Procedures

Drugs that function as supplies in a diagnostic test are always packaged into the APC payment for the principal procedure and not separately paid. Cysview® (hexaminolevulinate HCl) (described by HCPCS code C9275) is one such drug that is used in conjunction with blue light cystoscopy. White light (or standard) cystoscopy, typically performed by urologists, has been the gold standard for diagnosing bladder cancer. 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. Because blue light cystoscopy requires specialized imaging equipment to view cellular uptake of the dye that is not otherwise used in white light cystoscopy procedures, some practitioners consider blue light cystoscopy to be a distinct and adjunctive procedure to 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. The current CPT coding structure for cystoscopy procedures does not identify blue light cystoscopy in the coding descriptions separate from white light cystoscopy. For 2018, CMS proposed to create a new HCPCS C-code to describe blue light cystoscopy. For the proposed rule, CMS used a placeholder code (HCPCS code C97XX (Adjunctive blue light cystoscopy with fluorescent imaging agent (List separately in addition to code for primary procedure))). For the final rule, CMS replaced the placeholder code with HCPCS C9738 that has the same descriptor. In referring to its proposed rule policy, CMS uses the assigned HCPCS code C9738 rather than the placeholder code C97XX. CMS assigned a status indicator of “N” to this new code signifying that the service is always packaged.

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 new HCPCS code C9738. CMS then evaluated the costs of HCPCS code C9738 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 C9738 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 proposed to assign the combination of HCPCS code C9738 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. CMS indicated plans to track the utilization and costs associated with white light/blue light cystoscopy procedure combinations that will receive a complexity adjustment. CMS invited public comments on its proposal and also whether alternative procedures, such as narrow band imaging, may be disadvantaged by its proposed policy.

One commenter suggested that CMS submit a proposal to the American Medical Association for a new CPT code rather than establish its own HCPCS code. Other commenters suggested broader application of the complexity adjustment to all blue light cystoscopy with Cysview procedures; to pay separately for Cysview® or establish a “device-intensive like” payment for a cystoscopy procedure performed in the ASC.

CMS rejected these comments noting that it had a program need to establish the HCPCS code in the absence of a CPT code for this situation. CMS would retire HCPCS code C9738 if CPT were to establish a code that made HCPCS code C9738 unnecessary. CMS did not propose and public commenters did not provide any evidence to support waiving application of the complexity adjustment criteria that would allow broader application of CMS’ policy to APCs that are not C-APCs. As Cysview® is a drug that functions as a supply and CMS did not propose to change its packaging policy, CMS rejected comments suggesting separate payment for Cysview®. Similarly, CMS rejects comments for an “ASC device-intensive” policy for Cysview® as no such policy was proposed.

CMS received comments both in support of and opposed to complexity adjustments for narrow band imaging—an alternative to blue light cystoscopy with Cysview®. A comment from the manufacturer of narrow band imaging supported a complexity adjustment while the

manufacturer of Cysview® opposed it. CMS is not making a complexity adjustment for narrow band imaging because of the lack of cost information to support such adjustment and, unlike blue light cystoscopy with Cysview®, the procedure does not require the use of a contrast agent that has higher costs.

Analysis of C-APC Packaging under the OPPTS

CMS analyzed the effects of the C-APC policy in response to an August 22, 2016 Hospital Outpatient Panel (HOP) recommendation. As the HOP recommendation did not elucidate specific concerns with the C-APC policy or provide detailed recommendations on particular aspects of the policy to analyze, CMS broadly studied the policy to determine whether APC cost statistics and billing patterns were aberrant or showed a trend that would be expected.

CMS explained how it used 2014 to 2016 data to do its analysis. It found an increase in claim line frequency, units billed and Medicare payment for items and services subject to the C-APC policy suggesting that the policy did not adversely affect access or reduce payments to hospitals. CMS further found that cost statistics of major separately payable codes that were packaged into a C-APC prospectively were consistent with the cost statistics of the codes packaged on the claim, indicating that costs were appropriately redistributed. CMS concludes that the C-APC payment methodology is working as intended.

A few commenters appreciated CMS' analysis of C-APC packaging under the OPPTS and urged CMS to continue to monitor the data and report on any changes in billing patterns or utilization for particular items or services which CMS agreed to do.

c. 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 and multiple imaging services. CMS proposed to delete the low dose rate (LDR) prostate composite APC and assign CPT code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) to a C-APC.

Mental Health Services Composite APC (APC 8010)

For 2018, CMS proposed to continue its mental health services composite policy unchanged. CMS' policy limits the combined payment for individual mental health services furnished on the same date to the payment for a day of partial hospitalization, which the agency considers to be the most resource intensive of all outpatient mental health treatments. Under this policy, the code editor would continue to determine whether to pay for these specified mental health services individually, or to make a single payment at the same payment rate established for APC 5863 (Partial Hospitalization, 3 or more services per day). CMS received no public comments on its proposal and is finalizing the proposed policy without change.

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

For 2018, CMS proposed to continue the multiple imaging composite APC policies that it has applied since 2009. Under the multiple imaging policy, payment is based using five composite APCs:

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

One composite APC payment is made when a hospital bills more than one procedure described by HCPCS codes within an OPPTS imaging family (per imaging family designations provided in each year's regulation) on a single date of service. If the hospital performs a procedure without contrast during the same session as at least one other procedure with contrast using the same imaging modality, then the hospital would receive payment for the "with contrast" composite APC. When the conditions for a composite APC payment do not apply, CMS makes payment according to the standard OPPTS methodology through the standard (sole service) imaging APCs; this rule applies when a single imaging procedure is performed, or when the imaging procedures performed have HCPCS codes assigned to different OPPTS imaging families. CMS calculated the 2018 payment rates for the five multiple imaging composite APCs using the same methodology it has used since 2014.

For 2018, CMS identified approximately 634,918 "single session" claims out of an estimated 1.7 million potential claims for payment through composite APCs from its rate setting claims data, which represent approximately 36 percent of all eligible claims, to calculate the 2018 geometric mean costs for the multiple imaging composite APCs.

CMS received one comment in support of its APC imaging composite policy that requested that imaging APCs be paid separately when furnished in conjunction with a C-APC. CMS rejected this comment as inconsistent with the C-APC policy which packages all adjunctive procedures performed in the same session as the primary procedure that triggers a C-APC. CMS is finalizing its policy as proposed. Table 7 of the final rule lists the HCPCS codes that CMS is subjecting to the multiple imaging composite policy for 2018 and their respective families and approximate composite APC geometric mean.

3. Changes to Packaged Items and Services

For 2018, CMS proposed to conditionally package Level 1 and Level 2 Drug Administration Services and requested comment on whether to unconditionally package drug administration add-on codes. CMS also indicated in the proposed rule why it is not creating an APC composite for pathology services as recommended by the HOP and also requested comments generally on its packaging policies. More discussion on each of these issues follows.

Drug Administration

Conditionally packaged services are those services that are paid separately when furnished alone but packaged when furnished with another service that is paid independently. CMS adopted a policy to conditionally package payment for ancillary services assigned to APCs with a geometric mean cost of less than or equal to \$100 (prior to application of the conditional packaging status indicator). In the 2015 OPPTS/ASC final rule with comment period (79 FR 66819), CMS indicated that it was not packaging certain low-cost drug administration services because it was examining various alternative payment policies for drug administration, including the associated drug administration add-on codes.

The proposed rule indicated that separate payment for drug administration services is an example of inconsistent application of the packaging policy where CMS continues to pay separately for a service, regardless of cost and performance with another service. As part of review of the 2016 claims data used for rate setting, CMS examined drug administration billing patterns and payment for drug administration services under the OPPTS and found that the geometric mean cost for APC 5691 (Level 1 Drug Administration) is approximately \$37 and the geometric mean cost for APC 5692 (Level 2 Drug Administration) is approximately \$59. It also found that drug administration services in APC 5692 are frequently reported on the same claim with other separately payable services, such as an emergency department or clinic visit, while drug administration services in APC 5691 are sometimes reported with other separately payable services. These findings are consistent with the ancillary packaging policy that CMS adopted in 2015.

CMS further indicates that hospitals may receive separate payments for a clinic (office) visit and a drug administration service. In contrast, physicians are not eligible to receive payment for an office visit when a drug administration service is also provided. As a result, hospitals receive a higher payment than a physician for furnishing the same drug administration service. (Not stated but also true is that payment to the hospital and physician for drug administration are different irrespective of the policy on visits as payment for these services is determined under different methodologies.) The proposed rule indicated that conditional packaging of drug administration services would promote equitable payment between the physician office and the hospital outpatient hospital department. For these reasons, CMS proposed 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, therefore, proposed to continue to pay separately for Medicare Part B vaccine administration services. CMS did not propose to package any drug administration services in APC 5693 (Level 3 Drug Administration) or APC 5694 (Level Drug Administration), but requested public comment on whether services in these APCs may be appropriate for packaging.

Numerous commenters disagreed with CMS citing the following concerns:

- Low-cost drug administration services are dissimilar to other low-cost ancillary services in that drug administration services are separate and distinct stand-alone services and not adjunctive, supportive, or dependent to a primary procedure.
- The proposal would not promote equitable payment between the physician's office and the hospital outpatient department because, in accordance with CMS guidelines, there are clinical circumstances where a physician may receive payment for both a drug administration service and an office visit.
- Because all drugs are separately payable in the physician's office, unlike under the OPPTS, the proposal, if implemented, would exacerbate differences in payment between the hospital outpatient department and the physician office setting. Commenters expressed doubt that the full cost of a packaged drug administration service or drug would be appropriately and accurately reflected in the payment for another separately payable procedure.
- Packaging drug administration services with other services could result in hospitals scheduling patients for multiple visits, thereby reducing access to care and quality of care.
- Further analysis of the impact of packaging drug administration services should be conducted prior to making a policy change.
- In general, packaging discourages full reporting of hospital costs, which impacts the accuracy of cost data that are used to calculate OPPTS payment rates.
- The HOP recommended that CMS not implement its proposal to package drug administration services described under APC 5691 (Level 1 Drug Administration) and APC 5692 (Level 2 Drug Administration).

CMS disagreed that conditional packaging of low-level drug administration would lead to payment inaccuracy for hospital rates or to decreased access to drug administration services. CMS' analysis of 2016 OPPTS claims data showed that low-cost drug administration services are currently being provided as part of another separately payable service for which two separate payments are made. These data support a policy that packaging low-cost drug administration services, when they are reported with another separately payable service, is appropriate.

In response to the commenters that low-cost drug administration services are separate and distinct standalone services and not adjunctive, supportive, or dependent to a primary procedure, CMS disagrees noting that low-cost drug administration services are typically furnished with another primary service and are assigned to APCs with a geometric mean cost of less than or equal to \$100 (prior to the application of the conditional packaging status indicator).

CMS continues to believe that conditional packaging of drug administration services will promote equitable payment between the physician office and the hospital outpatient department although acknowledges that that Medicare will pay for both a drug administration and evaluation and management service when the office visit CPT code is reported with Modifier 25 (Significant, separately identifiable evaluation and management services by the same physician on the day of the procedure).

With respect to requests for further CMS analysis, CMS indicates that the data made available to the public as part of the proposed rule were appropriate, clear, and sufficient for interested parties to conduct analyses to evaluate facility-specific impacts of the proposed policy. CMS further notes that hospitals are expected to report all HCPCS codes that describe the services provided, regardless of whether those services are separately paid or their payment is packaged so that OPPTS relative payment weights reflect the relative resources required to furnish HOPD services. CMS further indicates that it is not accepting the HOP's recommendation.

One commenter recommended a 1-year implementation delay to allow providers time to assess the administrative and fiscal impact of the proposed policy. CMS responded that it does not see a reason to delay implementation of the policy indicating that stakeholders interested in a more comprehensive analysis of OPPTS claims data used to derive the CY 2018 OPPTS/ASC payment rates may purchase the "OPPTS Limited Data Set" (LDS) that is available on the CMS website at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/HospitalOPPSPHPLDS.html>

Some commenters believed that the proposal would conditionally package Medicare Part B vaccine administration. In addition, some commenters believed that if a hospital provides a low-cost drug administration service for a drug that is unconditionally packaged, CMS would make no payment to the hospital.

CMS responded that preventive vaccine administration is not subject to the conditional packaging policy and will continue to be separately paid. With respect to payment for a conditionally packaged low-cost drug administration service and an unconditionally packaged drug, the drug administration service is separately payable if not furnished with another separately payable service into which it is packaged, such as a clinic visit. Payment for the threshold-packaged drug would be packaged with the payment for the highest paying separately payable procedure reported on the claim. For example, if a threshold-packaged drug, a low-cost drug administration service, and a clinic visit are reported on the same claim, payment for the drug and drug administration service would be packaged with the clinic visit payment.

CMS is finalizing its policy as proposed. The status indicators for drug administration services in APC 5691 and APC 5692 are listed in Table 8 of the final rule, reproduced below.

Table 8—2018 Status Indicators for Drug Administration Services in Level 1 and Level 2 Drug Administration APCs

HCPCS Code	Short Descriptor	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
95146	Antigen therapy services	Q1
95165	Antigen therapy services	Q1

HCPCS Code	Short Descriptor	2018 Status Indicator
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 infus each addl seq	S

Comment Solicitation Regarding Unconditionally Packaging Drug Administration Add-on Codes

CMS did not finalize its proposal in the 2014 OPPTS rule to unconditionally package all drug administration services described by add-on codes because of concerns from public commenters that such a policy could disadvantage providers of longer duration drug administration services. In the 2014 final rule, CMS indicated that further study of the payment methodology for these services was warranted. CMS did not propose a policy change for 2018 but requested comment on:

- Whether to conditionally or unconditionally package drug administration services add-on codes;
- How to consider or incorporate the varied clinical drug protocols that result in different infusion times into a drug administration service add-on code payment proposal; and
- Other recommendations on an encounter-based payment approach for drug administration services that are described by add-on codes when furnished in the hospital outpatient setting.

Many commenters raised concerns about the appropriateness of packaging drug administration services add-on codes. Without explicit incremental payment for additional hours of infusion, some commenters suggested hospitals could discontinue offering the infusion. CMS indicated that it would take these comments into consideration for future rulemaking.

Analysis of Packaging of Pathology Services in the OPPTS

In response to a 2016 recommendation from the HOP Panel, CMS presents its analysis of a pathology composite APC when multiple pathology services are performed and billed without a separately payable service on the same claim. The HOP Panel's recommendation was motivated by a presenter's concern about the adequacy of payment when multiple conditionally packaged pathology services are billed on the same claim and payment is determined based on the cost of the highest paying service with payment bundled for all other services on the claim. The stakeholder requested that CMS create a pathology composite to more appropriately pay for claims with only multiple pathology services and no other separately payable service such as a surgical procedure or a clinic visit.

CMS' analysis in the proposed rule indicates low claims volume for the clinical scenario for which a pathology composite would be created. CMS further indicates that composites are less necessary as it moves towards larger payment bundles under the OPPTS and C-APCs. For these reasons, CMS did not propose to create a composite APC for pathology services. CMS did not receive any comments on its proposed rule analysis and is taking no further action.

Comment Solicitation on Packaging of Items and Services under the OPPTS

The proposed rule indicated that packaging and bundling payment for multiple interrelated services into a single payment creates incentives for providers to furnish services in the most efficient way by enabling hospitals to manage their resources with maximum flexibility, thereby encouraging long-term cost containment. However, CMS continues to hear concerns from stakeholders that packaging policies may be hampering patient access or resulting in other undesirable consequences even though CMS is finding that aggregate spending and utilization continue to increase for covered outpatient services making it unclear what, if any, adverse effect packaging has on beneficiary access to care. CMS requested comment on the following:

- Within the framework of existing packaging categories, such as drugs that function as supplies in a surgical procedure or diagnostic test or procedure, stakeholder feedback on common clinical scenarios involving currently packaged HCPCS codes for which stakeholders believe packaged payment is not appropriate under the OPPTS.
- Outside the framework of existing packaging categories, CMS is interested in stakeholder feedback on common clinical scenarios involving separately payable HCPCS codes for which payment would be most appropriately packaged under the OPPTS.

The final rule indicates that commenters expressed a variety of views on packaging under the OPPTS ranging from requests to unpackage most items and services that are either conditionally

or unconditionally packaged under the OPSS, including drugs and devices, to specific requests to unpackage a specific drug or device. CMS will consider these comments as it evaluates packaging policies that apply under the OPSS for future rulemaking.

4. Calculation of OPSS Scaled Payment Weights

CMS is continuing 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 is standardizing 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 OPSS 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 is following its past practice with respect to applying budget neutrality for changes in the OPSS 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. CMS did not receive any public comments on this process. Using this process, CMS calculates a final rule weight scaler of 1.4457. The unscaled 2018 relative payments are multiplied by 1.4457 to determine the 2018 scaled relative weights that are shown in Addendum A and B.

B. Conversion Factor Update

For the final rule, CMS calculates an OPSS conversion factor of \$78.636. CMS began with the 2017 conversion factor of \$75.001 and adjusted it by the fee schedule increase factor and various budget neutrality factors. As discussed earlier, the fee schedule increase factor equals the hospital inpatient market basket percentage increase, which is 2.7 percent, reduced by a multifactor productivity adjustment of 0.6 percentage points as required by the ACA, and further reduced by an additional 0.75 percentage points also required by the ACA. This provides for a fee schedule increase factor of 1.35 percent. Hospitals that fail to meet the OQR requirements are subject to a reduction of 2.0 percentage points in the fee schedule increase factor, as discussed in section XIII below.

In addition to the fee schedule increase factor, the final rule indicates that the following adjustments are applied in calculating the 2018 conversion factor:

- A wage index budget neutrality factor of 0.9997.
- A cancer hospital budget neutrality adjustment of 1.0008.
- Adjustment for drug purchased under the 340B program of 1.0319.
- An adjustment for pass-through spending of 0.2 percent. CMS estimates that 2018 pass-through spending for drugs, biologicals and devices will be \$26.2 million, or 0.04 percent of projected OPSS spending. In the 2017 OPSS/ASC Final Rule (81 FR 79678), CMS indicates

that the comparable figure for 2017 is 0.24 percent. The decrease in projected pass-through spending for 2018 therefore results in a positive adjustment of 0.20 percent.

The final rule indicates that the combined effect of these factors yields a 2018 conversion factor of \$78.636 for hospitals satisfying the requirements of the quality reporting program.

For ease of reference, we provide the calculation in the below table:

2017 CF	Pass-Through	Wage Index	Cancer	340B	Update	2018 CF ⁴
\$75.001	1.002	0.9997	1.0008	1.0319	1.0135	\$78.636

In section XIII. D, CMS indicates that the conversion factor for hospitals that do not submit quality data is \$77.064.⁵

C. Wage Index Changes

CMS continues its policy of adopting the final fiscal year IPPS post-reclassified wage index as the OPPTS calendar year wage index for adjusting the OPPTS standard payment amounts for labor market differences. The 2018 OPPTS final rule wage index is based on the FY 2018 IPPS final post-reclassified wage index; this includes adoption of revisions to several labor market areas made by the Office of Management and Budget (OMB) in OMB Bulletin No. 15-01 issued on July 15, 2015. The wage index tables are available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2018-Wage-Index-Home-Page.html>. For non-IPPS hospitals paid under the OPPTS, CMS continues 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.

CMS continues to use an OPPTS 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.

In the FY 2018 IPPS/LTCH PPS and the 2018 OPPTS/ASC proposed rules, CMS proposed to discontinue the imputed floor policy. However, in the FY 2018 IPPS/LTCH PPS final rule, CMS did not finalize its proposal and instead extended the imputed floor policy for FY 2018 under the IPPS. Similarly, CMS extends the imputed floor policy under the OPPTS for an additional year through the end of 2018. CMS will continue to assess the effects of the imputed floor policy and consider whether or not to continue it for the long term.

CMS finalizes its proposal to implement the ACA frontier state wage index adjustment in the same manner as it has since 2011. The adjustment requires a wage index floor of 1.0 in certain cases if the otherwise applicable wage index (including reclassification, rural floor, imputed

⁴ HPA gets a slightly different result than CMS: $\$75.001 \times 1.0002 \times 0.9999 \times 1.0008 \times 1.0319 \times 1.0135 = \78.635 .

⁵ It is not clear how CMS determined this conversion factor of \$77.064. Substituting the reduced update of -0.65% (0.9935) into the above formula would produce a CF of \$77.083.

floor, and rural floor budget neutrality adjustment) is less than 1. In the case of an OPD affiliated with a multi-campus hospital system, the OPD continues 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 applies to the OPD.

Core-based statistical areas (CBSAs) and constituent counties within CBSAs each have unique identifying codes. CMS notes that of the two lists of such codes (i.e., the Social Security Administration (SSA) codes and the Federal Information Processing Standard (FIPS) codes), the SSA codes are no longer maintained and updated. As CMS did in the FY 2018 IPPS/LTCH PPS final rule, CMS finalizes its proposal in the 2018 OPPTS ASC proposed rule to transition to using only FIPS codes for 2018 and subsequent years. CMS also finalizes its proposal to update the FIPS codes by incorporating 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.
- 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 will implement the revisions effective January 1, 2018, beginning with the 2018 OPPTS wages indexes.

CMS continues its policy of allowing non-IPPS hospitals paid under the OPPTS 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 Medicare Modernization Act (MMA). The list of counties eligible for the out-migration adjustment, as well as the non-IPPS hospitals, is available in Addendum L of the final rule.

In the 2015 OPPTS ASC final rule, CMS adopted a 3-year transition period for hospitals paid under the OPPTS but not under the IPPS that are currently located in urban counties that become rural under the new OMB delineations. During the transition, those hospitals maintained 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.

For Community Mental Health Centers (CMHCs), CMS continues to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. As with OPPTS hospitals and for the same reasons, the 2015 OPPTS ASC final rule established policies to use a 3-year transition period for CMHCs, ending December 31, 2017; it will not be applied in 2018. Consistent with current policy, the wage index that applies to CMHCs includes the rural floor adjustment, but it does not include the out-migration adjustment, which only applies to hospitals. CMS notes that because it extends its imputed floor policy for

another year, the wage index that applies to CMHCs will also include the imputed floor adjustment through the end of 2018.

D. Statewide Average Default CCRs

In addition to using CCRs to estimate costs from charges on claims for rate-setting, CMS uses overall hospital-specific CCRs calculated from the hospital's most recent cost report to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPTS during the OPPTS year. Default CCRs are used for hospitals for which the MACs cannot calculate a valid CCR, including certain hospitals that are new, hospitals that appear to have a CCR falling outside the predetermined ceiling threshold for a valid CCR, and hospitals whose most recent cost report reflects all-inclusive rate status until a hospital's MAC is able to calculate the hospital's actual CCR from its most recently submitted Medicare cost report.

The final rule updates the default ratios for 2018 using the most recent cost report data and CMS' standard method for calculating this update. For Maryland, CMS continues to use an overall weighted average CCR for all hospitals in the nation. CMS did not receive any comments on its proposed updates to the statewide average default CCRs.

Table 9 in the final rule provides the statewide default CCRs for urban and rural areas in each state for 2018 and the comparable default CCRs for 2017. The CCRs represent the ratio of total costs to total charges for those cost centers relevant to outpatient services from hospitals' most recently submitted cost reports, weighted by Medicare Part B charges. Most CCR changes shown in Table 10 are small. The largest reduction is for rural Alaska (-0.21) followed by urban Puerto Rico (-0.05). The largest increases are rural Connecticut (+0.078) and rural North Dakota (+0.045).

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 OPPTS, 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. Payment Adjustment for Certain Cancer Hospitals

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

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. Section 16002(b) of the 21st Century Cures Act amended section 1833(t)(18) of the Act to add subparagraph (C) to require that 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 OPPTS budget neutrality.

Section 16002(b) of the 21st Century Cures Act also indicates that the Secretary may consider making an additional percentage point reduction to the target PCR that takes into account payment rates for applicable items and services furnished by non-cancer hospital off-campus provider-based departments that are not paid under the OPPTS pursuant to section 603 of the Bipartisan Budget Act of 2015. The Secretary is not making an additional adjustment to the PCR under this authority.

Rather than a claims-based adjustment, CMS makes an aggregate payment, as necessary, to each cancer hospital at cost report settlement. CMS determines the cancer hospital's PCR (before a cancer hospital payment adjustment) and determines the lump sum amount necessary (if any) to make the cancer hospital's PCR equal to the weighted average PCR (or "target PCR") for the other OPPTS hospitals using the most recent submitted or settled cost report data that is available at the time of the final rule. If a cancer hospital's PCR (before the cancer hospital payment adjustment) is above the target PCR, the cancer hospital payment adjustment equals zero.

The target PCR is set in advance and is calculated using the same extract of cost report data from HCRIS as is used for OPPTS rate-setting. Public comments supported CMS' proposed cancer hospital payment adjustment for 2018. For the 2018 final rule, CMS updated its calculations to determine the target PCR using the latest available cost data (which, in most cases, are hospital cost reports from 2015) and determined target PCR of 0.89. Consistent with section 1833(t)(18)(C) of the Act, CMS is reducing the target PCR from 0.89 to 0.88 and not making this 1.0 percentage point reduction subject to OPPTS budget neutrality.

Table 10 in the final rule, reproduced below, shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals, with increases in OPPTS payments for 2018 ranging from 7.6 percent to 52.2 percent. As noted, the actual amount of the 2018 cancer hospital payment adjustment for each cancer hospital is determined at cost report settlement and depends on each hospital's 2018 payments and costs.

The 2018 final rule budget neutrality adjustment to the OPPTS conversion factor is 1.0008 for the cancer hospital adjustment reflecting CMS' projection that aggregate cancer hospital adjustments would be slightly lower in 2018 compared to 2017. Table 10 of the final rule includes the estimated percentage increase in OPPTS payments to cancer hospitals for 2017 to meet the target PCR.

G. Hospital Outpatient Outlier Payments

The OPPTS makes outlier payments on a service-by-service basis when the cost of a service exceeds the outlier threshold. For 2018, CMS is continuing to set aside 1.0 percent of the estimated aggregate total payments under the OPPTS 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 2018, 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.

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

Hospitals that fail to report data required for the quality measures selected by the Secretary incur a 2.0 percentage point reduction to their OPPTS annual payment update factor, resulting in reduced OPPTS 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.

CMS did not receive any public comments on its proposed hospital outpatient outlier payment methodology. To model hospital outlier payments and set the outlier threshold for 2018, CMS applied the hospital-specific overall ancillary CCRs available in the July, 2017 update to the Outpatient Provider-Specific File after adjustment (using a CCR inflation adjustment factor of 0.9856 to approximate 2018 CCRs) and applied a two-year total increase factor of 1.0936 to approximate 2018 charges from 2016 claims. The inflation adjustment factors for CCRs and charges are the same as were used for the FY 2018 IPPS rule.

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

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

discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of “Q1” and “Q2”) qualify for separate payment. CMS notes that, although blood and blood products with status indicator “R” and brachytherapy sources with status indicator “U” are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements.

I. Beneficiary Coinsurance

Medicare law provides that the maximum coinsurance rate for any service is 40 percent of the total OPPTS payment to the hospital and the minimum coinsurance is 20 percent. The statute also limits a beneficiary’s actual cost-sharing amount for a service to the inpatient hospital deductible for the applicable year, which is \$1,316 in 2017. The inpatient hospital deductible limit is applied to the *actual* co-payment amount after adjusting for the wage index. For this reason, the co-insurance levels shown in the OPPTS payment rate Addenda A and B to the final rule do not reflect application of the hospital deductible limit.

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

For 2018, CMS is determining the copayment amounts for new and revised APCs using the methodology first implemented in 2004. CMS refers readers to the November 7, 2003 OPPTS final rule with comment period (68 FR 63458) for a full description of this methodology, which is summarized in the 2018 final rule. Also, for 2018 as in prior years, CMS is reducing the beneficiary co-payment proportionately to the 2-percentage point conversion factor reduction when services are rendered in a hospital that does not report the required quality measures, or that reported them unsatisfactorily.

The final rule estimates that, in aggregate, the percentage of beneficiary liability for OPPTS payments in 2018 will be 18.5 percent, the same percentage estimated for 2017. As indicated above, the transition to all services being paid at a coinsurance rate of 20 percent appears to be at or nearly complete. Addendum A of the final rule shows that transition is at or nearly complete as the coinsurance percentages are at or round to 20 percent for all but a small number of APCs.

III. OPPTS Ambulatory Payment Classification (APC) Group Policies

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

Table 11 (reproduced below from the final rule) summarizes the process CMS uses for updating codes through the OPPTS quarterly update Change Requests (CRs), seeking public comment, and finalizing the status and payment of these codes under the OPPTS.

Table 11—Comment Timeframe for New or Revised HCPCS Codes

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 1, 2017	Level II HCPCS Codes	April 1, 2017	2018 OPPTS/ASC proposed rule	2018 OPPTS/ASC final rule with comment period
July 1, 2017	Level II HCPCS Codes	July 1, 2017	2018 OPPTS/ASC proposed rule	2018 OPPTS/ASC final rule with comment period
	Category I (certain vaccine codes) and Category III CPT codes	July 1, 2017	2018 OPPTS/ASC proposed rule	2018 OPPTS/ASC final rule with comment period
October 1, 2017	Level II HCPCS Codes	October 1, 2017	2018 OPPTS/ASC final rule with comment period	2019 OPPTS/ASC final rule with comment period
January 1, 2018	Level II HCPCS Codes	January 1, 2018	2018 OPPTS/ASC final rule with comment period	2019 OPPTS/ASC final rule with comment period
	Category I and Category III CPT Codes	January 1, 2018	2018 OPPTS/ASC proposed rule	2018 OPPTS/ASC final rule with comment period

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

Through the April 2017 OPPTS quarterly update, CMS made five new Level II HCPCS codes effective and assigned them interim OPPTS status indicators and APCs (see Table 12 of the final rule reproduced below). The payment rates, where applicable, can be found in Addendum B to the final rule. CMS solicited public comments on the proposed status indicators, APC assignments and payment rates for these new codes. CMS did not receive any public comments and is finalizing its proposed decisions without change. Several of the HCPCS C-codes have been replaced with HCPCS J-codes effective January 1, 2018. Their replacement codes are shown in Table 12.

Table 12—New Level II HCPCS Codes Effective April 1, 2017

2017 HCPCS Code	2018 HCPCS Code	2018 Long Descriptor	2018 SI	2018 APC
C9484	J1428	Injection, eteplirsen, 10 mg	G	9484
C9485	J9285	Injection, olaratumab, 10 mg	G	9485
C9486	J1627	Injection, granisetron extended release, 0.1 mg	G	9486

2017 HCPCS Code	2018 HCPCS Code	2018 Long Descriptor	2018 SI	2018 APC
C9487*	J3358	Ustekinumab, for intravenous injection, 1 mg	G	9487
C9488	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. Treatment of New HCPCS Codes That Were Effective July 1, 2017

Through the July 2017 OPPTS 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 OPPTS status indicators and to APCs. Three HCPCS codes are no longer payable under the OPPTS because they have been replaced with 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 13—New Category III CPT and Level II HCPCS Codes Effective July 1, 2017

2017 HCPCS Code	2018 HCPCS Code	2018 Long Descriptor	2018 SI	2018 APC
C9489	J2326	Injection, nusinersen, 0.1 mg	G	9489
C9490	J0565	Injection, bezlotoxumab, 10 mg	G	9490
C9745	C9745	Nasal endoscopy, surgical; balloon dilation of eustachian tube	J1	5165
C9746	C9746	Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed and/or fluoroscopy, when performed	J1	5377
C9747	C9747	Ablation of prostate, transrectal, high intensity focused ultrasound (HIFU), including imaging guidance	J1	5376
K0553	K0553	Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 Unit Of Service	Y	N/A
K0554	K0554	Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system	Y	N/A
Q9984	J9276	Levonorgestrel-releasing intrauterine contraceptive system (Kyleena), 19.5 mg	E1	N/A
Q9985	J7129	Injection, hydroxyprogesterone caproate, not otherwise specified, 10 mg	N	N/A
Q9986*	J1726	Injection, hydroxyprogesterone caproate (Makena), 10 mg	K	9074

2017 HCPCS Code	2018 HCPCS Code	2018 Long Descriptor	2018 SI	2018 APC
Q9987*	P9100	Pathogen(s) test for platelets	S	1493
Q9988*	P9073	Platelets, pheresis, pathogen reduced, each unit	R	9536
Q9989#	J3358	Ustekinumab, for intravenous injection, 1 mg	G	9487
0469T	0469T	Retinal polarization scan, ocular screening with on-site automated results, bilateral	E1	N/A
0470T	0470T	Optical coherence tomography (OCT) for microstructural and morphological imaging of skin, image acquisition, interpretation, and report; first lesion	M	N/A
0471T	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	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	Q1	5743
0473T	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	0474T	Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space	J1	5492
0475T	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	M	N/A
0476T	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	0477T	Recording of fetal magnetic cardiac signal using at least 3 channels; signal extraction, technical analysis, and result	Q1	5734
0478T	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 Q9986 replaced HCPCS code J1725 (Injection, hydroxyprogesterone caproate, 1 mg), HCPCS codes Q9987 and Q9988 replaced HCPCS code P9072 (Platelets, pheresis, pathogen reduced or rapid bacterial tested, each unit), and HCPCS code Q9989 replaced HCPCS code C9487 (Ustekinumab, for intravenous injection, 1 mg)

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 and its pass-through status continued.

3. Process for New Level II HCPCS Codes that will be Effective October 1, 2017 and January 1, 2018 for which CMS will be Soliciting Public Comments

CMS is soliciting comments on those new Level II HCPCS codes that are effective October 1, 2017 and January 1, 2018 in the 2018 OPPS/ASC final rule with comment period. The payments for these codes will be assigned a comment indicator “NI” in Addendum B to the OPPS/ASC final rule with comment period signifying that the codes are interim final subject to public comment. **CMS is inviting public comments on the status indicator, APC assignments, and payment rates for these codes, if applicable, which would then be finalized in the 2019 OPPS/ASC final rule with comment period.**

4. Treatment of New and Revised CY 2018 Category I and III CPT Codes that will be Effective January 1, 2018

For the 2018 OPPS update, CMS received the 2018 CPT codes from the AMA in time for inclusion in the 2018 OPPS/ASC proposed rule. The new, revised, and deleted 2018 Category I and III CPTs were assigned to new comment indicator “NP” in Addendum B of the proposed rule to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor. Comments were accepted on the proposed APC assignment and status indicator.

CMS responded to public comments in sections II.A.2.b. (Comprehensive APCs), III.D. (OPPS APC-Specific Policies), V. (OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals), and XII. (Updates to the ASC Payment System) of the 2018 OPPS/ASC final rule with comment period. The final status indicators, APC assignments, and payment rates for the new CPT codes that are effective January 1, 2018 can be found in Addendum B of the final rule.

B. OPPS Changes – Variations within APCs

1. Application of the 2 Times Rule

In accordance with section 1833(t)(2) of the Act, CMS annually reviews the items and services within an APC group to determine, with respect to comparability of the use of resources, if the highest cost item or service within an APC group is more than 2 times greater than the lowest cost item or service within that same group. In making this determination, CMS considers only those HCPCS codes that are significant based on the number of claims. Specifically, CMS considers only those HCPCS codes that have more than 1,000 single major claims or codes that have both greater than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant.

2. APC Exceptions to the 2 Times Rule

CMS may make exceptions to the 2 times limit on the variation of costs within each APC group in unusual cases, such as low-volume items and services. CMS uses the following criteria to decide whether to propose exceptions: resource homogeneity; clinical homogeneity; hospital outpatient setting utilization; frequency of service (volume); and opportunity for upcoding and code fragments. CMS notes that in cases in which a recommendation by the HOP appears to result in a violation of the 2 times rule, CMS generally accepts the HOP recommendations because those 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 listed 12 APCs that CMS proposed to except from the 2 times rule for 2018 based on established criteria and 2016 claims data. Based on the updated final rule CY 2016 claims data used for this 2018 final rule with comment period, CMS removed 6 of the 12 APC violations. The following 6 APCs no longer met the criteria for exception to the 2 times rule:

- APC 5161 (Level 1 ENT Procedures);
- APC 5311 (Level 1 Lower GI Procedures);
- APC 5461 (Level 1 Neurostimulator and Related Procedures);
- APC 5573 (Level 3 Imaging with Contrast);
- APC 5611 (Level 1 Therapeutic Radiation Treatment Preparation); and
- APC 5735 (Level 5 Minor Procedures).

Final rule claims data revealed a total of 11 APCs with violations of the 2 times rule. Of these 11 total APCs, 6 were identified in the proposed rule and 5 are newly identified APCs. The following 6 were identified in the proposed rule:

- APC 5112 (Level 2 Musculoskeletal Procedures);
- APC 5521 (Level 1 Imaging without Contrast);
- APC 5691 (Level 1 Drug Administration);
- APC 5731 (Level 1 Minor Procedures);
- APC 5771 (Cardiac Rehabilitation); and
- APC 5823 (Level 3 Health and Behavior Services).

For the final rule, CMS found the following 5 additional APCs that violated the 2 times rule:

- APC 5522 (Level 2 Imaging without Contrast);
- APC 5524 (Level 4 Imaging without Contrast);
- APC 5571 (Level 1 Imaging with Contrast);
- APC 5721 (Level 1 Diagnostic Tests and Related Services); and
- APC 5732 (Level 2 Minor Procedures).

Some commenters requested that CMS not adopt the exception to C-APCs, including C-APC 5112 (Level 2 Musculoskeletal Procedures), because they believed it would result in lowering the payments for the procedures assigned to C-APCs. One commenter suggested CMS should establish additional APC levels to avoid any exceptions to the 2 times rule. CMS declined to act on this comment indicating that APCs excepted from the 2 times rule in one year are usually resolved the following year based on later claims data. CMS is finalizing its 2 times violation policies as follows:

- Excepting 6 of 12 APCs from the 2 times rule as proposed for 2018 (APCs 5112, 5521, 5691, 5731, 5771, and 5823),
- Excepting 5 additional APCs (APCs 5522, 5524, 5571, 5721, and 5732).

Table 14 below lists the 11 APCs that are being excepted from the 2 times rule for 2018:

TABLE 14.—APC EXCEPTIONS TO THE 2 TIMES RULE FOR 2018

APC	2018 APC Title
5112	Level 2 Musculoskeletal Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5571	Level 1 Imaging with Contrast
5691	Level 1 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5732	Level 2 Minor Procedures
5771	Cardiac Rehabilitation
5823	Level 3 Health and Behavior Services

C. New Technology APCs

1. 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 proposed to narrow the increments for New Technology APCs 1901 – 1906 from \$19,999 cost bands to \$14,999 cost bands. It is also proposed 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. CMS did not receive any comments on its proposals and is finalizing them without change. Table 15 of the final rule reproduced below includes the new Technology APC numbers, titles and cost bands.

TABLE 15.—2018 ADDITIONAL NEW TECHNOLOGY APC GROUPS

2018 APC	2018 APC Title	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. Procedures Assigned to New Technology APC Groups for 2018

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

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 proposed to continue to assign CPT codes 0071T and 0072T to APC 5414 (Level 4 Gynecologic Procedures), with a payment rate of approximately \$2,189 for 2018. It also proposed to continue to pay APC 5414 as a C-APC meaning that all covered Part B services on the claim that paid under the OPPTS are packaged and not paid separately. CMS finalized its proposed policy without change.

CMS proposed to continue to assign HCPCS code C9734 (Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance) to APC 5114 (Level 4 Musculoskeletal Procedures), with a proposed payment rate of approximately \$5,385 for 2018. CMS also proposed to continue to make HCPCS code C9734 a procedure that triggers a C-APC payment. CMS finalized its proposed policy without change.

CMS received only one claim for CPT code 0398T used to treat essential tremor and proposed to continue assigning it to APC 1537 (New Technology - Level 37 (\$9,501-\$10,000)), with a

proposed payment rate of approximately \$9,751 for 2018. In response to a comment suggesting that this payment rate is too low, CMS agreed to assign CPT code 0398T to APC 1576 (New Technology – Level 39 (\$15,001-\$20,000)), with a payment rate of \$17,500.50 for 2018.

Table 16 of the final rule provides information about the status indicators and APC assignments for the above HCPCS codes. The 2018 payment rates can be found in Addendum B of the final rule.

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 OPPTS 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 OPPTS payment of \$95,000. This payment included 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 \$122,500, which is the new technology payment band consistent with the costs of this procedure.

The manufacturer of the retinal prosthesis requested that CMS reassign CPT code 0100T to a New Technology APC that would establish a payment rate near the 2017 payment rate of \$150,000. Commenters expressed concerns about the volatility in payment from year-to-year and also stated that CMS’ assigned the technology to a low paying APC in 2016 based on mistakenly low charges from the hospital which, in turn, forced the manufacturer to discount the cost of the device in 2016 so patients could access the technology. This now explains why CMS is seeing lower costs for the procedure than its actual costs. The commenters expect that claims for 2017 that will be used to set the 2019 rates will reflect a higher cost than for 2016.

CMS responded that additional 2016 claims received after issuance of the 2018 proposed rule show costs for this procedure of approximately \$94,455, which is more than \$55,000 less than the payment rate for the procedure in 2017. CMS notes that this procedure has extraordinarily high costs and low volume compared to many other procedures paid under the OPPTS. In 2016, the payment rate for implanting the Argus® II retinal prosthesis procedure was \$95,000. The payment rate increased to \$150,000 in 2017. For 2018, CMS proposed a payment rate of \$122,500 based on proposed rule data. CMS would assign the technology to an APC that pays \$95,000 based on final rule data—a decrease of \$55,000 from 2017 to 2018.

To address concerns about access to the procedure and payment instability, CMS is using its equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the proposed rate for this procedure, despite the lower geometric mean costs available in the claims data used for this final rule with comment period. For 2018, CMS is reassigning implant of the Argus® II procedure to APC 1904 (New Technology - Level 50 (\$115,001 - \$130,000)). This APC assignment will establish a payment rate for the Argus® II procedure of \$122,500.50, which is the arithmetic mean of the payment rates for the service for 2016 and 2017. As CMS does each year, it will continue to examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that OPPTS payments remain appropriate for procedures like the Argus® II procedure as they transition into mainstream medical practice.

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 from blood and blood product stakeholders that the previous CPT code used to describe pathogen tests for platelets, CPT code P9072 (Platelets, pheresis, pathogen reduced or rapid bacterial tested, each unit), 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 proposed to continue assigning HCPCS code Q9987 to New Technology APC 1493 until claims data are available to support assignment to a clinical APC. Public comments supported CMS' proposal and which it is finalizing without change.

Fractional Flow Reserve Derived from Computed Tomography (FFR_{CT})

For 2018, the AMA CPT Editorial Panel established four new CPT codes for fractional flow reserve derived from computed tomography (FFR_{CT}). CMS proposed to assign CPT codes 0501T and 0504T status indicator "M" (Not paid under OPPTS; Items and Services Not Billable to the MAC) to indicate that these services are not paid under the OPPTS, and to assign CPT codes 0502T and 0503T status indicator "N" (packaged) to indicate that the payment for these services is packaged into the primary service or procedure that is reported with the codes.

CMS initially considered the FFR_{CT} procedure to be image guidance, processing, supervision, or an interpretation service with payment should be packaged into the payment for the related computed tomography service. In a New Technology APC application for HeartFlow for 2018, the developer of the FFR_{CT} service proposed that the service be reported with CPT code 0503T and requested that the service be assigned to APC 1517 (New Technology - Level 17 (\$1501-\$1600)), with a payment rate of \$1,550.50. Because both the initial New Technology APC application and the reconsideration request were denied, CMS did not describe the associated New Technology APC application for HeartFlow in the 2018 OPPTS/ASC proposed rule.

Several commenters, including the developer of HeartFlow and some clinicians who have experience with it, supported having a FFRCT service paid as a separate service and not packaged into the payment for the coronary computed tomography angiography. CMS agreed that the FFRCT service is not image guidance or supervision because FFRCT does not produce images, does not appear to be a supportive guidance service that aids in the performance of an independent procedure, and, unlike typical supervision services, is not generally reported when the initial image is acquired. CMS was further persuaded that the FFRCT service should not be considered to be an image processing service because the diagnostic output of the FFRCT service yields functional values (that is, FFR values), which reflect pressure drops across a narrowing in a coronary artery as opposed to anatomic images. The agency further agrees that the quantitative diagnostic information about the function of the coronary arteries produced by the FFRCT service is not possible to derive from examining anatomic images of the arteries. Additionally, CMS agrees with the commenters that the FFRCT service does not support the diagnostic output of CCTA.

CMS is finalizing the proposal for CPT codes 0501T, 0502T, and 0504T without modification and reassigning CPT code 0503T from packaged status (status indicator “N”) to New Technology APC 1516 (New Technology - Level 16 (\$1401 - \$1500)), with a payment rate of \$1,450.50 for CY 2018. Table 19 of the final rule lists the final status indicator assignments for CPT codes 0501T, 0502T, 0503T, and 0504T.

D. OPPTS APC-Specific Policies

The final rule discusses 29 different APC areas where CMS considered or is making changes in the final rule. Of these 29 areas, only 4 were specifically discussed in the proposed rule preamble. This summary covers those 4 areas in more detail and lists CMS’ final decisions for the remaining areas.

1. Blood-Derived Hematopoietic Cell Harvesting

HCPCS code 38205 describes blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic. This code 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 proposed to change the status indicator assignment HCPCS code 38205 from “B” to “S”, which indicates that the procedure is paid under the OPPTS and receives separate payment. CMS proposed to assign HCPCS code 38205 to APC 5241 that has a geometric mean cost of approximately \$580.

Commenters opposed CMS’ proposal indicating hospitals may bill and receive payment only for services provided to the Medicare beneficiary who is the recipient of the stem cell transplant and whose illness is being treated with the stem cell transplant. Commenters expressed concern about erroneous separate payments if CMS changes the status indicator to “S”. The HOP

recommended that CMS retain status indicator “B” for HCPCS code 38205 indicating that it remains packaged. CMS agreed with the commenters and is not finalizing the proposal.

2. Radiology and Imaging Procedures and Services

Imaging APCs

As part of its comprehensive review of the structure of the APCs and procedure code assignments, CMS restructured the APCs that contain imaging services in 2016 and 2017. There are currently 7 imaging APCs including 4 imaging APCs without contrast and 3 imaging APCs with contrast. The Medicare statute requires the OPPTS to have APCs that distinguish payment for imaging services with and without contrast.

For 2018, CMS evaluated the resource costs and clinical coherence of the procedures associated with the 4 levels of imaging without contrast APCs and the 3 levels of imaging with contrast APCs as well as identified and corrected any 2 times rule violations. In addition, CMS reviewed and considered stakeholder recommendations to make additional refinements to the structure of the APC groupings of the imaging procedures classified within the imaging APCs.

As a result of this review, CMS proposed to create a Level 5 Imaging without Contrast APC to more appropriately group certain imaging services with higher resource costs. CMS indicated 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. CMS’ proposal would increase the imaging APCs from 7 APCs in 2017 to 8 in 2018.

Commenters generally disagreed with CMS’ proposal to add a fifth level within the Imaging without Contrast APC series because of the resultant reduction in payment to several vascular ultrasound procedures. After consideration of the public comments and suggestions, CMS is not finalizing the proposal to add a fifth level to the Imaging without Contrast APC series. Instead, it is making minor reassignments to the HCPCS codes within this series to resolve or mitigate any violations of the 2 times rule.

A few commenters objected to the proposed exception to the violation of the 2 times rule for APC 5573 (Level 3 Imaging With Contrast) and recommended alternative approaches to resolving the violation, such as the creation of a Level 4 Imaging With Contrast or maintaining the 2017 APC groupings. CMS agreed with commenters and is not adopting the proposal to reassign nine high-volume contrast MRI procedures from APC 5572 to APC 5573 and to allow for an exception for APC 5573 from the 2 times rule. In addition, CMS is making a few other code reassignments to resolve the 2 times rule violation in APC 5573. Table 54 of the final rule compares the 2017 and 2018 APC geometric mean costs for the imaging APCs.

Non-Ophthalmic Fluorescent Vascular Angiography (APC 5524)

For the 2018 OPPTS update, CMS proposed 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.

The service described by HCPCS code C9733 is primarily an intraoperative imaging service that is performed in combination with a number of primary procedures, including facial reconstruction and reanimation, muscle flaps, trauma reconstruction, digital and limb reattachment, and breast reconstruction. CMS proposed to continue conditionally packaging the service when performed in conjunction with other procedures on the same day but pay for it separately when performed as a stand-alone service.

Several commenters supported the proposed APC reassignment for HCPCS code C9733 to APC 5524. In addition, commenters requested that CMS change the status indicator assignment from conditionally packaged to separately payable. CMS declined to change the status indicator noting that the service is primarily an intraoperative imaging service that will typically be done in conjunction with another service. CMS is not finalizing its proposed reassignment of HCPCS code C9733 from APC 5523 to APC 5524 because it is maintaining the 2017 APC group assignments for imaging services and because the final rule cost data suggest the procedure is correctly assigned to APC 5523.

3. Comment Solicitation on Intraocular Procedure APCs

For 2018, CMS considered proposing a new intraocular procedure APC that would further distinguish the resource costs and clinical characteristics between cataract surgery and complex cataract surgery. While CMS did not make a proposal, it noted that the 2017 AMA CPT manual describes a complex cataract surgery case as “requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis).”

CMS indicated in the proposed rule that it may be more appropriate to assign CPT code 66982 (complex cataract surgery) to a newly created Level 2 Intraocular Procedures C-APC in between existing C-APCs 5491 and 5492 that is separate and with a higher payment than the C-APC assignment for CPT code 66984 (routine cataract surgery). If CMS undertook this change, it would monitor claims data for changes in the distribution of coding complex cataract surgery and routine cataract surgery.

Commenters, including several ophthalmologists and organizations representing ophthalmologists, did not support separation of complex cataract surgery and simple cataract surgery into separate APCs because the procedures are similar clinically and the modest variation in cost between the two procedures does not warrant reassignment of CPT code 66982 into a higher payment APC. Commenters supported CMS' intent to monitor the data for these

procedures and make future changes, if needed. CMS is continuing the assignment of simple and complex cataract surgery procedures to the same APC for 2018.

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

CMS indicated in the proposed rule 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 the agency proposed to adopt CPT replacement codes for 2018 for several of the care management services finalized for 2017. CMS asked for 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.

Commenters supported CMS’ proposed replacement codes for care management services. One recommended that the new chronic care management codes be removed from the financial settlement of accountable care organizations (ACOs). This commenter also recommended that CMS develop documentation and billing workflow to reduce administrative burden on providers billing transitional care management and chronic care management codes. CMS responded that ACO policy is outside the scope of this rulemaking. CMS finalizes its policies as proposed and provides the final codes, status indicators and APC assignment in Table 22 of the final reproduced below.

Table 22—Care Management Coding Changes Effective January 1, 2018

2017 HCPCS Code	2017 HCPCS Short Descriptor	2017 OPPTS SI	2017 OPPTS APC	2018 Replacement CPT Code	2018 Replacement HCPCS Short Descriptor*	2018 OPPTS SI	2018 OPPTS APC
G0502	Init psych care Manag, 70min	S	5822	99492	1st psyc collab care mgmt	S	5822
G0503	Subseq psych care man, 60mi	S	5822	99493	Sbsg psyc collab care mgmt	S	5822
G0504	Init/sub psych Care add 30 m	N	N/A	99494	1st/sbsq psyc collab care	N	N/A
G0505	Cog/func assessment outpt	S	5822	99483	Assmt & care pln pt cog imp	S	5822
G0507	Care manage serv minimum 20	S	5821	99484	Care mgmt. svc bhvl hlth cond	S	5821

*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 final rule.

4. All Other APC-Specific Issues for 2018

As indicated above, CMS did not discuss the below issues in the proposed rule but may have assigned codes and status indicators in the proposed rule Addenda. What is provided below summarizes those areas where CMS is making a change in the final rule from what it proposed for 2018 or where the code is new for the final and was not addressed in the proposed rule:

Brachytherapy Insertion Procedures (C-APCs 5341 and 5092). CMS is reassigning CPT code 5920 from C-APC 5341 to C-APC 5415 for 2018.

Cardiac Telemetry (APC 5721). CMS is revising the assignment for CPT code 93229 to APC 5721 for 2018 rather than APC 5734 where it was assigned in the proposed rule.

Collagen Cross-Linking of Cornea (C-APC 5503). CMS is reassigning CPT code 0402T to APC 5503 (Level 3 Extraocular, Repair, and Plastic Eye Procedures) for 2018 and will consider reassignment of CPT code 0402T to APC 5504 in 2019 rulemaking.

Esophagogastroduodenoscopy (EGD) (C-APC 5362). CMS is reassigning CPT code 43210 from C-APC 5331 to C-APC 5362 for 2018.

Hemorrhoid Treatment by Thermal Energy (APC 5312). CMS is reassigning CPT code 46930 from C-APC 5311 to C-APC 5312 for 2018.

Percutaneous Transluminal Mechanical Thrombectomy (C-APC 5192). CMS is finalizing its 2018 proposal, with modification, for CPT codes 37184 and 37187 and reassigning CPT codes 37184 and 37187 from APC 5183 to C-APC 5192.

Sclerotherapy (APC 5054). CMS proposed to assign new CPT codes 36465 and 36466 to APC 5053 (Level 3 Skin Procedures). In the final rule, CMS is assigning both codes to APC 5054, instead of proposed APC 5053 for 2018.

Skin Substitutes (APCs 5053, 5054, and 5055). CMS is assigning HCPCS code C5277 to APC 5053 and CPT code 15277 to APC 5054.

Subdermal Drug Implants for the Treatment of Opioid Addiction (APC 5735). CMS is establishing HCPCS G-codes G0516, G0517, and G0518 under the OPPTS, effective January 1, 2018 that are conditionally packaged and assigned to APC 5735 when separately paid.

Transurethral Waterjet Ablation of the Prostate (C-APC 5375). As a result of a change in Medicare coverage, CMS revised the OPPTS status indicator assignment for CPT code 0421T from “E1” (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) to “J1” (Hospital Part B services paid through a comprehensive APC) and assigned the code to C-APC 5374 (Level 4 Urology and Related Services) to indicate that the procedure would be paid separately under the OPPTS. In the final rule, CMS is revising the APC assignment for CPT code 0421T from proposed C-APC 5374 to C-APC 5375 for 2018.

Transurethral Water Vapor Thermal Therapy of the Prostate (C-APC 5373). CMS established HCPCS code C9748 to describe the Rezūm procedure—a procedure that utilizes water vapor for the treatment of benign prostatic hypertrophy. CMS proposed to assign HCPCS code C9748 to C-APC 5373 (Level 3 Urology and Related Services). **The APC and status indicators are subject to public comment in this final rule.**

IV. OPPTS 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 under OPPTS.

For pass-through payments approved before 2017, a device pass-through status expires at the end of the year when at least 2 years of pass-through payments has been made, regardless of the quarter in which the device was approved. In the 2017 OPPTS final rule, CMS finalized a policy change to allow for quarterly expiration of pass-through payments status for devices. This policy begins with pass-through devices approved in 2017. For devices that are no longer eligible for pass-through payments (except for brachytherapy sources), CMS packages the costs of the devices into the procedures with which the devices are reported in the claims data used to set the payment rates.

CMS finalizes that the pass-through payment status of the three device categories eligible for pass-through payments will expire on December 31, 2017:

- HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser) was established effective April 1, 2015;
- HCPCS code C2613 (Lung biopsy plug with delivery system) was established effective July 1, 2015; and
- HCPCS code C1822 (Generator, neurostimulator (implantable), high frequency with rechargeable battery and charging system) was established effective January 1, 2016.

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. For 2018, CMS will 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.

HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser). Various stakeholders, including physicians, device manufacturers, and professional societies opposed the proposal to package the costs of the devices described by HCPCS code C2623. Commenters opposed packaging of drug coated balloons for several reasons including concerns that the

procedure described by CPT code 37224 (Fem/pop/revas with tla) did not reflect the additional costs of drug-coated balloons over non-drug coated balloons and would limit patient access to the technology. Commenters also discussed the clinical benefits of the technology and recommended continuation of the pass-through status. CMS notes that the HOP Panel recommended that CMS continue to track CPT code 37224 and that a HOP subcommittee review the APCs for endovascular procedures to determine whether additional APCs are warranted.

CMS reiterates its policy for pass-through payments approved prior to 2017 and concludes that this device category is no longer eligible for pass-through payments. In response to the HOP Panel recommendation, CMS will continue to track CPT code 37224 and HCPCS code C2623 and will provide all necessary information to the Panel for review of the APCs for endovascular procedures.

Commenters also presented evidence that the geometric mean of claims billed with CPT code 37224 and HCPCS code C2623 (\$8,483) was higher than the geometric mean of claims including CPT code 37224 without HCPCS code C2623 (\$6,396) and higher than the total geometric mean costs for CPT code 37224, regardless of whether or not HCPCS C2623 is billed (\$7,153). CMS notes that there is no violation of the 2 times rule in this C-APC and disagrees with commenters request to create a new procedural HCPCS C-code or G-code to differentiate procedures that use drug-coated balloons from plain balloon angioplasty catheters. CMS also disagrees with a comment that the C-APC complexity adjustment policy should apply to C2623 because the use of a drug-coated balloon does not involve a separate procedure. In response to commenters referencing the HOP Panel's recommendation that CMS examine the number of APCs for endovascular procedures for 2018, CMS reiterates it will review and evaluate the APC groupings based on the latest available data in the next rulemaking cycle.

HCPCS code C1822 (Generator, neurostimulator (implantable), high frequency with rechargeable battery and charging system). Several commenters opposed the proposal to package the costs of the device (the Senza SCS System) described by HCPCS code C1822 and recommended an additional year of pass-through payment status. Commenters opposed package of the device for several reasons including lower costs reported by hospitals due to hospital cost reporting errors and commenters were concerned that ending the pass-through status would reduce success to the Senza SCS System. CMS again reiterates its policy for pass-through payments approved prior to 2017 and concludes this device is no longer eligible for pass-through payments. CMS also discusses the responsibility of hospitals to report correct cost report data; it is not CMS' general policy to judge the accuracy of hospital coding and charging for purposes of rate setting (see 75 FR 71838 for additional discussion).

2. New Device Pass-Through Applications

a. Background

Criteria for New Device Pass-Through Applications

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

1. If required by the FDA, the device must have received FDA premarket approval or clearance (except for a device that has received an FDA investigational device exemption

(IDE) and has been classified as a Category B device by the FDA), or meets another appropriate FDA exemption from premarket approval or clearance; and the pass-through application must be submitted within 3 years from the date of the initial FDA approval or clearance, if required, unless there is a documented, verifiable delay in the US market availability in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability;

2. The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury to improve the functioning of a malformed body part; and
3. The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion.

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

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

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

- Not appropriately described by an existing category or any category previously in effect established for transitional pass-through payments, and was not being paid for as an outpatient service as of December 31, 1996;
- Has an average cost that is not “insignificant” relative to the payment amount for the procedure or service with which the device is associated as determined under §419.66(d) by demonstrating:
 - (1) The estimated average reasonable costs of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices;
 - (2) The estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent; and
 - (3) The difference between the estimated average reasonable cost of the device in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service (with the exception of brachytherapy and temperature-monitored cryoblation, exempted from the cost requirements at §419.66(c)(3) and §419.66(e); and
- Demonstrates a substantial clinical improvement: substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

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

In 2016, CMS changed the OPPTS device pass-through payment evaluation and determination process. Device pass-through applications are still submitted through the quarterly subregulatory process, but the applications are subject to notice-and-comment rulemaking in the next applicable OPPTS annual rulemaking cycle. The current deadline for device pass-through payment applications continues to be the first business day in March, June, September, and December of a year for consideration for the next quarter (at the earliest) of the year involved.

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

b. Applications Received for Device Pass-Through Payments for 2018

CMS received five applications by the March 1, 2017 quarterly deadline, the last quarterly deadline in time for the 2018 OPPTS/ASC proposed rule. Applicants received for the remaining 2017 quarters (June 1, September 1, and December 1) will be discussed in the 2019 OPPTS/ASC 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 does not approve device pass-through payment status for 2018 for the five applications.**

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, the applicant received FDA clearance for Architect[®] Px on September 12, 2014 and its June 1, 2016 application was within 3 years of FDA clearance. CMS was concerned that if Unite Biomatrix, cleared by the FDA on June 20, 2007, and cited in the application as a predicate of Architect[®] Px was used to evaluate the newness criterion, Architect[®] Px may not meet this criterion.

In response to the manufacturer's comments explaining how Architect[®] Px is substantially different from its predicate product and is manufactured using a new process not available in 2014, CMS concludes that for purposes of the device pass-through payment process, Architect[®] Px meets the newness criterion.

With respect to the eligibility criterion, CMS confirms there is no existing pass-through payment device category for this product.

With respect to the substantial clinical improvement criterion, CMS acknowledges the additional information provided by the manufacturer about the potential beneficial qualities of Architect[®] Px but notes that the applicant only identified two references: one is a 2012 summary report of skin substitute products and the second is a small observational study. CMS determines that the evidence is insufficient to demonstrate that Architect[®] Px meets the substantial clinical improvement criterion.

With respect to the cost criterion, as discussed in the proposed rule, Architect[®] Px meets all the three cost significance tests and satisfies the cost significance criterion.

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

Aedicell, Inc. submitted an application for Dermavest and Plurivest products that use tissue sourced from the placenta disk, amnion/chorion, and umbilical cord to replace or supplement damaged tissue. These products replace or supplement damaged tissue or inadequate integumental tissue by providing a scaffold to entrap migrating cells for population. CMS notes that the application does not distinguish between the Dermavest and Plurivest products, the Aedicell website states the products differ by dosage with Plurivest having a lower cytokine/growth factors profile than Dermavest.

With respect to the newness criterion, the applicant stated that the product conforms to the FDA regulatory path under section 361 of the Public Health Services (PHS) Act and 21 CFR Part 1271 for Human Cells, Tissues, and Cellular and Tissue-Based Products. Using this regulatory path, Aedicell submitted its application to the FDA for annual registration/listing for HPCTM on November 9, 2015. The applicant noted that the initial registration for the manufacture of Dermavest was October 28, 2013 and for the manufacture of Plurivest was November 14, 2014. CMS was uncertain if the newness criterion is met.

The manufacturer provided additional information but CMS concludes it is unable to determine that Dermavest and Plurivest meet the newness criterion.

With respect to the eligibility criterion, CMS confirms there is no existing pass-through payment device category for this product.

With respect to the substantial clinical improvement criterion, CMS acknowledges the additional information provided by the manufacturer, including personal statements from physicians, about the benefits of the products. CMS notes, however, that the applicant provided several background studies showing evidence that placental tissue, umbilical cord, and amnion membrane products are effective in the treatment of various wounds and ulcers but none of these studies were specific to Dermavest and Plurivest. The applicant also submitted two poster presentations of case series specific to Dermavest and Plurivest. The commenters did not provide any new empirical evidence and CMS concludes that the evidence is insufficient to demonstrate that Architect[®] Px meets the substantial clinical improvement criterion.

With respect to the cost criterion, as discussed in the proposed rule, 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 allograft is implanted at the surgical site at the end of the procedure under direct visualization. The applicant stated the product helps healing.

With respect to the newness criterion, the applicant stated that the products conforms to the FDA regulatory path under section 361 of the Public Health Services (PHS) Act and 21 CFR Part 1271 for Human Cells, Tissues, and Cellular and Tissue-Based Products. Using this regulatory path, Applied Biologic submitted information to the FDA for two registrations, both forms list the product as FlōGraft®. The initial registration was dated June 8, 2015 and another registration was dated December 1, 2014. CMS noted the first date of US sales for FlōGraft® was May 23, 2013. CMS was not certain if the newness criterion is met.

Based on additional information provided by the manufacturer, CMS determines the product meets the newness criterion.

With respect to the eligibility criterion, CMS confirms there is not an existing pass-through payment device category for this product.

With respect to the substantial clinical improvement criterion, CMS acknowledges the additional information provided by commenters but notes that the commenters did not provide new empirical evidence that address the limitations of the unpublished studies submitted with the application. CMS notes that the studies were case studies, case series or retrospective cohort studies that lack blinding and a comparison group. CMS concludes 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, as discussed in the proposed rule, 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 confirms there is not an existing pass-through payment device category for this product.

With respect to the substantial clinical improvement criterion, CMS acknowledges the comments provided by the manufacturer but concludes that this information did not provide additional evidence for substantial clinical improvement. CMS notes that the applicant stated that individuals who would normally refuse to use skin substitute products from animal sources would use Kerecis™ Omega3 Wound because it is a fish-based skin substitute but did not provide any studies demonstrating improvement to this group of beneficiaries. The applicant submitted three studies in support of the application and CMS discusses the limitations of these studies. In response to a comment that other skin substitute products had presented less evidence for substantial clinical improvement and had been previously approved for pass-through payment status, CMS states that the commenter might have been referring to skin substitutes approved for pass-through payment prior to 2015. Since 2015, skin substitutes have been evaluated using the medical device pass-through payment process which includes the criterion for substantial clinical improvement (79 FR 66885 through 66888).. 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, as discussed in the proposed rule, 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, the applicant stated that the products conforms to the FDA regulatory path under section 361 of the Public Health Services (PHS) Act and 21 CFR Part 1271 for Human Cells, Tissues, and Cellular and Tissue-Based Products. Using this regulatory path, Applied Biologic submitted information to the FDA on December 30, 2015. CMS noted it was not clear when the Center for Biologics Evaluation and Research (CBER) filing occurred and CMS was not certain if the newness criterion is met.

Based on additional information provided by the manufacturer, CMS determines the product meets the newness criterion.

With respect to the eligibility criterion, CMS confirms there is not an existing pass-through payment device category for this product.

With respect to the substantial clinical improvement criterion, CMS noted that the applicant provided general effectiveness of amniotic fluid and amniotic membrane-based products. The applicant also submitted one study that was a retrospective review with prospective follow-up of eight patients. CMS acknowledges the comments received but notes they were based on clinical observations and the additional studies submitted were not specific to the product. Based on the evidence submitted, CMS concludes 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, as discussed in the proposed rule, X-WRAP[®], meets all the three cost significance tests and satisfies the cost significance criterion.

B. Device-Intensive Procedures

1. HCPCS Code-Level Device-Intensive Determination

In the 2017 OPPTS final rule (81 FR 79658), CMS finalized a change in its methodology to assign device-intensive status. CMS assigns device-intensive status to all procedures that require the implantation of a device and have an individual HCPCS code-level device offset of greater than 40 percent, regardless of the APC assignment. All procedures requiring the implantation of a medical device and having an individual HCPCS code-level device offset of greater than 40 percent are identified as device-intensive and are subject to the device edit and no cost/full credit and partial credit device policies.

For new HCPCS codes describing procedures requiring the implantation of medical devices that do not yet have associated claims data, CMS finalized a policy to apply a device-intensive status with a default device offset set at 41 percent until claims data are available to establish the HCPCS code-level device offset. CMS also finalized that in certain rare instances, such as in the case of a very expensive implantable device, CMS may temporarily assign a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer.

Additional information for CMS to use for its consideration of an offset percentage higher than the default of 41 percent, such as pricing data or invoices from a device manufacturer, should be sent to the Division of Outpatient Care⁶ or electronically to outpatientpps@cms.hhs.gov.

The full listing of the final device-intensive procedures for 2018 is available in Addendum P of this rule.

In response to several commenters suggestions for alternative device offset percentage thresholds, CMS believes its current methodology is appropriate. CMS will take into consideration for future rulemaking, commenters' suggestion that CMS develop a mechanism that prevents significant payment reductions for device-intensive procedures due to wage index adjustments.

In response to a comment requesting clarification about the criteria for device-intensive procedures pertaining to temporarily inserted devices, CMS clarifies that device-intensive procedures require the implantation of a device and are subject to the additional criteria:

- All procedures must involve implantable devices that would be reported if device insertion procedures were performed;
- The required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and
- The device offset amount must be significant, which is defined as exceeding 40 percent of the procedure's mean cost.

⁶ Division of Outpatient Care, Mail Stop C4-01-26, CMS, 7500 Security Boulevard, Baltimore, MD 21244-1850

In response to commenters' request to assign device-intensive designation to HCPCS codes 55874, 0275T and 28297, CMS notes that the device offset percentage for all three of these codes (or predecessor codes) is not above the 40 percent threshold and therefore are not eligible to be assigned device-intensive status.

2. Device Edit Policy

In the 2017 OPPTS final rule, CMS finalized 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 applies 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, satisfies the edit requiring a device code to be reported on a claim with a device-intensive procedure.

For 2018, CMS did not propose any changes to the device edit policy.

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

CMS reduces OPPTS payments by the full or partial credit a provider receives for a replaced device for the applicable device-dependent APCs. Hospitals report the amount of the credit in the amount portion for value code "FD" (credit received from the manufacturer for a replaced medical device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. CMS also limits the total amount of the device offset when the "FD" value code appears on a claim. CMS specifies a list of costly devices to which this APC payment adjustment would apply. For 2018, CMS will continue the existing policy of reducing OPPTS payment when a hospital furnishes a specified device without cost or with a full or partial credit.

For 2017, CMS finalized its policy to identify the services to which the adjustment would apply using the newly defined set of device-intensive procedures – procedures with an individual HCPCS level device offset greater than 40 percent. CMS also finalized its policy to use three criteria for determining the procedures to which the device-intensive policy will apply (see discussion in prior section).

For 2018, CMS did not propose any changes to the device edit policy.

4. Payment Policy for Low Volume Device-Intensive Procedures

For 2016, CMS used its equitable adjustment authority under section 1833(t)(2)(E) of the Act to use the median cost rather than the geometric mean cost to calculate the payment rate for the

procedure described by CPT code 0308T (Insertion of ocular telescope prosthesis including removal or crystalline lens or intraocular lens prosthesis). The procedure is the only code assigned to APC 5494 (Level 4 Intraocular Procedure). CPT code 0308T is a high-cost device-intensive surgical procedure that has a very low volume of claims (in part because most of the procedures described by CPT code 0308T are performed in ASCs), and CMS concluded that the median cost is a more appropriate measure of the central tendency for purposes of calculating the cost and the payment rate because the median cost is impacted to a lesser degree than the geometric mean cost by more extreme observations. The median cost for 2016 of the procedure described by CPT code 0308T is \$18,365 and the geometric mean cost is \$13,833.

In the 2017 OPPTS 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 proposed to continue this policy. Some commenters supported CMS' proposal to continue this policy. Other commenters requested that CMS limit the impact of geometric mean cost reductions by a certain percentage to ensure payment stability for low-volume procedures. CMS disagrees with commenters that a percentage-based limitation is necessary and continues the current policy.

In 2018, this policy will continue to apply only to the procedure described by CPT code 0308T in APC 5495 (Level 5 Intraocular Procedures). The final 2018 payment rate for CPT code 0308T is approximately \$17,560.

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

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

Section 1833(t)(6) of the Act provides for temporary additional payments or “transitional pass-through payments” for certain drugs and biologicals. For pass-through payment purposes, radiopharmaceuticals are “drugs.” As required by statute, transitional pass-through payments for a drug or biological can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the product as a hospital outpatient service under Medicare Part B. CMS makes transitional pass-through payment for drugs and biologicals using the average sales price (ASP) + 6 percent methodology. CMS designates 2018 pass-through drugs and biologicals and their designated APCs with status indicator “G” in Addenda A and B to the final rule.

CMS approves pass-through payments quarterly. Prior to 2017, CMS used the rulemaking process to expire pass-through payments at the end of a calendar year. However, beginning with pass-through applications approved in 2017, CMS will expire these payments in the calendar quarter that is not more than 3 years after payment was first made for the hospital outpatient service under Medicare. The 2017 policy change eliminated the variability of the pass-through payment eligibility period based on when a particular application was initially received and also

ensures that new pass-through drugs receive as close to three years of pass-through payment as possible. As the new policy only applies to pass-through drugs first receiving pass-through status beginning in 2017, CMS is continuing to use the rulemaking process to expire pass-through status for drugs first receiving pass-through payments prior to 2017.

For pass-through drugs first receiving pass-through payment beginning in 2017, pass-through payment expired at the end of a calendar quarter that is no more than three years after the pass-through payment began. For pass-through drugs first receiving pass-through payment prior to 2017, CMS is continuing to expire pass-through payments at the end of a calendar year through the rulemaking process

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

CMS proposed to expire pass-through payment on December 31, 2017 for 19 drugs and biologicals that were approved for pass-through status on or before January 1, 2016. Table 69 of the final rule lists the drugs and biologicals with expiring pass-through status. All of these will have received OPPTS pass-through payment for at least 2 years and not more than 3 years by December 31, 2017.

Once pass-through payment expires, drugs and biologicals are either policy packaged⁷ or paid separately if they have per day costs above the packaging threshold of \$120 for 2018. Following past practice, CMS will 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 will pay for these drugs at ASP + 6 percent.

CMS received comments asking that it not expire pass-through status for HCPCS code A9586 (Florbetapir f18) on December 31, 2017 (sold under the brand name Amyvid®)—an FDA-approved radioactive diagnostic agent for Positron Emission Tomography (PET) imaging of the brain to estimate beta-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer’s Disease and other causes of cognitive decline. The commenters said:

- CMS should continue pass-through payment for drugs that are under a “Coverage with Evidence Development (CED)” determination.
- The three-year period for pass-through payment was started by an erroneous payment by Medicare.
- Terminating pass-through payment while CED is in effect will skew trial results.
- CMS should create a new APC for PET procedures with Amyvid® to avoid violating the 2 times rule as the median cost of Amyvid® is approximately \$2,756; over two times the median cost of the PET scan procedure.

CMS disagreed with these comments noting that the one claim that it paid for Amyvid® was from a CED participant in 2015. From the start of the pass-through payment period through

⁷ 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).

December 31, 2017, Medicare will have provided OPPTS pass-through payment for at least 2 years and no more than 3 years by December 31, 2017 as allowed by statute. Providing pass-through payment for drugs covered under CED would not be consistent with the statute that limits the duration of pass-through payment to three years. It rejected creating a separate APC for PET procedures for a number of reasons including that the cost data do not support a separate APC. CMS disagreed that ending pass-through payment will skew CED results as there is nothing to prevent the drug from continuing to be furnished even though it no longer qualifies for pass-through payment.

Several commenters requested that CMS not package payment for Omidria® (described by HCPCS code C9447) upon expiration of pass-through payment status on December 31, 2017, and continue to pay separately for the drug at ASP + 6 percent. The manufacturer of Omidria, reiterated many previous arguments (81 FR 79667) for why CMS should dispense with classifying Omidria as a drug that functions as a surgical supply when used in a surgical procedure. In response, CMS noted that it addressed many of these comments in prior rulemaking (81 FR 79668) and that it will continue to package drugs that function as surgical supplies once pass-through payment ends.

Several commenters requested that CMS adopt a consistent policy of expiring pass-through payment on a quarterly basis for all drugs approved for pass-through payment irrespective of whether they were approved before January 1, 2017 or on or after January 1, 2017 saying that such a policy would not cause harm to providers or beneficiaries. CMS reiterated the policy that it adopted in the 2017 OPPTS/ASC final rule with comment period (81 FR 79662). The quarterly expiration of pass-through payment policy applies to drugs and biologicals newly approved for pass-through payment in 2017. It also noted that once a drug's pass-through payment status period expires, its costs are packaged into the associated procedure(s) with which it is billed. Accordingly, reversing past expirations of pass-through payment could cause payment rates established for a prior year for certain services to be incorrect.

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

CMS proposed to continue pass-through payment status in 2018 for 38 drugs and biologicals. None of these drugs and biologicals will have received OPPTS pass-through payment for at least 2 years and no more than 3 years by December 31, 2017. The APCs and HCPCS codes for these drugs and biologicals approved for pass-through payment status are assigned status indicator "G" in Addenda A and B of the final rule.

CMS proposed 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 proposed to update the ASP on a quarterly basis. If ASP data are not available for a radiopharmaceutical, CMS proposed 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 proposed to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent average wholesale price (AWP).

Public comments supported all of these proposals. The final rule indicates that 50 drugs and biologicals will continue to have pass-through payment status for 2018 or will have been granted pass-through payment status as of January 2018. Drugs and biologicals that will receive pass-through payment are shown in Table 70 of the final rule.

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

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 proposed 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 OPPTS/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 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.

CMS received a few comments that requested separating the costs of the diagnostic radiopharmaceuticals and stress agents from “packaged drug cost” in the APC offset file published with the yearly proposed and final rule. CMS does not believe the commenters’ suggestion is necessary “at this time.” Table 71 of the final rule lists APC to which a policy-packaged drug or radiopharmaceutical offset are applicable in 2018.

The website file providing the amounts and percentages of APC payment associated with packaged implantable devices, policy-packaged drugs, and threshold packaged drugs and biologicals for every OPPTS clinical APC can be found at: [2018 OPPTS APC Offset File](#).

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

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

CMS currently pays for drugs, biologicals, and radiopharmaceuticals that do not have pass-through payment status in one of two ways: packaged into the payment for the associated service or separate payment (individual APCs). Hospitals do not receive a separate payment for packaged items and hospitals may not bill beneficiaries separately for any packaged items; these costs are recognized and paid within the OPPTS payment rate for the associated procedure or service.

Cost Threshold for Packaging of “Threshold-Packaged Drugs”

“Threshold-packaged drugs” under the OPPTS are drugs, non-implantable biologicals and therapeutic radiopharmaceuticals whose packaging status is determined by the packaging threshold. If a drug’s average cost per day exceeds the annually determined packaging threshold, it is separately payable and, if not, it is packaged. For 2017, the packaging threshold for drugs, biologicals, and radiopharmaceuticals that are not new and do not have pass-through status is \$110.

To calculate the 2018 threshold, CMS uses the most recently available four quarter moving average Producer Price Index forecast levels for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from the CMS’ Office of the Actuary to trend the \$50 threshold forward from the third quarter of 2005 to the third quarter of 2018. CMS rounds the resulting dollar amount (\$118.52) to the nearest \$5 increment or \$120. The 2018 packaging threshold will be \$120.

CMS used the following process to determine the 2018 packaging status for all non-pass-through drugs and biologicals that are not policy packaged (with the exception of those drugs and biologicals with multiple HCPCS codes that include different dosages as described below). Using 2016 claims data, CMS calculates, on a HCPCS code-specific basis, the per day cost of all drugs, biologicals, and therapeutic radiopharmaceuticals (collectively called “threshold-packaged” drugs) that had a HCPCS code in 2016 and were paid (either packaged or separately) under the OPPTS.

To calculate the per day cost, CMS uses an estimated payment rate of ASP + 6 percent for each HCPCS code. CMS used the manufacturer-submitted ASP data from the 2nd quarter of 2017 (data that were used for payment purposes in the physician’s office setting effective October 1, 2017). For products that do not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, CMS uses their mean unit cost derived from the 2016 hospital claims data. CMS is packaging products with a per day cost of less than or equal to \$120 and paying separately for items with a per day cost greater than \$120 in 2018.

CMS continues to use quarterly ASP updates as follows:

- 4th quarter of 2016: budget neutrality estimates, packaging determinations, impact analyses, and Addenda A and B for the 2018 OPPTS proposed rule;
- 2nd quarter of 2017: payment rates for HCPCS codes for separately payable drugs and non-implantable biologicals included in Addenda A and B to the 2018 OPPTS final rule; and
- 3rd quarter of 2017: payment rates effective January 1, 2017 for HCPCS codes for separately payable drugs and non-implantable biologicals included in Addenda A and B; these are the same ASP data used to calculate payment rates effective January 1, 2018 for drugs and biologicals furnished in the physician office setting.

ASP-based payment rates for both the OPPTS and physician office settings are updated quarterly using quarterly reported ASP data with a two-quarter lag, and these updates are available on the CMS website. CMS continues its policy of making an annual packaging determination for a HCPCS code in the OPPTS final rule and not updating that code's packaging status during the year. Only HCPCS codes which are identified as separately payable in the 2018 final rule are subject to quarterly updates.

As in past years, CMS is continuing to apply the following policies to determine the 2018 final rule packaging status of a threshold-packaged drug when the drug's packaging status as calculated for the final rule, using more current data, differs from its status in the proposed rule.

- HCPCS codes that were separately payable in 2017, and were proposed for separate payment in 2018, are separately payable in 2018 even if the updated data used for the 2018 final rule indicate per day costs equal to or less than the \$120 threshold.
- HCPCS codes that were packaged in 2017, proposed for separate payment in 2018, and have per day costs equal to or less than \$120 based on the updated data used for the 2018 final rule, are packaged in 2018.
- HCPCS codes for which CMS proposed packaged payment in 2018 but have per day costs greater than \$120, based on the updated data used for the 2018 final rule, are separately payable in 2018.

As happens annually, CMS received comments requesting that it eliminate the packaging threshold and pay separately for all drugs and biologicals described by a unique HCPCS code. CMS rejected this request, referred readers to past responses to this comment and stated that packaging certain items is a fundamental component of a prospective payment system, that updating the packaging threshold is consistent with industry and government practices, and that the PPI for Prescription Drugs is an appropriate mechanism to gauge Part B drug inflation.

Policy Packaged Drugs, Biologicals, and Radiopharmaceuticals

As mentioned briefly earlier, in the OPPTS, CMS packages several categories of drugs, regardless of the cost of the products. CMS refers to these products as "policy-packaged." Policy packaged categories of drugs, biologicals and radiopharmaceuticals include the following:

- Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations (§ 419.2(b)(4));
- Intraoperative items and services (§ 419.2(b)(14));
- Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including but not limited to, diagnostic radiopharmaceuticals, contrast agents, and pharmacologic stress agents (§ 419.2(b)(15)); and
- Drugs and biologicals that function as supplies when used in a surgical procedure (including, but not limited to, skin substitutes and similar products that aid wound healing and implantable biologicals) (§ 419.2(b)(16)).

CMS did not propose any changes to its policy on policy packaged drugs and biologicals but did solicit public comment on its general OPPTS packaging policies. It received comments to allow separate payment for two products that are currently policy packaged:

- Cysview®, a contrast agent used in blue light cystoscopy described earlier.
- Exparel®, an FDA approved post-surgical analgesia drug.

CMS responded that it would not change the policy packaged status of these products because it did not propose to modify its policy-packaged drug policy for drugs that function as a supply when used in a diagnostic test or procedure nor did it receive information from commenters that caused the agency to believe that these products are not drugs that function as a supply.

Some commenters recommended that CMS continue to apply the nuclear medicine procedure radiolabeled product edits to ensure that all packaged costs are included on nuclear medicine claims in order to establish appropriate payment rates in the future. CMS rejected this comment as unnecessary as edits were in place between 2008 and 2014 creating sufficient time for hospitals to gain experience reporting procedures involving radiolabeled products and to grow accustomed to ensuring that they code and report charges so that their claims fully and appropriately reflect the costs of these products.

One commenter recommended that CMS use ASP information, when voluntarily reported by the manufacturer, as a better price input to account for the packaged costs of diagnostic radiopharmaceuticals. CMS disagreed with this recommendation as being inconsistent with its policy of using hospital-reported data to determine APC costs for policy-packaged and other costs.

High/Low Cost Threshold for Packaged Skin Substitutes

In the 2014 OPPTS final rule, CMS unconditionally packaged skin substitute products into the associated surgical procedures, including a methodology that divided skin substitutes into high- and low-cost groups for packaging purposes. Skin substitutes in the high-cost category are reported with the skin substitute application CPT codes and skin substitutes in the low-cost category are reported with the analogous skin substitute HCPCS C-codes. CMS continued this policy, with modifications, in 2015 and 2016. For a discussion of the 2016 high-cost/low-cost

methodology, CMS refers readers to the 2016 OPPTS/ASC final rule with comment period (80 FR 70434 through 70435).

For 2018, as in 2017, CMS is determining the high-/low-cost status for each skin substitute product based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold. Based on 2016 claims data available, CMS calculated a 2018 MUC threshold of \$46 per cm² (rounded to the nearest \$1) and a 2018 PDC threshold of \$861 (rounded to the nearest \$1).

CMS' policy is to assign skin substitutes with pass-through payment status to the high cost category. However, no skin substitutes will have pass-through payment status for 2018. Skin substitutes with pricing information but without claims data to calculate a MUC or PDC are assigned to either the high-cost or low-cost category based on the product's ASP + 6 percent payment rate as compared to the MUC threshold. If ASP is not available, CMS uses WAC + 6 percent or 95 percent of AWP to assign a product to either the high-cost or low-cost category. New skin substitutes without pricing information are assigned to the low-cost category until pricing information is available to compare to the 2018 MUC threshold.

In response to concerns about fluctuation in both the MUC threshold and PDC threshold from year-to-year which can result in reassignment of a skin substitute from the high-cost to the low-cost group and result in a payment difference of approximately \$1,000, CMS proposed and is finalizing a policy 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 2018 MUC or PDC thresholds. CMS' analysis has found that 10 skin substitute products that would have otherwise been assigned to the low-cost group for 2018 will instead be assigned to the high-cost group for the final rule. Table 72 in the 2018 final rule shows the high-/low-cost status for each skin substitute product in 2018. Skin substitute products identified with an "*" in Table 72 of the final rule are products that were assigned to the high-cost group for 2017 and are continuing to be included in the high-cost group for 2018 despite having costs that do not exceed the MUC or PDC threshold to be included in the high-cost group.

CMS is adopting this policy for 2018 only. In the proposed rule, CMS requested comments on methodologies to calculate the pricing thresholds as well as the payment groupings that recognize a low-cost group and a high-cost group for 2019 and subsequent years. CMS indicated particular interest in suggestions that are based on analysis of Medicare claims data from hospital outpatient departments that might better promote improved payment stability for skin substitute products under the OPPTS.

CMS summarized comments that it received on this proposal ranging from:

- improving the quality of claims data CMS uses to determine the MUC and PDC thresholds;
- using ASP pricing data for the skin substitutes either in addition to or in place of claims data to determine the MUC and PDC thresholds;
- limiting annual changes to the MUC and PDC thresholds to the change in the consumer price index;

- adding more cost groups where skin substitutes may be assigned;
- ending the packaging of skin substitute products in general and ending packaging costs for add-on codes into the primary service codes for skin substitute procedures;
- establishing device offsets when the cost of a skin substitute used in a procedure is more than 40 percent of total cost of the procedure; and
- reducing incentives that favor the use of more expensive skin substitutes or products that require an excessive number of applications.

Commenters generally supported continuing to assign a skin substitute to the high-cost group in 2018 if it was assigned to the high-cost group in 2017. One commenter opposed the proposal stating that it would lead to product overuse. CMS responded to these comments indicating that its purpose in continuing a product in the high-cost group despite not meeting the cost thresholds is to ensure price stability while CMS decides on other policy options to address long-term policy concerns about its skin-substitute policy. CMS will continue to study issues related to the payment of skin substitutes and take these comments into consideration for future rulemaking.

One commenter requested that CMS continue pass-through payment status for PuraPly and PuraPly antimic saying that it would be consistent with CMS' goal of maintaining price stability for skin substitute products. CMS rejected this comment saying that extending pass-through payment for PuraPly and PuraPly antimic for a fourth year would be contrary to the statute.

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

For 2018, CMS is continuing its policy unchanged 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. CMS did not receive any comments on this issue. The codes to which this policy applies, and their packaging status, are listed in Table 73 of the final rule.

2. 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 proposed to continue paying separately payable drugs and biologicals at ASP + 6 percent in 2018. Public comments supported the proposal that CMS is finalizing without change. This policy does not apply to drugs and biologicals acquired with a 340B discount. CMS' policy on drugs acquired under the 340B program is described below.

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

The payment rates shown for drugs and biologicals in Addenda A and B of the final 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). Payment rates for drugs and biologicals in Addenda A and B of the final rule for which there was no ASP information available for December 2016 are based on mean unit cost in the available 2016 claims data. If ASP information becomes available for payment for the quarter beginning in January 2018, CMS will pay for these drugs and biologicals based on the newly available ASP information. For drugs and biologicals that have ASP information available for the proposed rule or final rule that do not have ASP information available for the quarter beginning in January 2018, payment will be paid based on mean unit cost data derived from 2016 hospital claims.

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 proposed to continue this same payment policy. In the 2018 Medicare Physician Fee Schedule Proposed Rule, CMS requested public comment on its policies for coding and payment of biosimilar biological products. CMS received public comments on its biosimilar coding policy and how it interacts with its 340B proposal. CMS indicated that it addressed public comments on the biosimilar coding policy in 2018 Medicare Physician Fee Schedule Final rule and comments on the 340B policy with respect to biosimilars in section V.B.7 of the final rule which is summarized further below.

3. Payment Policy for Therapeutic Radiopharmaceuticals

For 2018, CMS is continuing 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. Reporting ASP information remains optional for manufacturers. For therapeutic radiopharmaceuticals for which ASP data are unavailable, CMS will determine 2018 payment rates based on 2016 geometric mean unit cost data derived from 2016 hospital claims. Some public commenters requested that CMS examine ways to compensate hospitals for their documented higher overhead and handling costs associated with radiopharmaceuticals. CMS responded that it continues to believe that the payment rate of ASP + 6 percent is appropriate to provide payment for both the radiopharmaceutical’s acquisition cost and any associated nuclear medicine handling and compounding costs incurred by the hospital pharmacy.

4. Payment Adjustment Policy for Radioisotopes Derived from Non-Highly Enriched Uranium (HEU) Sources⁸

For 2013, CMS finalized a policy to provide an additional payment of \$10 for the marginal cost of radioisotopes produced by non-HEU sources. CMS indicated that it would evaluate annually the continuing need for and the amount of this transitional payment. For 2018, CMS reassessed the \$10 additional payment amount and did not identify any new information that caused it to make a change. CMS rejected suggestions for indexing the \$10 payment to the rate of inflation (on the basis that the payment is intended to be transitional) and assessing the rate of utilization of non-HEU in response to the collection of beneficiary coinsurance (as payment of coinsurance is mandatory and it is optional for the hospital to bill for non-HEU radioisotopes). CMS indicated that it will consider including this additional payment for non-HEU in its annual “Drug Blood Brachy Cost statistics” file as suggested in the public comments.

5. Payment for Blood Clotting Factors

For 2018, CMS is continuing to pay for blood clotting factors using the same methodology that it uses to pay for other non-pass-through separately payable drugs and biologicals under the OPPTS, i.e. ASP + 6 percent. When blood clotting factors are provided in physicians’ offices under Medicare Part B and in other Medicare settings like the hospital outpatient department, Medicare also pays a furnishing fee. 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 is updating 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 will not be available for the final rule. CMS will announce the updated fee through program instructions and will post the updated rate on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html>.

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

CMS is continuing the same payment policy for 2018 as 2017 for non-pass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPTS hospital claims data. In priority order, CMS will pay for these products using ASP + 6 percent if ASP is reported, WAC + 6 percent⁹ 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 OPPTS hospital claims data is listed in Addendum B of the final rule.

⁸ Highly-enriched uranium is weapons grade uranium used in atomic weapons. CMS is providing the additional payment for non-HEU to assist with eliminating domestic reliance on weapons grade uranium for medical purposes.

⁹ 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 OPPTS.”

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

The below table compares the proposed and final rule policies. A more detailed summary of the final rule provisions is at the end of this section.

Comparison of Proposed and Final Rule Policies

Issue	Proposed Rule	Final Rule
Payment Rate for 340B Drugs	ASP - 22.5%.	Unchanged.
Modifier	Required for Drugs NOT Purchased under the 340B Program.	Required ONLY for Drugs Purchased under the 340B Program and may be used for packaged drugs and drugs on pass-through status without triggering the payment adjustment.
Drug Exclusions	Drugs on pass-through status, vaccines.	Unchanged.
Biosimilars	Included but only the first biosimilar to a given reference product can receive pass-through.	Included. Final rule modifies pass-through policy such that all biosimilars can receive pass-through.
Rural SCHs, children's hospitals and IPPS-exempt cancer hospitals	Included.	Exempt but hospitals are required to submit information-only modifier when billing for a drug acquired under the 340B Program. Modifier will NOT trigger a payment at ASP - 22.5%.
Budget Neutrality	\$900 million savings estimate applied to the OPPS conversion factor (not modeled in payment impact or applied to the proposed rule conversion factor.) Solicited comments on alternatives.	\$1.6 billion savings estimate applied to the OPPS conversion factor.

1. Background

All hospitals paid under the OPPS are currently paid the same rate for separately payable drugs (ASP + 6 percent). The rate does not vary based on the differential prices at which hospitals may acquire the drugs. Medicare beneficiaries are liable for 20 percent of the OPPS payment rate

which is currently ASP + 6 percent regardless of whether the hospital purchased the drug at a discounted rate.

The 340B Drug Discount Program allows eligible hospitals to purchase certain “covered outpatient drugs” at discounted prices from drug manufacturers. Eligible hospitals are those with a Medicare disproportionate share hospital (DSH) percentage above 11.75 percent. The ACA expanded 340B eligibility to other hospitals paid under the OPPTS: sole community hospitals with a DSH adjustment percentage of 8.0 percent or higher, rural referral centers with a DSH adjustment percentage of 8.0 percent or higher, and freestanding cancer hospitals with a DSH adjustment percentage above 11.75 percent. The ACA also expanded the 340B program to CAHs which are not paid under the OPPTS and are not subject payment under the ASP methodology. To be 340B eligible, DSH hospitals must be owned by a State or local government, or be a nonprofit hospital under contract with a State or local government to provide services to low-income patients who are not eligible for Medicare or Medicaid.

CMS indicates that several recent studies and reports on Medicare Part B payments for 340B purchased drugs highlight a difference in Medicare Part B drug spending between 340B hospitals and non-340B hospitals as well as varying differences in the amount by which the Part B payment exceeds the drug acquisition cost and some instances where the patient copayment exceeds the price at which the hospital acquired the drug. The final rule provides excerpts from Medicare Payment Advisory Commission (MedPAC)¹⁰, the Office of the Inspector General (OIG)¹¹ and General Accountability Office (GAO)¹² reports on:

- the magnitude of discounts hospitals received under the 340B program;
- the profitability to hospitals of furnishing 340B drugs;
- differential utilization and Medicare spending for oncology drugs and other drugs between 340B hospitals and other hospitals; and
- differential Medicare drug spending per beneficiary between 340B hospitals and other hospitals.

In 2009, CMS requested comments on whether Medicare should pay 340B hospitals for separately payable drugs differently than other hospitals. Since that time:

- The ACA expanded the 340B program to additional types of hospitals and the program has grown to include more hospitals generally (from 583 in 2005 to 1,365 in 2010 and 2,140 in 2014 according to MedPAC in its May 2015 Report);¹³
- MedPAC (March, 2016)¹⁴ recommended legislation to reduce payment rates for 340B hospitals’ separately payable 340B drugs by 10 percent of the ASP and direct the program

¹⁰ MedPAC. Report to the Congress: Overview of the 340B Drug Pricing Program. May 2015.

¹¹ OIG. “Part B Payment for 340B Purchased Drugs OEI-12-14-00030.” November 2015.

¹² GAO. “Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals GAO-15-442.” June 2015.

¹³ The increase from 2010 to 2014 was driven by growth in the number of CAHs and other types of hospitals that became eligible for 340B in 2010 through the ACA. CAHs are paid 101 percent of reasonable costs. To the extent that CAHs receive 340B discounts, it will reduce their reasonable costs and payments from Medicare.

¹⁴ MedPAC. March 2016 Report to the Congress: Medicare Payment Policy. March 2016.

savings from reducing Part B drug payment rates to the Part A pool of funds allocated to hospitals for uncompensated care pool; and

- OIG (November 2015) described three shared-savings arrangements that would have resulted in Medicare Part B savings of \$162 million to \$1.1 billion in 2013 while still providing covered entities with incentives to purchase those drugs through the 340B Program.

Analysis in several of these reports notes limitations in estimating 340B purchased drug acquisition costs and the inability to identify which drugs were purchased through the 340B program within Medicare claims data.

CMS believes it is timely to reexamine its policy of paying for separately payable drugs under the OPPTS at ASP + 6 percent to 340B hospitals that have acquired those drugs at significantly discounted rates. CMS expresses particular concern about the rising prices of certain drugs and the effect on Medicare beneficiary coinsurance, especially on low-income seniors. It is also concerned that the current payment methodology may lead to unnecessary utilization and potential overutilization of separately payable drugs.

2. OPPTS Payment Rate for 340B Purchased Drugs

CMS' goal in making changes to OPPTS payment for separately payable drugs is to make Medicare payment for those drugs more aligned with the resources expended by hospitals to acquire such drugs. CMS notes that the intent of the 340B program is to allow covered entities, including eligible hospitals, to stretch scarce resources while continuing to provide access to care. CMS proposed to limit its policy to separately payable drugs under the OPPTS; thus, the policy would not apply to CAHs that are paid based on 101 percent of reasonable costs under a separate provision of the statute. CMS would also exclude the following:

- Drugs on pass-through status; and
- Vaccines (which are excluded from the 340B program).

CMS finalized proposals to include drugs on pass-through status and vaccines. In the final rule, CMS also excludes rural SCHs, children's hospitals and IPPS exempt cancer hospitals from the policy. CMS solicited comment on whether other types of drugs, such as blood clotting factors, should be excluded from the reduced payment. The final rule does not exempt any specific type of drug product from the policy.

To address current data limitations that inhibit identification of which drugs were acquired under the 340B program in Medicare OPPTS claims data, CMS proposed 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. In response to commenters, CMS is not adopting its proposed policy and instead will only require this modifier when billing for drugs that are acquired under the 340B program. Rural SCHs, children's hospitals and IPPS exempt cancer hospitals will be required to use an information-only modifier when billing for drugs acquired under the 340B program. The modifier will not trigger the ASP - 22.5 percent adjustment for these hospital

types.¹⁵ Further details regarding this modifier are in the final rule and more information will be furnished in 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 proposed and is adopting an average discounted price of 22.5 percent of the ASP for non-pass-through separately payable drugs purchased under the 340B program, as estimated by MedPAC.¹⁶ CMS notes MedPAC's analysis is detailed and can be replicated by interested parties.

CMS cites section 1833(t)(14)(A)(iii)(II) the Act as its authority for making payment at ASP - 22.5 percent for drugs acquired under the 340B program. This section of the law allows the Secretary to pay separately payable drugs under the OPPTS at ASP + 6 percent when hospital acquisition cost data are not available "as calculated and adjusted by the Secretary as necessary for purposes of this paragraph." CMS is applying section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals as it has in past years. However, it is exercising the Secretary's authority to adjust the applicable payment rate as necessary for separately payable drugs and biologicals (other than drugs on pass-through status and vaccines) acquired under the 340B program by reducing ASP by 22.5 percent which the agency believes better represents the average acquisition cost for these drugs and biologicals.

CMS believes that using an average discount to set payment rates for separately payable drugs will achieve the dual goals of (1) adjusting payments to better reflect resources expended to acquire such drugs while (2) also protecting the confidential nature of discounts applied to a specific drug. CMS does not believe that Medicare beneficiaries should be liable for a copayment rate that is tied to the current methodology of ASP + 6 percent when the actual cost to the hospital to purchase the drug is much lower.

The final rule indicates that MedPAC believes its analysis is conservative and the actual average discount experienced by 340B hospitals is likely much higher than 22.5 percent. CMS indicates that GAO estimates that discounts under 340B range from 20 to 50 percent.¹⁷ Other factors that CMS uses to support its contention that the 22.5 percent reduction from ASP is likely a lower bound include:

- In the absence of the actual discounts, MedPAC found that 22.5 percent reflects the average minimum discount that 340B hospitals receive;
- Participation in the "Prime Vendor Program" (PVP) allows hospitals to receive "sub-ceiling prices" below the ceiling prices available to hospitals in the regular 340B program;

¹⁵ The rule clearly states that CAHs and hospitals paid under the Maryland waiver DO NOT report modifier "JG" that triggers payment for separately payable drugs at ASP - 22.5 percent. With respect to informational modifier "TB", the rule makes no statement as to whether it is required from CAHs and Maryland hospitals. It says "rural SCHs, children's hospitals and PPS-exempt cancer hospitals... will be required to report information modifier "TB" for 340B-acquired drugs, and will continue to be paid ASP + 6 percent."

¹⁶ MedPAC's May 2015 Report to Congress, page 7.

¹⁷ GAO. "Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement GAO-11-836" September 2011.

- Substitution of ASP (which includes additional rebates) for AMP could make the total discounts higher; and
- Drugs with pass-through status were included rather than excluded from the MedPAC analysis.

3. Comment Solicitation on Additional 340B Considerations

CMS requested stakeholder input in the proposed rule with regard to MedPAC's May 2015 analysis and the resulting estimate of ASP - 22.5 percent as the payment rate for separately payable, non-pass-through OPPTS drugs purchased under the 340B drug discount program in 2018 including:

- Whether a different discounted rate should be adopted;
- Whether paying ASP - 22.5 percent for 340B purchased drugs should be phased in over time (such as over a period of 2 to 3 years);
- Whether to identify the actual acquisition costs that each hospital incurs rather than using an average minimum discounted rate that would apply uniformly across all 340B hospitals;
- Whether to require 340B hospitals to report their acquisition costs in addition to charges for each drug on the Medicare claim;
- How to maintain confidentiality of 340B ceiling prices where the acquisition cost equals the ceiling price for a drug;
- Whether, due to access to care issues, exceptions should be granted to certain groups of hospitals, such as those with special adjustments under the OPPTS (for example, rural SCH or IPPTS-exempt cancer hospitals) if a policy were adopted to adjust OPPTS payments to 340B participating hospitals;
- Whether other types of drugs, such as blood clotting factors, should also be excluded from the reduced payment; and
- Whether hospital-owned or affiliated ASCs should have access to 340B discounted drugs.

CMS received the following comments:

- One commenter recommended that CMS establish specific guidelines and procedures for stakeholders to request exemptions for certain groups of hospitals.
- Commenters requested excluding the following products from the policy: blood clotting factors (because individuals with bleeding disorders are expensive to treat) and radiopharmaceuticals (because it is not possible for the manufacturer to accurately report final dose and pricing information).
- One commenter opposed transitioning the policy over 2 to 3 years arguing hospitals would use that time to "aggressively strong-arm independent community oncology practices to sell out to them."
- Commenters indicated that acquisition cost billing would require investment in expensive software upgrades, obtaining a second charge master, or devising burdensome manual workarounds. Another commenter said acquisition cost billing is unneeded as hospital cost reports already reflect the 340B acquisition cost based on expenses reported in the pharmacy cost center.

- Children’s hospitals, IPPS-exempt cancer hospitals, Rural Referral Centers (RRC) and Rural SCHs requested to be exempted from the policy for a variety of different reasons.

CMS responded that, to the extent that blood clotting factors and radiopharmaceuticals are covered outpatient drugs purchased under the 340B Program, it believes that the OPPTS payment rate for these drugs should account for the discounted rate at which they were purchased. CMS agreed that it is not necessary phase in the reduced payment and said it would take the comments regarding acquisition cost billing into account for future policymaking. It noted that several state Medicaid programs require reporting of actual acquisition cost for 340B drugs so the magnitude of the challenges to implement may be less than the commenter suggests.

CMS is exempting rural SCHs, children’s hospitals and IPPS-exempt cancer hospitals from the policy. In response to comments, CMS indicated that more study is needed before applying the adjustment to rural SCHs that receive a special 7.1 percent adjustment to their OPPTS payments for higher costs. Unlike rural SCHs, RRCs do not receive any special payments and will be subject to the policy.

Children’s hospitals and IPPS-exempt cancer hospitals are being exempted from the policy because these hospitals receive transitional outpatient payments (TOPs). As these hospitals are permanently held harmless to their “pre-BBA amount,” any reduction in payment for 340B drugs would potentially be paid back to these hospitals at cost report settlement through TOPs. While CMS is exempting rural SCHs, children’s and IPPS-exempt cancer hospitals from the 340B drug payment reduction, these hospitals are still being required to report informational modifier “TB” for tracking and monitoring purposes when they furnish drugs under the 340B program because CMS believes it is important to collect information on which drugs being billed to Medicare were acquired under the 340B Program.

4. General Policy Comments

Organizations representing physician oncology practices, pharmaceutical research and manufacturing companies, a large network of community-based oncology practices, and several individual Medicare beneficiaries, supported the proposal indicating that the policy will:

- Help address the growth of the 340B Program, stem physician practice consolidation with hospitals that has resulted in a 30 percent shift in the site of service for chemotherapy administration from the physician office setting to the more-costly hospital outpatient setting;
- Preserve patient access to community-based care and reduce drug costs for seniors;
- Control prices for drugs as drug manufacturers must offset the cost of the discounts with higher drug prices; and
- Continue to allow substantial savings for hospitals to use to provide direct and indirect patient benefits.

The Community Oncology Alliance supported the proposal and provided a report showing some 340B hospitals offered little charity care and turned away some patients in need because those

patients were uninsured.¹⁸ Some commenters urged HHS, specifically CMS and HRSA, to work with Congress to reform the 340B Program. One commenter requested greater transparency and accountability on how 340B savings are being used, as well as a specific definition of the “340B patient,” which the commenter noted would require a legislative change.

Other comments provided various opinions as to whether the proposal would achieve CMS’ goal of lowering drug prices and reducing beneficiary out-of-pocket costs:

- Some commenters stated that the proposal has the potential to alleviate the financial burden that high-cost drugs place on patients;¹⁹
- Other commenters stated that, because the proposal does not address the issue of expansion of 340B entities, the volume of 340B discounted drugs, and the affordability of drugs, especially oncology drugs, CMS should not finalize the proposal;
- One commenter said that it is imperative to ensure that an across-the-board reduction actually reflects the size of the 340B discount to avoid creating barriers to access, should both physician practices and the hospital outpatient departments be unable to cover actual acquisition costs.

Comments from organizations representing 340B-eligible safety-net hospitals in urban and rural areas and teaching hospitals opposed the policy make the following points:

- The Secretary lacks statutory authority to impose such a large reduction in the payment rate for 340B drugs,
- The proposal will effectively eviscerate the 340B Program by taking money intended for services to low-income patients and giving it to hospitals that don’t have that mission.
- Medicare payment cuts of this magnitude would greatly “undermine 340B hospitals’ ability to continue programs designed to improve access to services—the very goal of the 340B Program.”
- Rather than “punitively targeting” 340B safety-net hospitals serving vulnerable patients, including those in rural areas, CMS should instead redirect its efforts to halt the “unchecked, unsustainable increases” in the price of drugs.

¹⁸ Community Oncology Alliance. Report: “How Abuse of the 340B Program is Hurting Patients” September 2017. Available at: https://www.communityoncology.org/wpcontent/uploads/2017/09/COA_340B-PatientStories_FINAL.pdf.

¹⁹ Of note, CMS will be pay for separately payable drugs at ASP + 6 percent in physician offices and when hospitals do not acquire drugs under the 340B program. It will pay at ASP - 22.5 percent at a hospital when separately payable drugs are acquired under the 340B program. As a result, beneficiary coinsurance will be less for separately payable drugs acquired under the 340B program in a hospital than in a hospital that does not acquire the drugs under the 340B program or a physician’s office.

- Commenters disputed that 340B hospitals may be unnecessarily prescribing more drugs and/or more expensive drugs relative to non-340B hospitals. These commenters cited other studies in an effort to refute the evidence presented in the proposed rule.^{20 21}
- Medicare beneficiaries, including dual-eligible Medicare beneficiaries, would not directly benefit from a lowered drug copayment amount. The commenters noted that many beneficiaries have supplemental insurance that covers their out-of-pocket drug costs, in whole or in part.

CMS' general response to all of these comments was to acknowledge them; thank those supporting the proposal; and reiterate its justification for adopting the policy—the current OPPTS payment rate of ASP + 6 percent significantly exceeds the discounts received for covered outpatient drugs by hospitals enrolled in the 340B Program. The evidence it presented in the proposed rule supports that hospitals receiving 340B discounts bill for more drugs than hospitals that do not receive these discounts.

In response to comments about beneficiary liability, CMS said while many Medicare beneficiaries may have supplemental coverage that covers some or all of their out-of-pocket expenses, not all beneficiaries have such coverage. This policy will lower both the amount that a beneficiary is responsible to pay as well as the amount that any supplemental insurance, including the Medicaid program, will pay on behalf of the beneficiary. It further added that beneficiaries may pay more in the hospital setting as beneficiaries are both liable for cost-sharing for drugs they receive and a hospital “facility fee” that they do not have to pay when the service is provided outside the hospital.

5. Comments on the Statutory Authority for the 340B Payment Proposal

Many commenters challenged the statutory authority of various aspects of the proposal. This summary selectively highlights several key arguments:

Arguments Regarding Whether There is Statutory Authority for the Adjustment

Section 1833(t)(14)(A)(iii)(II) of the Act authorizes CMS to “calculate and adjust” ASP. The plain and ordinary meaning of the terms “calculate” and “adjust” express a limited and circumscribed authority to set the payment rate which restricts the agency to mathematically determining “an appropriate, slight alteration.”

- The Secretary’s limited adjustment authority under section 1833(t)(14)(A) (iii)(II) of the Act is an “explicit statutory directive” that the Secretary is must follow. The Secretary does not have authority to rewrite the statute. *Pettibone Corp. v. United States*, 34 F.3d 536, 541 (7th

²⁰ Dobson Davanzo & Associates, Update to a 2012 Analysis of 340B Disproportionate Share Hospital Services Delivered to Vulnerable Patient Populations Eligibility Criteria for 340B DSH Hospitals Continue to Appropriately Target Safety Net Hospitals (Nov. 15, 2016). Available at: http://www.340bhealth.org/files/Update_Report_FINAL_11.15.16.pdf.

²¹ Dobson DaVanzo, Analysis of the Proportion of 340B DSH Hospital Services Delivered to Low-Income Oncology Drug Recipients Compared to Non-340B Provider (2017). Available at: <http://www.340bhealth.org/files/LowIncomeOncology.pdf>.

Cir. 1994) (an agency’s authority to interpret a statute “must not be confused with a power to rewrite”).

- Subclause (I) of section 1833(t)(14)(A)(iii) establishes that the payment rate be set to the average acquisition cost of the drug taking into account hospital acquisition cost survey data found in other parts of paragraph (14). Considered in its entire context, the statute does not that does not provide the adjustment authority the Secretary proposes to use. The comment refers the agency to *Roberts v. Sea-Land Servs., Inc.*, 566 U.S. 93, 101 (2012) (Statutory provisions “...cannot be construed in a vacuum. It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme”).

CMS’s general response to these arguments is that it has broad discretion to adjust payments for drugs including taking into account when certain drugs are acquired at a significant discount under section 1833(t)(14)(A)(iii)(II) of the Act. The agency disagrees that the Secretary’s authority under section 1834(t)(14)(A)(iii)(II) of the Act to “calculate and adjust” drugs rates as necessary is limited to minor changes. CMS’ response further indicated that hospitals have their own data regarding their own acquisition costs, as well as data regarding OPPTS payment rates for drugs yet did not suggest an alternative minimum discount giving CMS confidence that the 22.5 percent discount is a lower bound and that the community does not believe there is some alternative discount that would be more accurate. CMS used this point to further argue that its policy does not “eviscerate” the 340B program as some commenters asserted because hospitals will continue to retain a portion of the discount to furnish services to low income patients.

Authority to Vary Payment by Hospital Group

- Only subparagraph (I), and not subparagraph (II), of section 1833(t)(14)(A)(iii) of the Act permits CMS to vary payment “by hospital group.” By including “by hospital group” in subparagraph (I) and omitting it in subparagraph (II), Congress expressed its intent that CMS may not vary prices by hospital group under subparagraph (II).
- The subparagraph (II) methodology must apply to “the drug” and CMS may not vary payment for the same drug based upon the type of hospital that furnishes it.

CMS acknowledged that explicit authority to vary payment rates by hospital group is in subclause (I) of section 1833(t)(14)(A)(iii) of the Act, not subclause (II) but stated authority under subclause (II) to “calculate and adjust” drug payments “as necessary for purposes of this paragraph” gives the Secretary broad discretion to adjust payments for drugs according to whether or not certain drugs are acquired at a significant discount for Medicare beneficiaries. Further, the policy is not adjusting payment by hospital group but by whether the drug is itself is acquired under the 340B program. CMS further argued that “it would be odd” for the statute to give the Secretary broad discretion throughout section 1833(t)(14) to determine prices for separately payable drugs and then assume the Secretary is foreclosed from taking into account considerations specified through section 1833(t)(14) from being applied in section 1833(t)(14)(A)(iii)(II).

Authority to Establish Payment Rates in the Absence of Acquisition Cost Survey Data and Authority to Base Payment on an Average Discount

- The Secretary ignored the statutory directive in section 1833(t)(14) of the Act to set payment rates at the average acquisition cost for specific drugs and not to use averages for all drugs.
- The Secretary impermissibly discards Congress' requirement that any survey data used in setting payment rates must be derived from statistically rigorous surveys by using MedPAC's estimate of average discounts as a proxy or replacement for the surveys required under subsection (iii)(I).

CMS indicated that unlike subclause (I), subclause (II) does not require taking survey data into account for determining average price for the drug in the year. Section 1833(t)(14)(A)(iii)(II) of the Act grants the Secretary the authority to calculate and adjust rates as necessary in the absence of acquisition cost. Because CMS is not using authority under subclause (I), CMS disagrees with the commenter's suggestion that the Secretary is using the MedPAC analysis to stand in the place of the survey requirement under subclause (I).

Current Agency View Contrasts with Longstanding Practice.

Public comments argued the proposal contrasts sharply with the agency's previous view and longstanding practice under section 1833(t)(14) of the Act that the statutory default of ASP+6 percent "requires no further adjustment" because it "represents the combined acquisition and pharmacy overhead payment for drugs and biologicals." CMS responded that the fact that the agency has not historically utilized its authority under section 1833(t)(14)(A)(iii)(II) of the Act to adjust payment amounts for separately payable 340B-acquired drugs does not mean the agency is permanently barred from adjusting these payments where it has a reasoned explanation for doing so.

Violation of Section 340B of the Public Health Service Act.

The proposed policy would transfer 340B discounts from hospitals eligible for the program and transfer them to hospitals ineligible for the 340B program. By granting 340B eligibility only to Medicare hospitals that serve large numbers of low-income or other underprivileged patients, Congress did not intend for non-340B hospitals to benefit from 340B drug discounts as is occurring under CMS' proposed policy. Congress has had ample opportunity to amend the Medicare statute governing Part B payments and/or the 340B statute to expressly permit CMS to reduce Medicare payments to 340B hospitals, but has not done so. The proposed cut to 340B hospitals is contrary to Congress's intent for the 340B Program to enable safety-net providers to reach more patients and furnish more comprehensive services.

CMS responded that there are no references in section 1833(t) of the Act that govern Medicare OPPTS payments and section 340B of the Public Health Service Act to each other—each statute stands on its own and neither is hindered or rendered null and void by the other. Congress' silence on this issue should not be viewed as a constraint on the broad authority conferred to the Secretary under section 1833(t) of the Act to establish payment rates under the OPPTS. CMS remains interested in exploring ways to better target 340B savings to hospitals that serve low-income and uninsured patients to address concerns that 340B discounts are increasing payments for non-drug OPPTS services for all hospitals.

Proposal is Procedurally Defective and Inconsistent with HOP Recommendations.

Commenters argued that the Secretary acted contrary to the statute by not consulting with the HOP in accordance with section 1833(t)(9)(A) of the Act prior to making the proposal. Nevertheless, at the August 21, 2017 meeting of the HOP, the Panel recommended CMS not finalize the proposal. Further, the proposal was “procedurally defective” because it was solely articulated through preamble and did not propose to amend the Code of Federal Regulations (CFR) when altering the substantive standards for payment.²²

CMS responded that section 1833(t)(9)(A) of the Act does not impose an obligation on the Secretary to consult with the HOP Panel *prior* to issuing a notice of proposed rulemaking nor does it require the Secretary to adopt the Panel’s recommendation(s). The HOP did meet after the proposed rule publication and did make recommendations on this issue which were taken into consideration in the development of the final rule. CMS disagreed that it is out of compliance with section 1871 of the Act and the APA noting that it is going through notice and comment rulemaking procedures to adopt its policy. As the rates for separately payable drugs have not been established in the CFR, there are no CFR provisions to modify.

6. Comments in Other Areas

Biosimilar Biological Products. One commenter requested that CMS use its equitable adjustment authority to apply the 340B policy to biosimilars on pass-through. The commenter indicated that CMS’ proposed policy will disadvantage a reference product relative to a biosimilar if a biosimilar is paid ASP + 6 percent of the ASP of the reference product while the reference product is paid ASP - 22.5 percent. Further, CMS’ policy of only making pass-through payment for the first biosimilar will apply the payment reduction to the reference product and all subsequent biosimilars favoring the first biosimilar to the detriment of the reference product and subsequent biosimilars. The commenter estimated that if the 340B drug policy is implemented as proposed, up to \$50 million of any savings could be lost due to hospitals switching to the biosimilar biological product receiving pass-through payment. Another commenter requested that CMS exclude biosimilar biological products from the proposed payment adjustment until such time as the biosimilar biological product market is better established.

CMS rejected the comments to apply the 340B policy to biosimilars receiving pass-through payment because section 1833(t)(6)(D)(i) of the Act provides for an explicit payment for drugs and biologicals eligible for pass-through payment. However, CMS is adopting a change in policy to allow pass-through payment for each FDA-approved biosimilar instead of only the first biosimilar for a particular reference product. Biosimilar biological products that are not on pass-through payment will be paid ASP - 22.5 percent of the reference product.

²² Section 1871 of the Social Security Act (42 U.S.C. 1395hh). “No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation...”

Nonexcepted Off-Campus Hospital Outpatient Departments. Commenters requested that CMS also apply the alternative payment methodology for 340B drugs furnished in nonexcepted off-campus PBDs to avoid creating financial incentives for hospitals to reallocate services to the site of care that pays the highest rate for an item or service. CMS responded that it will continue to monitor the billing patterns of claims submitted by nonexcepted off-campus outpatient PBDs noting that its policy only applies to covered outpatient department services which does not include services furnished in non-excepted off-campus hospital OPDs which are paid for separately payable drugs at ASP + 6 percent in accordance with section 1847A of the Act. CMS may consider adopting the requested policy in 2019 notice-and-comment rulemaking.

7. Payment Impact

Based on 2016 claims data, the total OPSS Part B drug payment is approximately \$10.2 billion. For the final rule, CMS uses the HRSA covered entity database to identify 1,338 OPSS hospitals participating in the 340B program. Of these, 270 were rural SCHs, 47 were children's hospitals, and 3 were PPS-exempt cancer hospitals. CMS does not assume any changes in the number of 340B hospitals or changes in volume of drugs purchased using a 340B discount. Using assumptions outlined in the final rule, CMS estimates OPSS payments for separately payable drugs, including beneficiary copayments, will decrease by approximately \$1.6 billion under the final rule policy.

The final rule indicates that there are potential offsetting factors, including possible changes in provider behavior and overall market changes that would likely lower the impact of the payment reduction. As a result, CMS indicates that it may need to make an adjustment in future years to revise the conversion factor once it has more accurate data on drugs purchased with a 340B discount within the OPSS, similar to the adjustment it made for the clinical diagnostic laboratory test packaging policy in the 2016 OPSS/ASC final rule with comment period (80 FR 70352 through 70357).

CMS proposed to include reduced payments for separately payable drugs and biologicals purchased under the 340B program in budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act. CMS notes that the budget neutral weight scaler is not applied in determining payments for these separately paid drugs and biologicals purchased under the 340B program. CMS solicited 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 OPSS;
- Increase payments generally under Part B (that is, other than services paid under the OPSS);
- 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
- Whether the redistribution of savings associated with this proposal would result in unnecessary increases in the volume of covered services paid under the OPSS which should be adjusted in accordance with section 1833(t)(2)(F) of the Act.

Public commenters generally disagreed with applying the budget neutrality adjustment for 340B savings in any other way than through an adjustment to the OPSS conversion factor. MedPAC reiterated its March 2016 recommendation for legislation that requires 340B savings to be distributed in proportion to the amount of uncompensated care that hospitals provide, “to make sure that dollars in the uncompensated care pool actually go to the hospitals providing the most uncompensated care.”

CMS’ final rule policy applies the budget neutrality adjustment through a 3.2 percent adjustment to the OPSS conversion factor. The estimated impacts of this policy are displayed in Table 88. The payment rates included in Addendum A and Addendum B do not reflect the reduced payments for drugs purchased under the 340B Program; however, they do include the increase to payment rates for non-drug items and services due to the corresponding increase in the conversion factor.

8. Summary of Final Rule Policies for 2018:

Below is a listing of CMS’ final rule policies. Effective January 1, 2018:

- Drug and biologicals (including biosimilars) that are acquired through the 340B Program or through the 340B PVP at or below the 340B ceiling price will be paid at ASP - 22.5 percent when billed by a hospital paid under the OPSS that is not excepted from the payment adjustment. Medicare will continue to pay drugs that were not purchased with a 340B discount at ASP + 6 percent.
- Hospitals paid under the OPSS, (other than CAHs, hospitals paid under the Maryland waiver, children’s hospitals, and IPSS-exempt cancer hospitals) are required to report modifier “JG” on the same claim line as the drug HCPCS code to identify a drug purchased under the 340B drug subject to payment at ASP - 22.5 percent.
- Rural SCHs, children’s hospitals and IPSS-exempt cancer hospitals will be required to report informational modifier “TB” for 340B-acquired drugs beginning January 1, 2018. Modifier “TB” is informational only and will not trigger a payment adjustment.
- Part B drugs or biologicals excluded from the 340B payment adjustment include vaccines (assigned status indicator “L” or “M”) and drugs with OPSS transitional pass-through payment status (assigned status indicator “G”).
- To maintain budget neutrality within the OPSS, the estimated \$1.6 billion in reduced drug payments will be redistributed in an equal offsetting amount to all hospitals paid under the OPSS through a 3.2 percent adjustment to the 2018 OPSS conversion factor that is used to determine payment rates for non-drug items and services furnished under the OPSS.

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

The estimate for total pass-through spending for drug and device pass-through payments during 2018 is approximately \$28.06 million, or 0.04 percent of total OPSS projected payments, 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. The final rule estimate for those device categories previously made eligible for pass-through payment that will continue to be eligible for pass-through payment in 2018 is \$0. CMS indicates that there will be no active device pass-through categories that were previously 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 final rule, CMS calculates a pass-through spending estimate of \$18.06 million in 2018 attributable to drugs and non-implantable biologicals and radiopharmaceuticals in the two groups described below.

The estimate for the first group of drugs and non-implantable biologicals is \$9.83 million. The first group consists of drugs and biologicals previously determined eligible for pass-through payments that will continue for 2018. CMS projects utilization based on the most recent Medicare physician claims data, information in pass-through applications, historical hospital claims data, pharmaceutical industry information, and clinical information.

The estimate for the second group of drugs and non-implantable biologicals is \$8.23 million. The second group consists of those drugs and biologicals CMS knows or projects could be approved for pass-through status in 2018, and includes contingent projections for new drugs and non-implantable biologicals that could initially be eligible in 2018. CMS projects utilization for this group using estimates from pass-through applications, pharmaceutical industry data, clinical information, recent trends in per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity. CMS also considers recent OPPTS experience in approving new pass-through drugs and biologicals.

CMS provides an offset to the APC payment to account for making pass-through payments that would otherwise be packaged into the APC payment. Because CMS pays for most non-pass-through separately payable drugs and biologicals and all pass-through drugs and biologicals at the same rate (ASP + 6 percent), its estimates for this group of items is zero.

However, the estimate of pass-through payment amounts for diagnostic radiopharmaceuticals and contrast agents with pass-through status is not zero because they are paid at ASP + 6 percent in lieu of being packaged into associated procedures as is the case for non-pass-through radiopharmaceuticals and contrast agents. Additionally, if CMS determines that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving

pass-through payment, it will offset the amount of pass-through payment for the policy-packaged drug or biological and also provide for a corresponding reduction in the estimate of pass-through payments for those drugs or biologicals. CMS' policy for the offset for this category of items is discussed above in section V.A.3.

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

CMS proposed no changes to the current clinic and emergency department hospital outpatient visits payment policies or to the payment policy for critical care services. CMS did not receive any public comments requesting changes to its OPPTS rates for hospital outpatient visits and critical care services for 2018. CMS solicited comments on potential changes it could make for future rulemaking cycles and did not receive any.

VIII. Payment for Partial Hospitalization Program (PHP) Services

A. PHP APC Update for 2018

For 2018, CMS continues its established policies to calculate the PHP APC per diem payment rates for Community Mental Health Centers (CMHCs) and hospital-based PHP providers based on geometric mean per diem costs using the most recent claims and cost data for each provider type. CMS uses CMHC APC 5853 (Partial Hospitalization (3 or more Services per Day)) and hospital-based PHP APC 5863 (Partial Hospitalization (3 or more Services per Day)) and actual claims data from 2016, and the most recent cost data, for each provider type for PHP service days providing 3 or more services. CMS believes that this best reflects actual geometric mean per diem costs and generates more appropriate payments for these services by avoiding the cost inversions that hospital-based PHPs experienced in the 2016 OPPTS/ASC final rule (80 FR 70459).

CMS analyzed PHP claims and cost data, including provider service usage, coding practices and rate setting methodology, and the agency identified aberrant data (defined as data so abnormal that they skew the resulting geometric mean per diem costs) from CMHCs and hospital-based providers which it excluded from the calculation of the proposed PHP geometric mean per diem costs. CMS excludes data from any CMHC when the CMHC's costs are more than ± 2 standard deviations from the geometric mean cost per day for all CMHCs, and excludes hospital-based PHP services days when a CCR greater than 5 is used to calculate costs for at least one of the component services. CMS excluded 4 CMHCs, adjusted the CCR for 1 CMHC, and removed 864 CMHC claims; it excluded 26 hospital-based PHP providers and adjusted the CCR for 2 hospital-based PHP providers.

Commenters expressed concerns with the single tier payment system, the trim methodologies, and the payment rate for CMHCs. They worry about unintended consequences of the policies, including that access to PHP services may be diminished (especially at CMHCs) because of the impact of the policies and the resulting payment rates. CMS believes that its policies are appropriate and that they provide for more accurate reimbursement than under previous PHP reimbursement methodologies. CMS notes that payment rates to CMHCs increased significantly

under this final rule as compared to 2017. CMS will monitor data for unintended consequences of its policies. The 2018 geometric mean per diem costs and payment rates are as follows:

2018 APC	Group Title	PHP APC Geometric Mean Per Diem Costs*	Payment Rates**
5853	Partial Hospitalization (3 or more services per day) for CMHCs	\$143.22	\$143.30
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	\$208.09	\$208.21

* Table 74 of the final rule shows the final PHP APC geometric mean per diem costs.

** The payment rates shown are reproduced from Addendum A to the final rule.

B. PHP Service Utilization

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.

CMS is concerned that its single-tier payment policy may result in PHP providers furnishing only 3 services per day while payment is heavily weighted to providing 4 or more services. Based on its review of the final update of 2016 claims data, 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 units of services should be the exception and not the typical PHP day which should include 5 to 6 hours of services.

As it did in the 2017 OPPTS 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.²³ 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 furnished.

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

²³ 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.

week).

Some commenters objected to the idea of linking edits to denial of payment; others expressed the position that the 20-hour-per-week requirement is not a condition for payment. Some comments suggested that edits would be premature until CMS could analyze data, consider the impact of the single payment tier, and engage the PHP provider community. It was also suggested that CMS educate the PHP provider community on the requirement and that Change Request 9880 be reissued because the commenters mistakenly believed it was rescinded.

Some commenters were concerned that denying payment for certain weeks would reduce access to the PHP benefit (and push patients out of PHPs and into Intensive Outpatient Programs) while others believed that the 20-hour requirement could be addressed through targeted medical review. A few commenters stated that CMS should not require weekly billing of claims to implement payment edits for the 20-hour requirement.

Commenters also provided examples of issues providers face in getting patients to attend a program for 20 hours a week. These included holidays, acute illness, family or childcare issues, weather, transportation issues, other medical or social service appointments, legal appointments, and emergencies or disasters. Additionally, there could be problems associated with medication compliance and adjustments. CMS will consider these comments in future rulemaking or sub-regulatory guidance. CMS does clarify that Change Request 9880 was not rescinded (though the MLN Special Edition article 1607 was rescinded since it incorrectly referred to required weekly billing). CMS does not currently require weekly billing though a PHP may elect to bill weekly.

C. Outlier Policy for CMHCs

For 2018, CMS designates 0.02 percent of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs for PHP outliers. CMS sets the cutoff point for the outlier payments for CMHCs for 2018 at 3.4 times the highest CMHC PHP APC payment rate (CMHC PHP APC 5853); the agency will pay 50 percent of CMHC geometric mean per diem costs over the threshold. Specifically, CMS will calculate a CMHC outlier payment equal to 50 percent of the difference between the CMHC's cost for the services and the product of 3.4 times the APC 5853 payment rate. CMS does not set a dollar threshold for CHMC outlier payments.

D. Regulatory Impact

CMS estimates that payments to CMHCs will increase by 17.2 percent in 2018. The estimate includes the trimming methodology, wage index, and other adjustments.

IX. Procedures That Would Be Paid Only as Inpatient Procedures

A. Changes to the Inpatient Only (IPO) List

CMS is continuing to use the same methodology to review the inpatient-only list. The criteria for a procedure to be removed from the IPO list include the following:

1. Most outpatient departments are equipped to provide the services to the Medicare population.
2. The simplest procedure described by the code may be performed in most outpatient departments.
3. The procedure is related to codes that CMS has already removed from the IPO list.
4. A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.
5. A determination is made that the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed for addition to the ASC list.

The rule indicates that not all of the established criteria need to be met for a procedure to be removed from the IPO list.

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

CPT Code	Code Descriptor	2018 OPPTS APC assignment	2018 OPPTS status indicator
27447	Arthroplasty, knee, condyle and plateau; medial 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

CMS is finalizing its proposal to remove these two procedures from the IPO list. CMS is also removing CPT codes 43282, 43272, 43773, 43774 and 92941 from the IPO list as described in more detail below. Addendum E of the final rule contains the complete list of codes that are to be paid only as inpatient procedures for 2018.

Laparoscopy, surgical prostatectomy

CMS is removing CPT code 55866 from IPO list and assigning it to C-APC 5362 (Level 2 Laparoscopy & Related Services) with a status indicator of “J1.” The proposed rule indicated that the procedure meets criteria 1 and 2 for IPO list removal, and CMS sought comment as to whether these or the other criteria listed above are met. All commenters except one supported the proposal, noting that the procedure could be safely performed on hospital outpatients and that many hospital outpatient departments are equipped to do so. One commenter opposed the proposal, saying that CPT code 55866 cannot be safely performed as an outpatient procedure for a majority of patients. CMS is finalizing its proposal without change to remove CPT code 55866 from the IPO list.

Total Knee Replacement

For a number of years, total knee arthroplasty (TKA) has been a topic of discussion for removal from the IPO list with both stakeholder support and opposition. CMS used the 2017 OPPTS/ASC proposed rule to solicit public comments on the removal of the TKA procedure from the IPO list, but without actually proposing to remove it. After considering comments received on the 2017 OPPTS/ASC rule, CMS decided to propose removing TKA from the IPO list for 2018. CMS determined that TKA meets criteria 1, 2 and 4 above for being removed from the IPO list. The 2018 OPPTS/ASC proposed rule requested comments on whether the public believes that these criteria are met and if TKA meets any other of the five criteria listed above. CMS indicates that it expects providers to carefully develop evidence-based patient selection criteria to identify patients who are appropriate candidates for an outpatient TKA procedure, as well as exclusionary criteria that would disqualify a patient from safely undergoing an outpatient TKA procedure.

CMS proposed that CPT code 27447 would be assigned to C-APC 5115 (Level 5 Musculoskeletal Procedures) with status indicator “J1.” The proposed rule further noted 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, CMS proposed to 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 for experience to accumulate with these procedures in 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.

Public Comments and Responses

(1) General Comments

There were comments both in support of and opposed to removing TKA from the IPO list. Supporters of the proposal made the following points:

- TKA meets CMS’ established criteria for removing a procedure from the IPO list;
- Appropriately selected patients who are in excellent health and with no or limited medical comorbidities and sufficient caregiver support could be successful candidates for outpatient TKA.

Supporters of the proposed policy also requested:

- CMS develop, with input from stakeholders, patient selection criteria and risk stratification protocols for TKA to be performed in an outpatient setting. Two orthopedic specialty societies stated that their organizations were in the process of developing these patient selection and protocol tools;

- CMS state explicitly that the surgeon is the final arbiter of the appropriate site for performance of the surgical procedure;
- CMS provide an incentive for outpatient and ambulatory settings performing TKA, PHA, and THA to be a part of a registry such as the American Joint Replacement Registry.

Concerns raised by opponents of the proposed policy and others included:

- Removal of TKA from the IPO list may lead commercial payers to implement coverage policies that would drive these procedures from the inpatient setting to lower cost outpatient settings that may not be sufficiently prepared to handle the complexities or risks associated with some outpatient TKA procedures.
- Removing TKA from the IPO list could drive TKA to specific facilities based on cost alone, which could result in significant further stresses in isolated rural care settings.
- TKA is not clinically appropriate for the outpatient setting because it is invasive and Medicare beneficiaries are more likely to have comorbidities that could make pain more difficult to control. Because of these comorbidities, Medicare beneficiaries will face greater complications, recovery times, and rehabilitation needs than non-Medicare populations to recover from TKA procedures.

CMS is finalizing its proposal to remove TKA from the IPO list. CMS responded 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. It does not address the concerns about private insurers which the agency says is outside of its authority.

Removal of any procedure from the IPO list does not require the procedure to be performed only on an outpatient basis. The "2-midnight" rule will apply to TKA. This guidance provides that if the physician expects the beneficiary to require hospital care that spans at least 2 midnights and admits the beneficiary based upon that expectation, the case is appropriate for payment under the IPPS (80 FR 70539). For stays for which the physician expects the patient to need less than 2 midnights of hospital care, an inpatient admission is payable under Medicare Part A on a case-by-case basis if the documentation in the medical record supports the admitting physician's determination that the patient requires inpatient hospital care. This documentation and the physician's admission decision are subject to medical review.

CMS will not create or endorse specific patient selection guidelines because it believes that surgeons, clinical staff, and medical specialty societies who perform outpatient TKA and possess specialized clinical knowledge and experience and are most suited to create such guidelines.

(2) Access to Post-Acute Care

Several commenters asked CMS to waive the 3-day prior inpatient stay for coverage of skilled nursing facility (SNF) care, stating that discharging outpatient TKA patients without a 3-day stay and subsequent access to adequate rehabilitation would increase the likelihood of further medical concerns including in readmissions. Readmissions and other complications will result in higher

expenses for the beneficiary, the Medicare program, and the hospital. Other commenters noted that the vast majority of beneficiaries who fit the criteria for an outpatient TKA procedure would not need institutional post-acute care services. Commenters also stated that a large percentage of TKA inpatients do not require a 3-day length of stay, and that removing TKA from the IPO list would not preclude these patients from meeting the 3-day qualifying stay requirement when warranted.

CMS reiterated its earlier response that removal of the TKA procedure from the IPO list does not require the procedure to be performed only on an outpatient basis. It further noted that Medicare Advantage plans may elect to provide SNF coverage without imposing the SNF 3-day qualifying stay requirement and that CMS has issued conditional waivers of the 3-day qualifying stay requirement as necessary to carry out the Medicare Shared Savings Program, and to test certain Innovation Center payment models, including the Next Generation ACO Model and the Comprehensive Care for Joint Replacement Model. CMS agreed with commenters that suggested properly selected candidates for outpatient TKA would not be expected to require SNF care following surgery.

(3) Bundled Payment Models

Numerous commenters were concerned that the proposal to remove TKA from the IPO list could result in younger and healthier patients preferentially undergoing outpatient TKA, so that a higher proportion of patients undergoing inpatient TKA would be high risk and/or more likely to require additional post-acute care support. The change in patient-mix could increase the average episode payment of the remaining inpatients in TKA BPCI and CJR hindering the hospital's ability to generate savings under the BPCI or CJR model. The commenters proposed refinements to the BPCI and CJR models to mitigate these effects, including adjusting the target price for BPCI and CJR episodes involving TKA to exclude procedures that could have been performed in the HOPD or allowing BPCI Model 2 and CJR episodes to be initiated by TKA performed in the hospital outpatient department.

CMS responded that it does not expect a significant volume of TKA cases currently being performed in the hospital inpatient setting to shift to the hospital outpatient setting as a result of removing TKA from the IPO list. Accordingly, CMS does not expect a substantial impact on the patient-mix for the BPCI and CJR models although it intends to monitor the overall volume and complexity of TKA cases performed in the hospital outpatient department to determine whether any future refinements to these models are warranted.

(4) Payment

Commenters requested that CMS only use claims for CPT 27447 that include a joint implant and to assign the procedure to APC 5116 (Level 6 Musculoskeletal Procedures). One commenter also stated that CMS failed to provide the general public with an explanation of the source of the geometric mean cost of the TKA procedure, which was CMS' basis for assigning the TKA procedure to a C-APC.

CMS responded that it assigned TKA to C-APC 5115 based on clinical similarity with

other musculoskeletal procedures. The 50th percentile IPPS payment for TKA without major complications or comorbidities (MS-DRG 470) is approximately \$11,760 for FY 2018. The geometric mean cost for C-APC 5116 is over \$15,000. As previously stated, CMS expects that beneficiaries selected for outpatient TKA would generally be less complex and not have major complications or comorbidities. Considering that there would be no room and board costs for outpatient TKA, CMS believes that its assignment to C-APC 5115 (mean costs=\$10,122) is correct. With respect to the billing concern, CMS indicated that it relies on hospital charges to include all items and services that are furnished with a procedure.

(5) Recovery Audit Contractor (RAC) Review of TKA Procedures

Commenters generally supported CMS proposed 2-year moratorium on RAC review for patient status for TKA procedures performed in the inpatient setting. Some commenters requested a longer or even a permanent moratorium. Others requested clarification that RAC review of a TKA inpatient case could only occur upon referral from a Quality Improvement Organization (QIO) consistent with the 2-midnight policy.

CMS finalized the 2-year moratorium on RAC review of inpatient TKA cases as proposed. It further stated that the initial medical reviews of claims for short-stay inpatient admissions are conducted by QIOs, which may refer providers to the RACs due to exhibiting persistent noncompliance with Medicare payment policies, including, but not limited to having high denial rates and consistently failing to adhere to the 2-midnight rule, or failing to improve their performance after QIO educational intervention.

Public Requests for Additions to or Removal of Procedures on the IPO List

Commenters requested that CMS remove several additional procedures from the IPO list. These additional procedures are listed in Table 77 reproduced from the final rule below.

TABLE 77.—PROCEDURES REQUESTED BY COMMENTERS TO BE REMOVED FROM THE CY 2018 INPATIENT ONLY LIST

CPT Code	2018 Long Descriptor
23470	Arthroplasty, glenohumeral joint; hemiarthroplasty
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (eg, total shoulder))
27125	Hemiarthroplasty, hip, partial (eg, femoral stem prosthesis, bipolar arthroplasty)
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft
27702	Arthroplasty, ankle; with implant (total ankle)
27703	Arthroplasty, ankle; revision, total ankle
43282	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when, performed; with implantation of mesh
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only

CPT Code	2018 Long Descriptor
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components
92941	Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel

CMS agreed to requests to remove CPT codes 43282, 43772, 43773, 43774 from the IPO list for 2018 and assigning them to APCs in the final rule. The final rule indicates that CMS is removing CPT code 92941 from the IPO because the procedure is performed emergently to treat acute myocardial infarction patients.²⁴ The remaining codes for which IPO list removal was requested describe joint replacement procedures. Given strong public interest in joint procedures and the IPO list, CMS is not removing these procedures from the IPO list at this time to allow for further discussion.

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

Partial hip arthroplasty (PHA) and total hip arthroplasty (THA)²⁵ were placed on the original IPO list in the 2001 OPPTS final rule (65 FR 18780) because of:

1. The invasive nature of the procedure;
2. The need for at least 24 hours of postoperative care;
3. The underlying physical condition of the patient who would require the surgery.

However, the final rule indicates that the geometric mean average length of stay for the DRG to which uncomplicated PHA and THA procedures has declined from 4.6 days in 2000 to 2.7 days in 2016.

In last year's OPPTS/ASC rule, several surgeons and other stakeholders commented that with thorough preoperative screening by medical teams with significant experience and expertise involving hip replacement procedures, the THA procedure could be provided on an outpatient basis for some Medicare beneficiaries. These commenters noted significant success involving same day discharge for patients who met the screening criteria and whose experienced medical teams were able to perform the procedure early enough in the day for the patients to achieve postoperative goals, allowing home discharge by the end of the day. The commenters believed that the benefits of providing the THA procedure on an outpatient basis will lead to significant enhancements in patient well-being, improved efficiency, and cost savings to the Medicare program, including shorter hospital stays resulting in fewer medical complications, improved results, and enhanced patient satisfaction.

²⁴Not stated but presumably removing the procedure from the IPO list would allow the procedure to be paid in the emergency department when done on an emergency basis.

²⁵CPTs 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).

The final rule indicates that recent innovations have enabled surgeons to perform PHA and THA procedures on an outpatient basis on non-Medicare patients (both in the HOPD and in the ASC). These innovations in PHA and THA care include minimally invasive techniques, improved perioperative anesthesia, alternative postoperative pain management, and expedited rehabilitation protocols. Patients undergoing minimally invasive surgical procedures instead of open surgical techniques generally benefit from shorter hospital stays.

However, the final rule indicates that not all patients are candidates for minimally invasive PHA or THA. Like most surgical procedures, both PHA and THA need to be tailored to the individual patient's needs. Patients with a relatively low anesthesia risk and without significant comorbidities who have family members at home who can assist them may likely be good candidates for an outpatient PHA or THA procedure. Patients with multiple medical comorbidities, aside from their osteoarthritis, would more likely require inpatient hospitalization and possibly post-acute care in a skilled nursing facility or other facility. Surgeons who have discussed outpatient PHA and THA procedures in public comments in response to CMS' 2017 OPPTS/ASC proposed rule emphasized the importance of careful patient selection and strict protocols to optimize outpatient hip replacement outcomes.

The final rule indicates some members of the public may misunderstand certain aspects of the IPO list. First, just because a procedure is not on the IPO list does not mean that the procedure cannot be performed on an inpatient basis. Second, the IPO list status of a procedure has no effect on the Medicare Physician Fee Schedule professional payment for the procedure.

Topics and Questions for Public Comments

In the proposed rule, CMS requested 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 requested 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?

The final rule indicates some commenters stated that it would not be clinically appropriate to remove PHA and THA from the IPO list. The patient safety profile of outpatient THA and PHA in the non-Medicare population is not well-established. Patients requiring a hemiarthroplasty (PHA) for fragility fractures are by nature higher risk, suffer more extensive comorbidities and require closer monitoring and preoperative optimization; therefore, it would not be medically appropriate to remove the PHA procedure from the IPO list.

Others supported removing PHA and THA from the IPO list, stating that most outpatient departments are equipped to provide THA to Medicare beneficiaries that are appropriate candidates for outpatient PHA and THA. Comments also requested that CMS address the impact on BPCI and CJR if THA and PHA are removed from the IPO list. There were also requests that these procedures be suspended from quality programs such as the Hospital Readmissions Reduction Program, the Hospital Value-Based Purchasing Program, and Hospital Inpatient Quality Reporting Program, if they are removed from the IPO list.

CMS indicated that it would consider these comments in future rulemaking.

X. Nonrecurring Policy Changes

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

Service Line Expansion

Section 603 of the Bipartisan Budget Act of 2015 (Public Law 114–74) excludes from the definition of covered OPD services “applicable items and services” furnished on or after January 1, 2017 by certain off-campus outpatient departments of a provider (generally those that did not furnish covered OPD services before November 2, 2015) and provides for payment for those services furnished by off-campus provider-based departments (PBDs) under the Medicare Physician Fee Schedule (MPFS) for the majority of nonexcepted items and services furnished by nonexempt off-campus PBDs.

In the 2017 rulemaking cycle, CMS proposed a number of implementation policies that raised major concerns with stakeholders, including a proposal (which it did not finalize) to limit expansion of services that an excepted off-campus PBD could offer and that would continue to be paid under the OPPTS. CMS noted it would continue to monitor service line expansion and consider how potential limitations on expansion might work, and it invited comments on the issue. In the 2018 OPPTS ASC proposed rule, CMS did not make any proposals to limit clinical service line expansion or volume increases at excepted off-campus PBDs of a hospital, but it again invited comment on the issue. CMS received comments (which it does not describe) and will consider them in determining whether to pursue future rulemaking on the issue. The

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 final rule; technical billing questions are addressed through applicable program instructions.

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 CMS an attestation by certain deadlines. The attestation would have to be provided 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 (at 42 CFR §413.65) after November 1, 2015, and before December 13, 2016 (the date of the enactment of the Cures Act). If an off-campus PBD of a cancer hospital first meets the provider-based rule requirements after December 13, 2016, it must attest that it meets 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 OPPTS payment provisions for cancer hospitals. These provisions provide supplemental payments to cancer hospitals at cost report settlement such that the target OPPTS payment-to-cost ratio for the cancer hospital equals the average payment-to-cost ratio for all other OPPTS 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 payment system (i.e., the MPFS) for non-cancer hospitals. See section II.F. above for a description of the calculation of the target payment-to-cost ratio for these hospitals for 2018.

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 (t) to section 1834 of the Act requiring the Secretary to make available to the public via a searchable website the estimated payment amount and beneficiary liability for an item or service payable under the OPPTS 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 application on its website as required by section 1834(t) of the Act. Details regarding the application will be issued through a sub-regulatory process. CMS anticipates the application will be made available in early 2018.

Public Comments and Responses: One commenter requested that CMS ensure that the application is designed in a user-friendly manner, and err on the side of including more services for display. Another commenter requested that application users be provided with the proper context for understanding some of the reasons for potential cost differences. CMS will take these comments into consideration as it develops the application.

C. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Section 218(b) of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93) directs the Secretary to establish a program to promote appropriate use criteria (AUC) for advanced diagnostic imaging services (the AUC program). Section 1834(q)(1)(B) of the Act defines AUC as criteria that are evidence-based (to the extent feasible) and assist professionals who order and furnish applicable imaging services to make the most appropriate treatment decisions for a specific clinical condition.

CMS is implementing the AUC program in four components:

- The first component was implemented in 2016 and includes the requirements and process for the establishment and specification of the AUC.
- The second component was implemented in 2017 and includes the specification of qualified clinical decision support mechanisms (CDSMs). A CDSM is the electronic tool through which the ordering practitioner consults AUC.

CMS proposed to implement the third component of the AUC program in 2018. The third component includes the requirements for an ordering professional to consult with a qualified CDSM when ordering an applicable imaging service and communicate information about the AUC consultation to the furnishing professional, and for the furnishing professional to include that information on claims for the service that is furnished in an applicable setting and paid under an applicable payment system.

The AUC program applies to advanced imaging services for which payment is made under the Medicare Physician Fee Schedule (MPFS); the OPPTS; and the ASC payment system. CMS' changes to the AUC program were made in the 2018 MPFS final rule. The final rule refers readers to 2018 MPFS final rule for further information governing the Medicare AUC program including public comments and responses.

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

In the 2009 OPPTS/ASC final rule, CMS clarified that direct supervision is required for hospital outpatient therapeutic services covered and paid by Medicare that are furnished in hospital outpatient departments. In the 2010 OPPTS/ASC final rule, CMS clarified that direct supervision of therapeutic services applies to CAHs as well as hospitals. From March 15, 2010 through December 31, 2013, the direct supervision requirements were subject to an enforcement moratorium either by statute or CMS instruction for CAHs and rural hospitals under 100 beds (since January 1, 2011 for small rural hospitals).

During this time, CMS established a process to receive recommendations from the HOP on changing the required supervision level from direct to general supervision for specific services. In response to the HOP recommendations, CMS changed the supervision level from direct to general for a number of services.

However, stakeholders have consistently requested that CMS continue the nonenforcement of the direct supervision of hospital outpatient therapeutic services for CAHs and small rural hospitals having 100 or fewer beds. Stakeholders stated that some small rural hospitals and CAHs have insufficient staff available to furnish direct supervision. Further, CMS indicates that it is not aware of any quality of care complaints from beneficiaries or providers relating to general physician supervision as compared to direct physician supervision for outpatient hospital therapeutic services.

CMS proposed 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 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 for a recommended change in the supervision level. CMS is finalizing the proposed enforcement moratorium without change. These hospitals would continue to be subject to conditions of participation for hospitals and other Medicare rules regarding supervision. CMS welcomes public comments on this proposal.

Public Comments/Response: A few commenters opposed CMS' proposal indicating the supervision requirements should be applied uniformly to hospitals in all care settings to ensure patient safety. Other commenters suggested that CMS adopt the nonenforcement policy permanently. There were comments requesting that CMS change the supervision level from direct to general for a number of services or make general supervision the default and only require direct supervision for specific services. CMS is finalizing its proposal without change. CMS agreed that patient safety is a critically important consideration for each service and notes that changes to the supervision level were outside the scope of the proposed rule and can be brought to the HOP's consideration per established process.

E. Payment Changes for Film X-Ray Services and 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 OPPTS 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. The payment reduction is exempt from the OPPTS budget neutrality requirements. Section 1833(t)(16)(F)(i) of the Act applies to X-ray services while section 1833(t)(16)(F)(ii) of the Act provides a phased-in reduction of payments for imaging services that are taken using computed radiography technology.

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 OPPTS 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 “FY” (X-ray taken using computed radiography technology/cassette-based imaging) 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 is applying the reduction required by the statute. However, the reduction does not apply when the CPT code to which it is applied is a packaged service that is not separately paid.

Although CMS adopted the film X-ray provision in the 2017 OPPTS/ASC final rule, it did not adopt corresponding regulation text. Therefore, it is codifying the policy already in place at 42 CFR 419.71 for film X-rays as well as its policy for computed radiography technology services. The regulatory changes at 42 CFR 419.71 also codify that these payment reductions are not subject to OPPTS budget neutrality. CMS finalized all of these policies as proposed.

Public Comments/Response: Public commenters indicated that use of the modifier will be burdensome and requested that CMS furnish list of specific HCPCS codes to which this new modifier (“FY”) and the film x-ray modifier (“FX”) would apply. Other commenters expressed concern with the statutory provision requiring hospitals to upgrade to digital radiography systems or face a financial penalty. These commenters indicated that the requirement is financially burdensome and difficult to justify given the costs associated with upgrading or replacing equipment. One commenter suggested replacing penalties with bonuses to provide incentives to transition to digital radiography technology. Other commenters indicated there is no clinical benefit to using digital radiography systems, and that, for certain clinical situations, computed radiography systems are preferable.

CMS responded that hospitals already used modifiers for a variety of purposes and this one is no more burdensome than others that are required for correct payment; additional guidance is unnecessary because hospitals should know when they are billing a HCPCS code that involves the use of an X-ray taken using computed radiography; and that the penalty for using film X-rays or X-ray taken using computed radiography is a statutory requirement beyond CMS’s authority to change.

F. Potential Revisions to the Laboratory Date of Service Policy

CMS did not propose a change of policy to the laboratory date of service (DOS) in the 2018 OPPTS/ASC proposed rule. However, the proposed rule provided specific and detailed changes to the DOS regulations that CMS indicated it was considering adopting for the final rule. CMS requested comments on those changes and solicited commenters on other issues. The below table compares provisions as they were considered for the proposed rule and the policies CMS adopted in the 2018 OPPTS/ASC final rule.

Comparison of Proposed and Final Rule Policies

Proposed Rule Policy	Final Rule Policy
The physician must order the test following the date of a hospital outpatient’s discharge from the hospital outpatient department.	Order requirement eliminated. The test must be performed following a hospital outpatient’s discharge from the hospital outpatient department.
The specimen must be collected from a hospital outpatient during an encounter.	No change.
The results of the test do not guide treatment provided during the hospital outpatient encounter.	No change.
The test was reasonable and medically necessary for the treatment of an illness.	No change
CMS requested comments on whether to apply the new DOS policy only to separately payable Advanced Diagnostic Laboratory Tests (ADLT) or both separately payable ADLTs and separately payable molecular pathology tests.	Will apply to both separately payable ADLTs and separately payable molecular pathology tests. CMS declined to expand policy beyond these tests.
Applies to outpatient department tests only.	No change. CMS declined to expand the policy to tests furnished to inpatients.

The 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.

1. 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 after 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 last four above conditions are met and:

- The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge;

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

2. Billing and Payment for Laboratory Services Under the OPPTS

Under current rules, Medicare will not pay for a service furnished to a hospital patient during an encounter by an entity other than the hospital unless the hospital has an arrangement (as defined in 42 CFR 409.3) with that entity to furnish that particular service to its patients, with certain exceptions and exclusions. These regulations, which are called “under arrangements” require that if the DOS falls during an inpatient or outpatient stay, payment for the laboratory test is usually bundled with the hospital service.

The DOS requirements determine whether a hospital bills Medicare for a clinical diagnostic laboratory test (CDLT) or whether the laboratory performing the test bills Medicare directly. If the DOS falls during an inpatient stay or an outpatient encounter, payment for the laboratory test is usually bundled with the hospital service or the hospital is required to bill for the test. However, if the DOS meets the above criteria under the 14-day rule or the special rules for chemotherapy sensitivity tests, the DOS is the date the test was performed, and the laboratory bills Medicare directly for the test.

Under current OPPTS policy, CMS conditionally packages most CDLTs and only pays separately for a laboratory test when it is:

1. The only service provided to a beneficiary on a claim;
2. Considered a preventive service;
3. A molecular pathology test; or
4. An advanced diagnostic laboratory test (ADLT) that meets specific criteria under section 1834A(d)(5)(A) of the Act. (See 78 FR 74939 through 74942; 80 FR 70348 through 70350; and 81 FR 79592 through 79594 for more information.)

Laboratory tests that are separately payable and are listed on the CLFS are paid at the CLFS payment rates.

3. Revisions to the Laboratory DOS Policy

In the December 1, 2006 Medicare Physician Fee Schedule final rule (71 FR 69706) that adopted the 14-day rule, CMS indicated that only tests that can legitimately be distinguished from the care a beneficiary receives in the hospital are subject to the 14-day rule. CMS has heard from laboratory stakeholders concerns about how the DOS rules apply to separately billable laboratory tests not conditionally packaged under the OPPTS. If the tests are ordered within 14 days of a patient's discharge from the hospital, Medicare still treats the tests as though they were ordered and furnished by the hospital itself. Under those circumstances, laboratories cannot directly seek Medicare payment for the molecular pathology test or ADLT. The hospital must bill Medicare for the test, and the laboratory must seek payment from the hospital. Stakeholders representing laboratories have expressed the following concerns:

- In order to receive payment, the current DOS policy requires hospitals to bill for tests they did not perform and that may have no relationship to or bearing on treatment received by the patient while in the hospital.
- The DOS policy may create inconsistent billing for specialty laboratories. For example, if the hospital is located in a different jurisdiction than the Medicare Administrative Contractor (MAC) used by the laboratory, a different MAC may be billed. MAC coverage policies may be different between the hospital's and the clinical laboratory's MAC jurisdiction.
- Hospitals may be discouraged from furnishing ADLTs because billing for such tests that are not performed by hospitals could create administrative and financial complexities.
- The DOS policy is a potential barrier to CMS' goal of promoting personalized medicine because the policy may disproportionately impact smaller laboratories performing innovative diagnostic tests.
- Billing complexities may affect beneficiary access to needed laboratory tests and therapies. For example, orders might be delayed until at least 14 days after discharge or even canceled to avoid the DOS policy. This may restrict patient access to tests and reduce efficacy of treatment plans due to hospitals delaying or forgoing patient testing to avoid financial risk.
- The DOS policy may limit access for Medicare beneficiaries under original Medicare fee-for-service (that is, Medicare Part A and Part B) due to the fact that Medicare Advantage Plans under Medicare Part C and private payers allow laboratories to bill directly for tests they perform.

In light of the concerns, CMS considered potential modifications to the DOS policy in the proposed rule that would allow laboratories to bill Medicare directly 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 requested 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 did not specifically propose a change but said that it was 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.

Public commenters generally supported revising the laboratory DOS policy urging CMS to finalize a policy that focuses on whether the test was performed outside the hospital after the outpatient encounter, rather than on the date the specimen was collected or the date the test was initially ordered. Several commenters recommended the following specific modifications to the potential changes CMS discussed in the 2018 OPPTS/ASC proposed rule:

- *Expand the laboratory tests subject to the DOS exception.* Include ADLTs and Multi-Analyte Assays with Algorithmic Analysis (MAAA), Genomic Sequencing Procedures (GSP), and Proprietary Laboratory Analysis (PLA) test codes, even if they are not currently excluded from the OPPTS packaging policy. This change would encompass all laboratory testing that has a different pattern of clinical use from routine testing and therefore is unconnected to the primary hospital outpatient service.
- *Remove the test order date requirement.* Testing on a "liquid-based" specimen is typically ordered before collection. Requiring the physician to *order* the test at least 1 day following the date of a patient's discharge from the hospital outpatient department would exclude a blood-based molecular pathology test from an exception to the laboratory DOS policy.
- *Require that it be "medically appropriate" to have collected the sample during the hospital outpatient encounter.* Commenters suggested a modification to the potential revised DOS policy to focus on what *is* medically appropriate rather than what is not medically appropriate to avoid providing inadvertent incentives for hospitals to require hospital outpatients to go elsewhere for liquid-based specimen collection when it would be medically appropriate to have those specimens collected in the hospital (i.e. it would not be medically inappropriate to collect the sample in a place other than the hospital).

CMS agreed with the comment that a requirement that it be "medically inappropriate" to have collected the specimen from the hospital outpatient other than during the hospital outpatient encounter is primarily applicable to tissue-based specimens. It would not be applicable to liquid-based samples because it could be medically *appropriate* to collect a liquid-based specimen in settings outside of a hospital outpatient encounter, such as an independent laboratory not associated with the hospital.

It also agreed with the commenters that requiring the physician to order the test following the date of a hospital outpatient's discharge from the hospital outpatient department could also inappropriately exclude tests performed on liquid-based specimens from the DOS exception, because a blood test is typically ordered before the sample is collected. CMS believes that

ADLTs and molecular pathology tests excluded from the OPPTS packaging policy are, by their nature, tests that are used to determine posthospital care, and therefore can be legitimately distinguished from the care the patient receives in the hospital even if they are ordered prior to the patient's discharge.

CMS disagreed with expanding DOS changes to additional tests beyond separately payable ADLTs and molecular pathology tests. Expanding the policy as suggested would be inconsistent with the current OPPTS packaging policy and would allow the laboratory to bill Medicare directly for a test that is not paid at the CLFS rate but paid under the hospital OPPTS bundled rate. Separately payable ADLTs and molecular pathology tests have a different pattern of clinical use than more conventional laboratory tests, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine tests that are packaged.²⁶

Other comments asked CMS to apply the policy to specimens collected from both inpatients and outpatients. CMS declined to apply the policy to samples taken from hospital inpatients saying that it did not discuss or propose an analogous DOS exception for tests performed on specimens collected from hospital inpatients in the CY 2018 OPPTS/ASC proposed rule. With outpatient specimens, the policy will reduce administrative burden by allowing a test that is separately payable to be billed by the laboratory that perform it instead of the hospital. With a test performed on a sample taken from an inpatient, the test is not separately billable.

There were also comments that requested CMS to apply the policy to "referred non-patient specimens" when hospitals receive tissue and/or blood samples for testing from a physician's office or other locations in circumstances in which no hospital encounter occurs. CMS did not see a reason to apply the policy to non-patient specimens as these tests remain separately billable. Because hospital outreach laboratories perform laboratory tests on specimens collected from beneficiaries who are not patients of the hospital, a revision to the laboratory DOS policy is not necessary to allow a hospital outreach laboratory to bill Medicare separately for the test.

4. Limiting the DOS Rule Exception to ADLTs

CMS also considered whether to revise the DOS rule only for separately payable 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. CMS considered limiting its policy change to separately payable 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 arrangements, 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.

In the proposed rule, CMS indicated the circumstances may be different for molecular pathology

²⁶ Note GSPs, PLAs and tests that are ADLTs by virtue of being FDA approved (as opposed to being designated as ADLTs by CMS) are not separately payable CLDTs under current policy. Therefore, the revised policy would not apply to these types of tests.

tests, which are not required to be furnished by a single laboratory. In particular, molecular pathology tests may be furnished as “kits” that a hospital can purchase, allowing the hospital to perform the test. Delayed access to medically necessary care, therefore, may be different for molecular tests than ADLTs, which must be performed by a single laboratory. CMS requested specific comments on potentially creating an exception to the DOS policy that is limited to tests that have been granted ADLT status by CMS.

Public comments disagreed with limiting revisions to the DOS policy only to separately payable ADLTs stating that such a limitation would not be consistent with current OPPTS packaging policy, which excludes molecular pathology tests and some ADLTs (those tests that received an ADLT designation from CMS and not through an FDA approval). These commenters said the same beneficiary access issues apply to separately payable molecular pathology tests as separately payable ADLTs. CMS agreed with these comments and is not limiting its changes to the DOS policy to separately payable ADLTs only.

5. Other Alternative Approaches

CMS also invited public comments on alternative approaches to addressing stakeholders’ concerns regarding the DOS policy, such as potentially modifying the “under arrangements” provisions in §410.42 and §411.15(m). Specifically, CMS requested comments on whether an exception should be added to §410.42(b) and/or §411.15(m)(3) for molecular pathology tests and ADLTs that are excluded from the OPPTS packaging policy under 42 CFR 419.2(b) and how such an exception should be framed. CMS was especially interested in comments regarding how the current DOS policy and “under arrangements” provisions may affect access to care for Medicare beneficiaries.

In response to the above comment solicitation, several commenters suggested that changing the “under arrangements” to allow all non-packaged laboratory tests which are paid at the CLFS rates would be consistent with the exceptions for other services (for example, physician services) that are paid separately from the hospital service and would make changes to the DOS policy unnecessary. CMS responded that the revisions it is finalizing to the current laboratory DOS policy is more consistent with how it has historically addressed laboratory DOS issues and, at this stage, is the appropriate way to address stakeholders’ administrative and billing concerns regarding these tests. CMS intends to continue to study this issue and specifically consider whether further revisions to the “under arrangements” provisions are warranted. If so, it will undertake revisions through future rulemaking.

6. Final Rule Policy:

In order to allow a laboratory to bill Medicare directly for an ADLT or molecular pathology test excluded from the OPPTS packaging policy, CMS is modifying 42 CFR 414.510(b) by adding a new paragraph (5) to establish that, in the case of a separately payable molecular pathology test or a separately payable test designated by CMS as an ADLT²⁷, the DOS of the test must be the date the test was performed only if—

²⁷ Laboratory tests granted ADLT status under section 1834A(d)(5)(B) (tests offered and furnished by a single laboratory that are cleared by the FDA) of the Act currently are not excluded from the OPPTS packaging policy.

- The test was performed following 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 in 42 CFR 410.2);
- It was medically appropriate to have collected the sample 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.

In response to comments, CMS stated that if a test meets the above criteria, the DOS is the date the test is performed and it must be billed by the laboratory and cannot be billed by the hospital unless the hospital performed the test. CMS intends to continue studying the laboratory DOS policy and determine whether any additional changes are warranted including whether to address any inconsistencies with the new exception, and any changes to the “under arrangements” provisions, including its policies for the hospital inpatient setting.

XI. 2018 OPPTS Payment Status and Comment Indicators

A. 2018 OPPTS Payment Status Indicator Definitions

For 2018, CMS did not propose any changes to status indicators and did not receive any public comments on them. Status indicators and their definitions can be found in Addendum D1 of the final rule. Payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B to the 2018 final rule.

B. 2018 Comment Indicator Definitions

For 2018, CMS will use the following comment indicators:

- “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.

Likewise, GSP testing, proprietary laboratory analysis tests, and protein-based MAAs that are not considered molecular pathology tests are also conditionally packaged under the OPPTS.

- “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.

The definitions of the OPPTS comment indicators for 2018 are listed in Addendum D2 of final rule. (Each of the definitions above are excerpted from the final rule exactly as written. NC is somewhat unclear but CMS appears to be requesting comments on the final APC assignment for a revised existing code but not a new code.) **Note: Any code in Addenda B, AA, and BB with “NI” in the commenter indicator field is subject to comment until December 31, 2017.**

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

Summary of Selected Key Elements of Final 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	1.0007	
2018 Update		
CPI-U update	1.7%	
Multi-factor productivity adjustment (MFP)	-0.5%	
Net MFP adjusted update	1.2%	
Penalty for not reporting quality data	0.0%	-2.0%
Net MFP and quality adjusted update	1.2%	-0.8%
2018 ASC Conversion Factor	\$45.575	\$44.663*

* This is the amount CMS published in its final rule. Using the specified update factors, however, the calculated conversion factor for ASCs not reporting quality data totals \$44.674, slightly higher than the published amount.

CMS estimates that under the final rule, total ambulatory surgical center (ASC) payments for 2018 will increase by \$130 million over 2017 levels.

As with the rest of the OPPTS final rule and other CMS rules, addenda related to the ASC section (and referenced in this summary) are available only on the CMS website, at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1678-FC.html>. All ASC Addenda to the final rule are contained in the zipped folders entitled Addendum AA, BB, DD1, DD2, and EE.

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

- Covered surgical procedures in an ASC are surgical procedures that are separately paid under the OPPTS and that would not be expected to:
 - Pose a significant risk to beneficiary safety when performed in an ASC; or
 - Require an “overnight stay”: active medical monitoring and care at midnight following the procedure.

- Separate ASC payments are made for selected ancillary items and services when they are provided integral to ASC covered procedures. Payment for ancillary items and services that are not paid separately are packaged into the ASC payment.
- ASC payments are based on the OPPTS payment policies.
- CMS provides quarterly update change requests (CRs) for ASC services throughout the year and makes new codes effective outside the formal rulemaking process via these quarterly updates. The annual rulemaking process is used to solicit comments and finalize decisions.

CMS defines a surgical procedure under the ASC payment system as any procedure described within the range of Category I CPT codes that the AMA CPT Editorial Panel defines as surgery (CPT codes 10000 through 69999). CMS also includes procedures described by Level II HCPCS codes or Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that it determines do not pose a significant safety risk, would not be expected to require an overnight stay, and are separately paid under the OPPTS. Stakeholders have suggested that certain procedures outside the CPT surgical range that are similar to procedures covered in the ASC setting should be covered in that setting. In response, CMS believes it might be appropriate for it to use the CPT surgical range as a guide rather than a requirement in determining whether a procedure is surgical for purposes of the ASC covered procedures list.

CMS sought comment in the proposed rule on services that may be appropriate to include as ASC covered surgical services notwithstanding that they are described by Category I CPT codes outside the surgical range or by HCPCS Level II codes or Category III CPT codes that do not directly crosswalk and are not clinically similar to procedures in the surgical range. In particular, CMS was interested in additional criteria that could be applied in determining whether the procedure can be safely and appropriately performed in an ASC and whether the required resources, staff and equipment would be typical of an ASC.

Commenters had mixed responses about revising the definition of ASC covered surgical procedures. Some commenters were concerned that revising the definition would inappropriately move procedures from a hospital setting to an ASC setting and place Medicare patients in greater risk. Others recommended that further evaluation be done on the impact of beneficiaries before revising the definition. Among those in favor of revising the definition of ASC covered surgical procedures, many believe that the current CPT surgical code range (10000-69999) does not properly account for technical advances in treatment and does not include invasive procedures that do not pose a significant safety risk. Several commenters gave examples of catheter-based procedures that they said could be appropriately performed in the ASC setting. In response, CMS acknowledged the need to have clear criteria, but made no changes to its definition and stated that it would take these comments into consideration for future rulemaking.

A. Treatment of New and Revised Codes

CMS continues to recognize the following codes on ASC claims:

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

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

CMS finalizes proposals for new codes in two categories:

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

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

CMS sets out in Table 79 its process and timeline for updating codes through the quarterly update CRs, seeking public comment, and finalizing treatment of the new codes.

Comment and Finalization Timeframes for 2018 for New and Revised HCPCS Codes (from Table 79)				
ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 1, 2017	Level II HCPCS Codes	April 1, 2017	2018 OPPTS/ASC proposed rule	2018 OPPTS/ASC final rule with comment period
July 1, 2017	Level II HCPCS codes Category I (certain vaccine codes) and III CPT codes	July 1, 2017		
October 1, 2017	Level II HCPCS Codes	October 1, 2017	2018 OPPTS/ASC final rule with	2019 OPPTS/ASC final rule with

			comment period	comment period
January 1, 2018	Level II HCPCS Codes	January 1, 2018	2018 OPPTS/ASC final rule with comment period	2019 OPPTS/ASC final rule with comment period
	Category I and III CPT codes		2018 OPPTS/ASC proposed rule	2018 OPPTS/ASC final rule with comment period

Treatment of New and Revised Level II HCPCS Codes Implemented in April 2017 for Which CMS Solicited Public Comments in the 2018 OPPTS/ASC Proposed Rule

CMS did not receive any public comments regarding the proposed ASC payment indicators and payment rates for new and revised Level II HCPCS codes that were effective April 1, 2017.

CMS, in the April 2017 change requests (CRs), made effective 6 new Level II HCPCS codes describing covered ASC services that were not included in the 2017 OPPTS final rule. Table 80 copied below set out the codes, descriptors, and 2018 payment indicators.

New Level II HCPCS Codes for Covered Ancillary Services Effective on April 1, 2017 (Table 31)			
2017 HCPCS Code	2018 HCPCS Code	2018 Long Descriptor	2018 Payment Indicator
C9484	J1428	Injection, eteplirsen, 10 mg	K2
C9485	J9285	Injection, olaratumab, 10 mg	K2
C9486	J1627	Injection, granisetron extended release, 0.1 mg	K2
C9487*	J3358	Ustekinumab, for intravenous injection, 1 mg	K2
C9488	C9488	Injection, conivaptan hydrochloride, 1 mg	K2
J7328	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

The final 2018 payment rates for these codes can be found in Addenda AA and BB of the final rule at the CMS website referenced above.

Treatment of New and Revised Level II HCPCS Codes Implemented in July 2017 for Which CMS Solicited Public Comments in the 2018 OPPTS/ASC Proposed Rule

CMS finalizes the proposed payment indicators for the Level II HCPCS codes and the new Category III CPT code that were newly recognized as ASC covered surgical procedures or covered ancillary services in July 2017 through the quarterly update CRs, as indicated (shown in Table 81, reproduced below).

CMS received one comment that correctly pointed out that the price for HCPCS code Q9986 stated in the July and October 2017 OPPTS and ASC addenda was based on 1mg dose rather than the revised 10mg dose descriptor. CMS agrees and states that it will correct the price for this code retroactive to July 1, 2017 in the respective January 2018 updates.

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

New Level II HCPCS Codes for Covered Surgical Procedures and Ancillary Services Effective on July 1, 2017 (Table 81)			
2017 HCPCS Code	2018 HCPCS Code	2018 Long Descriptor	2018 Payment Indicator
C9489	J2326	Injection, nusinersen, 0.1 mg	K2
C9490	J0565	Injection, bezlotoxumab, 10 mg	K2
C9745	C9745	Nasal endoscopy, surgical; balloon dilation of eustachian tube	J8
C9746	C9746	Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed and/or fluoroscopy, when performed	J8
C9747	C9747	Ablation of prostate, transrectal, high intensity focused ultrasound (HIFU), including imaging guidance	J8
Q9986	J1726	Injection, hydroxyprogesterone caproate (Makena), 10 mg	K2
Q9989*	J3358	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 (Table 82)			
2017 CPT Code	2018 CPT Code	2018 Long Descriptor	2018 Payment Indicator
0474T	0474T	Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space	J8

Process for New and Revised Level II HCPCS Codes That Will Be Effective October 1, 2017 and January 1, 2018 for Which CMS is Soliciting Public Comments in the 2018 OPPTS/ASC Final Rule with Comment Period

CMS proposes to continue to assign comment indicator “NI” in Addendum B to the 2018 OPPTS/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 OPPTS payment status for 2018.

CMS invites public comments in this 2018 final rule on the interim status indicators, APC assignments and payment rates that will be finalized in the 2019 OPPTS/ASC final rule with comment period.

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 OPPTS/ASC Final Rule

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

CMS finalizes, without modification, the proposed CY 2018 ASC payment indicator assignments for new and revised CPT codes, effective January 1, 2018.

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

1. Covered Surgical Procedures Designated as Office-Based

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

Based on its review of 2016 volume and utilization data, CMS finalizes its proposal 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 ASC payment indicator of “P2/P3” in 2018.
- CPT Code 67227 (Destruction of extensive or progressive retinopathy (e.g. diabetic retinopathy), cryotherapy, diathermy), with ASC payment indicator of “P2/P3” in 2018.

CMS also reviews 2016 volume and utilization data for 10 procedures finalized for temporary office-based status in last year’s final rule. CMS found that there were very few or no claims data for eight of these procedures, and finalizes its proposal to maintain the temporary office-based designations for these eight codes for 2018.

With respect to the two remaining procedures finalized for temporary office-based status in last year’s final rule CMS finalizes its proposal 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 OPPTS/ASC final rule. However, this code will be deleted by the AMA, effective December 31, 2017.

CMS finalizes its proposal to designate CPT code 38222 (Diagnostic bone marrow; biopsy(ies) and aspiration(s)) for ASC covered surgical procedures as temporary office-based for 2018, with the 2018 payment indicator “P3”. CMS did not receive any public comments on its proposal.

Table 84 in the final rule lists the procedures and the CMS payment indicators for 2018. CMS notes that the payment indicators (e.g. P2, P3, and R2) are based on a comparison of the rates according to the ASC standard rate setting methodology and the Medicare Physician Fee Schedule (PFS) rates. Current law specifies a 0.5 percent update to the Medicare PFS payment rates for CY 2018.

2. ASC Covered Surgical Procedures to Be Designated as Device-Intensive

Under its payment methodology for calculating the ACS payment rates for covered surgical procedures designated as device intensive, CMS defines an ASC device-intensive procedure as one with a HCPCS code-level device offset percentage greater than 40 percent based on the standard OPPTS APC rate setting methodology. CMS sums the ASC device portion and the ASC service portion of a device-intensive procedure to set the full payment rate under the revised ASC payment system. CMS derives the ASC device portion by applying the device offset percentage based on the standard OPPTS APC rate setting methodology to the OPPTS national unadjusted payment to determine the device cost. CMS calculates the service portion by applying the uniform ASC conversion factor to the service (i.e., non-device) portion of the OPPTS relative payment weight for the device-intensive procedure. Device-intensive procedures are subject to CMS policies on device credits and discontinued procedures.

In the 2017 OPPTS/ASC final rule, CMS adopted a policy for new HCPCS codes requiring the implantation of medical devices that do not yet have associated claims data; CMS applies device-intensive status with a default device offset set at 41 percent until claims data are available to establish the HCPCS code-level device offset. The purpose is to ensure ASC access for new procedures until claims become available. CMS notes that in certain rare instances, such as very expensive implantable devices, it may temporarily apply a higher offset percentage if warranted by additional information provided by a manufacturer.

For 2018, CMS finalizes its proposal to update the ASC list of covered surgical procedures that are eligible for payment according to the device-intensive payment methodology, reflecting the individual HCPCS code device offset percentages based on 2016 OPPTS claims and cost report data. The procedures are assigned the payment indicator “J8” and are included in Addendum AA (at the CMS ASC 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 will apply. In 2018, there are 144 device-intensive procedures that are paid at an adjusted rate.

CMS received limited comments. One commenter, for example, requested that CMS designate CPT code 55X87 (replaced by CPT code 55874 in this final rule) as a device-intensive procedure as the commenter states the implementation of this device represents a range of 80 to 87 percent of the procedure cost. CMS replies that once claims data are available, CMS will make a determination based on its standard policy.

3. 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 OPPTS in the 2014 final rule, but there is no mechanism in the ASC claims processing system for ASCs to submit the actual amount received when furnishing a device without cost or with full or partial credit.

CMS finalizes its proposal to continue its policy for ASCs for 2018:

- When the device is furnished at no cost or with full credit from the manufacturer, the contractor will reduce payment to the ASC by 100 percent of the device offset amount, which is the amount that CMS estimates as the cost of the device. The ASC will append the HCPCS “FB” modifier on the claim line with the procedure to implant the device.
- When the device is furnished with partial credit of 50 percent or more of the cost of the new device, the contractor will reduce payments to the ASC by 50 percent of the device offset amount. In order to report a partial credit, the ASC will have the option of either submitting the claim after the procedure, but prior to manufacturer acknowledgement of credit for the device, and having the contractor make a claim adjustment, or holding the claim for payment until a determination is made by the manufacturer. The ASC will then submit the claim with a “FC” modifier if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the replacement device. Beneficiary coinsurance will be based on the reduced payment amount.

CMS also finalizes its proposal to update the list of ASC covered device-intensive procedures which are subject to the full credit/partial credit policy to all device-intensive procedures in 2018.

4. Additions to the List of ASC Covered Surgical Procedures

CMS conducted its annual review of procedures paid under the OPPTS but not included on the list of covered ASC procedures. CMS finalizes its proposal 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 additions are as follows:

Additions to the List of ASC Covered Surgical Procedures for 2018 (Table 86)		
2018 CPT Code	2018 Long Descriptor	2018 ASC Payment Indicator
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyctomy 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 osteophyctomy 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 OPPTS inpatient list for possible inclusion on the ASC list of covered surgical procedures. While CMS proposed to remove from the OPPTS inpatient list the two procedures described by CPT codes 27447 and 55866,²⁸ it proposed 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.

Some commenters supported adding the three procedures (CPT codes 22856, 22858, and 58572) to the ASC list of covered surgical procedures. Another commenter expressed concern that adding these procedures to the ASC list would result in physicians inappropriately directing patients to receive these procedures in an ASC setting in which they have a financial relationship. CMS agrees that these procedures should be added to the list of covered surgical procedures and does not believe that doing so would lead to inappropriate shifting of patients to the ASC setting nor jeopardize patient access.

CMS finalizes its proposal to add the three procedures described by CPT codes 22856, 22858, and 58572 to the ASC list of covered surgical procedures. The code descriptors and 2018 payment indicators are displayed in Table 86 in the final rule (reproduced above).

5. Discussion of Comment Solicitation of Adding Additional Procedures to the ASC Covered Procedures List

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

- CPT code 27447 (Arthroplasty, knee, condyle and plateau; medial and lateral compartments with or without patella resurfacing (total knee arthroplasty))
- CPT code 27125 (Hemiarthroplasty, hip, partial (e.g. femoral stem prosthesis, bipolar arthroplasty)) and

²⁸ CPT codes 27447 (Arthroplasty, knee, condyle and plateau; medial 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).

- CPT code 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft)

Several commenters were in favor of adding these procedures to list of ASC covered surgical procedures. They argued that ASCs are equipped to perform these procedures and orthopedic surgeons in ASCs are increasingly performing these procedures safely and effectively on non-Medicare patients. Some suggested that it could be safer to perform these in an outpatient setting to prevent certain hospital-acquired infections. Other commenters in favor suggested a step-wise approach to transitioning TKA to the ASC setting and thus allow for 1 to 2 years of experience in the hospital outpatient department before transitioning to the ASC setting, and/or obtaining enhanced certification from a national accrediting organization.

Commenters opposed to adding these procedures believed that the vast majority of ASCs are not properly equipped to safely perform these procedures and moreover that most Medicare patients are not suitable candidates to receive “overnight” joint arthroplasty procedures in an ASC setting.

In response, CMS states that given the feedback, CMS is not adding these procedures to the ASC list of covered surgical procedures.

6. Covered Ancillary Services

CMS proposed to update the ASC list of covered ancillary services to reflect the payment status for the services under the OPPTS. CMS noted in the proposed rule 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 OPPTS. CMS proposed to continue this reconciliation of packaged status for subsequent years.

CMS did not include a discussion of this section in the final rule, but all ASC covered ancillary services and their payment indicators for 2018 (and labeled as final) are included in Addendum BB at the ASC section on the CMS website.

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

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

CMS finalizes its proposal to update payments for office-based procedures and device-intensive procedures using its established methodology, and using its definition for device-intensive procedures. CMS notes that because the OPPTS relative payment weights are based on geometric mean costs for 2018 and subsequent years, the ASC system will use geometric means to determine the relative payment weights under the ASC standard methodology. CMS will update the payment amount for the service portion of device-intensive procedures using the ASC standard rate-setting methodology, and the payment amount for the device portion based on the

2018 OPPTS device offset percentages. CMS will make payment for office-based procedures at the lesser of the 2018 Medicare PFS non-facility PE RVU-based amount, or the 2018 ASC payment amount calculated according to the standard methodology. CMS continues its policy for device removal procedures – such procedures that are conditionally packaged in the OPPTS will be assigned the current ASC payment indicators and continue to be paid separately under the ASC payment system.

In response to a comment, CMS modified its proposal to assign CPT code 0465T to payment indicator “R2” for 2018. CMS reiterated its established methodologies for updating ASC payment rates.

2. Payment for Covered Ancillary Services

CMS finalizes its proposal to update payments and make changes necessary to maintain consistency between the OPPTS and ASC payment system regarding the packaged or separately payable status of services. CMS also continues to set payment methodologies for brachytherapy services and separately payable drugs and biologicals equal to the 2018 OPPTS rates.

CMS also finalizes its proposal to continue to base payment for separately payable covered radiology services based on the lower of the 2018 Medicare PFS non-facility PE RVU-based amounts and the 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 OPPTS, payment for the radiology service will 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 continues to set payments based on the OPPTS relative payment weights, and therefore will include the cost of the diagnostic radiopharmaceutical. In the case of radiology services that use contrast agents, CMS continues to set payment based on the OPPTS relative payment rate, and will, therefore, include the cost of the contrast agent.

CMS also finalizes its proposal 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 finalizes its proposal 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 finalizes its proposal that the 2018 payment for devices that are eligible for pass-through payment under the OPPTS will be separately paid under the ASC payment system and contractor-priced.

Consistent with its current policy, CMS finalizes its proposal that certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPTS be covered ancillary services when they are integral to an ASC covered surgical procedure. CMS continues to pay for the tests at the lower of the Medicare PFS 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.

CMS did not receive any public comments on its proposals, and CMS finalizes its policies, as proposed.

D. New Technology Intraocular Lenses (NTIOL)

CMS did not receive any requests to establish a new NTIOL class for 2018 by the March 1, 2017 deadline. CMS did not change its payment adjustment of \$50 per lens for a 5-year period from the implementation date of a new NTIOL class.

E. ASC Payment and Comment Indicators

CMS finalizes its proposal to continue using the current comment indicators “NP” and “CH.” 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 will be labeled with the new comment indicator ‘NP’ to indicate that these codes were open for comment as part of the 2018 proposed rule.

Addenda DD1 and DD2 provide a complete list of the ASC payment and comment indicators for the 2018 update. CMS did not receive any public comments on the ASC payment and comment indicators.

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

1. Updating the ASC Relative Payment Rates for 2018 and Future Years

CMS finalizes its proposal to continue to update relative weights using the national OPPTS relative weights and the Medicare PFS non-facility PE RVU-based amounts when applicable. CMS scales the relative weights as under prior policy. Holding ASC use and mix of services constant from 2016, CMS computes the ratio of:

- Total payments using the 2017 relative payment rates, to
- Total payments using the 2018 relative payment rates.

The resulting ratio, 0.8990 (compared with 0.8995 in the proposed rule), is the weight scaler for 2018. The scaler will apply to the ASC relative payment weights of covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes which are covered ancillary services for which the ASC payments are based on OPPTS relative weights. The scaler will not apply to ASC payments for separately payable covered ancillary services that have a predetermined national payment amount and are not based on OPPTS relative payment weights (e.g., drugs and biologicals that are separately paid and services that are contractor-priced or paid at reasonable cost in ASCs). The supporting data file is posted on the CMS Web site at: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/ASCPaymentSystem.html>.

2. Updating the ASC Conversion Factor

CMS continues to compute the budget neutrality adjustment factor for provider level changes (notably for changes in wage index values) to the conversion factor in the same manner as the OPPTS wage index budget neutrality adjustment is calculated and applied to the OPPTS conversion factor. Holding constant ASC use and mix of services in 2016 and the 2018 national payment rates after application of the weight scalar, CMS computes the ratio of:

- ASC payments using the 2017 ASC wage indices, to
- ASC payments using the 2018 ASC wage indices.

The resulting ratio, 1.0007 (compared with 1.0004 in the proposed rule) is the wage index budget neutrality adjustment to the ASC conversion factor for 2018.

CMS continues 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 third quarter forecast, which projected a CPI-U update of 1.7 percent and a MFP adjustment of -0.5 percent. This yields an update of 1.2 percent for ASCs meeting quality reporting requirements.

CMS also continues its policy of reducing the update by 2.0 percentage points for ASCs not meeting the quality reporting requirements, yielding an update of -0.8 percent (a 0.992 update factor) for such ASCs. CMS notes that, as in prior years, it revised the updates from the proposed rule with more current CPI-U or MFP data as part of the final rule.

The resulting 2018 ASC conversion factor by CMS is \$45.575 for ASCs reporting quality data, and \$44.663 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 1.0007	
Net MFP-adjusted update	x 1.012	x 0.992
2018 ASC conversion factor	\$45.575	\$44.663*

* This is the amount CMS published in its final rule. Using the specified update factors, however, the calculated CF for ASCs not reporting quality data totals \$44.674, slightly higher than the published amount.

3. Comment Solicitation on ASC Payment Reform

CMS sought recommendations and ideas to reform the ASC payment system which has not been revised since its implementation in 2008. CMS notes that the absence of ASC-specific cost data makes it difficult to determine whether the facility rates are in line with facility resources costs and whether there is an impact on beneficiary access to care. CMS sought comment specifically on the following:

- The update factor applied to ASC payment rates;
- Whether and how ASCs should submit cost information;
- Whether ASCs should bill on the institutional claim form; and
- Other ideas to improve accuracy in ASC payment rates.

CMS received many comments that CMS briefly summarizes which include the following:

- Rate update factor. The vast majority of commenters favored applying the hospital market basket to update annual ASC payment.
- Collection of cost data. MedPAC recommended that CMS begin collecting new cost data and use that information to examine whether an existing Medicare price index is an appropriate proxy for whether an ASC-specific market basket should be developed. To reduce burden, MedPAC suggested a streamlined cost report or a random sample of ASCs to respond to annual surveys.
- Billing. A few ASC facilities expressed support for requiring ASCs to bill on a UB-04 (institutional claim).
- Payment relativity. Several commenters recommended that CMS apply the OPPTS relative weights to ASC services and discontinue applying the “secondary scaling adjustment”.

CMS stated that it would consider the feedback for future policymaking.

4. 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 89 of the final rule, replicated below, which assumes the same mix of services as reflected in 2016 claims data.

The eye and ocular adnexa group remains the largest source of payments, with a 1 percent increase attributable to the payment changes in 2018. The second largest group, digestive system, is estimated to see a 2 percent increase. Payments for ancillary items and services are estimated to see a 44 percent decrease.

Summary of Table 89: Aggregate 2018 Medicare Program Payments by Surgical Specialty, for the Six Largest Groups and Ancillary Items and Services.		
Surgical Specialty Group	Estimated 2017 ASC Payments (in Millions)	Estimated 2018 Percent Change
Total	\$4,460	1%
Eye and ocular adnexa	\$1,688	1%
Digestive system	\$852	2%
Nervous system	\$849	1%
Musculoskeletal system	\$530	3%
Genitourinary system	\$186	1%
Integumentary system	\$141	5%

Summary of Table 89: Aggregate 2018 Medicare Program Payments by Surgical Specialty, for the Six Largest Groups and Ancillary Items and Services.		
Surgical Specialty Group	Estimated 2017 ASC Payments (in Millions)	Estimated 2018 Percent Change
Ancillary items and services	\$55	-44%

CMS sets out estimated increases for 30 selected procedures in Table 90 in the final rule; the top 10 procedures are replicated below. CPT code 66984 (Cataract surgery with intraocular lens, 1 stage) is the largest aggregate payment procedure by far, and is estimated to see a 1 percent increase.

Excerpt from Table 90: Estimated Impact of the 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
66984	Cataract surg w/iol, 1 stage	\$1,172	1%
45380	Colonoscopy and biopsy	\$216	3%
43239	Egd biopsy single/multiple	\$178	2%
63685	Insert/redo spine n generator	\$151	-1%
45385	Colonoscopy w/lesion removal	\$146	3%
63650	Implant neuroelectrodes	\$118	4%
64483	Inj foramen epidural l/s	\$99	1%
66982	Cataract surgery, complex	\$94	1%
0191T	Insert ant segment drain int	\$86	1%
66821	After cataract laser surgery	\$69	0%

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-FC.html>.

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

XIII. Hospital Outpatient Quality Reporting Program Updates

CMS adopts changes to the Hospital Outpatient Quality Reporting (OQR) Program including the removal of six measures beginning with the 2020 payment determination; indefinite delay in implementing the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare

Providers and Systems (OAS CAHPS) measure; public reporting of one measure; and modifications to the data submission and data validation requirements. A summary table at the end of this section shows all OQR Program measures adopted for the 2015 through 2021 payment determinations.

A. Background

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

No changes are made to existing policies regarding the retention and removal of OQR Program measures, measure selection, or criteria for “topped out” measures. As established under the 2013 OPPTS final rule, once a measure is adopted for the Hospital OQR Program for a payment determination year it is automatically adopted for subsequent years until CMS removes, suspends, or replaces it. Previously, CMS adopted 25 mandatory (plus 1 voluntary) measures for the 2018 and 2019 payment determinations and 32 measures (plus 1 voluntary) for the 2020 payment determination.

B. Hospital OQR Program Quality Measures and Public Reporting

1. Accounting for Social Risk Factors

CMS describes comments it received in response to its request for 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). In requesting comment, CMS discussed recent reports by the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academies of Sciences, Engineering and Medicine, and described the National Quality Forum (NQF) trial period for adjustment of measures for social risk factors.²⁹ Social risk factors might include dual eligibility/low-income subsidy; race and ethnicity; and geographic area. CMS sought comment not only on which factors might be used to adjust or stratify measures, but also whether existing sources of information are available or whether new data collection would be required. Comments on operational considerations were also welcomed. Any related changes to the OQR Program would be proposed through future rulemaking.

²⁹ See Assistant Secretary for Planning and Evaluation, HHS. *Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs*. December 2016. <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicare-value-based-purchasing-programs> and National Academies of Sciences, Engineering, and Medicine. 2017. *Accounting for social risk factors in Medicare payment*. Washington, DC: The National Academies Press. <http://www.nationalacademies.org/hmd/Reports/2017/accounting-for-social-risk-factors-in-medicare-payment-5.aspx>

In responding to comments, CMS reiterates its concern about potentially masking disparities and minimizing incentives to improve outcomes for disadvantaged populations. Support among commenters for risk adjustment of measures was mixed. CMS acknowledges the limitations of claims data, and says it will investigate the feasibility and appropriateness of additional data sources for obtaining patient and community-level data. In investigating options for adjusting social risk factors, CMS will consider alignment across quality programs.

2. Removal of Measures

A total of six measures are removed from the OQR Program, with a modification on timing from the proposed rule. All six measures will be removed beginning with the 2020 payment determination. In the proposed rule, CMS would have removed two measures beginning with 2020 and the other four beginning in 2021. Commenters encouraged CMS to remove the measures as soon as possible, and CMS says that although while preparing the proposed rule it had believed it could not operationally remove all the measures at once, it has now concluded that this is feasible. CMS is finalizing removal, beginning with the 2020 payment determination, of the following six measures:

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

The reasons for removal of these measures vary. For OP-21: Median Time to Pain Management for Long Bone Fracture, it is potential misinterpretation of the measure's intent. While CMS is unaware of any studies that support association of this measure to opioid prescribing practices, it proposes to remove the measure out of an abundance of caution. OP-26 Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures is removed because it is not related to patient outcomes and because CMS believes the reporting burden outweighs the value of this measure. OP-1: Median Time to Fibrinolysis is removed because it is redundant with OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival, a measure more strongly associated with desired patient outcomes. The measures OP-4: Aspirin at Arrival and OP-25: Safe Surgery Checklist are removed because CMS has determined that they meet the criteria as topped out. OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional is removed because CMS agrees with issues identified by a Technical Expert Panel during regular measure maintenance review and concludes that the measure is not linked to improved patient outcomes.

CMS estimates that the removal of these six measures for the 2020 payment determination will reduce the aggregate reporting burden on hospitals by \$16.7 million.

3. Delay of OAS CAHPS Measure

CMS finalizes its proposal to delay indefinitely the implementation of the OAS CAHPS measures, previously scheduled for inclusion in the OQR Program measure set beginning with 2020 payment (2018 data collection). Specifically, in the 2017 OPPTS final rule, CMS adopted five OAS CAHPS based measures, including three composite measures. Since then, CMS has determined that it lacks operational and implementation data, and believes that the voluntary national implementation of the survey which began in 2016³⁰ 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.

In the view of CMS, the OAS CAHPS addresses aspects of care where the patient is the best or only source of information, and enables meaningful comparisons among hospitals. CMS plans to analyze the national implementation data and undertake any necessary changes to the survey tool or CMS systems for future rulemaking. CMS elsewhere in the final rule says that it will continue to evaluate the utility of individual questions and consider opportunities to shorten the survey, particularly whether to remove the demographic questions regarding age and gender.

Responding to comments, CMS thanks the hospitals for the work completed in beginning to prepare for OAS CAHPS implementation. It is actively exploring web-based surveys as possible options for the future, investigating whether hospitals receive reliable email addresses from patients, and assessing whether there is adequate access to the internet across types of patients.

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. OP-2 is considered by CMS as the most feasible measure for development as a eCQM out of all the current OQR Program measures.

Regarding comments opposing the use of eCQMs in the OQR Program until problems with eCQM reporting in the Inpatient Quality Reporting Program are resolved, CMS says that it will take lessons learned from that program into consideration. Commenters suggested other measures topics for the future, including measures addressing TKA and THA procedures and vaccines for adults.

5. Public Display of OP-18 Measure

CMS modifies its proposal to publicly report data on the measure OP-18: Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients. For this measure, data are stratified into four separate calculations: OP-18a is the overall rate; OP-18b is the reporting measure (currently displayed on *Hospital Compare*), which excludes psychiatric/mental health patients and transfer patients; OP-18c assesses psychiatric/mental health patients; and OP-18d assesses transfer patients. CMS had proposed to

³⁰ <https://oascahps.org/General-Information/National-Implementation>

add public reporting of OP-18c on *Hospital Compare* because this component includes numerous substance abuse ICD-10 codes and public reporting would address a behavioral health gap in the OQR Program measure set.

In lieu of reporting OP-18c on *Hospital Compare*, CMS will publish the data in downloadable forms on data.medicare.gov along with other OQR Program measure data. Affected parties will be notified of the availability of the downloadable files via CMS listservs, email, national provider calls and QualityNet announcements. Hospitals will be able to preview the data to be reported for OP-18c as part of the regular 30-day data preview process for OQR Program data. By releasing the data this way and not on *Hospital Compare*, CMS says it wants to be cautious and avoid any unintended consequences raised by commenters, as described below.

Related proposals to rename the component measures and modify Measure Information Form are not finalized.

In not going forward with public reporting of OP-18c on *Hospital Compare*, CMS is responding to comments expressing concern that public display of data on OP-18c could result in unintended consequences. In particular, CMS acknowledges concerns that the time to discharge for mental health patients may be influenced by the availability of community resources, and that the measure could be perceived as creating pressure on providers to inappropriately limit care to quickly discharge these patients. It cites literature showing that the number of inpatient psychiatric beds declined from 400,000 in 1970 to 50,000 in 2006. CMS will continue to work to find the best means to make the information from OP-18c more easily understandable to the public and consider other measures to help fill the behavioral health gap in the future.

C. Administrative and Data Submission Requirements

1. Continuation of Policies

CMS describes ongoing OQR Program policies for which no changes had been proposed. These policies involve 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 (NOP) Deadline

CMS does not finalize its proposal that hospitals must submit the NOP any time *prior to* registering on the QualityNet website. Because participants would have to login to QualityNet in order to submit the NOP, the proposal was not logistically possible. CMS says it received no public comments on this issue. It will revisit the issue in future rulemaking with a goal of making it easier for hospitals to meet the OQR Program participation requirements.

3. Data Submission Requirements for Newly Participating Hospitals

Hospitals that did not participate in the previous year's OQR Program will be required to submit data beginning with encounters occurring during the first calendar quarter of the year prior to the affected payment year. This replaces 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 are 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 final rule, CMS clarifies that the outlier value criterion refers specifically to hospitals with a poor score on a measure. CMS further codifies the procedures for targeting hospitals, including the clarification at 42 CFR 419.46(e)(3).

CMS formalizes its process for educational review and specifies 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 will 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, beginning with the 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 finalizes that during the educational review process, it will determine whether a quarterly validation score was correct using the same process adopted for reconsideration requests. Evaluation of the score will consist of reviewing data elements that were labeled as mismatched in the original validation results. CMS will 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 will be used to compute the hospital's final validation confidence interval at the end of the year. CMS notes that there is insufficient time to make calculations and conduct educational reviews for the last quarter of validation, but the existing reconsideration process will be used to dispute any

unsatisfactory validation result. Importantly, CMS will only use the educational review process to recalculate the validation confidence interval if the result favors the hospital.

5. Extraordinary Circumstances Extensions or Exemptions

CMS finalizes its proposal to align the OQR Program extraordinary circumstances extensions or exemptions (ECE) processes with similar processes for its other quality reporting and value-based purchasing programs. Beginning January 1, 2018, the nomenclature will be changed to “extraordinary circumstances exceptions” and the regulatory text modified accordingly. CMS further notes that it strives to complete its review of each ECE request within 90 days.

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

Existing policies with respect to computing and applying the payment reduction for hospitals that fail to meet the Hospital OQR Program requirements are continued for the 2018 update factor. The reduction ratio for hospitals that fail to meet OQR Program requirements, called the “reporting ratio”, is 0.98. It is calculated by dividing the final reduced conversion factor of \$77.064 by the final full conversion factor of \$78.636. Continuing previous policies, when applicable the reporting ratio is applied to all services calculated using the OPPTS 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 OPPTS.

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

CMS reports that for 2017 payment, 87 hospitals (out of 3,228) failed to meet the OQR Program requirements for a full update factor; 66 of these hospitals chose not to participate in the program. For 2018 and subsequent years, CMS estimates that approximately 100 hospitals will not receive the full OPD fee schedule increase factor.

E. Summary Table of OQR Program Measures

The table below shows 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 for 2015-2021								
NQF		2015	2016	2017	2018	2019	2020	2021
0287 ⁺	OP-1: Median Time to Fibrinolysis	X	X	X	X	X	Removed	
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	Removed	
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
	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	Removed	
0662	OP-21: ED- Median Time to Pain Management for Long Bone Fracture	X	X	X	X	X	Removed	
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

Summary Table—OQR Measures for 2015-2021								
NQF		2015	2016	2017	2018	2019	2020	2021
	OP-25: Safe Surgery Checklist Use	X	X	X	X	X	Removed	
	OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures	X	X	X	X	X	Removed	
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
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						Delayed	
	OP-37b: OAS CAHPS – Communication About Procedure						Delayed	
	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery						Delayed	
	OP-37d: OAS CAHPS – Overall Rating of Facility						Delayed	
	OP-37e: OAS CAHPS – Recommendation of Facility						Delayed	

+ CMS notes that NQF endorsement for the measure has been removed.

Note: The final rule table of measures for 2020 includes a link to procedure categories and corresponding HCPCS codes for OP-26; that link appears to be broken.

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

In the 2012 OPPTS/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: removes three measures from ASCQR Program beginning in 2019; delays implementation of the OAS CAHPS measure slated for 2020; and adds two more measures beginning in 2022. A measure regarding toxic anterior segment syndrome proposed for adoption in 2021 is not finalized. Previously adopted measures will continue unless at some point in the future they are proposed for removal.

1. Accounting for Social Risk Factors

CMS describes comments it received in response to its request for 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). The request for comments is described in item XIII above. CMS will continue to consider suggestions and conduct research as it explores options for accounting for social risk factors in the ASCQR Program. Any changes would be proposed through future notice and comment rulemaking.

2. Removal of Measures

Three measures are removed 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.

CMS concluded that both ASC-5 and ASC-6 meet the criteria as topped out measures. With respect to ASC-7, CMS says that it will continue to adopt measures regarding ASC performance on individual procedures, which are tied to outcomes and which will provide the public with more valuable information.

As part of the regulatory impact analysis, CMS estimates that the removal of ASC-6 and ASC-7 will reduce the data collection burden on ASCs by about \$48,066 across all ASCs. ASC-5 is a claims-based measure and its removal is estimated to result in only a nominal reduction in burden on ASCs.

3. Delay of OAS CAHPS Measure

CMS delays 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 change is discussed above with respect to the OQR Program (XIII.B.3).

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

Based on comments it received, CMS does not finalize its proposal to add this measure to the ASCQR Program beginning in 2021. The 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 is the number of ophthalmic anterior segment surgery patients diagnosed with TASS within 2 days of surgery; the denominator is all ophthalmic anterior segment surgery patients. More information on the measure can be found at:

<http://ascquality.org/documents/ASC-QC-Implementation-Guide-4.0-September-2016.pdf>

CMS decided not to finalize the measure because data show a low number of TASS cases, ranging from a few cases to 20 cases a year, which makes the measure inappropriate for national implementation in the ASCQR Program. CMS refers readers to the ASC Quality Collaboration (link above) which is independently collecting and publicly reporting the measure. Other comments on the measure are addressed.

5. Two New Measures Finalized for 2022

CMS adopts two new claims-based measures 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 assesses all-cause unplanned hospital visits within seven days of the specified orthopedic or urology ASC procedures.

Hospital visits include emergency department visits, observation stays, and unplanned inpatient admissions. The final rule provides details of the measure definition; cohort; risk adjustment; and plans for public reporting. Specifications for each of the new measures are available at: <https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>

CMS describes the numerous comments it received on these measures. In responding, it indicates that it intends to update the Measure Applications Partnership at the next appropriate opportunity with the final results of field testing on the measure, and completed measure specifications. CMS emphasizes that the rate of hospital visits is not expected to be zero, and that only *unplanned* hospital admissions are counted; ED visits and observation stays are never considered planned. CMS says the measure is intended to bring greater awareness as ASC providers are often unaware of patients' subsequent acute care visits. Although most ASCs are expected to have risk-standardized rates that are "no different than national rate" on these measures, CMS believes that *Hospital Compare* will still provide consumers with the ability to distinguish facilities because the data suggest there is still room for improvement. The measures were reviewed for possible risk adjustment for those SES factors available on Medicare claims (dual eligible status; African American race and AHRQ SES Index) and found that these adjustments would result in limited differences in measure results once age and comorbidities were accounted for. Other comments address the link between the measures and payment, measure reliability, and clinical

input in measure development. CMS notes there is an error in Table 4 of the May 2017 Measure Technical Report on ASC-18 in which the column labeled “number of unplanned visits” should read “number of procedures performed.” This will be corrected in future technical documentation.

6. ASCQR Program Measures for Future Consideration

CMS invited public comments on a measure developed by the Centers for Disease Control & Prevention for possible inclusion in the ASCQR Program in the future: Ambulatory Breast Procedure Surgical Site Infection outcome measure (NQF #3015). This measure assesses risk-adjusted standardized infection ratio for surgical site infections following breast procedures conducted at ASCs and reported to the CDC National Healthcare Safety Network. In its 2016 review, the MAP recommended inclusion of this measure in the ASCQR Program pending NQF endorsement, which occurred in January 2017. Some commenters supported the measure; others raised concerns. CMS will take the comments it received into account in future policymaking.

B. Administrative and Data Submission Requirements

Previously adopted ASCQR Program policies that continue unchanged involve 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 finalizes its proposal 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 will 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) will be assigned a vendor ID and an ASC’s representative will submit the Security Administrator form with the assigned vendor ID for the agent to establish their own QualityNet account. Once approved, the agent may submit data for any ASC associated with that ID, individually or in a batch, and access data reports for the same ASCs. Agents will only have access to data reports for facilities that have authorized them to have such access. For batch submission, agents will be provided an external file layout, and must meet all QualityNet account requirements. Details will be provided in future guidance in the Specifications Manual. Changes are made to the regulatory text to reflect this proposal and reference agents submitting data on behalf of an ASC.

2. Extraordinary Circumstances Extensions or Exemptions

CMS finalizes its proposal to align the ASCQR Program extraordinary circumstances extensions or exemptions (ECE) processes with similar processes for its other quality reporting and value-based purchasing programs. Beginning January 1, 2018, the nomenclature will be changed to

“extraordinary circumstances exceptions” and the regulatory text modified accordingly. CMS further notes that it strives to complete its review of each ECE request within 90 days.

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

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

CMS reports that for the 2017 payment determination, 209 of the 3,937 ASCs that met eligibility requirements for the ASCQR Program failed to meet the requirements for a full payment update.

D. Summary Table of ASCQR Program Measures

A table of showing ASCQR Program measures for 2014 through 2021 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									
	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	Removed			
ASC-6: Safe Surgery Checklist Use		X	X	X	X	Removed			
ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures (see below)		X	X	X	X	Removed			
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 #0658)			X	X	X	X	X	X	X
ASC-10 Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance			X	X	X	X	X	X	X

ASCQR Program Measures by Payment Determination Year									
	2014	2015	2016	2017	2018	2019	2020	2021	2022
of Inappropriate Use (NQF #0659)									
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-17: Hospital Visits After Orthopedic ASC Procedure									X
ASC-18: Hospitals Visits After Urology ASC Procedure									X
+ CMS notes that NQF endorsement for the measure has been removed.									

XV. Files Available to the Public via the Internet

To view the OPPTS Addenda to the 2018 final rule, go to:

<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>. Links to the Addenda can be found in the “Related Links” box.

To view the ASC payment system Addenda to the 2018 final rule, go to:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1678-FC.html>. Addenda can be found in the “Downloads” box.

**TABLE 88.—ESTIMATED IMPACT OF THE CY 2018 CHANGES FOR THE HOSPITAL
OUTPATIENT PROSPECTIVE PAYMENT SYSTEM**

	(1)	(2)	(3)	(4)	(5)	(6)
	Number of Hospitals	APC Recalibration (all changes)	New Wage Index and Provider Adjustments	340B Adjustment	All Budget Neutral Changes (combined cols 2-4) with Market Basket Update	All Changes
ALL FACILITIES *	3,878	0.0	0.0	0.0	1.3	1.4
ALL HOSPITALS	3,765	0.0	0.1	-0.1	1.4	1.5
(excludes hospitals permanently held harmless and CMHCs)						
URBAN HOSPITALS	2,951	0.1	0.1	-0.3	1.2	1.3
LARGE URBAN (GT 1 MILL.)	1,589	0.1	0.0	-0.2	1.2	1.3
OTHER URBAN (LE 1 MILL.)	1,362	0.0	0.2	-0.3	1.3	1.4
RURAL HOSPITALS	814	-0.3	0.0	1.4	2.5	2.7
SOLE COMMUNITY	372	-0.2	0.1	2.6	3.9	4.1
OTHER RURAL	442	-0.4	-0.2	0.0	0.8	0.9
BEDS (URBAN)						
0 - 99 BEDS	1,021	0.0	0.0	1.9	3.3	3.4
100-199 BEDS	850	0.0	0.2	1.2	2.8	2.9
200-299 BEDS	468	0.1	0.1	0.5	2.0	2.1
300-499 BEDS	399	0.1	0.0	-0.4	1.1	1.2
500 + BEDS	213	0.0	0.1	-2.2	-0.7	-0.6
BEDS (RURAL)						
0 - 49 BEDS	333	-0.5	-0.2	2.1	2.7	2.9
50- 100 BEDS	297	-0.2	-0.2	1.9	2.8	3.0
101- 149 BEDS	97	-0.3	0.1	1.1	2.3	2.5
150- 199 BEDS	49	-0.2	0.1	0.7	1.9	2.1
200 + BEDS	38	-0.3	0.4	0.8	2.4	2.5
REGION (URBAN)						
NEW ENGLAND	144	0.2	0.4	-0.3	1.7	1.7
MIDDLE ATLANTIC	348	0.1	-0.2	-0.1	1.2	1.3
SOUTH ATLANTIC	463	0.0	0.3	-0.4	1.3	1.4
EAST NORTH CENT.	471	0.0	0.1	-0.2	1.3	1.4

		(1)	(2)	(3)	(4)	(5)	(6)
		Number of Hospitals	APC Recalibration (all changes)	New Wage Index and Provider Adjustments	340B Adjustment	All Budget Neutral Changes (combined cols 2-4) with Market Basket Update	All Changes
	EAST SOUTH CENT.	178	-0.1	-0.1	-1.6	-0.4	-0.3
	WEST NORTH CENT.	191	0.0	0.5	-0.6	1.3	1.4
	WEST SOUTH CENT.	513	0.0	0.3	0.9	2.5	2.6
	MOUNTAIN	211	0.3	-0.9	-0.2	0.5	0.8
	PACIFIC	383	0.1	0.0	-0.6	0.8	0.9
	PUERTO RICO	49	-0.2	0.2	2.9	4.3	4.4
	REGION (RURAL)						
	NEW ENGLAND	21	0.1	1.5	1.2	4.2	4.2
	MIDDLE ATLANTIC	53	0.0	-0.5	1.8	2.6	2.7
	SOUTH ATLANTIC	124	-0.4	-0.6	0.7	1.1	1.2
	EAST NORTH CENT.	122	-0.2	0.0	1.5	2.7	2.8
	EAST SOUTH CENT.	155	-0.6	-0.1	0.0	0.7	0.8
	WEST NORTH CENT.	98	-0.1	0.2	2.4	3.9	4.1
	WEST SOUTH CENT.	161	-0.6	0.3	2.6	3.6	3.7
	MOUNTAIN	56	0.0	-0.3	1.9	3.0	3.3
	PACIFIC	24	-0.1	0.1	1.7	3.0	3.1
	TEACHING STATUS						
	NON-TEACHING	2,655	0.0	0.1	1.3	2.8	2.9
	MINOR	761	0.1	0.1	0.1	1.6	1.7
	MAJOR	349	0.1	0.0	-2.4	-1.0	-0.9
	DSH PATIENT PERCENT						
	0	10	0.0	0.2	3.2	4.8	4.9
	GT 0 - 0.10	272	0.2	-0.1	2.8	4.4	4.5
	0.10 - 0.16	263	0.1	0.0	2.7	4.3	4.4
	0.16 - 0.23	572	0.1	0.3	2.6	4.4	4.5
	0.23 - 0.35	1,132	0.0	0.1	-0.4	1.0	1.2
	GE 0.35	935	0.0	0.0	-2.2	-0.9	-0.8
	DSH NOT AVAILABLE **	581	-2.0	0.1	2.0	1.4	1.5
	URBAN TEACHING/ DSH						
	TEACHING & DSH	1,002	0.1	0.0	-1.1	0.3	0.4

		(1)	(2)	(3)	(4)	(5)	(6)
		Number of Hospitals	APC Recalibration (all changes)	New Wage Index and Provider Adjustments	340B Adjustment	All Budget Neutral Changes (combined cols 2-4) with Market Basket Update	All Changes
	NO TEACHING/ DSH	1,386	0.1	0.2	1.3	3.0	3.1
	NO TEACHING/NO DSH	10	0.0	0.2	3.2	4.8	4.9
	DSH NOT AVAILABLE**	553	-2.0	0.1	1.9	1.4	1.5
TYPE OF OWNERSHIP							
	VOLUNTARY	1,979	0.0	0.0	-0.3	1.2	1.3
	PROPRIETARY	1,293	0.1	0.1	2.7	4.4	4.5
	GOVERNMENT	493	-0.1	0.2	-1.6	-0.1	0.0
CMHCs		49	12.5	0.2	3.2	17.8	17.2

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

Column (2) includes all 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 FY 2018 hospital inpatient wage index, including all hold harmless policies and transitional wages. The rural adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the cancer hospital adjustment is 1.0008 because the target payment-to-cost ratio changes from 0.91 in CY 2017 to 0.89 in CY 2018 and is further reduced by 1 percentage point to 0.88 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 the 340B drug payment reductions and the corresponding increase in non -drug payments.

Column (5) shows the impact of all budget neutrality adjustments and the addition of the 1.35 percent OPD fee schedule update factor (2.7 percent reduced by 0.6 percentage points for the productivity adjustment and further reduced by 0.75 percentage point as required by law).

Column (6) 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 3,878 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.