hfma

healthcare financial management association

Final Rule
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 2019[1] final rule for Medicare's hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system on November 2, 2018; policies in the final rule will generally go into effect on January 1, 2019 unless otherwise specified. The rule will be published in the November 21st issue of the *Federal Register*. The p**ublic comment period on the interim ambulatory patient classification (APC) assignments and/or status indicators for new or replacement Level II HCPCS codes closes on December 3, 2018.** (Note: This is an earlier comment period deadline than usual has been specified in earlier years. In earlier years, the comment period typically ended on December 31.)

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-1695-FC.html. Unless otherwise noted, this weblink can be used to access any information specified as being available on the CMS website.

TABLE OF CONTENTS	Page

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

I. Overview

A. Estimated Impact on Hospitals

The total 2019 increase in Federal government expenditures due only to changes in the 2019 OPPS final rule is estimated to be approximately $440 million. Including estimated changes in enrollment, utilization, beneficiary cost-sharing and case-mix, CMS estimates that the 2019 increase in OPPS expenditures will be approximately $5.8 billion. Total OPPS expenditures are estimated to be about $74.1 billion in 2019. These spending estimates include the 2019 final rule policy to control for unnecessary increases in the volume of covered hospital outpatient department (HOPD) services by paying for clinic visits furnished at excepted off campus provider-based departments (PBD) at a rate that will be 70 percent of the OPPS rate for a clinic visit service. The final rule impact table indicates that Medicare makes payments under the OPPS to 3,840 facilities (3,727 hospitals excluding CMHCs and cancer and children's hospitals held harmless to their pre-OPPS payment to cost ratios).

CMS estimates that the update to the conversion factor and other adjustments (not including the effects of outlier payments, pass-through payment estimates, the application of the frontier state wage adjustment, and controlling for unnecessary increases in the volume of covered HOPD services) will increase total OPPS payments by 1.3 percent in 2019. As explained below, CMS estimates that the change in payments between 2018 and 2019, considering all factors will be an increase in total estimated OPPS payments by 0.6 percent.

The update equals the market basket of 2.9 percent reduced by a multifactor productivity adjustment of 0.8 percentage points and a statutory factor of 0.75 percentage points, resulting in the OPPS increase factor of 1.35 percent. 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. All other adjustments are the same for the two sets of hospitals. Of the 3,300 hospitals that met eligibility requirements to report quality data, CMS

determined that 36 hospitals did not meet the requirements to receive the full OPPS increase factor. One half of these hospitals (18 of 36), chose not to participate in the Hospital OQR Program.

Table 62 in the final rule (reproduced in the Appendix to this summary) includes the estimated impact of the final rule by provider type. It shows an estimated increase in expenditures of 0.6 percent for all facilities and 0.6 percent for all hospitals (all facilities except cancer and children's hospitals, and CMHCs). The following table shows components of the 0.6 percent total:

	% Change All Facilities
All changes	0.64
Fee schedule increase factor	1.35
Difference in pass through estimates for 2018 and 2019	-0.10
Difference from 2018 outlier payments (1.01% vs. 1.0%)	-0.01
Site Neutral Payment for Clinic Visits	-0.60

CMS estimates that pass-through spending for drugs, biologicals and devices for 2019 will be $100.8 million, or 0.14 percent of OPPS spending. For 2018, CMS pass-through spending would be 0.04 percent for 2018. The -0.10 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 2018 will represent 1.01 percent of total OPPS payments compared to the 1.0 percent set aside, for an estimated decrease in 2019 payments of 0.01 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 estimated increase of 0.6 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. Impacts for selected categories of hospitals are shown in the table below:

Facility Type	**2019 Impact**
All Hospitals	0.6
All Facilities (includes CMHCs and cancer and children's hospitals)	0.6
Urban	0.7
Large Urban	0.7
Other Urban	0.6
Rural	0.5
Beds	
0-99 (Urban)	1.1
0-99 (Rural)	1.3
500+ (Urban)	0.5
200+ (Rural)	0.1

Facility Type	2019 Impact
Major Teaching	0.4
Type of ownership:	
Voluntary	0.6
Proprietary	1.0
Government	0.5
CMHCs	-15.1

The larger increase for small urban hospitals (0-99 beds) is accounted for by APC recalibration (+0.4 percent) and a modestly lower reduction (-0.4 percent) from the site neutral policy than all hospitals (-0.6 percent). Similarly, the larger increase for small rural hospitals (0-49 beds) is accounted for by APC recalibration (+0.4 percent) and a lower reduction (-0.2 percent) from the site neutral policy. The smaller increase for large rural hospitals (+0.1 percent) relative to the average is accounted for by APC recalibration (-0.3 percent), changes to the wage index (-0.3 percent) and a lower impact from the site neutral policy (-0.5 percent). The larger increase for proprietary hospitals is accounted for by a lesser reduction from the site neutral policy (-0.2 percent) than the average for all hospitals.

By geographic region, the largest deviation from the national average estimated impact occurs in urban New England (+2.1 percent) and rural New England (-1.6 percent):

Region	Projected 2019 Impact
Urban New England	+2.1%
Rural New England	-1.6%

For urban New England, the larger increase is accounted for by wage index changes (+1.7 percent) compared to the national average (0.0 percent). CMS does not explain this larger increase for urban New England hospitals. However, the OPPS uses the same wage index as is used for the IPPS. In the FY 2019 IPPS final rule, CMS indicated:

> We estimate that Massachusetts hospitals will receive approximately a 3.3 percent increase in IPPS payments due to the application of the rural floor in FY 2019. We note that the significant increase in overall payments to hospitals in Massachusetts compared to past years is due primarily to the increase in the Massachusetts rural floor as a result of the recent reclassification of Brigham and Women's Hospital in the city of Boston as a rural hospital under §412.103. (83 FR 71748)

Given use of the same wage index for the OPPS and the IPPS, it seems likely that the increase in OPPS payments in urban New England results from the increase in the rural floor in Massachusetts that will benefit urban hospitals within the state. The larger reduction to payments to rural New England hospitals is accounted for by the wage index (-0.7 percent compared to 0.0 for all hospitals) and the site neutral policy (-2.0 percent compared to -0.6 percent for all hospitals).

The impact on CMHCs is explained by changes resulting from APC recalibration.

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 2019. 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.

II. Updates Affecting OPPS Payments

A. Recalibration of APC Relative Payment Weights

As described below, CMS is largely continuing past policies unchanged. The only changes CMS proposed are to exclude procedures assigned to new technology APCs from being packaged with C-APCs and to create three new C-APCs for ENT and vascular procedures.

1. Database Construction

a. Database Source and Methodology

For the 2019 final rule, CMS uses hospital final action claims for services furnished from January 1, 2017 through December 31, 2017 processed through the Common Working File as of June 30, 2018. Cost data are from the most recently filed cost reports, in most cases for cost reporting periods beginning in 2016. 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.

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 retrieve more data from multiple procedure claims.

For the 2019 final rule, CMS bypasses the 169 Healthcare Common Procedure Coding System (HCPCS) codes identified in Addendum N. CMS indicates the list of bypass codes may include codes that were reported on claims in 2017 but were deleted for 2018. CMS did not propose to delete any codes from the bypass list for 2019. CMS received no comments on these methodological issues and is adopting all policies as proposed without change.

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 cost-to-charge ratio (CCR) associated with each revenue code and cost center. To calculate CCRs for 2019, CMS is employing the same basic approach used for

APC rate construction for 2007 and each subsequent year. 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 of CCRs for each revenue code. The current crosswalk is available for review and continuous comment on the CMS website at the link provided at the beginning of this summary. CMS notes that no new revenue codes were added for 2017, which is the year of claims data used for deriving the 2019 payment rates. 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.

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

CMS proposed extending the transition policy by an additional year through 2019.

Table 1 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 2 of the final rule provides statistical values based on the CT and MRI standard cost center CCRs using the different cost allocation methods. Table 1 and Table 2 are reprinted below.

Table 1—Percentage Change in Estimated Cost for CT and MRI APCs when Excluding Claims from Providers Using "Square Feet" as the Cost Allocation Method

APC	APC Descriptor	Percentage Change
5521	Level 1 Imaging without Contrast	-4.0%
5522	Level 2 Imaging without Contrast	5.6%
5523	Level 3 Imaging without Contrast	4.2%
5524	Level 4 Imaging without Contrast	5.3%
5571	Level 1 Imaging with Contrast	7.8%
5572	Level 2 Imaging with Contrast	8.3%
5573	Level 3 Imaging with Contrast	2.8%
8005	CT and CTA without Contrast Composite	14.1%
8006	CT and CTA with Contrast Composite	11.5%
8007	MRI and MRA without Contrast Composite	6.5%
8008	MRI and MRA with Contrast Composite	6.8%

Table 2—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	0.0370	0.0512	0.0774	0.1020
Square Feet Only	0.0300	0.0453	0.0682	0.0928

Cost Allocation Method	CT		MRI	
	Median CCR	Mean CCR	Median CCR	Mean CCR
Direct Assign	0.0554	0.0642	0.1003	0.1198
Dollar Value	0.0435	0.0588	0.0866	0.1134
Direct Assign and Dollar Value	0.0438	0.0589	0.0868	0.1133

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 1, eliminating these hospitals from the OPPS rate setting methodology increases the payment for all but one of the imaging APCs because hospitals that use the square foot allocation have lower CCRs for their imaging cost centers.

Comments/Responses: Commenters supported CMS' proposal. Public comments also requested that CMS discontinue the use of CT and MRI CCRs and use a single diagnostic radiology CCR instead because of concerns that the CT and MRI CCRs are flawed. Their use will result in OPPS payments being below physician fee schedule (PFS) payments resulting in further reduction in PFS payments that are capped at the OPPS payment amount.

CMS responded to comments requesting that CMS discontinue use of the CT and MRI cost centers by including two additional tables showing the distribution of the CCRs by cost allocation method for the CT and MRI cost centers. These tables are reprinted below:

TABLE 3—SELECTED DISTRIBUTION OF CT CCR STATISTICAL VALUES BASED ON USE OF DIFFERENT COST ALLOCATION METHODS

Cost Allocation Method	Minimum	5th Percentile	10th Percentile	90th Percentile	95th Percentile	Maximum
All Providers	0.0036	0.0115	0.0147	0.1010	0.1399	0.4052
Square Feet Only	0.0036	0.0099	0.0121	0.0922	0.1379	0.4052
Direct Assign	0.0055	0.0222	0.0259	0.1223	0.1534	0.2282
Dollar Value	0.0046	0.0180	0.0223	0.1087	0.1458	0.4009
Direct Assign and Dollar Value	0.0046	0.0179	0.0224	0.1087	0.1493	0.4009

TABLE 4—SELECTED DISTRIBUTION OF MRI CCR STATISTICAL VALUES BASED ON USE OF DIFFERENT COST ALLOCATION METHODS

Cost Allocation Method	Minimum	5th Percentile	10th Percentile	90th Percentile	95th Percentile	Maximum
All Providers	0.0106	0.0292	0.0355	0.1975	0.2653	0.6700
Square Feet Only	0.0106	0.0247	0.0305	0.1822	0.2469	0.6563
Direct Assign	0.0271	0.0456	0.0525	0.2119	0.2904	0.6081
Dollar Value	0.0175	0.0365	0.0446	0.2187	0.2920	0.6700
Direct Assign and Dollar Value	0.0175	0.0365	0.0447	0.2155	0.2916	0.6700

CMS concludes that the CT CCR distributions and MRI CCR distributions are largely similar across the cost allocation method. CMS acknowledges the concerns in the comments and will

monitor the impact on payments, however, it does not believe another extension in 2020 will be warranted. It expects to determine the imaging APC relative payment weights for 2020 using cost data from all providers, regardless of the cost allocation method employed.

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

From the inception of the OPPS 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, an outpatient hospital visit—the most commonly furnished service billed under the OPPS. CMS is continuing to follow this basic process for 2019. The 2017 claims data that CMS is using for 2019 includes data from off-campus PBDs paid at a PFS comparable amount under section 603 of the Bipartisan Budget Act (BBA) of 2015. These claims have modifier "PN" on the claim. CMS is eliminating claims with modifier "PN" from the relative weight calculation as they are not paid under the OPPS.

Comments/Responses: CMS received two comments on the data development process. One comment indicated that CMS inadvertently excluded revenue code 0815 (Allogeneic Stem Cell Acquisition Services) from the packaged revenue code list for use in the OPPS rate setting. CMS agreed with this comment and is including this revenue code for determining the final rule relative weights. The second comment requested CMS not remove claims with the "PN" modifier from the OPPS rate setting process indicating that doing so would result in unfair adjustments against HOPDs with a large off-campus provider-based department presence. CMS responded that removing these claims has a nominal effect on APC geometric mean costs and will remove the claims because they are not paid under the OPPS.

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 2019, 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. The relative weights for blood and blood product APCs are determined by converting charges to costs using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and 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. HCPCS codes and their associated APCs for blood and blood products are identified with a status indicator of "R" (Blood and Blood Products) in Addendum B of the final rule.

Pathogen-Reduced Platelets and Rapid Bacterial Testing for Platelets

CMS recounts the history and coding for pathogen-reduced platelets and rapid bacterial testing of platelets going back to 2016. Pathogen reduction is a costlier service than rapid bacterial testing; however, a single code was created for both services. As a result, CMS was concerned that the OPPS relative weight for pathogen reduction would be too low as evidence suggested a single code was being used to bill for two different services which vary significantly in costs. Until this concern could be addressed, CMS created a code for pathogen reduction only and crosswalked its relative weight until claims data were available to price code P9073 under the normal claim's methodology. For the proposed rule, CMS was confident in the accuracy of the billing for the temporary predecessor codes to P9073 and proposed to use its normal methodology to develop pricing for 2019.

Comments/Responses: Public commenters objected to CMS' proposal requesting that it continue the crosswalk through either 2019 or 2020 because of continued concerns about coding errors and confusion and costs in the claims being lower than the actual cost of the services. CMS agreed with the commenters and is continuing its crosswalk methodology for pathogen-reduced platelets for 2019.

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. Since 2010, CMS has used the standard OPPS payment methodology for brachytherapy sources, with payment rates based on source-specific costs as required by statute. CMS proposed no changes to its brachytherapy policy for 2019

If CMS does not have billing data to set the payment rates, it may use external data to set prices for brachytherapy sources. CMS proposed to use external data to set the APC payment rate for HCPCS code C2645 ((Brachytherapy planar source, palladium-103, per square millimeter) at $4.69 per mm^2, the same payment rate that was in effect for 2017 and 2018. CMS proposed to assign status indicator "E2" (Items and Services for Which Pricing Information and Claims Data Are Not Available) to HCPCS code C2644 (Brachytherapy cesium-131 chloride).

Recommendations for HCPCS codes that describe new brachytherapy sources 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.

Comments/Responses: One commenter objected to CMS using its traditional OPPS rate setting methodology for brachytherapy services on the basis that low volume makes the payment rates unstable from year to year. CMS acknowledged that payment rates can be unstable for low

volume services from year to year but presented data in the final rule showing the relative stability of payment rates for brachytherapy sources.

CMS is finalizing all of its proposals without change. The final payment rates appear in Addendum B to the final rule and are identified with status indicator "U" (Paid under OPPS; separate APC payment).

b. Comprehensive APCs (C-APCs) for 2019

A C-APC is defined as a classification for a primary service and all adjunctive services provided to support the delivery of the primary service. 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.

CMS also assigns a C-APC to specific services performed in combination with each other. Applying C-APC policies to these code combinations means that other OPPS payable services and items reported on the claim are treated as adjunctive to the comprehensive service. A single prospective payment is made for the comprehensive service based on the costs of all reported services on the claim.

Certain combinations of comprehensive services are recognized for higher payment through complexity adjustments. Qualifying services are reassigned from the originating C-APC to a higher paying C-APC in the same clinical family of comprehensive APCs. Currently, code combinations satisfying the complexity criteria are moved to the next higher cost C-APC within the clinical family, unless (1) the APC reassignment is not clinically appropriate, or (2) 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.

Additional C-APCs for 2019

CMS proposed to add three C-APCs under the existing C-APC payment policy beginning in 2019: C-APC 5163 (Level 3 ENT Procedures); C-APC 5183 (Level 3 Vascular Procedures); and C-APC 5184 (Level 4 Vascular Procedures).

Comments/Responses: There were comments in support of adding these three new C-APCs; a number of comments concerned about the C-APC policy in general; requests for the addition of new C-APCs; and concerns about a variety of existing C-APCs. CMS is finalizing the new C-APCs as proposed without any changes. In response to the other comments, CMS generally continued to support the existing C-APC policies and declined to make changes to C-APCs where it had not specifically made any proposals. Table 7 of the final rule includes a list of all of the C-APCs for 2019.

Exclusion of Procedures Assigned to New Technology APCs from C-APC Packaging

CMS proposed to exclude procedures assigned to new technology APCs from being packaged into C-APCs because of a concern that packaging payment reduces claims for the new technology that are available for APC pricing. The proposed rule indicated that packaging in this circumstance is contrary to the objective of the New Technology APC payment policy, which is to gather sufficient claims data to enable CMS to assign the service to an appropriate clinical APC.

Comments/Responses: Commenters supported CMS' proposal that it is finalizing without change.

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 unchanged composite policies for mental health services and multiple imaging services for 2019.

3. Changes to Packaged Items and Services

Drugs that function as a supply are packaged under the OPPS and the ASC payment system, regardless of the costs of the drugs. CMS examined this policy for 2019 in response to the President's Commission on Combating Drug Addiction and the Opioid Crisis (the Commission). The Commission recommended that CMS "…review and modify rate setting policies that discourage the use of non-opioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors, particularly those options for treating immediate postsurgical pain…."[2] The Commission's concern is that the policy leads to incentives to prescribe opioid medications to patients for postsurgical pain instead of administering non-opioid pain medications.

Utilization of Non-Opioid Alternatives in the Outpatient Department

CMS evaluated utilization patterns associated with specific drugs that function as a supply from 2013 to 2017 to determine whether the packaging policy has reduced the use of these drugs. CMS did not observe significant declines in the total number of units used in the HOPD for a majority of the drugs included in its analysis. CMS observed the opposite effect for several drugs that function as a supply including Exparel (HCPCS code C9290), a liposome injection of bupivacaine, an amide local anesthetic, indicated for single-dose infiltration into the surgical site to produce postsurgical analgesia. According to CMS, utilization of this drug in the HOPD continued to increase beyond the period of pass-through payment even though payment for the drug was packaged with its associated surgical procedure. Despite these findings, CMS invited public comments on separate payment for Exparel in the hospital outpatient setting and peer-

[2] President's Commission on Combating Drug Addiction and the Opioid Crisis, Report (2017). Available at: https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf

reviewed evidence that an increase in utilization for this product would decrease opioid use and addiction among Medicare beneficiaries.

Comments/Responses: Public commenters supported paying separately for Exparel in the hospital outpatient setting with the product's manufacturer indicating that growth in utilization of the drug plateaued after the drug was packaged in 2015. CMS declined to pay separately for Exparel or other non-opioid drugs indicating that commenters did not furnish evidence that the OPPS packaging policy creates a barrier to use of these products in the hospital setting. The final rule indicates that growth in utilization of a new product would be expected to plateau after an initial period of significant utilization growth following introduction into the market.

Utilization of Non-Opioid Alternatives in the Ambulatory Surgical Center

CMS' findings in the ASC setting were different than the HOPD. During 2013 through 2017, CMS found a decrease in claims and utilization of Exparel after pass-through payments ended. As a result of declining utilization of Exparel in the ASC setting once the drug stopped receiving pass-through payment, CMS proposed to unpackage and pay separately for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for 2019.

Comments/Responses: Several commenters supported CMS' proposal to unpackage and pay separately for the cost of non-opioid pain management drugs that function as surgical supplies, such as Exparel, in the ASC setting for 2019. These commenters stated that packaged payment for non-opioid alternatives presents a barrier to care and that separate payment for non-opioid pain management drugs would be an appropriate response to the opioid drug abuse epidemic. Other commenters, including the Medicare Payment Advisory Commission (MedPAC), opposed CMS' proposal as counter to OPPS packaging policies created to encourage efficiencies and could establish a precedent to unpackage other items and services. Other commenters were concerned that CMS' proposed policy would lead to legitimate use of opioids not being prescribed.

CMS responded that it is appropriate to pay separately for non-opioid pain management drugs where there is evidence that their use leads to decreased opioid use and/or addiction among Medicare beneficiaries following an outpatient visit or procedure. While CMS acknowledges that its policy is a departure from the current ASC packaging policy, it also believes that the limited scope of this policy is sufficiently narrow and will not set an unwarranted precedent for the unpackaging other ASC services. CMS does not believe that this policy will limit access to opioid prescriptions for beneficiaries for whom an opioid prescription would be appropriate. The decision on how to best treat a patient is a complex medical judgment made by the physician based on each individual beneficiary's unique clinical circumstances.

Evidence that Non-Opioid Alternatives Lead to Reduced Use of Opioids

CMS also sought public comments and peer-reviewed literature regarding whether separate payment would provide incentives to use Exparel or other non-opioid drugs or devices during an

outpatient visit or procedure and lead to a decrease in opioid use and addiction among Medicare beneficiaries.

Comments/Responses: One commenter submitted studies that claimed that the use of Exparel by Medicare patients undergoing total knee replacement procedures reduced prescription opioid consumption by 90 percent compared to the control group measured at 48 hours post-surgery. The commenter submitted additional studies claiming statistically significant reductions in opioid use with use of Exparel for various surgeries including laparotomy, shoulder replacement, and breast reconstruction. Several commenters submitted supporting studies which claimed that a non-opioid intrathecal infusion drug indicated for the management of severe chronic pain reduced opioid use in patients with chronic pain. Public commenters suggested many products that could function as non-opioid treatment alternatives for which Medicare could provide separate payment.

Providing an Add-on Payment or Reorganizing the APC Structure for Non-Opioid Treatment Alternatives

CMS solicited comments regarding whether to provide an equitable adjustment using its authority at section 1833(t)(2)(E) of the Act to provide an add-on payment for non-opioid treatment alternatives. Alternatively, CMS requested comments on reorganizing or establishing more granular APC groupings to provide incentives for increased use of non-opioid alternatives.

Comments/Responses: Some commenters suggested that CMS support multi-modal pain management and enhanced recovery after surgery and encourage patient access to certified registered nurse anesthetist pain management. One commenter also suggested that CMS reduce cost sharing and eliminate the need for prior authorization for non-opioid pain management strategies. In response to these and other comments, CMS thanked the commenters for their suggestions but is not taking any additional action in the final rule.

Final Rule Policy: After reviewing the studies provided by the commenters, CMS believes separate payment is appropriate for Exparel at average sales price plus 6 percent in the ASC setting but has not found compelling evidence for other non-opioid pain management drugs to warrant separate payment. To the extent that other non-opioid pain management drugs that function as a surgical supply become available in the U.S. market in 2019, this policy would also apply to those drugs. CMS plans to take suggestions for separate payment for other products into consideration for future rulemaking.

4. Calculation of OPPS Scaled Payment Weights

As in past years, CMS will standardize the relative weights based on APC 5012 (Level 2 Examinations and Related Services) because that is the APC where HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) is assigned. G0463 is the most commonly billed OPPS service. CMS is giving APC 5012 a relative weight of 1.0 and dividing the geometric mean costs of all other APCs by the geometric mean cost for APC 5012 to determine its associated relative payment weight. Even though CMS is paying for clinic visits furnished in off-campus PBDs at a PFS equivalent rate under a site neutral policy, CMS is

continuing to use visits in these settings to determine the relative weight scaler because the PFS adjuster is applied to the payment, not the relative weight. CMS' site neutral policy is not budget neutral while changes to the weights are budget neutral.

CMS is following its past practice with respect to applying budget neutrality for changes in the OPPS relative weights. Holding all other variables constant, CMS multiplies the 2018 and 2019 relative weights respectively for each APC by its associated volume from 2017. It sums the 2018 and 2019 relative weights respectively, and then divides the 2018 aggregate relative weights by the 2019 aggregate relative weights to determine the weight scaler. Using this process, CMS is adopting a weight scaler of 1.4574. The unscaled 2019 relative payments are multiplied by 1.4574 to determine the 2019 scaled relative weights that are shown in Addendum A and B.

B. Conversion Factor Update

CMS is adopting a conversion factor for 2019 of $79.490 for hospitals receiving the full update for outpatient quality reporting (OQR). The calculation is as shown in the below table:

2018 Conversion Factor	$78.636
Update	1.0135
Cancer Hospital Adj.	1.0000
Wage Index Budget Neutrality	0.9984
Pass-Through Budget Neutrality	0.9990
2019 Conversion Factor	$79.490

- The update of 1.0135 equals the market basket of 2.9 percent less 0.8 percentage points for multifactor productivity and 0.75 percentage points required by statute.
- CMS is not making any changes to the cancer hospital adjustment so that factor is 1.0.
- The wage index budget neutrality factor of 0.9984 or -0.16%.
- Pass-through spending for drugs, biologicals and devices for 2019 are estimated to be $100.8 million, or 0.14 percent of projected OPPS spending. The adjustment to the rates of -0.1 percent reflects the difference between this projection and the 0.04 percent estimate for 2018.

CMS reports that the reduced conversion factor for hospitals not meeting the OQR requirements will be $77.900. However, it is unclear how CMS determined the reduced conversion factor. CMS alternately says in three different places in the rule that it arrived at the reduced conversion factor by multiplying the full conversion factor by a "reporting ratio" of 0.98 and determined the reporting ratio by dividing the reduced conversion factor by the full conversion factor. Elsewhere in the final rule, CMS indicates that the update for hospitals not meeting the OQR will receive a reduced update that is 2.0 percentage points less than the update for hospitals that meet the OQR requirements. Substituting an update of 0.9935 (1.0135-0.020) for the full update into the above calculation produces a conversion factor of $77.922 which would be slightly higher than conversion factor CMS calculates for hospitals not meeting the OQR requirements.

C. Wage Index Changes

CMS continues its policy of using the final fiscal year IPPS post-reclassified wage index for urban and rural areas as the OPPS calendar year wage index to adjust the OPPS standard payment rate and the copayment standardized amount for labor market differences. The 2019 OPPS final rule wage index is based on the FY 2019 IPPS final post-reclassified wage index; any adjustments for the FY 2019 IPPS final post-reclassified wage index are reflected in the final 2019 OPPS wage index.

CMS retains the OPPS labor-related share of 60 percent for purposes of applying the wage index for 2019 and notes that the wage index adjustment is made in a budget neutral manner.

CMS finalizes its proposal to use the OMB statistical area delineations implemented beginning with FY 2015 and updated by OMB Bulletin numbers 13-01, 15-01 and 17-01 to calculate the area wage indexes. OMB Bulletin No. 17-01 (the latest update) was issued on August 15, 2017, and in it, OMB announced that one Micropolitan Statistical Area (Twin Falls, Idaho (CBSA 46300)) qualifies as a Metropolitan Statistical Area. CMS incorporates the updates into the final 2019 OPPS wage index, rate setting, and tables.

CBSAs and constituent counties within CBSAs each have unique identifying codes. CMS notes that, effective January 1, 2018, it transitioned to using only Federal Information Processing Standard (FIPS) code updates for the OPPS wage index. CMS uses the Census Bureau update changes to counties and county equivalent entities to calculate area wage indexes consistent with the CBSA-based methodologies finalized in the FY 2015 IPPS/LTCH PPS final rule.

With respect to the wage index adjustments called for in the ACA, CMS finalizes its proposals to continue established policies in implementing those adjustments. The adjustments include the "frontier state" adjustment that requires a wage index floor of 1.0 in certain cases if the otherwise applicable wage index (including reclassification, rural floor, and rural floor budget neutrality adjustment) is less than 1.0. Because an HOPD receives a wage index based on the geographic location of the specific inpatient hospital with which it is associated, the frontier state wage index adjustment applicable for the inpatient hospital also applies for any associated HOPD.

Several commenters objected to the application of the budget neutrality adjustment for the rural floor on a national basis under the OPPS. They believe this policy disadvantages hospitals in most states while benefitting those in a few states that take advantage of a rural hospital that has a higher wage index than most or all of the urban hospitals in the state. CMS responds that it is reasonable and appropriate for the agency to continue its current policy of applying budget neutrality for the rural floor on a national basis consistently under the OPPS and the IPPS.

In the FY 2019 IPPS/LTCH PPS final rule, CMS finalized its proposal to discontinue the imputed floor policy (both the original methodology and alternative methodology) for fiscal year 2019 and subsequent fiscal years. For purposes of the OPPS, CMS discontinues the application of the imputed floor policy to hospitals paid under the OPPS effective for 2019 and subsequent years.

For non-IPPS hospitals paid under the OPPS for 2019, CMS continues its policy of assigning 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 also continues its policy of allowing non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a county designated as an out-migration county under section 505 of the MMA. Addendum L to the final rule contains information from Table 2 of the FY 2019 IPPS/LTCH PPS final rule which identifies counties eligible for the out-migration adjustment as well as IPPS hospitals that will receive the adjustment for FY 2019; it also contains information on non-IPPS hospitals that will receive the section 505 out-migration adjustment under the 2019 OPPS.

CMS reminds readers that, in the 2015 final OPPS rule, it adopted a 3-year transition period for hospitals paid under the OPPS but not under the IPPS that were located in urban counties that would 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 was 2017, and it was not applied in 2018.

For CMHCs, CMS will continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. CMS notes that consistent with its current policy, the wage index that applies to CMHCs includes the rural floor adjustment (other than the imputed floor adjustment which CMS discontinues), but it does not include the out-migration adjustment, which only applies to hospitals.

D. Statewide Average Default CCRs

In cases where there is no data to calculate a hospital's CCR, CMS uses the statewide average to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS. Among other reasons, the statewide average is used for hospitals that are new, hospitals that have not accepted assignment of an existing hospital's provider agreement, and hospitals that have not yet submitted a cost report. CMS also uses the statewide average default CCRs to determine payments for hospitals that appear to have a CCR falling outside the predetermined ceiling threshold for a valid CCR or for hospitals in which the most recent cost report reflects an all-inclusive rate status. CMS is updating the default statewide average CCRs for 2019 using the most recent cost report data. Table 9 lists the statewide average default CCRs for OPPS services furnished in 2019. They appear to have changed very little from the 2018 CCRs.

E. Sole Community Hospital Adjustment for 2019

For 2019, CMS is continuing to apply a 7.1 percent payment adjustment under section 1833(t)(13)(B) of the Act for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs. The adjustment is budget neutral and is applied before calculating outliers and copayments.

Comments/Responses: CMS received comments asking it to revisit the 7.1 percent adjustment using updated data and that the adjustment be expanded to urban SCHs and Medicare dependent hospitals. In response, CMS said that it periodically reviews the calculations used to generate the adjustment. For any given year, the level of increased costs for rural SCHs and EACHs may be higher or lower than the current 7.1 percent adjustment. Since being established in 2008, CMS believes the payment increase of 7.1 percent has continued to reasonably reflect the increased costs that rural SCHs and EACHs face when providing outpatient hospital services. CMS declined to expand the adjustment to other hospitals noting that its analysis did not support an adjustment for any other types of hospitals.

F. Cancer Hospital Adjustment for 2019

Medicare law exempts 11 cancer hospitals meeting statutory classification criteria for exclusion from payment under the IPPS. Since the inception of the OPPS, Medicare has paid these hospitals under the OPPS for covered outpatient hospital services. The ACA requires an adjustment to cancer hospitals' outpatient payments sufficient to bring each hospital's payment-to-cost ratio (PCR) up to the level of the PCR for all other hospitals—the target PCR. The change in these additional payments from year to year is budget neutral. The 21st Century Cures Act reduced the target PCR to 1.0 percentage point less than all other hospitals. The additional 1.0 percentage point reduction is excluded from OPPS budget neutrality.

The cancer hospital adjustment is applied at cost report settlement rather than on a claim by claim basis. For 2019, CMS updated its calculations using the latest available cost data and determined a 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. This additional 1.0 percentage point reduction is not subject to OPPS budget neutrality.

Table 10 in the final rule shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals, with increases in OPPS payments for 2019 ranging from 8.4 percent to 54.3 percent. CMS indicates that no budget neutrality adjustment is required for additional cancer hospital payments in 2019.

G. Hospital Outpatient Outlier Payments

The OPPS makes outlier payments on a service-by-service basis when the cost of a service exceeds the outlier threshold. For 2019, CMS is continuing to set aside 1.0 percent of the estimated aggregate total payments under the OPPS for outlier payments. It calculates the fixed-dollar threshold using the same methodology that was used to set the threshold for 2018 and previous years. 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 ($4,600) are met.

For the 2019 final rule, CMS provides that the outlier threshold would be met when a hospital's cost of furnishing a service or procedure exceeds 1.75 times the APC payment amount and also exceeds the APC payment rate plus a $4,825 fixed-dollar threshold (compared to $4,150 in 2018). The proposed rule outlier threshold for 2019 was $4,600.

CMS is again setting aside a portion of the 1.0 percent outlier pool, specifically an amount equal to less than 0.01 percent of outlier payments, for 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 OPPS annual payment update factor, resulting in reduced OPPS payments for most services. For hospitals failing to satisfy the quality reporting requirements, CMS is continuing its policy that a hospital's costs for the service are compared to the reduced payment level for purposes of determining outlier eligibility and payment amount.

To model hospital outlier payments and set the outlier threshold for the final rule, CMS applied the hospital-specific overall ancillary CCRs available in the October, 2018 update to the Outpatient Provider-Specific File after adjustment (using a CCR inflation adjustment factor of 0.9813 to approximate 2019 CCRs) and to charges on 2017 claims. CMS is using the 1-year average annualized rate-of-change in charges per case equal to 1.0434. Not mentioned in the final rule but this should result in a two-year increase of 1.08868 to approximate 2019 charges. The inflation adjustment factors for CCRs and charges are the same as were used for the FY 2019 IPPS proposed rule.

Comments/Responses: One commenter requested that the increase in the outlier threshold be transitioned over three years because its magnitude would have an adverse effect on access to services for Medicare beneficiaries. CMS declined to adopt that suggestion indicating that the increase in the fixed-dollar outlier threshold does not necessarily result in a decrease in aggregate OPPS outlier payments. Rather, it ensures that the aggregate pool remains at 1 percent and that outlier payments are directed towards the high cost and complex procedures associated with potential financial risk.

H. Calculation of an Adjusted 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 OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: "J1," "J2," "P," "Q1," "Q2," "Q3,""Q4," "R," "S," "T," "U," or "V" (as defined in Addendum D1 to the 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 Copayments

Medicare law provides that 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 will be $1,364 in 2019. The inpatient hospital deductible limit is applied to the *actual* co-payment amount after adjusting for the wage index. For this reason, the co-insurance levels shown in the OPPS payment rate Addenda A and B to the final rule do not reflect application of the hospital deductible limit.

III. OPPS Ambulatory Payment Classification (APC) Group Policies

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

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

TABLE 11: COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 1, 2018	Level II HCPCS Codes	April 1, 2018	CY 2019 OPPS/ASC proposed rule	CY 2019 OPPS/ASC final rule with comment period
July 1, 2018	Level II HCPCS Code	July 1, 2018	CY 2019 OPPS/ASC proposed rule	CY 2019 OPPS/ASC final rule with comment period
	Category I (certain vaccine codes) and Category III CPT codes	July 1, 2018	CY 2019 OPPS/ASC proposed rule	CY 2019 OPPS/ASC final rule with comment period
October 1, 2018	Level II HCPCS Codes	October 1, 2018	CY 2019 OPPS/ASC final rule with comment period	CY 2020 OPPS/ASC final rule with comment period
January 1, 2019	Category I and Category III CPT Codes	January 1, 2019	CY 2019 OPPS/ASC proposed rule	CY 2019 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2019	CY 2019 OPPS/ASC final rule with comment period	CY 2020 OPPS/ASC final rule with comment period

1. Treatment of New HCPCS Codes That Were Effective April 1, 2018 for Which CMS Solicited Public Comments in the 2019 Proposed Rule

In the April 2018 OPPS quarterly update, CMS made effective 9 new Level II HCPCS codes and assigned them to interim OPPS status indicators and APCs. Table 12 in the final rule lists the finalized APC and status indicators for these codes.

In addition, there were twelve new laboratory CPT Multianalyte Assays with Algorithmic Analyses (MAAA) codes (M codes) and Proprietary Laboratory Analyses (PLA) codes (U codes) that were effective April 1, 2018 but released by the AMA too late for CMS in include in the April 2018 OPPS Update CR and in the April 2018 Integrated Outpatient Code Editor (IOCE). These codes were included in the July 2018 OPPS Update with an effective date of April 1, 2018. Table 13 in the final rule lists the finalized APC and status indicators for these codes.

The final payment rates can be found in Addendum B to this final rule.

2. Treatment of New HCPCS Codes That Were Effective July 1, 2018 for Which CMS Solicited Public Comments in the 2019 Proposed Rule

In the July 2018 OPPS quarterly update, CMS made effective 4 new Category III CPT codes and 10 new Category III CPT codes and assigned them to interim OPPS status indicators and APCs. Except for HCPCS code QQ9994 (In-line cartridge containing digestive enzyme(s) for enteral feeding), the codes are separately payable under the OPPS. Because QQ994 describes the same drug as its predecessor code C9469, CMS proposed to continue the drug's pass-through payment status and assign the new code to the same APC and status indicators as its predecessor code.

Table 14 in the final rule lists the finalized APC and status indicators for these codes. CMS finalized its proposal to continue the pass-through payment status for QQ994.

In addition, there were seventeen new codes (U codes) that were effective July 1, 2018 but were too late to be included in the July 2018 OPPS Update. These codes were included in the October 2018 OPPS Update with an effective date of July 1, 2018. Table 15 in the final rule lists the finalized APC and status indicators for these codes.

The final payment rates, where applicable, can be found in Addendum B to this final rule.

3. Process for New Level II HCPCS Codes Effective October 1, 2018 or Will Be Effective January 1, 2019 for Which CMS Is Soliciting Public Comments in this 2019 Final Rule with Comment Period

CMS continues the practice of providing interim payment status indicators, APC assignments and payment rates, if applicable, for new Level II HCPCS codes that are effective October 1, 2018 or January 1, 2019 in Addendum B to the 2019 final rule. These codes are flagged with comment indicator "NI" in Addendum B, indicating that CMS has assigned the codes an interim OPPS payment status for 2019. These status indicators and APC assignments would be

applicable in 2019. **CMS invites public comments about the status indicators, APC assignments, and payment rates for these codes** and this information will be finalized in the 2020 OPPS/ASC final rule with comment period.

The interim payment rates, where applicable, can be found in Addendum B to this final rule.

4. Treatment of New and Revised 2019 Category I and Category III CPT Codes That Will Be Effective January 1, 2019 - CMS Solicited Public Comments in The Proposed Rule

CMS received the new and revised 2019 Category I and III CPT codes from the AMA in time for inclusion in the proposed rule. The new and revised CPT codes were included in Addendum B to the proposed rule. CMS assigned a new comment indicator "NP" and requested comments on the proposed APC assignment, payment rates and status indicators. (NP indicates that the code is new for the next CY or the code is an existing code with substantial revision to its code descriptor in the next CY as compared to the current CY, with a proposed APC assignment and that comments will be accepted on the proposed APC assignment and status indicator.) CMS proposed to finalize the status indicators and APC assignments for these codes in the 2019 OPPS/ASC final rule.

Commenters addressed several of the new CPT codes that were assigned to comment indicator "NP". CMS responds to these comments in the following sections in the final rule: section II.A.2.b. (Comprehensive APCs), III.D. (OPPS APC-Specific Policies), IV.B. (Device-Intensive Procedures) and XII. (Updates to the ASC Payment System).

The final payment rates, where applicable, can be found in Addendum B to this final rule.

B. 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.

The Secretary is also required to consult with an expert outside advisory panel composed of appropriate representatives of providers to review the clinical integrity of the APC groups and the relative payment weights and advise the Secretary about any issues. The Panel recommendations for specific services for the 2019 OPPS and CMS' responses will be discussed in the 2019 OPPS final rule.

For 2019, CMS identified APCs with violations of the 2 times rules and proposed changes to the procedure codes assigned to these APCs in Addendum B to the proposed rule (identified with comment indicator "CH"). CMS noted that in many cases, the proposed procedure code reassignments and associated APC configurations for 2019 were related to changes in costs of services that were observed in the 2017 claims data.

2. APC Exceptions to the 2 Times Rule

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

Table 12 in the proposed rule listed sixteen APCs that CMS proposed to exempt from the 2 times rule for 2019 based on established criteria and based on claims data from January 1, 2017, through December 31, 2017 and processed on or before December 31, 2017.

Based on the updated claims data used for this final rule (claims data for dates of service from January 1, 2017 and December 31, 2017 that were processed on or before June 30, 2018 and updated CCRs, if available), CMS found that APC 5735 (Level 5 Minor Procedures) no longer meets the criteria for exception to the 2 times rule. Based on its analysis, CMS found that 17 APCs with violations of the 2 times rule: 15 were identified in the proposed rule and 2 are newly identified.

CMS finalizes the exception of the APCs listed in the table below from the 2 times rule for 2019.

APCs with Violations of the 2 Times Rules	
APC	**TITLE**
5071	Level 1 Excision/Biopsy/Incision and Drainage
5113	Level 3 Musculoskeletal Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5571	Level 1 Imaging with Contrast
5612	Level 2 Therapeutic Radiation Treatment Preparation
5691	Level 1 Drug Administration
5692	Level 2 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5724	Level 2 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5732	Level 2 Minor Procedures
5822	Level 2 Health and Behavior Services
5823	Level 3 Health and Behavior Services

APCs with Violations of the 2 Times Rules	
APC	**TITLE**
5193*	Level 3 Endovascular Procedures
5524*	Level 4 without Contrast
* APC identified with violations of the 2 times rule using the final rule period claims data	

C. New Technology APCs

1. New Technology APC Groups

Currently, there are 52 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 1908 (New Technology – Level 52 ($145,001 - $160,000)). Payment for each APC is made at the mid-point of the APC's assigned cost band.

The final payment rates for these New Technology APCs are included in Addendum A to this final rule.

2. Establishing Payment Rate for Low-Volume New Technology Procedures

One of CMS' objectives of establishing New Technology APCs is to generate sufficient claims data for a new procedure for assignment to an appropriate clinical APC. CMS considers procedures with fewer than 100 claims annually as low volume procedures. CMS was concerned that there is a higher probability that the payment data for these procedures may not have a normal statistical distribution, which could affect the quality of the standard cost methodology used to assign services to an APC. CMS also noted that services with fewer than 100 claims per year are not generally considered to be a significant contributor to the APC rate setting calculations and are not included in the assessment of the 2 times rule.

CMS has used its equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how it determines the costs for low-volume services assigned to New Technology APCs (82 FR 59281). Instead of using this authority on a case-by-case basis, CMS proposed to establish a different payment methodology for these low-volume services using its equitable adjustment authority. CMS finalizes the following methodology:

- Use 4 years of claims data to establish a payment rate for each applicable service both for assigning a service to a New Technology APC and for assigning a service to a regular APC at the conclusion of payment for the service through a New Technology APC;
- Use the geometric mean, the median, or the arithmetic mean to calculate the cost of furnishing the applicable service;
- Include the results of each statistical methodology will be in annual rulemaking and solicit public comment on which methodology should be used to establish the payment rate; and

- Assign the service to the New Technology APC with the cost band that includes its finalized payment rate.

CMS disagrees with a commenter's request to expand the proposal to cover all low-volume procedures with fewer than 100 claims annually in the OPPS. CMS notes that because a procedure has been assigned to a clinical APC means it has some idea of the resources used and what the cost of the procedure should be. CMS also states that it retains the ability to use its equitable adjustment authority under section 1833(t)(2)(E) of the Act when it determines it is needed.

3. Procedures Assigned to New Technology APC Groups for 2019

CMS finalizes its proposal to continue its current policy to retain services within New Technology APC groups until they obtain sufficient claims data to justify reassignment of the service to a clinically appropriate APC. CMS notes, that in cases where it determines, based on additional information, 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. This policy allows CMS to reassign a service in less than 2 years if sufficient claims data are available and also retain a service in a New Technology APC for more than 2 years if there is not sufficient claims data to base a reassignment.

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

As shown in Table 17, there are 4 CPT/HCPCS codes that describe MRgFUS procedures. For 2019, CMS proposed to assign 3 of the codes to standard APCs and proposed to reassign procedures described by CPT code 0398T to a different New Technology APC. CPT code 0398T was first assigned to a New Technology APC in 2016. CMS had only identified 3 paid claims (1 in 2016 and 2 in 2017). CMS was concerned that the reported geometric mean cost for 2017 was significantly lower than the reported cost of the 2016 claim.

Using the proposed methodology for low-volume services, based on the 3 claims, CMS calculated an arithmetic mean of $12,849.11, a geometric mean of $8,579.91, and a median of $4,676.77. CMS believed the arithmetic mean was the most appropriate representative cost of the procedures described by CPT code 0398T, which considers the payment rates for the procedures in 2017 and 2018. Using the arithmetic mean, CMS proposed reassigning CPT code 0398T from APC 1576 (New Technology – Level 39 ($15,001-$20,000)) to APC 1575 (New Technology – Level 38 ($10,0001-$15,000)).

Several commenters opposed the proposed assignment of CPT code 0398T to APC 1575 (payment rate of $12,500) and asked CMS to maintain the 2018 assignment to APC 1576 (payment range $15,001 - $20,000). The commenters believed the cost of the service is more than the proposed payment rate and reducing payment would discourage the use of this new technology. CMS discusses its updated claims analysis that found that for claims billed with CPT code 0398T, the geometric mean was $5,360.99, the arithmetic mean cost was $6,654.68, and the median cost was $4,581.45. CMS is concerned that this data would result in a payment

rate of $56,750.50 (the mid-point of New Technology APC 1531), a $10,750 reduction in the payment rate in 1 year and could potentially create an access to care issues for services described by CPT code 0398T. Although the proposed payment rate of $12,500.50 is also a decrease from the current rate, CMS believes it would be appropriate to finalize this proposed rate.

After consideration of comments, CMS finalizes its proposal to reassign CPT code 0398T to New Technology APC 1575. CMS used its equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the proposed rate for this procedure. Table 17 in the final rule lists the final status indicators, APC assignments, and payment rates for the MRgFUS procedures.

Retinal Prosthesis Implant Procedure

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

For 2017, CMS reassigned the procedure described by CPT code 0100T from APC 1599 to APC 1906 (New Technology – Level 51 ($140,001 - $160,000)) with a final payment rate of $150,000. For 2018, CMS reassigned the procedure described by CPT code 0100T from APC 1599 to APC 1904 (New Technology – Level 50 ($115,001 - $130,000)) with a final payment rate of $122,500.50.

Using the proposed methodology for low-volume services, CMS analyzed the last years of claims data available: this included claims from the last year (2015) that Argus® II received transitional device pass-through payments and the first 2 years since the device pass-through payment status expired. CMS calculated an arithmetic mean of $134,619, a geometric mean of $129,891, and a median of $133,679. CMS believed that the arithmetic mean is the most appropriate representative cost of this procedure, which considers the higher payment rates for the procedures in 2015 and 2017. Using the arithmetic mean, CMS proposed reassigning the Argus® II procedure from APC 1904 (New Technology – Level 50 ($115,001-$130,000)) to APC 1906 (New Technology – Level 51 ($130,0001-$145,000)) which results in a proposed payment rate of $137,500.50.

CMS also proposed to exclude payment for all procedures assigned to New Technology APCs from being bundled into the payment for procedures assigned to a C-APC. This proposal is based on the finding that payment for the Argus® II procedure was sometimes bundled into the payment for another procedure. CMS noted this proposal would allow for separate payment for

the Argus® II procedure even when it is performed with another comprehensive service, which would provide more cost information about the procedure.

Several commenters opposed the proposed assignment of CPT code 0100T to APC 1906 (payment rate of $12,500) and asked CMS to assign the procedure to APC 1908 (payment range $145,001 - $1600,000). The commenters were concerned that the proposed APC 1906 would not cover all the costs of the procedure. CMS discusses it updated claims analysis which found the updated geometric mean cost for the procedure is $145,808, the arithmetic mean cost is $151,367, and the median cost to be $151,266. All three methods of calculating the cost of the procedure map to the cost band associated with APC 1908 with a payment rate of $152,500.50.

After consideration of comments, for 2019, CMS finalizes the reassignment of the Argus® II procedure (CPT code 0100T) to APC 1908 (New Technology- Level 52). For 2019, CMS also finalizes its proposal to exclude payment for all procedures assigned to New Technology APCs from being bundled into the payment for procedures assigned to a C-APC.

Bronchoscopy with Transbronchial Ablation of Lesion(s) by Microwave Energy
CMS established HCPCS code C9751, effective January 1, 2019, for bronchoscopy with transbronchial ablation of lesion(s) by microwave energy. Based on its review of the New Technology APC application for this service and the service's clinical similarity to existing services, CMS estimates the likely cost of the procedure to be between $8,001 and $8,500. CMS assigned the procedure described by HCPCS code C0751 to New Technology APC 1571 (New Technology- Level 31) with a payment rate of $8,250.50 for CY 2019 (see Table 18 in the final rule).

D. APC-Specific Policies

Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and revise the groups and their relative payment weights to account for various factors including changes in medical practices, changes in technology, the addition of new services and new cost data.

Each year, CMS revises and makes changes to the APC groupings based on the latest hospital outpatient claims data. All of these APC changes were not discussed in the proposed and final rules. Addendum B to the proposed rule identified with a comment indicator "CH" those HCPCS codes for which CMS proposed a change to the APC assignment or status indicator.

The final rule discusses 20 different APC-specific policies where CMS considered or is making changes. Highlights of the discussion are summarized below; the numbering is consistent with the preamble format. The reader is referred to the final rule for more specific details.

1. Benign Prostatic Hyperplasia Treatments (APCs 5373 and 5374)

For the 2019, CPT code 53854 is a new code to describe the Rezum Therapy procedure, which is also known as steam therapy or water vapor therapy, and is used for the treatment of benign prostatic hyperplasia. Prior to January 1, 2019, the Rezum Therapy procedure was described by

HCPCS code C9748 and was assigned to APC 5373 (Level 3 Urology and Related Services). CMS proposed to delete HCPCS code C9748 and assign the new replacement code, CPT code 53854, to APC 5373, with a proposed payment rate of approximately $1,731.

Several commenters addressed the proposed APC assignment for Rezum Therapy and the APC assignments for other benign prostatic hyperplasia treatments: Transurethral microwave therapy (TUMT) (CPT code 53580 which was proposed to APC 5374) and transurethral needle ablation procedure (TUNA) (CPT code 53852 which was proposed to APC 5375, Level 5 Urology and Related Services).

Based on its review of the procedures assigned to the Urology APCs, including its evaluation of the latest claims data for the TUMT, TUNA, and Rezum Therapy, CMS finalizes the proposed APC assignment for CPT codes 53850 and 53854, and revises the APC assignment for CPT code 53852 from APC 5375 to APC 5374. CMS notes that based on information presented at the August 2018 HOP Panel meeting, the HOP Panel made no recommendation to revise the APC assignment for the Rezum Therapy procedure. Table 19 in the final rule, lists the final APC and status indicators for these codes.

2. Cardiac Contractility Modulation (CCM) Therapy (APC 5231)

CMS proposed to continue to assign CPT code 0408T to APC 5231 with a proposed payment rate of approximately $22,242.

In response to comments, CMS reevaluated the APC assignment for CPT codes 0408T, 33249, and 33270. Based on its review, CMS finalizes its proposal to assign CPT code 0408T to APC 5231, and to continue to assign CPT code 33249 and 33270 to APC 5232.

3. Cardiac Resynchronization Therapy (APCs 5221,5222, 5231, 5731, and 5741)

CMS proposed to assign eight new CPT codes for cardiac resynchronization therapy to various APCs (Table 20 in the final rule).

In response to comments, CMS reevaluated the APC assignments for these codes. CMS finalizes its proposed APC assignments for CPT codes 0518T, 0519T, 0521T, and 0522T. CMS modifies its proposed APC assignments for CPT codes 0515T, 0516T, 0517T, and 0520T. Table 21 in the final rule provides detailed information for these codes.

4. Chimeric Antigen Receptor T-Cell (CAR T) Therapy (APCs 5694, 9035, and 9094)

As indicated in the proposed rule the HCPCS code to describe KYMRIAH® (HCPCS code Q2040) has been active for OPPS since January 1, 2018 and the HCPCS code to describe YESCARTA® (HCPCS code Q2041) has been active for OPPS since April 1, 2018. CMS notes the HCPCS coding for these approved CAR T-cell therapies include leukapheresis and dose preparation procedures because these services are included in the manufacturing of these biologicals. Both of these therapies were approved for transitional pass-through payment status, effective April 1, 2018. CMS finalizes its proposal to continue pass-through payment status for

HCPCS code Q2040 (which is being depleted and replaced with Q2042) and HCPCS code Q2041 (discussed in section V.A.4. of the final rule).

In response to comments, CMS does not believe the addition of a new cost center is necessary for tracking CAR-T cell related costs. The final 2019 APC assignments and SI for these codes in summarized in Table 22 (reproduced below).

Table 22: Final 2019 APC and Status Indicator (SI) for HCPCS Codes Q2040, Q2041, and Q2042

HCPCS Code	Descriptor	2018 SI	2018 APC	October 2018 Payment	Final 2019 SI	Final 2019 APC	Final 2019 Payment Rate
Q2010	Tisagenlecleucel, up to 250 million car-t cells including leukapheresis and dose preparation procedures, per infusion*	G	9081	$500,901	D	N/A	N/A
Q2041	Axicabatagene, including leukapheresis and dose preparation procedures, per therapeutic dose**	G	9035	$395,380	G	9035	Refer to OPPS Addendum B
Q2042	Tisagenlecleucel, up to 600 million car-t viable cells, including leukapheresis and dose preparation procedures, per therapeutic dose				G	9194	Refer to OPPS Addendum B
*CMS deleted HCPCS code Q2040 and replaced it with Q2042 effective January 1, 2019.							

The AMA created four new Category III CPT codes that are related to CAR T-cell therapy, effective January 1, 2019 (see Table 23 in the final rule, reproduced below). CMS proposed status indicator "B" for these codes to indicate these services are not paid under the OPPS ("B" indicates codes not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13X).

At the summer 2018 HOP Panel meeting, the HOP Panel recommended that CMS reassign the status indicators for these new codes from "B" to "S" and recommended APC assignments. Some commenters also disagreed with the proposed "B" status indicator. Commenters discussed how these new services are similar to stem cell transplant services and should be assigned to similar APCs.

Some commenters also supported the creation of a new Autologous HCT C-APC to adequately compensate providers for providing CAR T-cell related services. Some commenters requested revision of the existing Q-codes to reference only the CAR T-cell products and that leukapheresis and other services be separately coded and paid. Some commenters asked CMS to provide guidance on how to bill for CAR-T cells and its administration, including how to bill for incomplete or partial services. A commenter did support the proposal not to pay separately for the new CPT codes; the commented supported the appropriateness of including these steps in the drug payment.

CMS does not believe that separate payment is necessary for CPT codes 0537T, 0538T, and 0540T because the procedures described by these codes are for various steps required to collect and prepare the modified T-cells. CMS notes that Medicare does not generally pay separately

for each step used to manufacture a drug or biological. In addition, these preparations are included in the Q codes. CMS does agree that CPT code 0540T is appropriate for the administration of CAR T-cell services.

After reviewing the comments and input from its medical advisors, as summarized in Table 23 (reproduced below) CMS revises its proposal and finalizes status indicator "S" to CPT code 0540T and assign this code to APC 5694. CMS finalizes its proposal to assign status indicator "B" to CPT codes 0537T, 0538T, and 0539T.

Table 23: Proposed and Final 2019 Status Indicator (SI) and APC for CPT Codes 0537T, 0538T, 0539T, and 0540T

2019 Proposed Rule Placeholder Code	2019 CPT Code	Descriptor	Proposed 2019 SI	Final 2019 SI	Final 2019 APC
05X1T	0537T	CAR-T therapy; harvesting of blood-derived T lymphocytes for development of CAR-T cells, per day	B	B	N/A
05X2T	0538T	CAR-T therapy; preparation of blood-derived T lymphocytes for transportation (e.g. cryopreservation, storage)	B	B	N/A
05X3T	0539T	CAR-T therapy; receipt and preparation of CAR-T cells for administration	B	B	N/A
05X4T	0540T	CAR-T therapy; CAR-T cell administration, autologous	B	S	5694

5. Drug-Eluting Implant (APC 5733)

CMS proposed to continue to assign CPT code 0356T to APC 5733 and status indicator "Q1" ("Q1" indicates packaged APC payment if billed on the same claim as a HCPCS code assigned to status indicator "S", "T", or "V"; or composite APC payment for specific combinations of services; or in other circumstances, payment is made through a separate APC payment). Several commenters disagreed with this proposal.

After consideration of comments, CMS finalizes its proposal to assign CPT code 0356T to status indicator "Q1" and assigned to APC 5733.

6. Endovascular Procedures (APCs 5191 through 5194)

For 2018, the HOP Panel recommended that CMS examine the number of APCs for endovascular procedures. The HOP Panel also recommended that the appropriate Panel subcommittee review the APCs for endovascular procedures to determine whether more APCs are warranted. In the 2018 OPPS final rule CMS maintained the current C-APC levels for these procedures and stated it would continue to review this issue.

For 2019, CMS did not find any violations of the 2 times rule within the current Endovascular Procedures C-APCs. CMS discussed the input it received from stakeholders suggesting alternative structures, including a five-level structure and a six-level structure. CMS proposes to maintain the existing four-level structure for this C-APC. CMS invites comments on its proposal, as well as the stakeholder-requested five-level and six-level structures.

Several commenters supported CMS' proposal to continue with a four-level APC structure and agreed with CMS' assignment of the procedures to these APCs. Other commenters believed the current structure violates the 2 times rule when certain code combinations are reported in combination (such as CPT code 37224 in combination with HCPCS code C2623). These commenters requested CMS make a complexity adjustment by assigning cases when CPT code 37224 in reported in combination with HCPCS code C2623 to APC 5193. Some commenters continued to believe that the current APC structure is insufficiently granular and requested CMS create a six-level Endovascular Procedure APC (summarized in table below). These commenters also had specific suggestions about assignment of procedures to specific APC levels. Several of these commenters requested CMS create new HCPCS code modifiers to differentiate drug-coated device procedures from non-drug coated device procedures.

Proposed Six-Level for Endovascular Procedure APC		
APC	**Description**	**Approximate Cost**
5191	Level 1 Endovascular APC	$2,000 - $4,000
5192	Level 2 Endovascular APC	$4,000 to $6,750
519X /New 5193	Level 3 Endovascular APC	$6,750 to $9,000
5193/ New 5194	Level 4 Endovascular APC	$9,000 to $11,000
519Y/ New 5195	Level 5 Endovascular APC	$11,000 to $14,000
Current 5194/New 5196	Level 16Endovascular APC	$14,000+

CMS appreciates commenters' suggestions and used the most recent available data, analyzed the various alternative suggestions. CMS notes that when it modeled the six-level APC and modeled a reconfiguration of significant HCPCS code placement, it noticed significant downward payment fluctuations for several services relative to the 2018 payment rate. Based on these findings, CMS does not believe it should pay for a complexity adjustment when certain related codes are reported in combination. CMS does have similar concerns about the significant differential payments between procedures assigned to the current four-level structure and intends to revisit this issue in future rulemaking.

After consideration of comments, CMS maintains the current four levels for the Endovascular Procedures APC (Table 24 in the final rule reproduced below).

Table 24: 2019 C-APC Structure for Endovascular Procedures	
C-APC	**Geometric Mean Cost**
5191 – Level 1 Endovascular Procedures	$2.834
5192 – Level 2 Endovascular Procedures	$4,719
5193 – Level 3 Endovascular Procedures	$9,752
5194 – Level 4 Endovascular Procedures	$15,487

7. Fine Needle Aspiration Biopsy (APC 5071)

CMS proposed to assign new CPT codes 10009 and 10011 to APC 5071 with a proposed payment of approximately $582.

CMS disagrees with a commenter suggestion that CPT code 10009 should be assigned to APC 5072 and CPT code 10011 to APC 5071. After considering the comment and input from its medical advisors, CMS finalizes its proposal to assign CPT codes 10009 and 10011 to APC 5071 (Table 25 in the final rule).

8. Fluorescence in Situ Hybridization (FISH) Assays (APCs 5672 and 5673)

CMS proposed to assign CPT codes 88364 and 88377 to status indicator "N" to indicate a packaged payment status, or status indicators "Q1" and "Q2" to indicate a conditionally packaged payment status and with APC assignments to APC 5672 or APC 5673 (Table 26 in the final rule).

CMS disagrees with a comment urging CMS to exclude certain FISH assays from the OPPS packaging policy. In response, CMS notes that payment for certain diagnostic laboratory tests listed on the CLFS are packaged in the OPPS as integral, ancillary, supportive, dependent or adjunctive to the primary service provided in the hospital outpatient setting (81 FR 79593). CMS has established exception to this packaging policy for molecular pathology tests, certain ADLTs, and preventive laboratory tests. In addition, laboratory tests are also paid separately when they are only service provided to a beneficiary on a claim. CMS states that the CPT codes included in the request are not molecular pathology laboratory tests, ADLTs, or preventive laboratory tests and that it should continue to package these services under the OPPS.

After consideration of the comment, CMS finalizes its proposed to assign the services described by CPT codes 88364 – 88369, 88373, 88374, and 88377 to status indicators "N", "Q1" or "Q2". Table 26 in the final rule lists the APC and status indicators for these codes.

9. Immediate Breast Implant Following Mastopexy/Mastectomy (C-APC 5092)

CMS proposed to continue to assign the procedures described by CPT code 19340 to C-APC 5092, with a proposed payment rate of approximately $4,960. Another commenter requested a review of C-APCs 5092 and 5093.

CMS disagrees with comments requesting reassignment of these procedures. The analysis of hospital outpatient claims used for this final rule, does not support a reassignment of the procedure. After consideration of comments and based on its analysis, CMS finalized its proposal to continue to assign by CPT codes 19340, 19325, and 19342 to C-APC 5092.

10. Intracardiac Ischemia Monitoring (APCs 5221, 5222, 5223, and 5741)

CMS proposed to assign eight new intracardiac ischemia monitoring CPT codes to various APCs (Table 27 in the final rule).

In response to comments, CMS reevaluated the APC assignments for these codes. CMS finalizes its proposed APC assignments for CPT codes 0525T through 0532T. Table 28 in the final rule provides detailed information for these codes.

11. Intraocular Retinal Electrode Programming and Reprogramming (APCs 5742 and 5743)

CMS proposed to continue to assign CPT code 0472T to APC 5743 and CPT code 0473T to APC 5742. A commenter supported this proposal and CMS finalizes this proposal. Table 29 in the final rule provides detailed information for these codes.

12. Kidney Dilation of Tract (C-APC 5373)

CMS proposed to assign CPT code 50436 to APC 5373.

A commenter disagreed and proposed assignment of CPT code 50436 to C-APC 5374. Because CPT code 50436 is a new code, CMS does not have claims data to base a payment rate and reviewed the clinical characteristics of the procedure to determine the appropriate APC. After review of the procedure and input from its clinical advisors, CMS finalizes its proposal to assign CPT code 50436 to APC 5373.

13. Intraocular Procedures (APC 5494)

In previous years, based on estimated costs CPT code 0308T has been assigned to APC 5495. The review of claims data for the proposed rule found only two claims containing CPT code 0308T, with a geometric mean of $5,438.99 and a median of $8,237,56. Based on this information, CMS proposed to reassign CPT code 0308T from APC 5495 to APC 5493 and to delete APC 5495.

A commenter requested that the procedure be assigned to a New Technology APC based on the proposed low-volume New Technology policy and if that wasn't an option, the commenter requested that CMS continue to assign CPT code 0308T to APC 5495. In response, CMS states it has concerns about assigning the code to a New Technology APC without receiving an application and also the procedure described by CPT code 0308T has been assigned to a clinical APC since the 2013 OPPS. CMS, however, recognizes the commenter's concerns about the low number of claims and notes that based on the claims data for the final rule, the estimated cost of the single claim with CPT code 0308T as the primary service is $12,939.75.

After consideration of the comment, CMS modifies its proposal and assigns CPT code 0308T to APC 5494.

14. Magnetocardiography

CMS proposed to assign the services described by new CPT codes 0541T and 0542T to status indicator "E1" (Table 30 in the final rule). "E1" indicates these codes are not payable by

Medicare when submitted on an outpatient claim because the services are either not covered by a Medicare outpatient benefit category, statutorily excluded, or not reasonable and necessary.

A commenter disagreed with the "E1" status indicator because the technology was approved by the FDA and requested assignment to APC 5593 or 5724. CMS discusses that the services associated with these codes are currently in clinical trial and that the clinical study does not meet CMS' standards for coverage nor is it included on the CMS Approved IDE list. In addition, it found no evidence or clearance of the Cardioflux System and it appears that an application is pending with FDA. If this technology later meets CMS' standards for coverage, it will reassess the APC assignment for the codes in a future quarterly update and/or rulemaking cycle.

After consideration of the public comment, CMS finalizes its proposal to assign status indicator "E1" to CPT codes 0541T and 0542T.

15. Musculoskeletal Procedures (APCs 5111 through 5116)

In 2016, CMS consolidated the APCs for musculoskeletal procedures to a six-level structure (80 FR 70397 through 70398). In the proposed rule, CMS recognized that commenters had previously expressed concerns about the granularity of the current APC levels and had requested establishment of additional APC levels. CMS solicited comments on the creation of a new APC level between the current Level 5 and Level 6 within the Musculoskeletal APC series.

Many commenters requested CMS maintain the current six-level APC structure. Several commenters requested CMS create additional levels and assign specific codes to either the new levels or existing levels within the relative structure. CMS appreciates the comments it received and based on this input it will maintain the existing six level Musculoskeletal Procedures APC structure. In response to comments, CMS evaluated the proposed assignments of CPT codes 27279, 28740, 28297, and 27447 and concludes these codes are properly assigned. CMS reiterates that it expects beneficiaries selected for outpatient total knee arthroplasty procedures (CPT code 27447) would generally be less complex that those treated as hospital patients and it does not believe it would be appropriate for the OPPS payment rate to exceed the IPPS payment rate for total knee arthroplasty procedures without major complications/comorbidities.

After consideration of comments, CMS finalizes the six level Musculoskeletal Procedure APC structure and maintains the proposed assignments of the procedures described by CPT codes 27279, 28740, 28297, and 27447.

16. Nasal Airway Obstruction Treatment (APC 5164)

CMS proposed to continue to assign HCPCS code C9749 to APC 5164 with a proposed payment rate of $2,241. HCPCS code C9749 describes the Latera absorbable implant procedure for nasal airway obstruction.

One commenter disagreed with the proposed assignment and stated that the cost for a pair of Latera implants is $1,325. The commenter suggested that the complexity and resources to perform the Latera implant procedure are similar to procedures assigned to APC 5165. In

response, CMS discusses the New Technology Application for the Latera implant and its assignment for the April 2018 OPPS update to APC 5164.

After consideration of the comment and input from the clinical advisors, CMS does not finalize its proposal and instead finalizes the reassignment of HCPCS code C9749 to APC 5165. (The text in the final rule has conflicting information about the final assignment but Addendum B confirms assignment to APC 5165.)

17. Nerve Procedures and Services (APCs 5431 through 5432)

CMS proposed to continue the existing two-level structure of the Nerve Procedures APCs (Table 32 in the final rule).

One commenter requested CMS create a new modifier to identify the performance of continuous nerve block procedures that are performed as a secondary procedure and to allow payment for these procedures instead of application of CMS' packaging policy. The commenter also suggested the creation of a new HCPCS code modifier to track, research, and identify the use of non-opioid pain management alternatives. The commenter also included a list of applicable continuous nerve blocks procedure codes that would be appropriate for the new HCPCS modifier and that this modifier could indicate that the procedure would receive separate payment. CMS appreciates these suggestions but believes it is appropriate to continue to package payment for continuous nerve block procedures. CMS notes it will consider the creation of a new HCPCS modifier and separate payment for non-opioid alternatives in future rulemaking.

Another commenter suggested that CMS restructure the two-level Nerve Procedure APCS by creating a third level. The commenter also recommended that CMS develop two new HCPCS G-codes to describe radiofrequency nerve ablation procedures: one G-code for procedures involving the genicular nerve and the other G-code for procedures describing procedures involving the sacroiliac joint. In addition, the G codes could be created to describe non-opioid treatment alternatives for chronic care management. CMS appreciates this comment but believes that the current two-level structure is appropriate. It will continue to review the APCs' structure in future rulemaking. CMS notes that it will take the commenter's request for new HCPCS G-codes under consideration.

After consideration of comments, CMS finalizes its proposed two-level structure for Nerve Procedures APCs.

18. Radiology and Procedures and Services

a. Imaging Procedures and Services (APCs 5521 through 5524 and 5571 through 5573)

In 2016, as part of the comprehensive reviews of the structure of APCs, CMS restructured the APCs groupings for imaging services to better reflect the costs and clinical characteristics of the procedures within each APC. In 2017, in response to comments, CMS further consolidated the Imaging APCs from 17 in 2016 to 7 in 2017 (4 Imaging without Contrast APCs and 3 Imaging

with Contrast APCs). In 2018, CMS proposed to establish a new Level 5 Imaging without Contrast APC; based on public comment, CMS did not finalize this proposal.

For 2019, CMS proposed to maintain the seven Imaging APCs and to make minor reassignments to the HCPCS codes within this series to resolve any violations of the 2 times rule. The seven Imaging APCs consist of four levels of Imaging without Contrast APCs and three levels of Imaging with Contrast APCs (Table 33 in the final rule).

Many commenters requested CMS maintain the current seven-level APC structure. Commenters recommended that any revisions should be considered for future rulemaking and be subject to review and comment from stakeholders. In response to comments, CMS evaluated the proposed assignments of CPT codes 99307, 75561, 75574 and HCPCS code G0297 and concludes these codes are properly assigned. In response to comments about HCPCS code G0297, CMS believes the methodology it uses for establishing the geometric mean for estimating service costs for the Imaging APCs is appropriate. CMS notes it will continue to monitor payment for these services and will consider the most appropriate methodology for rate setting for these services in future rulemaking.

After consideration of comments, CMS finalizes the seven level Musculoskeletal Procedure APC structure and maintains the proposed assignments of the procedures described by CPT codes 99307, 75561, 75574 and HCPCS code G0297.

b. Non-Ophthalmic Fluorescent Vascular Angiography (APC 5572)

CMS proposed to continue to assign HCPCS code C9733 to APC 5523 with a proposed payment rate of approximately $232. CMS also proposed to maintain the status indicator “Q2” (T-packaged) to indicate that payment is conditionally packaged when performed in conjunction with other procedures on the same day but paid separately when performed as a stand-alone service.

A commenter stated that HCPCS code C9733 describes a procedure that includes disposable components and a contrast agent (indocyanine green) that cost hospitals approximately $455. In addition, the commenter believed that hospitals are underreporting the costs for the procedure. In response, CMS states that based on its review of the 2019 final rule claims data, HCPCS code C9733 has a geometric mean cost of approximately $250 based on 173 single claims (out of 982 total claims). Because this product involves the use of a contrast agent, CMS believes that a reassignment to one of the Imaging with Contrast APCs would be more appropriate for HCPCS code C9733. As to the comment about hospitals underreporting the costs, CMS reiterates it relies on hospitals to accurately report the correct use of codes and to report services on claims and charges and costs appropriately.

After consideration of the comment, CMS modifies its proposal and reassigns the procedure described by HCPCS code C9733 to APC 5572 instead of APC 5523.

19. Remote Physiologic Monitoring (APCs 5012 and 5741)

CMS proposed to assign new CPT code 99453 to APC 5012 and CPT code 99454 to APC 5741. A commenter supported this proposal and CMS finalizes this proposal. Table 34 in the final rule provides detailed information for these codes.

20. Sclerotherapy (APC 5054)

CMS proposed to continue to assign CPT codes 36465 and 36466 to APC 5054 with a proposed payment rate of approximately $1,565.

In response to comments, CMS reevaluated the APC assignments for these codes. CMS finalizes its proposed APC assignments for CPT codes 36465 and 36466. Table 35 in the final rule provides detailed information for these codes.

IV. OPPS Payment for Devices

A. Pass-Through Payments for Devices

1. Beginning eligibility Date and Expiration of Transitional Pass-Through Payments

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. To allow a pass-through payment period that is as close to a full 3 years as possible, in the 2017 OPPS final rule (81 FR 79655), CMS finalized a policy change to allow for quarterly expiration of pass-through payments status for devices. This policy began with pass-through devices approved in 2017. Except for brachytherapy sources, for devices that are no longer eligible for pass-through payments, CMS packages the costs of the devices into the procedures with which the devices are reported in the claims data used to set the payment rates.

Currently, there are no device categories eligible for pass-through payment.

2. New Device Pass-Through Applications

a. Background

Criteria for New Device Pass-Through Applications

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

1. If required by the FDA, the device must have received FDA premarket approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has be classified as a Category B device by the FDA), or meets another appropriate FDA exemption from premarket approval or clearance; and the pass-through application must be submitted within 3 years form the date of the initial FDA approval or

clearance, if required, unless there is a documented, verifiable delay in the US market availability in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability;

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

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

1. Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); 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 cryoablation, exempted from the cost requirements at §419.66(c)(3) and §419.66(e); and

- Demonstrates a substantial clinical improvement: substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

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

In 2016, CMS changed the OPPS device pass-through payment evaluation and determination process. Device pass-through applications are still submitted through the quarterly sub regulatory process, but the applications are subject to notice-and-comment rulemaking in the next applicable OPPS annual rulemaking cycle. All applications that are preliminary approved during the quarterly review are automatically included in the next rulemaking cycle. Approved applications will continue to be granted access to pass-through payment at the beginning of the next quarter following approval. Submitters of applications that are not approved during the quarterly review have the option of being included in the next rulemaking cycle or withdrawing their application. Applicants may submit new evidence for consideration during the public comment period.

The current deadline for device pass-through payment applications continues to be the first business day in March, June, September, and December of a year for consideration for the next quarter (at the earliest) of the calendar year involved. More details on the requirements for device pass-through applications are included in the application form on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payments/HospitalOutpatientPPS/passthrough_payment.html. CMS notes it is also available to meet with applicants or potential applicants to discuss research trial design in advance of submitting any application.

b. Applications Received for Device Pass-Through Payments for 2019

CMS received seven applications by the March 1, 2018 quarterly deadline, the last quarterly deadline in time for this proposed rule. None of the seven applications were approved for device pass-through payment during the quarterly review process.
CMS notes that applications received for the remaining 2018 quarters (June1, September 1, and December 1) will be discussed in the 2020 OPPS/ASC proposed rule. Detailed instructions for submission of an application are on the CMS Web site at:
http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payments/HopsitalOutpatientPPS/Downloads/catapp.pdf.

The summary below provides a high-level discussion of each application; readers are advised to review the final rule for more detailed information.

After consideration of public comment, CMS approves device pass-through payment status for the remedē® System. CMS does not approve device pass-through payment for the remaining six applications.

1. AquaBeam System

PROCEPT BioRobotics Corporation applied for the AquaBeam System, a device used in the treatment of patients with lower urinary tract symptoms caused by benign prostatic hyperplasia (BPH). According to the applicant, the combination of surgical mapping and robotically

controlled resection of the prostate is designed to offer predictable and reproducible outcomes, independent of prostate size, prostate shape or surgeon experience.

Eligibility. According to the applicant, the AquaBeam System is integral to the service provided, is used for only one patient, comes in contact with human skin, and is applied in or on a would or other skin lesion. The applicant also stated that the device meets the eligibility requirements of §419.66(b)(4) because it is not an instrument, apparatus, or implement, or items for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

In the 2000 final rule (65 FR 67804 – 67805) CMS discussed its interpretation of §419.43(e)(4)(iv). CMS considers a device to be surgically implanted or inserted if it is surgically inserted or implanted via a natural or surgically created orifice, or inserted or implanted via a surgically created incision. CMS does not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted. CMS does not believe the function of these items is different and distinct from other devices used for surgical implantation or insertion. In addition, CMS expects that surgical implantation of a device occurs after the surgeon uses certain primary tools, supplies, or instruments to create the surgical path or site for implanting the device. CMS concluded it did not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted. CMS invited public comment on whether the AquaBeam System met the eligibility criteria at §419.66(b).

Commenters, including the manufacturer of AquaBeam and stakeholders, believed that the AquaBeam System met the eligibility criteria. CMS reiterates it does not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted (70 FR 68630). Because CMS determined that the AquaBeam system does not meet the eligibility status, it did not evaluate the other criteria.

CMS does not approve device pass-through payment status for the AquaBeam System.

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

BioMonde US, LLC applied for the BioBag® (Larval Debridement Therapy in a Contained Dressing). The applicant contained similar information that was provided in a previous application that was evaluated in the 2017 OPPS final rule (81 FR 79650). CMS noted that the only new information provided were additional studies addressing substantial clinical improvement.

According to the applicant, BioBag® is a bio-surgical wound treatment consisting of disinfected, living larvae in a polyester net bag. The larvae remove dead tissue from wounds; BioBag® is indicated for debridement of nonhealing necrotic skin and soft tissue wounds. The other similar product is “free-range” or uncontained larvae.

Newness. The applicant received FDA clearance for BioBag® through the premarket notification section 510(k) process on August 38, 2013 and the first US sale of BioBag® was in April 2015.

CMS received the application for a transitional pass-through on June 1, 2017; this is more than 3 years after FDA clearance but less than 3 years after its first US sale.

The manufacturer stated the BioBag® was not commercially available in the U.S. until 2015 when its American-based production facility was established. Based on this clarification, CMS determines that BioBag® meets the newness criterion.

Eligibility. Although the applicant claims BioBag® is an integral part of wound debridement and is used for only one patient. In the 2017 OPPS final rule, CMS determined that BioBag® is a surgical supply similar to a surgical dressing that facilitates debridement and it would not be eligible for device pass-through payments.

The manufacturer presented several reasons why the BioBag® is a treatment for wound debridement and not a medical supply. Based on this additional information, CMS determines that BioBag® is not a material or medical supply and meets the eligibility criterion.

Criteria established at §419.66(c).

Existing payment category. CMS has not identified an existing pass-through payment category that describes the BioBag®.

Substantial clinical improvement. CMS acknowledges that the applicant provided substantial evidence that larval therapy may improve outcomes compared to other methods of wound debridement. CMS is concerned, however that the evidence did not compare BioBag® to Medical Maggots®, another form of larval therapy that has been on the market since 2004. CMS believed it has insufficient evidence that the BioBag® provides substantial clinical improvement over other treatments for wound care.
CMS reviewed comments, including the additional journal citations. CMS concludes that it has not been provided with sufficient support from clinical studies that the BioBag® meets the substantial clinical improvement criterion.

Cost. CMS believes the BioBag® meets all the cost criteria.

CMS does not approve device pass-through payment status for BioBag® because it does not meet the substantial clinical improvement criterion.

3. BlastX™ Antimicrobial Wound Gel

Next Science applied for BlastX™, a PEG-based aqueous hydrogel indicated for wound management such as Stage I-IV pressure ulcers, partial and full thickness wounds, and postsurgical wounds. According to the applicant, BlastX™ works by disrupting and eliminating the biofilm matrix, a major barrier to wound healing.

Eligibility. Based on the evidence in the application, CMS stated that BlastX™ is not a skin substitute and cannot be considered for transitional pass-through status as a device. Under the OPPS, CMS noted that a skin substitute needs to be applied in or on a wound on other skin lesion

based on 42 CFR 419.66(b)(3). The product is primarily used in conjunction with the skin graft procedures described by CPT codes 15271-15278 or HCPCS codes C5271-5278 (78 FR 74937). According to the manufacturer, BlastX™ may be used in many other procedures other than skin graft procedures, including several debridement and active wound care management procedures. CMS also noted the manufacturer stated that the product would be used in association with any currently available skin substitute product. CMS concluded that BlastX™ is not integral to the service provided (a skin graft procedure using a sheet skin substitute), is a material or supply furnished incidentally to a service, and is not surgically inserted into a patient. Thus, BlastX™ did not meet the basic criterion of being an eligible device for transitional pass-through payment. CMS did not receive any comments regarding the eligibility of BlastX™. CMS does not approve device pass-through payment status for BlastX™.

4. EpiCord ®

MiMedx applied for EpiCord®, a skin substitute product. According to the applicant, EpiCord® is a minimally manipulated, dehydrated, devitalized cellular umbilical cord allograft for homologous use to provide a protective environment for healing. EpiCord® is comprised of the protective elements of the umbilical cord with a thin amnion layer and a thicker Wharton's Jelly mucopolysaccharide component.

Newness. EpiCord® was added to the MiMedx registration for human cells, tissues, and cellular and tissue-based products (HCT/Ps) on December 31, 2015. According to the applicant the first date of sale within the US was December 31, 2015.

MiMedx asserted that EpiCord® conforms to the requirements for HCT/Ps regulated solely under section 361 of the Public Health Services (PHS) Act and the regulations at 21 CFR Part 1271. CMS noted that no documentation regarding an FDA determination that EpiCord® is appropriate for regulation solely under section 361 of the PHS Act had been submitted. CMS discusses that a product that is regulated solely under section 361 of the PHS Act and the regulations in 21 CFR Part 1271 is not regulated as a device and that the applicant did not submit documentation that EpiCord® is regulated as a device by FDA.

In comments, the manufacturer stated that HCT/P products are regulated by the FDA through a registration process and have been made by CMS under the current regulatory system. The manufacturer believed the requirement for FDA approval should only apply when FDA approval is required. The manufacture stated that the pass-through payment application was submitted within 3 years of EpiCord® being introduced in the U.S. market. CMS agrees that FDA approval cannot be required when there is no requirement for a new product to receive FDA approval. CMS concludes the best alternative to establish the date a product is considered new is to rely on registration to the FDA HCT/P registry. After consideration of comments, CMS determines that EpiCord® meets the newness criterion.

Eligibility. According to the applicant, EpiCord® is a skin substitute product that is integral to the service provided, is used for only one patient, comes in contact with human tissue, and is surgically inserted into the patients. The applicant also claims the device meets the requirements of §419.66(b)(4).

CMS concludes that EpiCord® meets the eligibility criterion.

Criteria established at §419.66(c).
Existing payment category. CMS did not identify an existing pass-through payment category that describes the EpiCord®.

Substantial clinical improvement. CMS discussed the evidence submitted and stated it has insufficient evidence that EpiCord® provides a substantial clinical improvement over other treatments for wound care.

CMS acknowledges the detailed additional information provided by the manufacturer. CMS concludes that none of the information provided demonstrates that EpiCord® has a superior performance to other side products and determines that EpiCord® does not meet the substantial clinical improvement criterion.

Cost. CMS believes EpiCord® meets all the cost criteria.

CMS does not approve device pass-through payment status for EpiCord® because it does not meet the substantial clinical improvement criterion.

5. remedē® System Transvenous Neurostimulator

Respicardia, Inc applied for the remedē® System used as a transvenous phrenic nerve stimulator in the treatment of adult patients with moderate to severe central sleep apnea (CSA). The technology consists of an implantable pulse generator, a stimulation lead, and a sensing lead. Both leads, in combination with the pulse generator, function to sense respiration, and when appropriate, generate an electrical signal to the phrenic nerve to restore regular breathing patterns.

Newness. The remedē® System received approval of its PMA application from the FDA on October 6, 2017. CMS received the application for a transitional pass-through on May 31, 2017, which is within 3 years of the date of the initial FDA approval or clearance.

Eligibility. According to the applicant, remedē® System is integral to the service provided, is used for only one patient, comes in contact with human tissue, and is surgically inserted into the patients. The applicant also claims the device meets the requirements of §419.66(b)(4).

Criteria established at §419.66(c).

Existing payment category. CMS has not identified an existing pass-through payment category that describes the remedē® System.

Substantial clinical improvement. The applicant claims that the remedē® System has been found to significantly improve apnea-hypopnea index (AHI), an index used to indicate the severity of sleep apnea. CMS summarized the findings from the pivotal study, and although the applicant reported a reduction in AHI in the treatment group CMS was concerned the applicant did not

establish that the level of change was biologically meaningful in the studied populations. CMS was also concerned about the potential for complications with the remedē® System in patients with coexisting cardiac devices, such as pacemakers or ICDs. CMS believed additional studies were needed to determine long-term effects of the device as well as its efficacy compared to existing treatments of CPAP or medications. CMS believed it had insufficient evidence that the remedē® System provides substantial clinical improvement over other treatments for wound care.

After reviewing the additional information provided by the manufacturer, CMS agrees the remedē® System improves patients symptoms of CSA, improves quality of life, requires minimal patient compliance compared to other treatments, and has a low adverse profile. The manufacturer noted that the studies were not powered to demonstrate a mortality benefit. CMS concludes that the remedē® System offers a treatment option for patients diagnosed with moderate to severe CSA and have no other available treatment options. CMS determines that the remedē® System has demonstrated substantial clinical improvement.

Cost. CMS believes the remedē® System meets all the cost criteria.

CMS approves device pass-through payment status for the remedē® System.

6. Restrata® Wound Matrix

Acera Surgical, Inc. applied for Restrata® Wound Matrix used in local wound management. According to the applicant, Restrata® Wound Matrix is made from synthetic biocompatible materials and works as a wound care management product by acting as a protective covering for wound defects by providing an environment for natural healing to occur. The product allows for cellular infiltration, new tissue formation, neovascularization, and wound healing before completely degrading.

Eligibility. According to the applicant, Restrata® Wound Matrix is integral to the service provided, is used for only one patient, comes in contact with human skin, and is surgically inserted into the patient. CMS noted the description shows the product meets the device eligibility requirements of §419.66(b)(4).

CMS did not receive any comments on whether Restrata® Wound Matrix meets the eligibility criteria. After the proposed rule was released, CMS states it determined that Restrata® Wound Matrix is an alginate dressing described with the HCPCS code series A6196 through A6198 (Alginate or other fiber gelling dressing, wound cover, sterile). CMS notes that alginate dressings are considered supplies and are not skin substitute products.

After consideration of all the information, CMS determined that Restrata® Wound Matrix is an alginate dressing and is a supply and does not meet the eligibility criterion. Because CMS determined that Restrata® Wound Matrix does not meet the eligibility status, it did not evaluate the other criteria.

CMS does not approve device pass-through payment status for the Restrata® Wound Matrix.

7. SpaceOAR System®

Augmenix, Inc. applied for the SpaceOAR System®, a polyethylene glycol hydrogel spacer that temporarily positions the anterior rectal wall away from the prostate to reduce the radiation delivered to the anterior rectum during prostate cancer radiotherapy treatment. The applicant stated the system reduces some of the side effects associated with radiotherapy, known as "rectal toxicity". The SpaceOAR System® is implanted several weeks before radiotherapy and is completely absorbed by the body within 6 months.

Newness. FDA classified the SpaceOAR System® as a class II device on April 1, 2015. CMS received the application for pass-through payment status on June 1, 2017, within 3 years of the date of the initial FDA approval or clearance.

Eligibility. According to the applicant, the SpaceOAR System® is integral to the service provided, is used for only one patient, comes in contact with human skin, and is surgically inserted into the patient. CMS noted the description shows the product meets the device eligibility requirements of §419.66(b)(4).

Criteria established at §419.66(c).

Existing payment category. CMS has not identified an existing pass-through payment category that describes the SpaceOAR System®.

Substantial clinical improvement. The applicant submitted several studies which generally discussed the benefits for using hydrogel spacers and also submitted several studies that specifically examined the effect that the SpaceOAR System® had on mitigating outcomes such as toxicity associated with radiation therapy for prostate cancer. CMS comments about these studies include the findings that in the phase III trial the control rate had low rates of rectal toxicity and that there were no statistically significant differences in mean score changes for urinary, bowel, or sexual bother between the SpaceOAR System® and control groups. CMS noted it is not evident that SpaceOAR System® is superior to existing alternative biodegradable biomaterials currently utilized for spacing during prostate radiotherapy. CMS believed it has insufficient evidence that the SpaceOAR System® provides substantial clinical improvement over other treatments for wound care.

CMS acknowledges the detailed additional information provided by the manufacturer and comments provided by various oncological and urologic specialty societies. CMS concludes that the clinical results of the studies were equivocal and did not provide definitive evidence substantial clinical improvement of radiation toxicity and quality of life scores after radiation therapy. CMS determines that SpaceOAR System® does not meet the substantial clinical improvement criterion.

Cost. CMS believes the SpaceOAR System® meets all the cost criteria.

CMS does not approve device pass-through payment status for SpaceOAR System® because ® it does not meet the substantial clinical improvement criterion.

B. Device-Intensive Procedures

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

1. HCPCS Code-Level Device-Intensive Determination

In the 2017 OPPS 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.

In the 2018 OPPS final rule (82 FR 52474), CMS clarified that procedures that meet the criteria listed below are identified as device-intensive procedures and are subject to all policies applicable to procedures assigned device-intensive status. Specifically, device-intensive procedures require the implantation of a device and must meet the following 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.

2. Changes to the Device-Intensive Procedure Policy for 2019 and Subsequent Year

In response to stakeholder's comments and as part of an effort to better capture costs for procedures with significant device costs, for 2019 CMS proposed to modify the criteria for device-intensive procedures. CMS no longer believed that whether a device remains in the patient's body should affect its designation as a device-intensive procedure. In addition, to allow a greater number of procedures to qualify as devices-intensive CMS proposed to lower the device offset percentage threshold from 40 to 30 percent. CMS believes this will help ensure these procedures receive more appropriate payment in the ASC setting. CMS also stated this change will help to ensure more procedures containing relatively high-cost devices are subject to device edits, which leads to more correct coding and greater accuracy in the claims data.

Specifically, for 2019 and subsequent years, CMS finalizes its proposal that device-intensive procedures would be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device-offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost.

To align the device-intensive policy with the criteria used for device pass-through status, CMS finalizes its proposal for 2019 and subsequent years, for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA IDE and has been classified as a Category B device by the FDA in accordance with 42 CFR 405.203 – 405.207 and 405.211 – 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not any of the following:

    a. Equipment, an instrument, 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 (CMS Pub. 15-1); or
    b. 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).

The majority of commenters supported CMS' proposal to modify the device-intensive criteria to allow procedures that involves single-use devices, regardless of whether they remain in the body after the conclusion of the procedure, to qualify as device-intensive procedures. The majority of commenters also supported the proposal to lower the device offset percentage threshold for procedures to qualify as device-intensive form greater than 40 percent to greater than 30 percent. Some commenters recommended lowering the device-intensive threshold to 25 percent. In response, CMS believes that applying a device offset percentage threshold of greater than 30 percent for device-intensive is most appropriate. CMS notes that because the ASC payment system is budget neutral and it is important that the threshold is not set too low or it will transfer payments from procedures with high device offsets to procedures with low device offsets, which is the opposite of the intended purpose of this policy.

CMS also finalizes its proposal to apply a 31-percent until claims data are available to establish the HCPCS code-level device offset. CMS will continue its current policy of temporarily assigning a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer. Additional information should be directed to the Division of Outpatient Care at outpatient@cms.hhs.gov.

CMS also clarified that the associated claims data used for purposes of determining whether or not to apply the default device offset are the associated claims data for either the new HCPCS code or any predecessor code, as described by CPT coding guidance, for the new HCPCS code. In addition, when a new HCPCS code does not have a predecessor code as defined by CPT, but describes a procedure that was previously described by an existing code, CMS finalized its proposal to use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining whether or not to apply the default device offset to the new HCPCS code.

Commenters supported the proposal to apply a default device offset of 31 percent to procedures requiring devices that do not yet have claims data, as well as related proposals. A few commenters suggested that CMS only adjust the non-device portion of the payment by the wage index, similar to the policy for separately payable drugs and biologicals. CMS will take this comment into consideration for future rulemaking and notes that such a policy would increase payments to providers with a wage index value of less than 1 and be offset by a budget neutral decrease in providers to other providers.

CMS also solicited comments on the full list of proposed 2019 device-intensive procedures provided in Addendum P.[3] CMS received requests identifying additional procedures that should receive and not receive device-intensive status according to the proposed criteria. The full listing of the final 2019 device intensive procedures is included in Addendum P to the final rule.

3. Device Edit Policy

In the 2017 OPPS final rule, CMS finalized it would 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 device-intensive procedures. In addition, CMS created HCPCS code C1889 to recognize devices furnished during a device intensive procedure that are not described by a specific Level II HCPCS Category C-code. Any device code, including C1889, when reported on a claim with a device-intensive procedure, will satisfy the edit requiring a device code to be reported on a claim with a device-intensive procedure.

For 2019, CMS did not propose any changes to the device edit policy.

Some commenters identified twenty codes (listed in Table 36 in the final rule) that do not always require the involvement of an implantable or insertable single-use device and therefore could be subject to the claims edit requiring device-intensive procedures to be billed with a device even when the procedure may not require the involvement of a device. In response, CMS reviewed these procedures and believes the codes meet the OPPS device-intensive criteria. To address any potential claims processing issue pertaining to the device edit policy,

[3] Addendum P is available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.

CMS states it will use sub regulatory authority to ensure that the device edit does not improperly prevent correctly coded claims from being paid.

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

CMS reduces OPPS payments by the full or partial credit a provider receives for a replaced device for the applicable device-dependent APCs. Hospitals report the amount of the credit in the amount portion for value code "FD" (credit received from the manufacturer for a replaced medical device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device

For 2019 and subsequent years, CMS finalizes its proposal to apply the no cost/full credit and partial credit device policies to all procedures that qualify as device-intensive under the proposed modified criteria discussed above.

5. 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 was 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.

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

For 2019, CMS finalizes its proposal to continue this policy. For 2019, there are no procedures to which this policy would apply.

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

A. Transitional Pass-Through Payments

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 under the OPPS. CMS makes transitional pass-through payment for drugs and biologicals using the ASP+6 percent methodology with quarterly updates

to ASP. Pass-through drugs and biologicals for 2019 and their designated APCs are assigned status indicator "G" in Addenda A and B of 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 expires pass-through 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 as possible of pass-through payment. 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.

1. Drugs and Biologicals with Expiring Pass-Through Payment Status in 2018

CMS is ending pass-through payment for 23 drugs and biologicals that were approved for pass-through status on or before January 1, 2017 effective January 1, 2019. Table 37 of the final rule lists the drugs with expiring pass-through status. All of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2018.

Once pass-through payment expires, drugs are either policy packaged[4] or paid separately if they have per day costs above the packaging threshold of $125 proposed for 2019. If paid separately, CMS will pay these drugs at ASP+6 percent unless acquired through the 340B program. If separately payable drugs are acquired through the 340B program, CMS will pay for the drugs at ASP-22.5 percent.

Comments/Responses: A number of commenters requested that pass-through payment status for HCPCS code A9515 (Choline c-11, diagnostic, per study dose up to 20 millicuries) be extended until March 2019 to give 3 full years of pass-through payment status for the drug consistent with CMS' policy for expiring pass-through for drugs and biologicals approved for pass-through payment on or after January 1, 2017. The commenters indicate this suggestion would allow for the collection of more cost data and address concerns that the cost of HCPCS code A9515 exceeds the payment rate for the nuclear medicine services with which HCPCS code A9515 will be packaged. CMS declined to take the action requested in this comment indicating that the payment rate for the medical procedure will be adjusted to reflect the additional cost of the newly packaged radiopharmaceutical in the overall cost of the medical procedure.

Other commenters recommended that CMS allow products covered by Medicare through a coverage with evidence development (CED) clinical trial to retain their pass-through payment status for the duration of the CED trial. The commenters were concerned that ending pass-

[4] 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).

through payment could negatively impact CED trials. CMS rejected these comments indicating that the
statute limits the period of pass-through payment eligibility to no more than 3 years after the product's is first paid under the OPPS.

2. Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Payment Status in 2019

CMS is continuing pass-through payment status in 2019 for 49 drugs and biologicals. All 49 of these drugs and biologicals are listed in Table 38 of the final rule.

Forty-five of these drugs and biologicals will continue to be eligible for OPPS pass-through payment as of December 31, 2019. Pass-through payment is being extended for an additional 2 years for 4 drugs whose pass-through payment ended on December 31, 2017 consistent with requirements of section 1301(a)(1) of the Consolidated Appropriations Act (CAA). (More on this can be found in #3 below).

If ASP data is not available, CMS will provide pass-through payment at wholesale acquisition cost (WAC)+3 percent rather than its current policy of paying at WAC+6 percent consistent with a policy CMS adopted in the 2019 PFS rule. If WAC information also is not available, CMS will provide payment for pass-through drugs and biologicals at 95 percent of its most recent average wholesale price (AWP).

3. Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Status as a Result of Section 1301 of the Consolidated Appropriations Act of 2018 (Pub. L. 115-141)

Consistent with requirements of section 1301(a)(1) of the CAA, pass-through payment is being extended for an additional 2 years for 4 drugs where pass-through payment ended on December 31, 2017. Section 1301(a)(1) of CAA required that payment for these four products will be the higher of ASP+6 percent on December 31, 2017 or the most current ASP+6 percent for October 1, 2018 through March 31, 2019. CMS addressed 2018 payment for these products through Transmittal 4123: "October 2018 Update of the Hospital Outpatient Prospective Payment System (OPPS)" available on the CMS website at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4123CP.pdf

In the proposed rule, CMS indicated that it is currently approving pass-through payments for skin substitutes as devices but one of the four products (Q4172 (PuraPly, and PuraPly Antimicrobial, any type, per square centimeter)) affected by the CAA provision is a skin substitute that was approved as a biological under a prior policy. For this reason, CMS proposed to pay for PuraPly using ASP+6 percent rather charges reduced to cost as would be used for device pass-through payment.

Comments/Responses: Several commenters objected to this proposal saying that it would give PuraPly a competitive advantage over other skin substitutes and CMS should treat the product like a device just as it treats all other skin substitutes. These commenters also objected to extending pass-through payment for PuraPly. CMS rejected these comments arguing that the

CAA provision requires the extension of pass-through payments on the same basis upon which the pass-through payments were originally made. Table 39 lists the four products (5 codes as PuraPly has been split into two codes) subject to the CAA provision with extended pass-through.

4. 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 or as supplies in a surgical procedure, they are packaged under the OPPS. Therefore, an offset is necessary in order to avoid payment duplication when these products are also paid a pass-through. CMS deducts an amount reflecting the portion of the APC payment associated with predecessor products from the pass-through payment in order to ensure no duplicate payment is made.

For 2019, CMS is continuing to apply the current offset policies for all of the policy-packaged drugs, biologicals, and radiopharmaceuticals. CMS will continue to annually post a file on its website 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. (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files-Items/2019-Annual-Policy-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending.) Table 40 lists the APCs to which an offset will be applicable.

B. Payment for Non-Pass-Through Drugs, Biologicals, and Radiopharmaceuticals

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 may not bill beneficiaries separately for any packaged items: these costs are recognized and paid within the OPPS payment rate for the associated procedure or service.

Cost Threshold for Packaging of "Threshold-Packaged Drugs"

"Threshold-packaged drugs" under the OPPS are drugs, non-implantable biologicals and therapeutic radiopharmaceuticals whose packaging status is determined by the packaging threshold. If a drug's average cost per day exceeds the annually determined packaging threshold, it is separately payable and, if not, it is packaged. For 2018, the packaging threshold for drugs, biologicals, and radiopharmaceuticals that are not new and do not have pass-through status is $120.

To calculate the 2019 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 2019. CMS

rounds the resulting dollar amount ($127.01) to the nearest $5 increment. Based on this calculation, CMS proposed to adopt a packaging threshold for 2019 of $125.

Comments/Responses: A few commenters requested that CMS lower the packaging threshold rather than increasing it because of concerns that annual increases have outpaced conversion factor updates and placed a financial burden on providers. CMS responded that packaging is a fundamental component of a prospective payment system, that updating the packaging threshold of $50 from the 2005 OPPS is consistent with industry and government practices, and that the PPI for Prescription Drugs is an appropriate mechanism to gauge Part B drug inflation. The agency is finalizing a 2019 packaging threshold of $125.

CMS used the following process to determine the 2019 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 2017 claims data, CMS calculates, on a HCPCS code-specific basis, the per day cost of all drugs, biologicals, and therapeutic radiopharmaceuticals that had a HCPCS code in 2017 and were paid (either as packaged or separate payment) under the OPPS.

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 fourth quarter of 2017 (data that were used for payment purposes in the physician's office setting effective April 1, 2018). 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 2017 hospital claims data. CMS is packaging products with a per day cost of less than or equal to $125 and pay separately for items with a per day cost greater than $125 in 2018.

CMS continues to use quarterly ASP updates as follows:

- 4th quarter of 2017: Proposed rule per day cost, budget neutrality estimates, packaging determinations, impact analyses, and Addenda A and B for the 2019 OPPS proposed rule;
- 2nd quarter of 2018: Payment rates for HCPCS codes for separately payable drugs and non-implantable biologicals included in Addenda A and B to the 2019 OPPS final rule; and
- 3rd quarter of 2018: payment rates effective January 1, 2019 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, 2019 for drugs and biologicals furnished in the physician office setting.

ASP-based payment rates for both the OPPS and physician office settings are updated quarterly using quarterly reported ASP data with a two-quarter lag, and these updates are available on the CMS website. CMS is continuing its policy of making an annual packaging determination for a HCPCS code in the OPPS final rule and not updating that code's packaging status during the year. Only HCPCS codes which are identified as separately payable in the 2019 final rule are subject to quarterly updates.

As in past years, CMS is applying the following policies to determine the 2019 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 2018 and were proposed for separate payment in 2019 are separately payable in 2019 even if the updated data used for the 2019 final rule indicate per day costs equal to or less than the $125 threshold.
- HCPCS codes that were packaged in 2018, proposed for separate payment in 2019, and have per day costs equal to or less than $125 based on the updated data used for the 2019 final rule are packaged in 2019.
- HCPCS codes for which CMS proposed packaged payment in 2018 but have per day costs greater than $125 based on the updated data used for the 2019 final rule are separately payable in 2019.

High/Low Cost Threshold for Packaged Skin Substitutes

In the 2014 OPPS final rule, CMS unconditionally packaged skin substitute products into the associated surgical procedures, including a methodology that divided 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 OPPS/ASC final rule with comment period (80 FR 70434 through 70435).

CMS proposed to continue policies in place since 2016 that determine the high/low cost status for each skin substitute product based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the 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 2017 claims data available for the proposed rule, CMS calculated a proposed 2019 MUC threshold of $49 per cm^2 (rounded to the nearest $1) and a proposed 2019 PDC threshold of $895 (rounded to the nearest $1).

CMS' policy is to assign skin substitutes with pass-through payment status to the high cost category. Skin substitutes with pricing information but without claims data to calculate a MUC or PDC are assigned to either the high cost or low-cost category based on the product's ASP+6 percent payment rate as compared to the MUC threshold. If ASP is not available, CMS proposed to use WAC+3 percent in place of WAC+6 percent consistent with its proposed use of WAC in the 2018 PFS proposed rule 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 2019 MUC threshold.

In response to concerns about fluctuation in both the MUC and PDC thresholds 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 adopted a policy for 2018 only that would assign a skin substitute to the high cost group for 2018 that was assigned to

the high cost group for 2017, even if it did not exceed the 2018 MUC or PDC thresholds. CMS further sought comments on methodologies that would improve pricing stability for skin substitutes for 2019 and subsequent years.

In response to those comments, CMS presented four alternatives that it will consider for 2020 rulemaking:

- *Establish a lump-sum "episode-based" payment for a wound care episode*. Under this option, a hospital would receive a lump sum payment for an "episode" (such as 12 weeks) for all wound care services involving procedures using skin substitutes. Quality metrics could be established to ensure the beneficiary receives appropriate care while limiting excessive additional applications of skin substitute products.
- *Eliminate the high cost/low cost categories.* Under this option, CMS would establish a single payment category that has a payment rate between the current rates paid for high cost and low-cost skin substitute procedures.
- *Pay add-ons based on the size of the skin graft*. Under this option, payment for skin substitutes would be made based on the size of the skin substitute product being applied.
- *Change the threshold used to assign skin substitutes in the high-cost or low-cost group*. Under this option, CMS would consider fixing the MUC or PDC threshold at an amount from a prior year or setting global payment targets for high-cost and low-cost skin substitutes and establishing a threshold that meets the payment targets.

Comments/Responses: CMS received comments both in support of and opposed to these options. CMS did not respond to these comments but will take them into consideration for 2020 proposed rule.

In the interim until CMS establishes a permanent policy, it proposed to continue its 2018 policy of assigning a skin substitute to the high cost category in 2019 if it was assigned to the high cost category in 2018. Otherwise, skin substitutes will be assigned to the high or low-cost categories based on how the product's costs compare to the proposed MUC or PDC thresholds for 2019. Some commenters opposed having a high and low-cost categories policy arguing the policy encourages overutilization of high cost skin substitutes. Other comments supported CMS' proposed policy of maintaining assignment to the high cost group for 2019 if that was the skin substitute's assignment for 2018.

CMS is finalizing its proposed policies without change. Table 41 of the final rule shows the 2018 and proposed 2019 assignment of each skin substitute to either the high or low-cost category.

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

For 2019, CMS is continuing its policy of making packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, in the case of multiple HCPCS codes describing the same drug or biological but with different dosages. The codes to which this policy applies, and their packaging status, are listed in Table 42 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 will continue to pay for separately payable drugs and biologicals at ASP+6 percent in 2019. CMS is continuing its policy to pay for drugs acquired with a 340B discount at ASP-22.5 percent. Medicare's payment represents the combined acquisition and pharmacy overhead payment for drugs and biologicals. Consistent with a proposal in the 2019 PFS rule, CMS proposed to pay for drugs without an ASP that are paid based on WAC at WAC+3 percent instead of WAC+6 percent.

Comments/Responses: Commenters supported and opposed CMS proposal to utilize a 3 percent add-on instead of a 6 percent add-on for drugs that are paid based on WAC. Supporters indicated that CMS' proposed policy is a first step to lowering drug costs for beneficiaries and the Medicare as well as removing the financial incentive associated with a specific prescribing choice. Opponents of the proposal are concerned that paying less for new drugs may discourage the use of innovative drugs and would only affect the provider not the pharmaceutical manufacturer. Commenters encouraged other modifications to ASP reporting, such as requiring all Part B drug manufacturers to report pricing information and for all Part B drugs to be included in the ASP quarterly update file. Some commenters requested specific types of products be excluded from being paid WAC+3 percent and requested CMS continue to pay for these products at WAC+6 percent.

CMS responded that a WAC+3 percent add-on is more comparable to an ASP+6 percent add-on, as the WAC pricing does not reflect many of the discounts associated with ASP, such as rebates. The utilization of a 3 percent add-on instead of a 6 percent add-on for drugs that are paid based on WAC is consistent with MedPAC's analysis and recommendations cited in its June 2017 Report to the Congress. This policy also decreases beneficiary cost-sharing for these drugs. CMS declined to exclude any drug products from the policy indicating that these commenters did not provide any evidence to justify the exclusion of any particular product.

CMS is finalizing its policy as proposed. Drugs paid using WAC acquired under the 340B program would be paid at WAC-22.5 percent (see explanation in #7 below). 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, CMS does not, however, apply the budget neutral weight scaler in determining payments for these separately paid drugs and biologicals due to the statutory requirement that their payments 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, 2019. These rates will be updated through the quarterly update process to reflect the actual payment rates that will be used beginning January 1, 2019. Payment rates effective January 2019 will be released near the end of December 2018 and will be based on ASP data submitted by manufacturers for the third quarter of 2018 (July 1, 2018 through September 30, 2018). Payment rates for drugs and biologicals in Addenda A and B of the final rule for which there was no ASP information available for October 2018 are based on mean unit cost in the available 2017 claims data. If ASP

information becomes available for payment for the quarter beginning in January 2019, 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 2017 hospital claims.

Biosimilar Biological Products

CMS pays for biosimilar biological products using parallel policies that it uses for other drugs and biologicals with one important distinction. The 6 percent add-on to ASP and the 22.5 percent subtraction from ASP is based on the ASP of the reference product, not the ASP of the biosimilar. The 6 percent add-on is consistent with the statutory requirement in section 1847A of the Act that applies to drugs and biologicals furnished in physicians' offices. CMS' policy to subtract 22.5 percent of the reference product's ASP from the ASP of the biosimilar for biosimilars acquired under the 340B program was adopted in the 2018 OPPS final rule when CMS established its 340B drug payment policy.

In response to concerns that there will be a larger subtraction from ASP when 22.5 percent is based on the higher price of the reference product than the biosimilar's own ASP, CMS proposed to pay ASP-22.5 percent of the biosimilar's ASP and not the reference product's ASP except where a biosimilar is paid on pass-through when a drug is acquired under the 340B program. When a biosimilar is paid on pass-through, it will continue to receive ASP+6 percent of the reference product's ASP.

Comments/Responses: Many commenters supported CMS' biosimilar pricing proposal. Other commenters supported CMS' policy to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. Some commenters opposed that policy and recommended eliminating it over concern that the policy could potentially encourage inappropriate treatment changes from a reference product without pass-through payment to a biosimilar product with pass-through payment.

CMS is not convinced that making all biosimilar biological products eligible for pass-through payment will lead to inappropriate treatment changes from a reference product without pass-through payment to a biosimilar product with pass-through payment and is continuing that policy unchanged. It is also finalizing without change its proposal to pay non-pass-through biosimilars acquired under the 340B Program at the biosimilar's ASP minus 22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP.

3. Payment Policy for Therapeutic Radiopharmaceuticals

For 2019, CMS proposed to continue to pay for therapeutic radiopharmaceuticals at 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

proposed to determine 2019 payment rates based on 2017 geometric mean unit cost data derived from 2016 hospital claims.

Comment/Response: Commenters supported continuing ASP+6 percent payment for therapeutic radiopharmaceuticals but requested a higher add-on payment than 6 percent to recognize the higher overhead and handling costs associated with radiopharmaceuticals. CMS directed commenters to earlier responses on this issue (82 FR 59352) and indicated that 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. CMS is finalizing its policy as proposed.

4. Payment Adjustment Policy for Radioisotopes Derived from Non-Highly Enriched Uranium Sources

For 2013, CMS finalized a policy to provide an additional payment of $10 for the marginal cost of radioisotopes produced by non-HEU sources. For the 2019 proposed rule, CMS reviewed a 2016 report from the National Academies of Sciences, Engineering, and Medicine that anticipates the conversion of Tc-99m production from non-HEU sources will not be complete until at least the end of 2019. Thus, CMS proposed continuing to provide an additional $10 payment for radioisotopes produced by non-HEU sources in 2019.

Comment/Response: CMS received comments asking that the additional payment for radioisotopes produced by non-HEU sources be increased to either $30 or $10 plus the percentage increase in hospital charges for this product. One of the commenters supported this request by supplying provider cost data showing the cost difference between HEU Mo-99 and non-HEU Mo-99 in 2017 per curie was around $30. CMS responded that it is open to further study of this issue and is interested in exploring whether a higher add-on payment, such as $30, may be warranted for a future year. For this year's final rule, CMS indicated that the purpose of the add-on payment continues to be mitigating any adverse impact of transitioning to non-HEU sources. Therefore, CMS is maintaining the current payment rate of $10. CMS intends to reassess this payment policy once conversion to non-HEU sources is closer to completion or has been completed.

5. Payment for Blood Clotting Factors

For 2019, CMS is continuing to pay for blood clotting factors at ASP+6 percent and updating the furnishing fee by the Consumer Price Index (CPI) for medical care. The CPI won't be available until after publication of the 2019 OPPS final rule so 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/ClotFactorFurnishFee.html

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

CMS is continuing the same payment policy in 2019 for non-pass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data. The rule refers readers to the 2016 OPPS final rule (80 FR 70442-70443). In priority order, CMS will pay for these products using ASP+6 percent if ASP is reported, WAC+6 percent[5] if a WAC is available and at 95 percent of AWP if ASP and WAC are unavailable. The 2019 payment status of each of the non-pass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data is listed in Addendum B of the final rule.

7. OPPS Payment Methodology for 340B Purchased Drugs

In the 2018 OPPS/ASC final rule, CMS adopted a policy to pay for separately payable drugs acquired through the 340B program at ASP-22.5 percent instead of ASP+6 percent. CMS has received questions about whether the 340B payment adjustment applies to drugs that are priced using either WAC or AWP. The proposed rule indicated that it has been CMS' policy to subject 340B-acquired drugs that use these pricing methodologies to the 340B payment adjustment by paying WAC-22.5 percent and 69.46 percent of AWP for AWP-priced drugs.

The 69.46 percent of AWP is calculated by first reducing the original 95 percent of AWP price by 6 percent to generate a value that is similar to ASP or WAC with no percentage markup and then applying a 22.5 percent reduction. The number of separately payable drugs receiving WAC or AWP pricing that are affected by the 340B payment adjustment is small—consisting of less than 10 percent of all separately payable Medicare Part B drugs in April 2018.

For 2019, CMS proposed to continue the 340B Program policies that were implemented in 2018 with the exception of calculating payment for 340B-acquired biosimilars at ASP-22.5 percent of the biosimilar's ASP rather than minus 22.5 percent of the reference product's ASP.

Comment/Response: MedPAC and another commenter supported CMS' continuing its policy of paying ASP-22.5 percent for drugs acquired under the 340B program. Many other commenters continued to oppose the policy reiterating comments on the 2018 proposed rule for why CMS' policy should not be adopted or continued. CMS referred readers to 2018 final rule (82 FR 59369 through 59370) for its responses to these commenters. The agency is continuing its policy of paying ASP-22.5 percent (or the relevant percentage of WAC or AWP) for drugs acquired under the 340B program in 2019.

[5] The + 6 percent for WAC is not specifically stated in the 2016 rulemaking cited by CMS as the source of its policy but would be consistent with "ensur[ing] that new non-pass-through drugs, biologicals, and therapeutic radiopharmaceuticals would be treated like other drugs, biologicals, and therapeutic radiopharmaceuticals under the OPPS." Presumably, this rationale would also apply to changing the WAC add-on to 3 percent instead of 6 percent consistent with 2019 PFS rule and policies elsewhere in the 2019 OPPS rule.

VI. Estimate of OPPS Transitional Pass-Through Spending

CMS estimates total pass-through spending for drug and device pass-through payments during 2019 is approximately $100.8 million, or 0.14 percent of total OPPS projected payments for 2019, which is less than the applicable pass-through payment percentage statutory limit of 2.0 percent.

A. Devices

CMS estimates spending of $10 million for device categories CMS knows or projects may be approved for pass-through status in 2019 and includes contingent projections for new device categories in 2019. CMS includes implantable biologicals newly eligible for pass-through payment in the estimate for this group.

B. Drugs and Biologicals

CMS estimates pass-through spending of $90.8 million in 2019 for drugs and biologicals ($50.9 million those recently eligible for pass-through payments that will continue for 2019 and $39.9 million for those CMS knows or projects could be approved for pass-through status in 2019).

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

CMS solicited comments but did not propose any changes to the current clinic and emergency department hospital outpatient visits payment policies or to the payment policy for critical care services when these services are provided on the campus of a hospital. CMS did not receive any comments. For on-campus PBDs, CMS proposed to pay for clinic visits at 40 percent of the current OPPS rate. See section X. B. for details.

VIII. Payment for Partial Hospitalization Services (PHP) Services

A. PHP APC Update for 2019

For 2019 and subsequent years, CMS finalizes proposals to continue its established policies to calculate the PHP APC per diem payment rates for 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. For 2019, CMS calculates 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)) using actual claims data from 2017 and the most recent cost data for each provider type for PHP service days providing 3 or more services. This rate setting methodology was finalized in the 2016 OPPS/ASC final rule (80 FR 70462-70466) as modified in the 2017 OPPS/ASC final rule, including the application of a ±2 standard deviation trim on costs per day for all CMHCs and a CCR greater than 5 (CCR>5) trim for hospital-based PHP providers.

CMS analyzes PHP claims and cost data, including provider service usage, coding practices and rate setting methodology, and the agency identifies 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 excludes from the calculation of the PHP geometric mean per diem costs. For 2019, CMS continues its policy of excluding data from any CMHC when the CMHC's costs are more than ±2 standard deviations from the geometric mean cost per day for all CMHCs and to exclude hospital-based PHP services days when a CCR greater than 5 (CCR>5) is used to calculate costs for at least one of the component services. CMS also defaults any CMHC CCR that is greater than 1 to the statewide hospital ancillary CCR.

CMS excluded 7 CMHCs, adjusted the CCR for 3 CMHCs, and removed 425 CMHC claims. CMS excluded 49 hospital-based PHP providers as follows: one with all service days having a CCR greater than 5, and 48 with zero daily costs and no PHP payment. No hospital-based PHP was defaulted to using its overall hospital ancillary CCR due to outlier cost center CCR values.

The final 2019 geometric mean per diem costs and payment rates are as follows:

2019 APC	Group Title	Final PHP APC Geometric Mean Per Diem Costs*	Final Payment Rates**
5853	Partial Hospitalization (3 or more services per day) for CMHCs	$121.62	$120.58
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	$222.76	$220.86

* Table 43 of the final rule shows the proposed PHP APC geometric mean per diem costs.
** The final payment rates are from Addendum A to the final rule.

B. Changes to the Revenue-Code-to-Cost Center Crosswalk

CMS added a new cost center "Partial Hospitalization Program," on line 93.99 of Worksheet A for hospital-based PHPs for cost reporting periods ending on or after September 30, 2017.[6] The cost center includes all costs associated with providing PHP services and excludes costs for non-PHP outpatient mental health services. The Revenue-Code-to-Cost Center crosswalk identifies primary, secondary (if any), and tertiary (if any) cost centers associated with each PHP revenue code which are used for the CCRs in rate setting.

CMS must update the crosswalk for hospital-based PHP cost estimation to correctly match hospital-based PHP revenue code charges with the PHP cost center CCR for future rate setting. Because PHP-allowable revenue codes are also used to report non-PHP mental health services, CMS was not able to designate the PHP cost center as the primary cost center in the existing OPPS Revenue-Code-to-Cost Center crosswalk. Thus, CMS proposed to create a separate PHP-only Revenue-Code-to-Cost Center crosswalk for 2019 and subsequent years. CMS finalized the proposal without change. CMS notes the policy will not apply to CMHCs because they do not have a crosswalk.

As finalized, the new PHP-only Revenue-Code-to-Cost Center crosswalk consists of the existing PHP allowable revenue codes and maps each of those codes to the new PHP cost center line

6 See Transmittals 12 and 13 available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R12P240.pdf.

93.99 as the primary cost center source for the CCR. The new secondary cost center is the current primary cost center, and the new tertiary cost center is the current secondary cost center. However, CMS establishes a special rule for revenue code 0904: the current secondary cost center [3550 ("Psychiatric/Psychological Services")] and the current tertiary cost center [9000 ("Clinic")] continue to apply for revenue code 0904. Table 44 in the final rule shows the previous and newly finalized PHP-only Revenue-Code-to-Cost Center crosswalks.

C. 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 2017 claims data (the first year of data that reflect the change to the single-tier PHP APCs) shows that the provision of individual therapy by CMHCs has decreased but hospital-based PHPs have greatly increased individual therapy. Table 46 of the final rule shows the percentage of PHP days by service unit frequency from 2015 through 2017 using the final update of 2017 claims data.

Because of its single-tier payment policy, CMS continues to be concerned that PHP providers may provide only 3 services per day when payment is heavily weighted to providing 4 or more services. Based on its review of 2017 claims, CMS believes that PHPs maintained an appropriately low utilization of 3 service days as compared to the two preceding years, but the agency will continue to monitor utilization of days with only 3 PHP services. CMS notes the data on declining utilization of days with 3 services and the increased utilization of days with 4 and 5 or more services by hospital-based PHP providers indicate that these providers did not reduce care for this population. CMS reiterates its expectation that days with only 3 services should be the exception and not the typical PHP day; it believes that the typical PHP day should generally consist of 5 or 6 units of service.

D. Outlier Policy for CMHCs

For 2019, CMS will continue to calculate the CMHC outlier percentage, cutoff point and percentage payment amount, outlier reconciliation, outlier payment cap, and fixed-dollar threshold pursuant to established policies. In the preamble to the rule, CMS provides a more detailed explanation of the steps involved in calculating the CMHC outlier percentage.

CMS will designate less than 0.01 percent of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs for PHP outliers. CMS notes that it updated the CMHC CCRs and claims data used to model the PHP payment rates. CMS will set the cutoff point for the outlier payments for CMHCs for 2019 at 3.4 times the highest CMHC PHP APC payment rate (CMHC PHP APC 5853), and to 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 also continues its outlier reconciliation policy for 2019. Providers whose outlier payments meet a specified threshold ($500,000 for hospitals and any outlier payments for CMHCs) and

whose overall ancillary CCRs change by plus or minus 10 percentage points or more are subject to outlier reconciliation (pending approval of the CMS Central Office and Regional Office involved).

In the 2017 OPPS/ASC final rule, CMS implemented an outlier payment cap of 8 percent; thus, an individual CMHC may not receive more than 8 percent of its total per diem payments in outlier payments. CMS will continue this policy for 2019 which only impacts CMHCs.

CMS will not set a dollar threshold for CMHC outlier payments that it applies to other OPPS outlier payments; this is due to the relatively low cost of CMHC services.

E. Regulatory Impact

CMS estimates that payments to CMHCs will decrease by 15.1 percent in 2019 compared to 2018. The estimate includes the impact of the trimming methodology, wage index, and other adjustments.

IX. Changes to the Inpatient Only List

The IPO list specifies those procedures and services for which the hospital will be paid only when the procedures are provided in the inpatient setting because of the nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged. 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 includes the following:

1. Most HOPDs are equipped to provide the services to the Medicare population.
2. The simplest procedure described by the code may be performed in most HOPDs.
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.

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 following codes from the IPO list:

- CPT code 31241 (Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery), to be removed from the IPO list on the basis that the service is related to other codes that CMS has already removed from the IPO list. CMS proposed to designate the service as a primary procedure that would trigger assignment to C-APC 5153 (Level 3 Airway Endoscopy).
- CPT code 01402 (Anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty), to be removed on the basis that the service is typically billed with knee replacement surgery (CPT code 27447) that was already removed

from the IPO list and is performed in numerous hospitals on an outpatient basis. Like other anesthesia services, CMS proposed to designate the service as unconditionally packaged.

Comment/Response: A majority of the commenters supported the proposed removal of CPT code 31241 from the IPO list and the proposed assignment to C-APC 5153 with a status indicator of "J1". They agreed that the procedure is related to codes that CMS has already removed from the IPO list. One commenter opposed the proposal but did not say why. CMS is finalizing its proposal without change.

Commenters both supported and opposed the removal of CPT code 01402 from the IPO list. Supporters agreed with CMS' rationale for removing the procedure from the IPO list while opponents believe there would be potential detrimental impacts on hospitals participating in the Comprehensive Care for Joint Replacement Model, the Bundled Payments for Care Improvement Initiative, the Hospital Value-Based Purchasing Program, and the Hospital Readmissions Reduction Program. One commenter requested that CMS provide guidance and education regarding the removal of TKA procedures from the IPO list as many hospital systems and Medicare Advantage plans are requiring Medicare patients to undergo their TKA procedures as hospital outpatients.

CMS responded that removing CPT code 01402 from the IPO list does not affect a provider's ability to participate in any of the initiatives mentioned and that the removal of any procedure from the IPO list does not mandate that all cases be performed on an outpatient basis. CMS is adopting as final its proposal to remove CPT code 01402 from the IPO list.

CMS proposed to add HCPCS code C9606 to the IPO list based on the nature of the procedure and its similarity to CPT code 92941 that is already on the IPO list—both codes are either percutaneous or open-heart procedures undertaken during an acute myocardial infarction. Commenters agreed with CMS' proposal. CMS is finalizing its proposal without change.

CMS solicited public comments on removing CPT code 0266T from the IPO list on the basis that it is similar to other codes already removed from the IPO list. CPT code 0266T describes the implantation or replacement of carotid sinus baroreflex activation device. Commenters argued that procedures related to CPT code 0266T are commonly being performed safely in the HOPD. CMS agreed and is removing CPT code 0266T from the IPO list.

Table 48 lists several procedures that commenters requested CMS remove from the IPO list for 2019 not addressed by CMS in the proposed rule. One of these procedures is anesthesia for extensive spine and spinal procedures. The others are laminectomy procedures. CMS agreed to remove the anesthesia procedure (CPT code 00670) from the IPO list as it is related to other procedures already removed from the IPO list. CMS will consider whether to remove the other procedures from the IPO list in future years.

The complete list of procedure codes on the IPO list for 2019 is in Addendum E of the final rule. Table 49 contains the final changes to the IPO list for 2019.

X. Nonrecurring Policy Changes

A. Collecting Data on Services Furnished in Off-Campus Provider-Based Departments

In the 2019 OPPS/ASC proposed rule, CMS announced that effective January 1, 2019, it will implement a new modifier (ER-Items and services furnished by a provider-based off-campus emergency department) to collect data to assess the extent to which OPPS services are shifting to off-campus provider-based emergency departments. The requirement for the new modifier was done through the sub regulatory HCPCS modifier process. CMS notes that the modifier must be reported with every claim line for outpatient hospital services furnished in off-campus provider-based emergency departments. The modifier will be reported on the UB-04 form (CMS Form 1450) for hospital outpatient services. However, critical access hospitals will not have to report this modifier.

As noted in the proposed rule, CMS shares the concerns of the Medicare Payment Advisory Commission (MedPAC) and other entities that higher payment rates for services furnished in off-campus provider-based emergency departments may be a significant factor in the growth of the number of these emergency departments. Higher payment in these settings is due in part to the section 603 exemption from payment under the applicable payment system (i.e., the PFS) for all services (emergency and nonemergency) furnished in emergency departments of off-campus outpatient departments of a provider. CMS believes it must collect data to assess the extent to which OPPS services are shifting to off-campus provider-based emergency departments.

CMS reports that it received comments on the data collection; however, it notes that the implementation of the modifier was an announcement and not a policy proposal. MedPAC supported the use of the modifier; others opposed it as an undue and unnecessary administrative burden on hospitals.

B. Method to Control Unnecessary Increases in the Volume of Outpatient Services

In the final rule, CMS repeats the discussion that led to its proposal to apply a 60-percent reduction to payment for a clinic visit (HCPCS code G0463) in all HOPDs not subject to section 603 of the BBA 2015 (off-campus PBDs subject to section 603 are already being paid at 40 percent of the full OPPS rate for a clinic visit and all other services they provide). CMS' basic argument for its proposal is that higher Medicare rates for clinic visits in the HOPD are shifting utilization from physician offices to HOPDs and also leading hospitals to acquire physician offices and make them PBDs to get the higher rate. While section 603 addressed the issue for new off-campus PBDs that opened after November 2, 2015, the higher rate continues to be paid in all other PBDs.

CMS proposed to reduce payment for a clinic visit under section 1833(t)(2)(F) of the Act which provides the Secretary with authority to develop a method for controlling unnecessary increases in the volume of covered OPD services. As CMS views the shift of services from the physician office to the HOPD as unnecessary, it believes this statutory provision is applicable to its proposal. In addition, CMS argues that its proposal is not subject to budget neutrality because

the change to the payment rate is not an "adjustment" and the statute only requires budget neutrality to apply to "adjustments."

Comments/Responses:

Comments in Support of the Proposal

Health insurance plans, physician associations, specialty medical associations, and individual Medicare beneficiaries, supported the proposal. Two commenters provided information showing higher costs and utilization of specific services in the HOPD than the physician office. One commenter said PFS rates were inadequate and savings from this proposal should be used to raise PFS rates. MedPAC supported the proposal noting that it had previously recommended this policy be phased in over 3 years and that payment reductions to hospitals with a disproportionate share (DSH) patient percentage at or above the median be limited to 2 percent of overall Medicare payments.

CMS declined to increase PFS rates indicating that those rates are established under different statutory provisions. In response to MedPAC, CMS is implementing its policy over two years rather than three years.

Legal Arguments Against the Proposal Other than Non-Budget Neutral Implementation

Several commenters contend that section 1833(t)(2)(F) of the Act does not confer direct authority on CMS to modify OPPS payment rates for specific services. Rather, the commenters assert that section 1833(t)(2)(F) only permits the agency to develop a "method," which the commenters interpreted to mean a "way of doing things" or a "plan." Other comments indicated that Congress' enactment of section 603 of the BBA 2015 explicitly exempted on-campus PBDs and off-campus PBDs opened before November 2, 2015 from the payment change CMS is applying.

The agency interprets its authority under section 1833(t)(2)(F) of the Act to allow its method of controlling for the increase in the volume of unnecessary HOPD services to apply when provided at any HOPD, even those that are excepted from section 603 of the BBA 2015. CMS believes it is appropriate to apply the 1833(t)(2)(F) method regardless of where the service is provided because the clinic visit service is the same service furnished in excepted and nonexcepted off-campus PBDs.

The final rule argues that Medicare expenditures for outpatient services are growing at a higher rate now than when Congress passed section 603 of the BBA 2015 making it clear that the more specific payment adjustment has not adequately addressed the overall increase in the volume of these types of OPD services. CMS argues that it would not be able to adequately address the unnecessary increases in the volume of clinic visits in HOPDs if it did not apply this policy to all off-campus HOPDs.

Legal Arguments Concerning Non-Budget Neutral Implementation of the Policy

Several commenters believe that because CMS lacks the authority to reduce clinic visit payment rates as a method to control unnecessary increases in the volume of covered HOPD services under section 1833(t)(2)(F) of the Act, the provision cannot provide authority for the payment reduction to be made in a non-budget neutral way. The commenters also argue that the only non-budget neutral option available to the agency is to adjust the conversion factor in a subsequent year, as provided under section 1833(t)(9)(C) of the Act. The commenters argued that if Congress had intended to give CMS the authority to make a volume control method non-budget neutral in the way CMS proposes, it would have done so in clearer and more express terms.

CMS maintains that while certain changes under the OPPS must be made in a budget neutral manner, those provisions do not apply to the volume control "method" under section 1833(t)(2)(F) of the Act. Budget neutrality applies to "adjustments" such as the wage adjustment, outlier, transitional pass-through, and equitable adjustments under section 1833(t)(2)(E) of the Act not to payment changes made under the volume control methodology authorized by section 1833(t)(2)(F). Further, section 1833(t)(9)(C) of the Act authorizes the Secretary to adjust the update to the conversion factor otherwise applicable in a subsequent year if expenditures increase more than under the section 1833(t)(2)(F) volume control methodology. CMS interprets this provision to mean that the Secretary will have implemented a volume control method under section 1833(t)(2)(F) of the Act in a non-budget neutral manner in the year in which the method is implemented.

Clinical Concerns about the Proposal

These commenters expressed concern that the proposal is based on unsupported assertions and assumptions regarding increases in volume. The commenters were concerned that other factors, such as the shift from inpatient services to outpatient services or the 2-midnight policy, might be driving the increases in the volume of outpatient services. Other commenters asserted that patients seen in HOPDs exhibit higher severity of illness and other characteristics that make them costlier to treat than patients in physician offices.

CMS responded that shifts in the sites of service are inherently unnecessary if the beneficiary can safely receive the same services in a lower cost setting. While CMS indicates that it did receive some data illustrating that HOPDs serve unique patient populations and provide services to medically complex beneficiaries, these data did not demonstrate the need for higher payment for all clinic visits provided in HOPDs. The final rule cites information from the Government Accountability Office (GAO) that utilization of E/M (evaluation and management or clinic visits) is higher in counties with higher levels of vertical consolidation. Higher levels of vertical consolidation and high utilization of E/M office visits in HOPDs remained even after controlling for differences in county-level characteristics and other market factors that could affect the setting in which E/M office visits are performed. GAO's study did not support that HOPDs were treating sicker patient populations.

Hospital Outpatient Panel (HOP) Recommendation and Concerns about Rural Impacts

Several commenters supported the recommendation from the HOP Panel not to implement this proposal and to instead study the matter to better understand the reasons for increased utilization. CMS responded that it consulted with HOP Panel as required by the statute and considered its recommendations in adopting the final rule policy.

In response to concerns about the impact of this proposal on rural areas, CMS references the various special payment provisions for rural providers to maintain access and deliver high quality care to beneficiaries. CMS further asserts a 2-year phase-in will help mitigate the immediate impact on rural hospitals and CMS may consider potential exemptions for rural hospitals for the 2020 OPPS.

Comment Solicitation on Maintaining Access to Innovation and Expanding Secretary's Authority to Control for Unnecessary Utilization of HOPD Services

In the proposed rule, CMS solicited public comments on how to maintain access to new innovations while controlling for unnecessary increases in the volume of covered hospital OPD services. In addition, it solicited public comments on how to expand the application of the Secretary's statutory authority under section 1833(t)(2)(F) of the Act to additional items and services paid under the OPPS that may represent unnecessary increases in HOPD utilization. CMS received a number of comments that it will consider for future rulemaking.

Final Rule Policy: CMS will use its authority under section 1833(t)(2)(F) of the Act to pay for HCPCS code G0463 in all HOPDs at 70 percent of the full OPPS rate in 2019 and 40 percent of the full OPPS rate in 2020. The final payment amount will equal the site neutral PFS payment rate for services furnished at off-campus PBDs subject to section 603 of the BBA 2015.

CMS is not making this payment rate change in a budget neutral manner. Considering the effects of estimated changes in enrollment, utilization, and case-mix, this policy results in estimated 2019 savings of approximately $380 million, with approximately $300 million of the savings accruing to Medicare, and approximately $80 million saved by Medicare beneficiaries in the form of reduced copayments.

C. 340B Drug Payment Policy for Nonexcepted Off-Campus Departments of a Hospital

Under section 603 of the BBA, CMS is precluded from paying off-campus HOPDs that opened after November 2, 2015 (with limited exceptions) under the OPPS. These sites are referred to as "non-excepted off-campus HOPDs" to distinguish them from other HOPDs that may still be paid under the OPPS. CMS pays for services in non-excepted off-campus HOPDs at 40 percent of the OPPS. CMS calls this payment a "physician fee schedule" even though it is different than the PFS used to pay for physician services. Part B drugs furnished in non-excepted off campus HOPDs are paid at 106 percent of ASP and are not subject to CMS' policy that pays for drugs acquired under the 340B drug discount program in all other HOPDs at ASP-22.5 percent. CMS cannot apply its 340B policy to Part B drugs furnished in these sites because CMS adopted that policy under OPPS statutory authority and these sites cannot be paid under the OPPS.

In the 2018 OPPS final rule, CMS discussed concerns that not applying the 340B drug payment policy to non-excepted off-campus HOPDs creates an incentive for hospitals to move drug administration services for 340B-acquired drugs to non-excepted off-campus HOPDs to receive a higher payment. CMS expressed concern that this payment difference could undermine CMS' goal of reducing beneficiary cost-sharing for these drugs and biologicals and moving towards site neutrality for services paid in non-excepted off-campus HOPDs.

To address this concern, CMS proposed to pay the adjusted payment amount of ASP-22.5 percent for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program when they are furnished by non-excepted off-campus HOPDs of a hospital effective January 1, 2019. CMS proposed to exempt rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals from this payment adjustment consistent with the policy it applies for on-campus HOPDs and excepted off-campus HOPDs. CMS believes the proposed policy would better reflect the resources and acquisition costs that non-excepted off-campus HOPDs incur for drugs and biologicals acquired under the 340B program.

Comments/Responses:

General Comments

The commenters that supported CMS' proposal generally argued in favor of the policy for the same reasons that they supported CMS' policy of paying at ASP-22.5 percent adopted in the 2018 OPPS rule—to address the growth of the 340B Program, stem physician practice consolidation with hospitals, preserve patient access to community-based care, and address the significant incongruity between the payment amounts for 340B-acquired drugs depending upon the setting in which they are furnished. Opponents of the proposed policy generally reiterated their 2018 opposition to reducing payment for 340B drugs—the policy harms hospitals' ability to treat low-income patients and the proposals to continue and expand the cuts would worsen the impact.

CMS also reiterated prior responses to these comments indicating that it believes the large margin between the price paid for a drug by the hospital and the amount paid by Medicare is leading to excessive utilization of Part B drugs. In support of its proposal, CMS indicated that the difference in the payment amounts for 340B-acquired drugs furnished by excepted HOPDs versus nonexcepted off-campus HOPDs creates an incentive for hospitals to move drug administration services for 340B-acquired drugs to nonexcepted off-campus HOPDs to receive a higher payment amount for these drugs.

Expanding Exceptions

Other commenters requested additional exemptions beyond those already adopted by CMS for children's hospitals, rural sole community hospitals and IPPS-exempt cancer hospitals to include urban sole community hospitals, Medicare-dependent hospitals, and rural referral centers. CMS

believes that an analogous payment policy should apply across hospital settings, regardless of the status of each PBD and declines to grant additional exemptions.

MedPAC

MedPAC reiterated past recommendations that payment rates for all separately payable drugs provided in a 340B hospital be reduced by 10 percent of the current payment rate of ASP+6 percent and that CMS work with Congress to enact legislation needed to direct savings to a Medicare-funded uncompensated care pool. Legislation would also allow Medicare to apply the policy to all OPPS separately payable drugs, including those on pass-through payment status. MedPAC stated that CMS should ensure that payment for 340B-acquired drugs is equal across settings. CMS repeated its past response that it does not believe that reducing the Medicare payment rate by only 10 percentage points below the current payment rate of ASP+6 percent would better reflect the acquisition costs incurred by 340B-participating hospitals than the policy it adopted.

Legal Concerns

Many commenters stated that the Secretary lacks statutory authority to apply the OPPS Medicare payment rate to nonexcepted off-campus PBDs in 340B-participating hospitals because section 1833(t)(21)(C) of the Act does not authorize CMS to pay at a rate that is less than under the selected "applicable payment system." Specifically, a few commenters asserted that payment for these drugs and biologicals is determined pursuant to the rules of section 1842(o)(1)(C) of the Act, which mandates that payment is to be made for these drugs and biologicals when furnished by nonexcepted off-campus PBDs pursuant to the rules of section 1847A of the Act (ASP+6 percent).

CMS responded that payment under the "applicable payment system" pursuant to section 1833(t)(21)(C) of the Act is made under the PFS for most services, including for the many drugs that are packaged under the OPPS, using a PFS relativity adjuster that is applied to the OPPS payment rate. As such, the PFS payment for nonexcepted items and services in nonexcepted off-campus PBDs is made on a prospective payment basis, and therefore, CMS is not required to make payment under section 1847A/1842(o) of the Act for those packaged drugs, many of which would be separately payable under the PFS.

Payment Estimates and Budget Neutrality

A few commenters asserted that CMS provided no data to support its $48.5 million savings estimate for 2019. Other commenters suggested the policy be implemented in a budget neutral manner. CMS responded with the following information about its estimates: Based on the most recent claims data from 2017 reporting, CMS found 117 unique nonexcepted off-campus PBDs associated with 340B hospitals that billed for status indicator "K" drugs. Their "K" billing represents approximately $182.5 million in Medicare payments based on a payment rate of ASP+6 percent. CMS estimates that the Medicare Program and beneficiaries would save approximately $49 million under the PFS.

Regarding budget neutrality requirements, CMS indicates that when it initially established the ASP methodology under section 1847A/1842(o) of the Act as the "applicable payment system" for separately payable drugs under section 1833(t)(21)(C) of the Act, there was no applicable budget neutrality requirement. For the proposed change in 2019 to establish the PFS as the applicable payment system for separately payable 340B acquired drugs furnished by nonexcepted off-campus PBDs, CMS believes the site-specific PFS payment for these drugs and biologicals represents new utilization under the PFS and would, consequently, not be subject to the PFS budget neutrality requirements under 1848(c) of the Act for 2019. CMS will consider any applicable budget neutrality requirements regarding the site-specific payment under the PFS for future rulemaking.

Final Rule Policy: CMS is finalizing its proposal, without modification.

D. Expansion of Clinical Families of Services at Excepted Off-Campus Departments of a Hospital

Background

As noted earlier, section 603 of the BBA 2015 excludes from the definition of covered OPD services "applicable items and services" furnished on or after January 1, 2017 by certain off-campus outpatient departments of a provider (generally those that did not furnish covered OPD services before November 2, 2015) and provides for payment for those services furnished by off-campus provider-based departments (PBDs) under the applicable payment system (i.e. PFS) for the majority of nonexcepted items and services furnished by nonexcepted off-campus PBDs.

In implementing section 603, CMS had proposed to limit the items and services for which payment would be made under the OPPS in an excepted off-campus PBD to those items and services furnished before November 2, 2015, and to pay for items and services not included as part of a clinical family of services furnished by the excepted off-campus PBD before that date to payment under the applicable payment system. CMS did not propose to limit the volume of excepted items and services within a clinical family of services that an excepted off-campus PBD could furnish. Stakeholders expressed concerns about the proposal, including that CMS lacked the authority to implement the policy, that limiting service expansion would stifle innovative care delivery and new technologies, and that the proposal was not workable. The agency did not finalize this proposal but indicated it would continue to monitor service line expansion and consider how potential limitations on expansion might work; it sought comments on the issue.

2019 Proposal Not Finalized

Citing its previous concerns about expansion of services in excepted off-campus PBDs, CMS had again proposed to revise the definition of "excepted items and services" under §419.48 to limit the scope of the exception to only those items and services from clinical families of services from which the excepted off-campus PBD furnished an item or service (and subsequently billed for that item or service under the OPPS) during certain baseline periods (generally from November 1, 2014 through November 1, 2015).

CMS received numerous comments on the proposal. Those favorable comments echoed the positions CMS stated in the proposed rule. The majority of comments opposed the proposal, and commenters cited a variety of objections, such as lack of statutory authority, potential reduction in access to new technologies, concerns with the clinical families of services policies, and administrative burden. Ultimately, the agency determined its proposal was operationally complex and could create an administrative burden for hospitals, CMS, and CMS contractors. CMS intends to continue to monitor expansion of services in off-campus PBDs and, if it determines it is appropriate, may propose to adopt a limitation on expansion of excepted services in future rulemaking.

Thus, an excepted off-campus PBD will continue to receive payments under the OPPS during 2019 for all billed items and services regardless of whether the facility furnished those services before the enactment of section 603; this presumes the facility remains "excepted" within the terms of the statute and regulations, including compliance with relocation and change of ownership rules.

XI. 2019 OPPS Payment Status and Comment Indicators

A. 2019 OPPS Payment Status Indicator Definitions

For 2019, CMS did not propose any changes to status indicators. Status indicators and their definitions can be found in Addendum D1 of the final rule. Each status indicator will identify whether a given code is payable under the OPPS or another payment system, and also, whether particular OPPS policies apply to the code. The 2019 payment status indicator assignments for APCs and HCPCS codes are shown in Addenda A and B respectively.

One commenter asked that CMS split status indicator "C" into "C1" and "C2" to identify inpatient only (IPO) procedures that are on the separate procedure list (as determined by the American Medical Association). CMS responded that this additional status indicator is unnecessary as these procedures are bypassed when performed incidental to a surgical procedure with status indicator "T", or effective January 1, 2015, if reported on a claim with a comprehensive APC procedure (status indicator = "J1").

B. 2019 Comment Indicator Definitions

For 2019, CMS proposed to continue using 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.

- ‘‘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.

CMS received no comments and is finalizing its proposal without change. The definitions of the OPPS comment indicators for 2019 are listed in Addendum D2 of the final rule.

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

Summary of Selected Key Elements of ASC Payment Rates for 2019		
	ASCs reporting quality data	**ASCs not reporting quality data**
2018 ASC Conversion Factor	$45.575	
Wage index budget neutrality adjustment	1.0004	
2019 Update		
Hospital market basket update*	2.9%	
Multi-factor productivity adjustment (MFP)	-0.8%	
Net MFP adjusted update	2.1%	
Penalty for not reporting quality data	0.0%	-2.0%
Net MFP and quality adjusted update	2.1%	0.1%
2019 ASC Conversion Factor	$46.551	$45.639
*CMS finalizes its proposal to change from the CPI-U to the hospital market basket to determine the update factor.		

CMS estimates that under the final rule, total ASC payments for 2019 will increase by $80 million over 2018 levels.

As with the rest of the OPPS final rule and other CMS rules, addenda related to the ASC section (and referenced in this summary) are available only on the CMS website, at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1695-FC.html. All ASC Addenda to the final rule are contained in the zipped folders entitled Addendum AA, BB, DD1, DD2, and EE.

A. Background

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

- Covered surgical procedures in an ASC are surgical procedures that are separately paid under the OPPS and that would not be expected to:
  - Pose a significant risk to beneficiary safety when performed in an ASC; or

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

Since the implementation of the ASC prospective payment system, CMS notes that it has defined a surgical procedure 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 OPPS.

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. Commenters have pointed to, for example, the AMA's CPT code manual that states that the listing of a procedure in a specific section of the book should not be interpreted as strictly classifying the procedure as "surgery" or "not surgery" for insurance purposes. In particular, some stakeholders have suggested adding certain cardiovascular procedures to the ASC Covered Procedures List (CPL) due to their similarity to currently-covered peripheral endovascular procedures in the surgical code range. While CMS continues to believe using the CPT code range to define a surgical procedure is straightforward and logical, it recognizes that it should be used as a guide rather than a strict determinant, which would give it more flexibility to include "surgery-like" procedures on the ASC CPL.

CMS finalizes its proposal to revise its definition of "surgery" for 2019 to account for "surgery-like" procedures that are assigned codes outside the CPT surgical range (10000-69999). Specifically, CMS define newly-eligible "surgery-like" procedures as procedures that are described by Category I CPT codes that are not in the surgical range but, like procedures described by Level II HCPCS codes or by Category III CPT codes under its current policy, directly crosswalk or are clinically similar to procedures in the Category I CPT surgical range. In addition, these Category I CPT codes would need to meet the ASC setting criteria—does not pose a significant safety risk, would not be expected to require an overnight stay when performed in an ASC, and is separately paid under the OPPS.

Expanding the definition of surgery was supported by the majority of commenters. They cited in their comments that such an expansion would allow Medicare beneficiaries access to these procedures at a safe, lower-priced and more convenient site of service. One commenter expressed concern that revising the definition of surgery might expose Medicare beneficiaries to a significant safety risk when performed in an ASC. In response, CMS appreciate commenters

support and states it understands the dynamic nature of ambulatory surgery and the continued shift of services from the inpatient setting to the outpatient setting over the past decade. CMS does not share the commenters' concern about safety risk as any procedure added is evaluated against the existing regulatory criteria and believes physicians are well-equipped to decide whether the ASC setting is appropriate based on the clinical needs of the patient. CMS finalizes its proposal.

B. Treatment of New and Revised Codes

CMS continues to recognize the following codes on ASC claims:

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

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

CMS sets out proposals for new codes in two categories:

- Codes previously identified during the year in the quarterly update process and on which it is seeking comments in this proposed rule; and
- New codes for which it will be seeking comments in the forthcoming 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 proposed rule. CMS sets out in Table 52 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 New or Revised HCPCS Codes (from CMS Table 52)				
ASC Quarterly Update CR	**Type of Code**	**Effective Date**	**Comments Sought**	**When Finalized**
April 1, 2018	Level II HCPS Codes	April 1, 2018	2019 OPPS/ASC proposed rule	2019 OPPS/ASC final rule with comment period
July 1, 2018	Level II HCPCS codes Category I (certain vaccine codes) and III CPT codes	July 1, 2018		
October 1, 2018	Level II HCPCS Codes	October 1, 2018	2019 OPPS/ASC final rule with comment period	2020 OPPS/ASC final rule with comment period
January 1, 2019	Category I and III CPT codes	January 1, 2019	2019 OPPS/ASC proposed rule	2019 OPPS/ASC final rule with comment period
	Level II HCPCS Codes		2019 OPPS/ASC final rule with comment period	2020 OPPS/ASC final rule with comment period

Treatment of New and Revised Level II HCPCS Codes and Category III CPT Codes Implemented in April and July of 2018 for Which CMS Solicited Public Comments

CMS, in April and July of 2018 change requests (CRs), made effective 17 new Level II HCPCS codes and 1 new Category III CPT Code describing covered ASC services that were not included in the 2018 OPPS final rule. Tables 53-55, copied below, set out the codes, descriptors, and the 2019 payment indicators.

CMS notes that HCPCS code C9749 has been assigned a payment indicator of "J8" and is therefore designated as device-intensive (results in higher payment). CMS adopts as final the 2019 proposed payment indicators for new level II HCPCs codes for covered surgical procedures and ancillary services effective on April 1, 2018 (as shown in Table 53).

New Level II HCPCS Codes for Covered Surgical Procedures and Ancillary Services Effective on April 1, 2018 (Table 53)			
2018 HCPCS Code	**2019 HCPCS Code**	**Long Descriptor**	**Final 2019 Payment Indicator**
C9462	C9462	Injection, delafloxacin, 1 mg	K2
C9463	J0185	Injection, aprepitant, 1 mg	K2
C9464	J2797	Injection, rolapitant, 0.5 mg	K2
C9465	J7318	Hyaluronan or derivative, Durolane, for intra-articular injection, per dose	K2

New Level II HCPCS Codes for Covered Surgical Procedures and Ancillary Services Effective on April 1, 2018 (Table 53)			
2018 HCPCS Code	**2019 HCPCS Code**	**Long Descriptor**	**Final 2019 Payment Indicator**
C9466	J0517	Injection, benralizumab, 1 mg	K2
C9467	J9311	Injection, rituximab and hyaluronidase, 10 mg	K2
C9468	J7203	Injection, factor ix (antihemophilic factor, recombinant), glycopegylated, Rebinyn, 1 i.u.	K2
C9469*	J3304*	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	K2
C9749	C9749	Repair of nasal vestibular lateral wall stenosis with implant(s)	J8
*HCPCS code C9469 was deleted June 30, 2018 and replaced with HCPCS code Q9993, which was effective July 1, 2018; this code will be replaced by HCPCS code J3304 effective January 1, 2019.			

CMS did not receive any public comments regarding the proposed payment indicators and payment rates for the new Category III CPT code and Level II HCPCS codes that were expected to be newly recognized as ASC covered surgical procedures or covered ancillary services in July 2018 through the quarterly update CRs. CMS adopt as final the 2019 proposed payment indicators for these codes, as indicated in Table 54 and 55.

New Level II HCPCS Codes for Ancillary Services Effective on July 1, 2018 (Table 54)			
2018 HCPCS Code	**2019 HCPCS Code**	**Long Descriptor**	**Final 2019 Payment Indicator**
C9030	J9057	Injection, copanlisib, 1 mg	K2
C9032	J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genome	K2
Q5105	Q5105	Injection, epoetin alfa, biosimilar, (Retacrit) (for esrd on dialysis), 100 units	K2
Q5106	Q5106	Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units	K2
Q9991	Q9991	Injection, buprenorphine extended-release (Sublocade), less than or equal to 100 mg	K2
Q9992	Q9992	Injection, buprenorphine extended-release (Sublocade), greater than 100 mg	K2
Q9993*	J3304*	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	K2
Q9995	J7170	Injection, emicizumab-kxwh, 0.5 mg	K2
*HCPCS code C9469 was deleted June 30, 2018 and replaced with HCPCS code Q9993 effective July 1, 2018.This code will be replaced by HCPCS code J3304 effective January 1, 2019.			

New Category III CPT Code for Covered Ancillary Service Effective on July 1, 2018 (CMS Table 55)			
2018 CPT Code	**2019 CPT Code**	**Long Descriptor**	**Final 2019 Payment Indicator**
0508T	0508T	Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia	Z2

CMS notes that the final 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 codes at the CMS website referenced above.

Process for New and Revised Level II HCPCS Codes That Will Be Effective October 1, 2018 and January 1, 2019 for Which CMS Is Soliciting Public Comments in this 2019 OPPS/ASC Final Rule with Comment Period.

CMS proposed to continue to assign comment indicator "NI" in Addendum B to the 2019 OPPS/ASC final rule for those new and revised Level II HCPCS codes that are effective October 1, 2018 and January 1, 2019. This indicates that CMS has assigned the codes an interim OPPS payment status for 2019.

CMS invites comments in this 2019 OPPS/ASC final rule with comment period on the interim status indicator and APC assignments, and payment rates for these codes that will be finalized in the 2020 OPPS/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, 2019 for Which CMS Is Soliciting Comments in the 2019 OPPS/ASC Final Rule with Comment Period

For new and revised Category I and III CPT codes effective January 1, 2019 that are received in time to be included in the proposed rule, CMS proposes 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 Addenda AA and BB, and the long descriptors are in Addendum O at the ASC website

CMS states, however, that it inadvertently omitted most of the new Category I and III CPT codes effective January 1, 2019 from ASC Addenda AA, BB, and EE to the 2019 OPPS/ASC proposed rule. Thus, CMS is flagging these codes with comment indicator "NI" in ASC Addenda AA, BB, and EE in this final rule with comment period.

CMS invites comments on the interim ASC payment indicator assignments and payment rates for these codes that it intends to finalize in the 2020 OPPS/ASC final rule with comment period.

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

Covered Surgical Procedures Designated as Office-Based

CMS annually reviews volume and utilization data to identify "office-based" procedures that are added to the ASC list of covered surgical procedures and are performed more than 50 percent of the time in physicians' offices and that CMS' medical advisors believe are of a level of complexity consistent with other procedures performed routinely in physicians' offices. Based on its review of 2017 volume and utilization data, CMS proposed to permanently designate four additional procedures as office-based (shown in Table 37 in the proposed rule).

Based on comments received, CMS does not designate CPT codes 36902 and 36905 as office-based procedures for 2019 and will retain their current payment indicator, "G2". CMS states it plans to reevaluate these procedures in its 2020 rulemaking period. The procedures CMS is designating as permanently office-based beginning in 2019 are listed in Table 56 in the final rule (and reproduced below).

ASC Covered Surgical Procedures to be Newly Designated as Permanently Office-Based for 2019 (CMS Table 56)			
2019 CPT Code	**Long Descriptor**	**2018 Payment Indicator**	**2019 Payment Indicator**
31573	Laryngoscopy, flexible; with therapeutic injection(s) (e.g., chemo denervation agent or corticosteroid, injected percutaneous, transoral, or via endoscope channel), unilateral	G2	P3
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous,mechanochemical; first vein treated	P2	P2
36513	Therapeutic apheresis; for platelets	G2	R2
36901	Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report.	P2	P3
G0429	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies	P3	P3
*Payment indicators are based on a comparison of the proposed rates according to the ASC standard rate setting methodology and the Medicare PFS final rates.			

CMS also reviewed 2017 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 four of these procedures and proposed to maintain the temporary office-based designations for these four codes (CPT codes 38222, 65785, 67229, and 0402T) for 2019. The volume and utilization data for the remaining six procedures (CPT codes 10030, 36473, 36901, 64461, 64463, and HCPCS code G0429) was sufficient to indicate that these procedures are performed predominately in physicians' offices and thus CMS proposed to assign them an office-based indicator ("P2", "P3", or "G2") in 2019. Table 38 in the proposed rule lists the procedures and CMS' proposed payment indicators for 2019. After consideration of comments, CMS finalizes its proposal, without modification, to designate the procedures shown in Table 57 in the final rule as temporarily office-based for 2019 (CPT codes 38222, 65785, 67229, and 0402T).

CMS proposed to designate eight new 2019 CPT codes for ASC covered surgical procedures as temporary office-based, using a 5-digit CMS placeholder code. Table 39 in the proposed rule (reproduced below) lists the procedures and proposed payment indicators. CMS did not receive any comments, and finalizes, without modification, its proposal to designate the procedures listed in Table 58 in the final rule as temporarily office-based.

2019 Payment Indicators for New 2019 CPT Codes for ASC Covered Surgical Procedures Designated as Temporary Office-Based (CMS Table 58)			
2019 CMS Placeholder Code	**Final 2019 CPT Code**	**Long Descriptor**	**2019 ASC Payment Indicator***
06X1T	0512T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	R2
10X12	10005	Fine needle aspiration biopsy, including ultrasound guidance; first lesion	P3
10X14	10007	Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion	P3
10X16	10009	Fine needle aspiration biopsy, including CT guidance; first lesion	P2
10X18	10011	Fine needle aspiration biopsy, including MR guidance; first lesion	R2
11X02	11102	Tangential biopsy of skin (e.g., shave, scoop, saucerize, curette); single lesion	P3
11X04	11104	Punch biopsy of skin (including simple closure, when performed); single lesion	P2
11X06	11106	Incisional biopsy of skin (e.g., wedge) (including simple closure, when performed); single lesion	P3
*Payment indicators are based on a comparison of the proposed rates according to the ASC standard rate setting methodology and the Medicare PFS final rates.			

ASC Covered Surgical Procedures to Be Designated as Device-Intensive

Under its payment methodology for calculating the ASC 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 OPPS 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 OPPS APC rate setting methodology to the OPPS 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 OPPS 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 OPPS/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.

As discussed in more detail in section IV.B.2 of this summary, CMS proposed to modify its criteria for device-intensive procedures. CMS proposed to allow procedures that involve surgically inserted or implanted, high-cost, single use devices to qualify as device-intensive procedures. In addition, CMS proposed to modify its criteria to lower the device offset percentage threshold from 40 percent to 30 percent. CMS is also proposing changes to align the device-intensive policy with the criteria used for device pass-through status.

Based on CMS' proposed modifications to its device-intensive criteria, CMS proposed to update the ASC list of covered surgical procedures that are eligible for payment according to the device-intensive payment methodology for 2019, reflecting the proposed individual HCPCS code device offset percentages based on 2017 OPPS claims and cost report data.

In addition, for 2019, CMS proposed to only apply its proposed device-intensive procedure payment methodology to device-intensive procedures under the ASC payment system when the device-intensive procedure is furnished with a surgically inserted or implanted device (including single use medical devices). CMS explained that the payment rate under the ASC payment system for device-intensive procedures furnished without an implantable or inserted medical device would be calculated by applying the uniform ASC conversion factor to both the device portion and service (non-device) portion of the OPPS relative payment weight for the device-intensive procedure and summing both portions (device and service) to establish the ASC payment rate.

The majority of commenters supported the CMS proposal to lower the device offset percentage threshold for procedures to qualify as device-intensive from greater than 40 percent to greater

than 30 percent. Likewise, most commenters supported the CMS proposal to modify the device-intensive criteria to allow procedures that involve single-use devices, regardless of whether they remain in the body after conclusion of the procedure, to qualify as device-intensive procedures. One commenter requested, and CMS agreed, to assign device-intensive status payment indicator "J8" to CPT codes 0410T, 0411T, and 0414T. CMS also assigned 0409T as device-intensive.

In summary, CMS finalizes its proposal to modify its criteria for device-intensive procedures to better capture costs for procedures with significant device costs. CMS finalizes its proposal to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. In addition, CMS finalizes its proposal to modify its criteria to lower the device offset percentage threshold from 40 percent to 30 percent. Specifically, for 2019 and subsequent years, CMS finalizes its proposal that device-intensive procedures would be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost. Corresponding to this change in the cost criterion CMS proposed that the default device offset for new codes that describe procedures that involve the implantation of medical devices would be 31 percent beginning in 2019.

CMS also designates the ASC covered surgical procedures displayed in Addendum AA a device-intensive and subject to the device-intensive procedure payment methodology for 2019.

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

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

CMS finalizes its proposal to continue its policy for ASCs for 2019:

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

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

credit is 50 percent or more (but less than 100 percent) of the cost of the replacement device. Beneficiary coinsurance would be based on the reduced payment amount.

CMS updates the list of ASC covered device-intensive procedures which would be subject to the full credit/partial credit policy to all device-intensive procedures in 2019.

Additions to the List of ASC Covered Surgical Procedures

As discussed earlier, CMS proposed (and finalized) a revision to its definition of surgery for 2019 to include "surgery-like" procedures that are assigned codes outside the CPT surgical range. Using its proposed revised definition, CMS conducted its annual review of procedures paid under the OPPS but not included on the list of covered ASC procedures.

CMS proposed to add 12 cardiac catheterization 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 twelve proposed additions are CPT codes 93451-93462 and have a proposed payment indicator of "G2", except for CPT code 93462, which has a proposed payment indicator of "N1". CMS noted that even though these procedures involve blood vessels that could be considered major, CMS believed these procedures are similar to other procedures currently on the ASC list of covered surgical procedures, and that they may be appropriately performed in an ASC.

After considering the comments, CMS finalizes its proposal to add 12 cardiac catherization procedures to the list of ASC covered surgical procedures. In response to comments, CMS also adds five procedures performed during cardiac catheterization procedures to the list of ASC covered surgical procedures (CPT codes 93566, 93567, 93568, 93571, and 93572). The 17 procedures that CMS adds to the list of ASC covered surgical procedures is shown in Table 60 in the final rule.

Review Recently Added Procedures to the ASC Covered Procedures List

Historically, CMS has evaluated the ASC covered procedures list (CPL) each year to determine whether procedures should be added or removed from the list, and changes to the list are often made in response to specific concerns raised by stakeholders. CMS states that it may be appropriate to reevaluate recently-added procedures given that when the procedure is added to the list, the provider community has limited experience in performing the procedure on the Medicare population. As such, CMS proposed to review all procedures that were added to the ASC CPL within the 3 calendar years prior to the year in which it engages in rulemaking to assess the safety, effectiveness, and beneficiary experience of these newly-added procedures when performed in the ASC setting. CMS begins with procedures added to the ASC CPL in 2015, 2016, and 2017, and assess whether newly-added procedures continue to meet its criteria. CMS proposed to review all 38 procedures that were added to the ASC CPL for 2015, 2016, and 2017. These were shown in Table 41 in the proposed rule.

CMS sought comments about whether these recently-added procedures continue to meet the criteria to remain on the ASC CPL. In addition, CMS solicited comments regarding how its

systematic review should be structured in the future, including the length of time procedures should be considered recently-added, how frequently reviews should be performed in light of the time required to accumulate meaningful data and whether any future reviews should examine procedures added during a period of time greater or less than the previous 3 completed calendar years.

Commenters generally supported the CMS proposal to review procedures that were recently added to the ASC CPL. A number of commenters supported retaining the 38 procedures and believes that these procedures can be safely and effectively performed in an ASC setting. Other commenters believed that there was insufficient data to assess these procedures without a minimum of 3-5 years of data and asked for additional information regarding the methodology and supporting material that CMS would use to make their determination whether a procedure remained on the ASC Covered Procedures List.

In response, CMS agreed with commenters that a longer timeframe may provide better data to adequately determine whether or not the procedure meet its criteria and would consider that recommendation for future rulemaking. CMS would use all available data including clinical characteristics, utilization and pricing data, prevailing medical practice, and any public comments received. CMS retains the procedures displayed in Table 61 on the ASC CPL for 2019 (with the exception of CPT codes 0171T and 0172T which were deleted as of January 1, 2017). CMS does not finalize any proposal regarding ongoing reviews of recently added procedures at this time, but will consider future refinements.

Covered Ancillary Services

CMS finalizes, without modification, its proposal to update the ASC list of covered ancillary services to reflect the payment status for the services under the OPPS. CMS notes that this may result in packaged status under the ASC payment system for covered ancillary services that were separately payable in a preceding year if the covered ancillary service is proposed for packaged status under the OPPS. CMS continues this reconciliation of packaged status for subsequent years. All ASC covered ancillary services and their payment indicators for 2019 are included in Addendum BB at the ASC website.

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

Payment for Covered Surgical Procedures; Update to ASC Covered Surgical Procedure Payment Rates for 2019

CMS finalizes its proposal to update payments for office-based procedures and device-intensive procedures using its established methodology and using its modified definition for device-intensive procedures. CMS notes that because the OPPS relative payment weights are based on geometric mean costs, 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 2019 OPPS device offset percentages. CMS

will make payment for office-based procedures at the lesser of the 2019 PFS non-facility PE RVU-based amount, or the 2019 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 OPPS would be assigned the current ASC payment indicators and continue to be paid separately under the ASC payment system.

Payment for Covered Ancillary Services

CMS continues to update payments and make changes necessary to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services. CMS continues to set payment methodologies for brachytherapy services and separately payable drugs and biologicals equal to the 2019 OPPS rates.

CMS continues to base payment for separately payable covered radiology services on the lower of the 2019 PFS non-facility PE RVU-based amounts and the 2019 ASC rate calculated under standard rate-setting methodology (except in the case of nuclear medicine procedures and services that use contrast agents). If the radiology service is packaged or conditionally packaged under the OPPS, payment for the radiology service would be packaged into the payment for the ASC. Addendum BB indicates the payment status for each radiology service. In the case of nuclear medicine procedures designated as radiology services paid separately when provided integral to a surgical procedure on the ASC list, CMS continues to set payments based on the OPPS relative payment weights, and therefore would include the cost of the diagnostic radiopharmaceutical. In the case of radiology services that use contrast agents, CMS continues to set payment based on the OPPS relative payment rate, and will, therefore, include the cost of the contrast agent. CMS continues to not make separate payment for procurement of corneal tissue when used in any noncorneal transplant procedure.

With regards to contractor-priced codes, CMS proposes to continue to designate hepatitis B vaccines as contractor-priced based on the invoiced costs for the vaccine, and corneal tissue acquisition as contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplant. In addition, consistent with its established ASC payment policy, CMS proposes that the 2019 payment for devices that are eligible for pass-through payment under the OPPS would be separately paid under the ASC payment system and contractor-priced.

Consistent with its current policy, CMS continues its policy that certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS be covered ancillary services when they are integral to an ASC covered surgical procedure. CMS proposes to pay for the tests at the lower of the 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 2019.

CMS made a new proposal for 2019 to pay separately for evidence-based non-opioid pain management drugs that function as a supply in a surgical procedure in the ASC setting to address the decreased utilization of these drugs and to encourage use of these types of drugs rather than prescription opioids. Specifically, CMS proposed to unpackage and pay separately for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in

the ASC setting for 2019. CMS proposed to pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as a supply when used in a surgical procedure when the procedure is performed in the ASC setting. This proposal would only currently apply to Exparel – the only non-opioid pain management drug that functions as a supply when used in a surgical procedure that is covered under Medicare Part B. CMS proposed conforming changes to its regulations at 42 CFR 416.164(a)(4) and to 42 CFR 416.164 (b)(6).

After consideration of comments, CMS finalizes its policy to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for 2019 as proposed. CMS also finalizes its proposed conforming changes to 42 CFR 416.164(a)(4) to exclude non-opioid pain management drugs that function as a supply when used in a surgical procedure from its policy to package payment for drugs and biologicals for which separate payment is not allowed under the OPPS into the ASC payment for the covered surgical procedure. CMS also adds a new paragraph (6) to 42 CFR 416.164(b) to include non-opioid pain management drugs that function as a supply when used in a surgical procedure as covered ancillary services that are integral to a covered surgical procedure. Finally, CMS finalizes its proposed change to 42 CFR 416.171(b)(1) to exclude non-opioid pain management drugs that function as a supply when used in a surgical procedure from its policy to pay for ASC covered ancillary services an amount derived from the payment rate for the equivalent item or service set under the OPPS.

E. New Technology Intraocular Lenses (NTIOL)

CMS did not receive any requests for review to establish a new NTIOL class for 2019 by the March 1, 2018 deadline. CMS not p making any change to its payment adjustment of $50 per lens for a 5-year period from the implementation date of a new NTIOL class.

F. 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 were labeled with the proposed new comment indicator ‘NP” to indicate that these codes were open for comment as part of the 2019 proposed rule.

Addenda DD1 and DD2 provide a complete list of the ASC payment and comment indicators for 2019.

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

Updating the ASC Relative Payment Rates for 2019 and Future Years

CMS continues to update relative weights using the national OPPS relative weights and the 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 2017, CMS computes the ratio of:

- Total payments using the 2018 relative payment rates, to
- Total payments using the 2019 relative payment rates.

The resulting ratio, 0.8792, is the weight scaler for 2019. The scaler would 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 OPPS relative weights. The scaler would not apply to ASC payments for separately payable covered ancillary services that have a predetermined national payment amount and are not based on OPPS relative payment weights (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.

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 OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor. Holding constant ASC use and mix of services in 2017 and the 2019 national payment rates after application of the weight scaler, CMS computes the ratio of:

- ASC payments using the 2018 ASC wage indices, to
- ASC payments using the 2019 ASC wage indices.

The resulting ratio, 1.0004, is the wage index budget neutrality adjustment to the conversion factor for 2019.

Instead of using the CPI-U to measure the update factor for ASCs as it has done in the past, CMS finalizes its proposal to apply a hospital-market basket update to ASCs for an interim period of 5 years. In its discussion, CMS cites several advantages including that an alternative update factor could stabilize the differential between the OPPS and ASC payment and encourage the migration of services to lower cost settings as clinically appropriate. CMS notes that it is cognizant of concerns that Medicare does not currently collect cost data from ASCs, which makes it difficult to assess payment adequacy or establish an ASC-specific market basket.
CMS plans to revise its regulations at 42 CFR 416.171(a)(2) to reflect this policy. While the majority of commenters supported the proposal to update ASC payment rates using the hospital market basket update, others, including MedPAC, disagreed with the proposal and recommended collecting cost data from ASCs to inform an ASC-specific market basket index.

CMS will utilize the hospital market basket update of 2.9 percent minus the multifactor productivity adjustment (MFP) of 0.8 percent. This yields an update of 2.1 percent for ASCs meeting quality reporting requirements. If the CPI-U had been used the update would have been 1.8 percent.

CMS continues its policy of reducing the update by 2.0 percentage points for ASCs not meeting the quality reporting requirements, yielding an update of 0.1 percent for such ASCs. The resulting 2019 ASC conversion factor is $46.551 for ASCs reporting quality data, and $45.639 for those that do not, computed as follows:

	ASCs reporting quality data	ASCs not reporting quality data
2018 ASC conversion factor	$45.575	
Wage adjustment for budget neutrality	x 1.0004	
Net MFP-adjusted update	x 1.021	x 1.001
2019 ASC conversion factor	$46.551	$45.639

Impact

CMS sets out estimated aggregate increases for the six specialty groups and ancillary items and services that account for the most ASC utilization and spending, assuming the same mix of services from the 2017 claims data. (Table 63 of the final rule and reproduced below). The eye and ocular adnexa group remains the largest source of payments, with 1 percent decrease in payments attributable to the changes in 2019. CMS notes that this could be a result of a number of factors, including updated data, and a reduction in hospital reported costs for this category which lowers the payment weight for this group partially offsetting the 2.1 percent ASC rate update. The second largest group, nervous system, is estimated to see a 3 percent increase. Payments for ancillary items and services are estimated to see a 79 percent increase. This is largely attributed to the introduction of utilization data for HCPCS code C9447 (a high-cost skin substitute).

Summary of Table 63: Aggregate 2019 Medicare Program Payments by Surgical Specialty or Ancillary Items and Services Group		
Surgical Specialty Group	Estimated 2018 ASC Payments (in Millions)	Estimated 2019 Percent Change
Total	**$4,772**	**2%**
Eye and ocular adnexa	$1,737	-1%
Nervous system	$993	3%
Digestive system	$873	3%
Musculoskeletal system	$574	3%
Genitourinary system	$188	1%
Integumentary system	$145	-1%
Ancillary items and services	$64	79%

CMS sets out estimated increases for 30 selected procedures in Table 64 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 have a 2 percent

decline in payment. The second largest aggregate payment procedures, CPT code 45380, is expected to see a 4 percent increase.

Excerpt from Table 64: Estimated Impact of the 2019 Update to the ASC Payment System on Aggregate Payments for the Top 10 Procedures			
CPT/ HCPS Code	Short Descriptor	Estimated 2018 ASC Payments (in Millions)	Estimate 2019 Percent Change
66984	Cataract surg w/iol, 1 stage	$1,206	-2%
45380	Colonoscopy and biopsy	$228	4%
63685	Insert/redo spine n generator	$221	-1%
43239	Egd biopsy single/multiple	$180	1%
63650	Implant neuroelectrodes	$166	-3%
45385	Colonoscopy w/lesion removal	$156	4%
64483	Inj foramen epidural l/s	$101	13%
0191T	Insert ant segment drain int	$96	4%
66982	Cataract surgery complex	$89	-2%
64635	Destroy lumb/sac facet jnt	$75	-1%

As noted at the beginning of this ASC section, Addenda tables available only on the website provide additional details; they are at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1695-FC.html They include:

- AA -- List of ASC Covered Surgical Procedures for 2019 (Including surgical procedures for which payment is packaged)
- BB -- ASC Covered Ancillary Services Integral to Covered Surgical Procedures for 2019 (Including Ancillary Services for Which Payment is Packaged)
- DD1 -- ASC Payment Indicators for 2019
- DD2 -- ASC Comment Indicators for 2019
- EE -- Surgical Procedures to be Excluded from Payment in ASCs for 2019

XIII. Requirements for the Hospital OQR Program

In this section, CMS finalizes changes to the factors it considers with respect to removing measures from the OQR Program and removes 8 measures, one beginning with the 2020 payment determination and the others beginning with 2021 payment. The total number of mandatory measures is reduced from 21 previously adopted for the 2020 and 2021 payment determinations to 20 measures for 2020 and 13 measures for 2021 payment. Other changes remove the requirement that hospitals submit a notice of participation form, update the measure specifications manual less frequently, and lengthen the reporting period for one claims-based measure.

No changes were proposed to current policies regarding priorities for OQR program measure selection; retention of measures; data submission deadlines; public display of OQR Program measures; QualityNet account and security administrator requirements; data submission requirements; data validation; extraordinary circumstances exceptions; or reconsiderations and appeals.

CMS says that its changes to the OQR Program are intended to improve the usefulness and usability of quality program data by streamlining how facilities report and access data while maintaining or improving consumer understanding of publicly reported data. They were developed to be consistent with the Meaningful Measures Initiative[7], which CMS launched in October 2017 as part of its effort to reduce the regulatory burden on the healthcare industry, lower health care costs, and enhance patient care.

A. Accounting for Social Risk Factors in the OQR Program

CMS reviews past discussion of how to account for social risk factors (also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors) in its quality reporting and value-based purchasing programs. It cites the work of the Assistant Secretary for Planning and Evaluation (ASPE) and the July 2017 final report of the National Quality Forum (NQF) on its 2-year trial period of risk adjustment for social risk factors, and notes that NQF has launched a follow-up 3-year initiative that will continue to include social risk factors in outcome measures submitted for endorsement and will also explore unresolved issues that surfaced in the initial trial.

The public comments that CMS sought and received during the 2018 rulemaking regarding whether and how to account for social risk factors in its quality programs are also described. This includes comments on the types of factors and the usefulness of stratifying measures by social risk factors.

As a next step, CMS is considering options to increase the transparency of quality measure disparities shown among patient groups within and across hospitals, such as stratification of Inpatient Quality Reporting Program outcome measures. It plans to continue to work with ASPE, the public, and other stakeholders to identify policy solutions that improve health equity while minimizing unintended consequences.

No comments on these issues were sought in the proposed rule, but CMS says it did receive comments and will consider them in future rulemaking.

B. Policies for Removal of Quality Measures from the OQR Program

In general, once adopted for the OQR Program, measures are retained for subsequent years unless otherwise specified, and regular rulemaking is used to remove a measure unless there are specific patient safety concerns associated with continuing the measure. In the case of patient safety concerns, a process for immediate removal can be used. CMS finalizes codification of the measure retention and removal policies.

In this rule, CMS finalizes changes to the factors it uses to determine whether to remove a measure from the OQR Program and codifies the list. Measures meeting any of these criteria are

---

7 See https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiavevGenInfo/MMF/General-info-Sub-Page.html.

not automatically removed; CMS considers removals on a case-by-case basis. The final factors consider whether 1) performance on the measure is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (the measure is "topped out"); 2) performance or improvement on the measure does not result in better patient outcomes; 3) the measure does not align with current clinical guidelines or practice; 4) another more broadly applicable (across settings, populations, or conditions) measure for the topic is available; 5) a measure that is more proximal in time to desired patient outcomes for the topic is available; 6) another available measure is more strongly associated with the desired patient outcomes; 7) collection or public reporting of the measure leads to negative unintended consequences other than patient harm and 8) the costs associated with a measure outweigh the benefit of its continued use in the program.

While the first seven factors were previously used (with some wording differences), factor 8 is newly adopted. It has also been finalized for use in other quality reporting programs including the inpatient hospital quality reporting and value-based purchasing programs and quality reporting programs for PPS-exempt cancer hospitals, long-term care hospitals, hospices, inpatient rehabilitation facilities, skilled nursing facilities, and inpatient psychiatric facilities. In responding to concerns from some commenters about factor 8, CMS acknowledges that stakeholders may have different perspectives on the costs and benefits associated with a measure. Because of this, it plans to consider input from a variety of stakeholders in evaluating the costs and benefits of measures.

CMS clarifies its calculations for factor 1 regarding "topped out" measures. A measure is considered topped out when (1) there is statistically indistinguishable performance at the 75^{th} and 90^{th} percentiles of national facility performance on the measure; and (2) the measure's truncated coefficient of variation (TCOV) is less than or equal to 0.10 (79 FR 66942). The TCOV is calculated as the truncated standard deviation divided by the truncated mean. CMS believes that the TCOV is a good measure of variability and provides a methodology for comparing different types of measures.

In this rule, two measures (OP-11 and OP-14, as discussed below) are removed as "topped out" using a modified calculation of TCOV. These measures each assess the rate of rare undesired events for which a lower rate is preferred. In the case of a rare event measure the TCOV calculation is distorted because the mean for the measure is very low and the TCOV therefore is very high. CMS clarifies that it used the mean of non-adverse events in the denominator to calculate the TCOV. CMS says that this method results in a TCOV that is comparable to those calculated for other measures.

C. Removal of Measures

Applying the newly finalized measure removal criteria, and considering the goals of the Meaningful Measures Initiative, CMS removes 8 measures from the OQR Program. One measure is removed beginning with 2020 payment and the others beginning with 2021 payment. As discussed further below, two additional measures, one voluntary, were proposed for removal but are retained in this rule. The measures finalized for removal in this rule are listed here.

- OP-27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) is removed beginning with the 2020 payment determination based on the new factor 8, costs outweigh the benefits. The vast majority of OQR Program participating facilities report this measure for other programs, and the inpatient version of the measure captures the vast majority of hospital personnel. As discussed in section XIV.C below, CMS also removes this measure from the ASC quality reporting program.
- OP-5: Median Time to ECG (NQF #0289) is a chart-abstracted measure removed based on factor 8. While not meeting the definition of topped out, CMS determined that the measure shows minimal performance variation and is not useful in helping beneficiaries make informed decisions about their care.
- OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use (NQF #0659) is a chart-abstracted measure removed based on factor 8. In addition to the general burden of chart abstraction, CMS believes this measure is uniquely burdensome because it requires facilities to conduct extensive patient histories and to contact other facilities to document a patient's history of adenomatous polyps. CMS notes that it is retaining a related measure on this topic, OP-29, which is less burdensome to report. As discussed in section XIV.C below, a similar measure is removed from the ASCQR Program.
- OP-9: Mammography Follow-up Rates is removed based on factor 3, measure does not align with current clinical guidelines or practice. Specifically, this measure does not take into account more recent guidelines and literature on the clinical benefits of diagnostic digital breast tomosynthesis. CMS will investigate respecification of this measure.
- OP-11: Thorax Computed Tomography (CT) – Use of Contrast Material (NQF #0513) and OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT are removed on the basis of being topped out (factor 1). In response to comments, CMS notes that it would consider re-proposing these measures for the OQR Program in the future if research indicates hospital performance in this area has declined.
- OP-12: The Ability for Providers with HIT (Health Information Technology) to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data and OP-17: Tracking Clinical Results between Visits are removed on the basis of factor 2, performance or improvement does not result in better patient outcomes. These measures assess functionality of health information technology and do not address patient outcomes, and CMS does not believe they are consistent with the goals of its Meaningful Measures Initiative.

Two additional measures were proposed for removal under factor 8 but are retained in this final rule. (In both cases, parallel measures are also retained for the ASCQR Program as discussed in section XIV.C below.)

- OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) is retained because CMS was persuaded by some commenters that this measure provides distinct and valuable information for beneficiaries about the outpatient hospital setting where a high volume of colonoscopies are performed, and is less burdensome to report than OP-30, which is being removed. CMS cites literature showing overuse of surveillance colonoscopies on low-risk patients. In proposing its removal, CMS had cited the costs of reporting and the

availability of similar measures (namely OP-32: Facility 7-Day Risk Standardized Hospital Visit Rate After Outpatient Colonoscopy (NQF #2539). CMS no longer believes the costs of reporting this measure outweigh the benefits.

- The voluntary measure OP 31: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) is retained because CMS has concluded that although only a small number of facilities report this measure (between 52 and 66 for the 2017 through 2019 payment determinations), it is meaningful to those that do report it. In addition, no other OQR Program measure addresses cataract surgery, a common outpatient hospital procedure. Finally, because the measure is not mandatory CMS concludes it is inherently not more burdensome than valuable.

CMS responds to numerous comments regarding the removal of these measures. Regarding the impact of removing measures that are included in the Hospital Overall Star Ratings calculations (OP-5, OP-14, OP-27, and OP-30) CMS says that a "representative measure set remains.[8]"

In the Collection of Information Requirements section of the final rule, CMS estimates that the removal of one chart abstracted measure (OP-5) and three measures submitted by HOPDs using a web-based tool (OP-12, OP-17, and OP-30) reduce reporting burden and save a total of $24.9 million nationally for 2021. Burden reduction associated with the removal of OP-27 is not included in this estimate.

D. Summary Table of OQR Program Measures

The table below shows the final OQR Program measure sets for payment years 2015 through 2021. (In a few cases other measures were adopted and data collection was suspended prior to the measure being removed. Those 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 Payment Determination Years 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	Removed

[8] CMS lists the OQR Program measures included in the Overall Star Ratings calculation (OP-3, OP-4, OP-18, OP-22, OP-23, OP-30, and OP-33). However, CMS does not note that OP-4 (aspirin at arrival) was previously removed from the OQR Program measure set effective with the 2020 payment year. More information on the hospital star ratings is available at https://www.medicare.gov/hospitalcompare/About/Hospital-overall-ratings.html.

Summary Table—OQR Measures for Payment Determination Years 2015-2021								
NQF		**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**
	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	Removed
	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	Removed
	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	Removed
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	Removed
0491+	OP-17: Tracking Clinical Results between Visits	X	X	X	X	X	X	Removed
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
	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	Removed	

Summary Table—OQR Measures for Payment Determination Years 2015-2021								
NQF		**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**
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	Removed
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						Voluntary	
	OP-37b: OAS CAHPS – Communication About Procedure						Voluntary	
	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery						Voluntary	
	OP-37d: OAS CAHPS – Overall Rating of Facility						Voluntary	
	OP-37e: OAS CAHPS – Recommendation of Facility						Voluntary	
+ CMS notes that NQF endorsement for the measure has been removed.								

E. OQR Measures and Topics for Future Consideration

CMS requested and received public comment on possible measure topics for the OQR Program, which it will consider for the future.

F. Notice of Participation Form

CMS finalizes and codifies removal of the requirement that hospitals submit a notice of participation form for participation in the OQR Program. Submission of any OQR Program data will indicate a hospital's status as a program participant. A hospital must still (1) register on the QualityNet website before beginning to report data; (2) identify and register a QualityNet security administrator and (3) submit data.

G. Frequency of OQR Program Specifications Manual Release

CMS changes the frequency of OQR program specifications manual releases, with a change from the proposed rule. Beginning with 2019, instead of continuing to update the OQR Program measure specifications manual every 6 months (and addenda as necessary), it will update the manual every 12 months and release addenda as necessary. CMS believes that regular twice-a-year updates are unnecessary. It had proposed to update the manual every 6 to 12 months but agrees with commenters that such an ad hoc schedule could be confusing.

H. Extension of Reporting Period OP-32: Hospital Visit Rate after Outpatient Colonoscopy

CMS finalizes a change to the reporting period for the claims-based measure OP-32 from one year of data to 3 years of data because it believes that better information would be provided to beneficiaries. While its analysis of data from the 2015 dry run of this measure has supported the finding that using 1 year of data provides sufficient reliability for measure calculation, CMS also found that using a 3-year reporting period increases the reliability and precision of the measure. In addition, the longer period is estimated to increase the number of HOPDs with eligible cases for this measure by 5 percent, adding 235 facilities to the measure calculation. However, in responding to comments CMS emphasizes that the purpose of the change is to improve measure reliability.

The change to the reporting period for OP-32 will begin with the 2020 payment determination, which will use claims from calendar years 2016, 2017 and 2018 instead of 2018 alone. A similar pattern will occur for later payment determinations. Because prior years are being added payment determinations and public display of the measure will not be disrupted.

I. Payment Reduction for Hospitals that Fail to Meet the OQR Program Requirements

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 2019 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 $77.900 by the final full conversion factor of $79.490. Continuing previous policies, when applicable the reporting ratio is applied to all services calculated using the OPPS conversion factor and applied to all HCPCS codes to which CMS has assigned status indicators J1, J2, P, Q1, Q2, Q3, R, S, T, V, or U, excluding services paid under the New Technology APCs to which CMS has assigned status indicators S and T.

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

CMS reports that for 2018 payment, 36 hospitals (out of about 3,300) failed to meet the OQR Program requirements for a full update factor; half (18) of these hospitals chose not to participate in the program.

XIV. Requirements for the ASCQR Program

CMS finalizes changes to the factors it uses when considering removal of measures from the ASCQR Program, removes two measures from the program, and suspends reporting for four others beginning with the 2021 payment determination. The total number of measures that ASCs must report is nine for the 2020 payment determination and four for 2021. Two additional measures were previously finalized for addition to the program beginning with the 2022 payment determination, for which a total of six measures will be required. One voluntary measure is continued, and CMS has previously delayed reporting on the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey measures. Also, under this final rule, the reporting period for one claims-based measure is lengthened.

No changes were proposed to existing policies for ASCQR Program measure selection; public reporting of measures; maintenance of measure specifications; data submission deadlines; public display of measures; QualityNet account and security administrator requirements; participation status requirements; data submission; extraordinary circumstances exceptions; or reconsideration procedures.

A. Accounting for Social Risk Factors in the ASCQR Program

This section of the final rule is virtually identical to the one described in XIII.A above regarding the OQR Program.

B. Policies for Removal of Quality Measures from the ASCQR Program

CMS finalizes and codifies changes to the factors it will use for determining whether to remove a measure from the ASCQR Program. The final eight factors are the same as those finalized for the OQR Program, and consider whether 1) performance on the measure is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (the measure is "topped out"); 2) performance or improvement on the measure does not result in better patient outcomes; 3) the measure does not align with current clinical guidelines or practice; 4) another more broadly applicable (across settings, populations, or conditions) measure for the topic is available; 5) a measure that is more proximal in time to desired patient outcomes for the topic is available; 6) another available measure is more strongly associated with the desired patient outcomes; 7) collection or public reporting of the measure leads to negative unintended consequences other than patient harm and 8) the costs associated with a measure outweigh the benefit of its continued use in the program.

Calculations for factor 1 regarding "topped out" measures are clarified.[9] Specifically, where a measure is assessing the rate of rare, undesired events for which a lower rate is preferred, CMS

[9] A measure is considered topped out when (1) there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance on the measure; and (2) the measure's truncated coefficient of variation

will calculate the TCOV using the mean of non-adverse events in order to have a result that is comparable to other measures.

C. Removal of ASCQR Program Measures for the 2020 and 2021 Payment Determinations

Applying the finalized measure removal criteria, and considering the goals of the Meaningful Measures Initiative, CMS removes 2 measures from the ASCQR Program. Six other measures, described further below, that were proposed for removal are instead retained in this final rule. The two measures finalized for removal follow.

- ASC-8: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) is removed from the ASCQR Program beginning with the 2020 payment determination based on removal factor 8, costs outweigh the benefits. The rationale parallels that discussed in section XIII.C above for the removal of this measure (OP- 27) from the OQR Program. In this case, CMS notes that unlike acute care hospitals, ASCs are only required to participate in the NHSN reporting system for the purpose of reporting this measure and therefore have a greater burden in reporting this measure.
- ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use (NQF #0659) is removed based on new factor 8, costs outweigh benefits. CMS cites the duplication of this measure through the Merit-based Incentive Payment System (MIPS) for physicians, and the additional burden to ASCs in obtaining patient records. The parallel measure (OP-29) is removed from the OQR Program as discussed in section XIII.C above.

These measures were proposed for removal but are retained in the final rule:

- ASC-1: Patient Burn (NQF #0263); ASC-2: Patient Fall (NQF #0266); ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267); and ASC-4: All-Cause Hospital Transfer/Admission (NQF #0265) were proposed for removal as topped out measures (factor 1) but in considering public comments, CMS re-evaluated its data and reviewed studies and has concluded that the measures have more value to stakeholders than it previously understood. Despite little room for improvement, CMS now understands that the measures provide beneficiaries with patient safety information that is useful in choosing an ASC for care and that the measures are valuable to the ASC community. In addition, these four measures apply to all ASCs regardless of specialty area. Commenters raised concern about the data submitted for these measures, and CMS is also concerned about the inability of ASCs to correct QDC codes used to calculate the measures from claims once they are submitted. It believes that revising the data submission method for these measures, such as through QualityNet would allow for corrections and result in more complete and accurate data. Therefore, although they are retained, **CMS is suspending data collection for these four measures beginning with 2019 reporting period (2021 payment)** until it takes further action in future rulemaking to update the data submission method.

(TCOV) is less than or equal to 0.10. The TCOV is calculated as the truncated standard deviation by the truncated mean.

- ASC-9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) was proposed for removal based on factor 8, costs outweigh benefits. Based on public comments and its reevaluation of the data, CMS no longer believes the measure costs outweigh its benefits, under the same rationale for its decision to retain the parallel measure (OP-30) in the OQR Program, as discussed in section XIII.C above.
- ASC-11: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) was proposed for removal based on factor 8, but CMS has concluded that although only a small number of ASCs report this voluntary measure, it is considered very meaningful by those that do. (Between 107 and 137 reported it for the 2017 through 2019 payment determinations; 38 submitted the measure consistently for these years.) It is also the only measure related to cataract surgery. As with the parallel OQR Program measure (OP-31), CMS further concludes that a voluntary measure inherently is not more burdensome than valuable.

In the Collection of Information section of the final rule, CMS estimates that its final decision to remove ASC-10 from the ASCQR Program beginning with 2021 payment will reduce the information collection burden across 3,937 ASCs by $2.3 million in 2021. Burden reduction associated with the removal of ASC-8 beginning in 2020 is not included in this estimate.

D. Summary Table of ASCQR Program Measures

The table below shows the ASCQR Program measures finalized in this rule for the 2020 and 2021 payment determinations along with measures previously adopted for payment determinations beginning in 2015. Specifications for ASCQR Program measures are available on the QualityNet website: https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772475754.

Final ASCQR Program Measures by Payment Determination Year								
	2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**
ASC-1: Patient Burn (NQF #0263)+	X	X	X	X	X	X	Suspended*	
ASC-2: Patient Fall (NQF #0266)	X	X	X	X	X	X	Suspended*	
ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267)+	X	X	X	X	X	X	Suspended*	
ASC-4: All-Cause Hospital Transfer/Admission (NQF #0265)+	X	X	X	X	X	X	Suspended*	
ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing (NQF #0264)+	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	Removed		
ASC-9 Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658)		X	X	X	X	X	X	X

Final ASCQR Program Measures by Payment Determination Year								
	2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**
ASC-10 Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use (NQF #0659)		X	X	X	X	X	Removed	
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 until further action*		
ASC-15b: OAS CAHPS – Communication About Procedure						*Delay until further action*		
ASC-15c: OAS CAHPS – Preparation for Discharge and Recovery						*Delay until further action*		
ASC-15d: OAS CAHPS – Overall Rating of Facility						*Delay until further action*		
ASC-15e: OAS CAHPS – Recommendation of Facility						*Delay until further action*		
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. *Measure suspended until further action on data submission methods.								

E. Possible Future Validation of ASCQR Program Measures

In the proposed rule, CMS sought public comment on the possible future validation of chart-abstracted ASCQR Program measures. It believes that the program may benefit from providing more reliable estimates of national performance on measures, and that ASCs may also benefit from the opportunity to better understand their data and examine potential discrepancies.

The OQR Program validation policy is offered as a good model for this purpose. Under that process, CMS selects a random sample of 450 hospitals for validation and another 50 hospitals using targeted criteria (failing the previous year's validation or having an outlier value for a measure). Hospitals selected for validation have 45 days to submit medical record documentation. The data validation requirement is met if the hospital achieves at least a 75 percent reliability score as determined by CMS.

CMS believes it would be beneficial to begin validation with just one measure, such as ASC-13: Normothermia Outcome. It cites ASC-14: Unplanned Anterior Vitrectomy as another possibility, but ASC-13 has a larger population of cases from which to sample.

The comments received are described; a number of commenters raised concerns about the possible choice of ASC-13 as the initial measure for validation noting, among other things, that

not all ASCs report these measures. CMS says that it will investigate the feasibility of validating ASC-1, ASC-2, and ASC-3 which are broadly applicable. Moving forward in the least burdensome way possible remains a goal.

F. Extension of Reporting Period for ASC-12: Hospital Visit Rate after Outpatient Colonoscopy

CMS finalizes its proposal to change the reporting period for the claims-based measure ASC-12 from one year of data to 3 years of data because it believes that better information would be provided to beneficiaries. A similar change is adopted for the parallel measure OP-32 as discussed above in section XIII.H. CMS believes the longer period increases the precision and reliability of measure scores and will increase the number of ASCs with eligible cases for this measure by 10 percent, adding 235 ASCs to the measure calculation.[10] The reporting period for ASC-12 is changed beginning with the 2020 payment determination, for which claims from calendar years 2016, 2017 and 2018 will be used instead of 2018 alone. A similar pattern will occur for later payment determinations. Because prior years are added, CMS says payment determinations and public display of the measure will not be disrupted.

Responding to a comment, CMS discusses differences between the ASC-12 and OP-32 measures. Specifically, because outpatient hospital cases subject to the 3-day payment window are bundled with the inpatient claim, for OP-32 these cases are identified with a matching algorithm that uses inpatient and physician claims to attribute the colonoscopy procedure to the appropriate HOPD. CMS intends to update publicly available resource material to clarify that the ASC-12 and OP-32 measures are calculated separately using different benchmarks and should not be compared. Data are provided in the final which CMS says demonstrates that the impact of quality on the outcome rate is substantial. Specifically, CMS concludes that a patient receiving a low-risk colonoscopy has a 23 percent increase in the odds of a hospital visit if the procedure was performed at a higher-risk HOPD compared to a lower-risk HOPD. The parallel odds of a hospital visit for patients receiving a low-risk colonoscopy procedure in a higher-risk ASC are 19 percent higher than if the procedure was performed at a lower-risk ASC.

G. 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

[10] The final rule states that in the case of both HOPDs (discussed in section XIII.H) and ASCs, an additional 235 facilities would be added to the measure calculation under a 3-year reporting period. That figure is said to represent 5 percent of HOPDs and 10 percent of ASCs participating in the respective quality reporting programs, but seems inconsistent with CMS counts, particularly of the number of participating ASCs. CMS says that 6,683 ASCs met eligibility requirements for the ASCQR Program for 2018.

are paid based on OPPS payment rates, and others. When the update reduction is applied to a facility, beneficiary copayments are based on the reduced payment rate.

CMS reports that for the 2018 payment determination, 233 of the 6,683 ASCs that met eligibility requirements for the ASCQR Program failed to meet the requirements for a full payment update.

XV. Request for Information

A. Promoting Interoperability and Electronic Health Care Information Exchange

In the 2019 OPPS proposed rule, CMS included a Request for Information (RFI) related to promoting interoperability and electronic health care information exchange. The agency received over 60 timely pieces of correspondence on this RFI. CMS neither summarizes nor responds to these comments or indicates whether it will act on them at a future date.

B. Improving Beneficiary Access to Provider and Supplier Charge Information

In the 2019 OPP proposed rule, CMS included an RFI related to improving beneficiary access to provider and supplier charge information. CMS received over 90 timely pieces of correspondence on this RFI. This RFI is related to a similar policy in the FY 2019 IPPS rule that required hospitals to post standard charges in a machine-readable format on their website. CMS neither summarizes nor responds to these comments or indicates whether it will take any future or additional action on provider and supplier charge information.

C. Competitive Acquisition Program for Part B Drugs and Biologicals Innovation Center Model

In the CY 2019 OPPS proposed rule, CMS included an RFI related to leveraging the authority for the Competitive Acquisition Program (CAP) for Part B drugs and biologicals for a potential CMS Innovation Center Model. CMS received approximately 80 timely pieces of correspondence on this RFI. CMS does not summarize or respond to comments on this RFI.

However, on October 25, 2018, CMS released an advanced notice of proposed rulemaking (ANPRM) requesting comment on a potential model that includes elements of the CAP program in combination with an international price index (IPI) and other delivery system reforms for Part B drugs. The ANPRM was published was published in the October 30, 2018 issue of the *Federal Register* with a public comment period that ends at 5:00 PM (time zone unspecified but is usually eastern time) on December 31, 2018.

XVI. Additional Inpatient Quality Reporting (IQR) Program Policies

With a change from the proposed rule, CMS finalizes removal of the 3 communication about pain questions from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) measure used in the Hospital Inpatient Quality Reporting (IQR) Program beginning in October 2019 for the FY 2021 payment determination.[11] Further, CMS finalizes that there

11 The HCAHPS requirements are available http://www.hcahpsonline.org/.

will be no public reporting of these questions. CMS intends to continue to consider how best to capture and assess facets of pain management through quality measurement, including the role of appropriate communication about pain during a hospital stay, informing patients about the risks of opioid use and educating patients on non-opioid alternatives to pain management.

The history of the HCAHPS pain questions is reviewed, including the replacement of the original pain management questions with the communication about pain questions now being removed. The communication about pain questions were finalized for addition to the survey beginning with 2018 discharges (FY 2020 payment), and the first public reporting of these new questions was scheduled for October 2020 (data for 2019 discharges). The three communication about pain questions are:

HP1: "During this hospital stay, did you have any pain?"
☐ Yes
☐ No
HP2: "During this hospital stay, how often did hospital staff talk with you about how much pain you had?"
☐ Never
☐ Sometimes
☐ Usually
☐ Always
HP3: "During this hospital stay, how often did hospital staff talk with you about how to treat your pain?"
☐ Never
☐ Sometimes
☐ Usually
☐ Always

Most commenters were supportive of removing these questions from the survey. Although it is not aware of any scientific studies that support an association between scores on the communication about pain questions and opioid prescribing practices, CMS believes that is appropriate to remove the communication on pain questions out of an abundance of caution in order to avoid unintended consequences. Stakeholders have reported that these questions encourage inappropriate prescribing of opioids, and CMS also cites recommendations of the President's Commission on Combating Drug Addiction and the Opioid Crisis.[12] CMS believes that the national epidemic and the importance of removing any perceived pressure for opioid overprescribing justifies removal of the questions.

Moreover, Section 6104 of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patient and Communities Act (P.L. 115-271) was enacted on October 24, 2018 and prohibits HCAHPS surveys conducted on or after January 1, 2020 from including questions about a patient's communication with hospital staff about pain unless the individual is informed of opioid risks. It also prohibits public reporting of the

12 The report is available at https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf.

HCAHPS pain communication measures on the *Hospital Compare* website in 2018 or 2019 and in the Hospital Value-based Purchasing Program.

CMS had proposed later removal of the questions (January 2022 for the FY 2024 payment determination) but in light of the SUPPORT Act requirements and public comments, CMS has determined that it is operationally feasible to remove the questions beginning with October 2019 discharges. Instead of continuing public reporting of measure data until October 2022 as it had proposed, CMS finalizes that it will not report any of these data publicly in keeping with the SUPPORT Act and the concerns about how the questions might encourage inappropriate opioid prescribing.

The confidential preview reports that are provided to hospitals will include these questions beginning as early as July 2019 reflecting four quarters of data for 2018, and then updated quarterly as additional data become available until all the data through September 30, 2019 have been presented. The reports will include state and national averages for comparison purposes.

Responding to those commenters who were concerned that removal of these questions would minimize the importance of appropriate communication about pain management, CMS says that pain management is a routine part of patient care and it expects that hospitals will still focus on maintaining a high level of performance in this regard. In addition, since January 2018, engaging patients in treatment decisions about their pain management is required under the enhanced pain assessment and management requirements for Joint Commission accreditation.

CMS emphasizes that the HCAHPS survey was never intended to assess the performance of individual clinicians or provider groups within a hospital and it does not endorse the use of the survey data in this way. Such comparisons are unreliable without the proper sample size and the general nature of the questions makes it inappropriate to use the survey this way. CMS strongly discourages using HCAHPS scores to compare wards, floors, and individual staff hospital members with a hospital.[13]

Comments that CMS received providing specific feedback it had requested are discussed. These address whether CMS should issue guidance suggesting that hospitals should not administer any surveys with pain-related questions; suggestions for other measures that capture facets of pain management; and other relevant comments.

In the Collection of Information section of the final rule, CMS estimates that removal of the 3 communication about pain questions from the HCAHPS survey will result in a burden reduction of $1.0 million nationally for the FY 2021 payment determination.

XVII. Additional PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program Policies

As part of the Inpatient Prospective Payment System (IPPS) rulemaking for FY 2019, CMS proposed removal of two measures from the PCHQR Program beginning with the FY 2021

[13]See *HCAHPS Quality Assurance Guidelines* at http://www.hcahpsonline.org/en/quality-assurance/.

program year. Both are infection measures from the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) and were proposed for removal under the new cost removal factor 8: the costs associated with a measure outweigh the benefit of its continued use in the program. The two measures are NHSN Central Line Bloodstream Infection (CLABSI) (NQF #0139) and NHSN Catheter Associated Urinary Tract Infection (CAUTI) (NQF #0138).

In making the proposal to remove these two measures CMS noted both the reporting burden and the low volume of results making the measures unavailable for public reporting and therefore of no use to beneficiaries. However, in the IPPS final rule for FY 2019, CMS deferred a final decision on removal of these measures and stated that it was conducting additional data analyses to assess measure performance based on new information provided by the CDC.

In this rule CMS announces its decision to retain the measures. The CLABSI and CAUTI measures were recently updated to use new standardized infection ratio calculations that allow for stratified patient care locations within the PPS-exempt Cancer Hospitals and no predictive models or comparisons are used in the rate calculations. CMS believes these measures have the potential to provide valuable information to beneficiaries on performance of the 11 PCHs, and intends to propose to use these updated measures in future rulemaking. Until then, it believes the current measures should be retained in the PCHQR Program while public display will continue to be deferred until CMS has evaluated performance data from the updated versions of these measures. Public display will occur as soon as practicable.

The final rule includes a table summarizing the public display requirements for the PCHQR Program for FY 2021, which indicates that public reporting is deferred for the CLABSI and CAUTI measures and that it will begin as soon as practicable for other NHSN measures regarding MRSA, CDI, surgical site infections, and influenza vaccine among healthcare personnel. CMS also indicates that it plans to propose a timeframe for public reporting of the measure of patients receiving outpatient chemotherapy in IPPS rulemaking for FY 2020.

XVIII. Files Available to the Public via the Internet

Addenda for the 2019 OPPS final rule are available on the following CMS website:

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1695-FC.html

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

For addenda related to 2019 ASC payments, please see:

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1695-FC.html
Scroll to the “Related Links” sections to find ASC Addenda Addendum AA, BB, DD1, DD2, and EE.

TABLE 62—ESTIMATED IMPACT OF THE CY 2019 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**	**All Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update**	**Off-Campus Provider-Based Department Visits Policy**	**All Changes**
ALL FACILITIES *		3,840	0.0	0.0	1.3	-0.6	0.6
ALL HOSPITALS		3,727	0.0	0.0	1.4	-0.6	0.6
(excludes hospitals permanently held harmless and CMHCs)							
URBAN HOSPITALS		2,938	0.0	0.0	1.4	-0.6	0.7
	LARGE URBAN	1,542	0.1	-0.1	1.3	-0.5	0.7
	(GT 1 MILL.)						
	OTHER URBAN	1,396	0.0	0.1	1.5	-0.7	0.6
	(LE 1 MILL.)						
RURAL HOSPITALS		789	0.1	-0.2	1.3	-0.6	0.5
	SOLE COMMUNITY	370	-0.1	-0.2	1.1	-0.7	0.2
	OTHER RURAL	419	0.4	-0.1	1.6	-0.6	0.9
BEDS (URBAN)							
	0 - 99 BEDS	1,018	0.4	-0.1	1.6	-0.4	1.1
	100-199 BEDS	846	0.1	-0.1	1.4	-0.5	0.7
	200-299 BEDS	468	0.0	0.1	1.5	-0.5	0.9
	300-499 BEDS	390	-0.1	0.0	1.3	-0.6	0.5
	500 + BEDS	216	0.0	0.1	1.4	-0.8	0.5
BEDS (RURAL)							
	0 - 49 BEDS	328	0.4	0.0	1.7	-0.2	1.3
	50- 100 BEDS	288	0.2	-0.1	1.4	-0.8	0.5
	101- 149 BEDS	89	0.2	-0.2	1.3	-0.5	0.7
	150- 199 BEDS	47	0.1	-0.4	1.1	-1.1	-0.1

		(1)	(2)	(3	(4)	(5)	(6)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update**	**Off-Campus Provider-Based Department Visits Policy**	**All Changes**
	200 + BEDS	37	-0.3	-0.3	0.7	-0.5	0.1
REGION (URBAN)							
	NEW ENGLAND	143	0.2	1.7	3.3	-1.0	2.1
	MIDDLE ATLANTIC	336	0.0	-0.2	1.1	-0.4	0.6
	SOUTH ATLANTIC	469	0.0	-0.4	1.0	-0.5	0.4
	EAST NORTH CENT.	469	0.0	-0.3	1.0	-0.8	0.1
	EAST SOUTH CENT.	178	0.0	-0.2	1.2	-0.2	0.9
	WEST NORTH CENT.	182	-0.2	-0.2	1.0	-0.6	0.1
	WEST SOUTH CENT.	517	0.1	0.0	1.4	-0.5	0.8
	MOUNTAIN	214	0.0	0.2	1.5	-0.6	0.8
	PACIFIC	384	0.1	0.5	1.9	-0.6	1.1
	PUERTO RICO	46	-0.6	-1.2	-0.4	0.0	-0.4
REGION (RURAL)							
	NEW ENGLAND	21	-0.1	-0.7	0.5	-2.0	-1.6
	MIDDLE ATLANTIC	54	0.2	0.1	1.6	-1.0	0.5
	SOUTH ATLANTIC	122	0.1	-0.2	1.3	-0.2	1.0
	EAST NORTH CENT.	120	0.3	-0.2	1.5	-0.8	0.5
	EAST SOUTH CENT.	152	0.1	0.1	1.5	-0.3	1.1
	WEST NORTH CENT.	95	-0.2	-0.2	1.0	-0.8	-0.2
	WEST SOUTH CENT.	151	0.5	0.2	2.0	-0.3	1.6
	MOUNTAIN	51	-0.2	-0.6	0.5	-0.2	0.9
	PACIFIC	23	0.1	-0.4	1.1	-1.0	-0.1
TEACHING STATUS							
	NON-TEACHING	2,599	0.1	-0.1	1.4	-0.4	0.9
	MINOR	776	0.0	0.0	1.3	-0.6	0.5

		(1)	(2)	(3	(4)	(5)	(6)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update**	**Off-Campus Provider-Based Department Visits Policy**	**All Changes**
	MAJOR	352	0.0	0.1	1.5	-0.9	0.4
DSH PATIENT PERCENT							
	0	11	-0.8	-0.5	0.1	0.0	0.2
	GT 0 - 0.10	265	0.1	-0.2	1.3	-0.4	0.8
	0.10 - 0.16	241	0.0	-0.1	1.2	-0.4	0.7
	0.16 - 0.23	575	-0.1	-0.2	1.0	-0.6	0.3
	0.23 - 0.35	1,113	0.1	0.0	1.4	-0.7	0.6
	GE 0.35	953	0.1	0.1	1.6	-0.6	0.8
	DSH NOT AVAILABLE **	569	2.5	0.0	3.9	-0.3	3.4
URBAN TEACHING/DSH							
	TEACHING & DSH	1,013	0.0	0.1	1.4	-0.7	0.5
	NO TEACHING/DSH	1,369	0.1	0.0	1.4	-0.4	0.9
	NO TEACHING/NO DSH	10	1.2	-1.0	1.5	0.0	1.3
	DSH NOT AVAILABLE**	545	2.5	0.0	3.9	-0.3	3.4
TYPE OF OWNERSHIP							
	VOLUNTARY	1,977	0.0	0.0	1.4	-0.7	0.6
	PROPRIETARY	1,281	0.1	0.0	1.4	-0.2	1.0
	GOVERNMENT	469	0.0	0.1	1.4	-0.7	0.5
CMHCs		46	-16.8	0.7	-15.0	0.0	-15.1
Column (1) shows total hospitals and/or CMHCs.							
Column (2) includes all CY 2019 OPPS policies and compares those to the CY 2018 OPPS.							
Column (3) shows the budget neutral impact of updating the wage index by applying the FY 2019 hospital inpatient wage index. The rural SCH 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 because in CY 2019 the target payment-to-cost ratio is the same as it was in CY 2018 (0.88).							

		(1)	(2)	(3	(4)	(5)	(6)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update**	**Off-Campus Provider-Based Department Visits Policy**	**All Changes**
Column (4) shows the impact of all budget neutrality adjustments and the addition of the 1.35 percent OPD fee schedule update factor (2.9 percent reduced by 0.8 percentage point for the productivity adjustment and further reduced by 0.75 percentage point as required by law).							
Column (5) shows the additional impact of the policy to pay clinic visits for nonexcepted providers under the otherwise applicable payment system. We note that we are applying a 2-year phase-in so the amount of the reduction will be 50 percent of the difference in CY 2019 (or payment at 70 percent of the OPPS rate).							
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 3,840 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.							