

Proposed 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 2019¹ proposed rule for Medicare’s hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system on July 25, 2018; policies in the proposed rule are generally proposed to go into effect on January 1, 2019. The rule was published in the July 31st issue of the *Federal Register*. **The 60-day public comment period ends at 5:00 PM EST on September 24, 2018.**

The proposed 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 proposed 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.

CMS does not make a proposal but requests comments on: 1) promoting interoperability and electronic health care information exchange through revisions to health and safety requirements; 2) transparency of charge information and out-of-pocket costs for patients; and 3) an Innovation Center demonstration where the Competitive Acquisition Program (CAP) for Part B drugs could be used to reduce drug costs. CMS solicited comment on the first two of these three issues in prior regulations.

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-P.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending>. Unless otherwise noted, this weblink can be used to access any information specified as being available on the CMS website.

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

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I. Overview

A. Estimated Impact on Hospitals

CMS estimates that, compared to 2018, its proposed policies will increase total payments under the OPSS by \$90 million², including beneficiary cost-sharing and excluding estimated changes in enrollment, utilization, and case-mix. Taking into account estimated changes in enrollment, utilization, and case-mix, CMS estimates that OPSS expenditures for 2019 will be approximately \$74.6 billion; an increase of approximately \$4.9 billion compared to 2018 OPSS payments. CMS estimates the proposed update to the conversion factor and other adjustments (not

² This increase of \$90 million does not reconcile with information elsewhere in the proposed rule that shows payments going down by 0.1 percent. In an email exchange, CMS indicated that this discrepancy is explained by the \$90 million figure not including budget neutrality adjustments for outliers and pass-through payments.

including non-budget neutral adjustments) will increase OPPS payments by 1.3 percent. With all adjustments (including CMS’ 2019 proposal to control for “unnecessary increases” in the volume of the outpatient services by paying for clinic visits in off-campus PBDs at the physician fee schedule (PFS) equivalent rate), the proposed rule estimates that OPPS payments will decline by 0.1 percent. The proposed rule impact table indicates that Medicare makes payments under the OPPS to 3,806 facilities (3,695 hospitals excluding CMHCs and cancer and children’s hospitals held harmless to their pre-OPPS payment to cost ratios).

CMS proposes a conversion factor increase of 1.25 percent, based on the hospital inpatient market basket percentage increase of 2.8 percent for inpatient services paid under the IPPS³, minus the multifactor productivity adjustment of 0.8 percentage points minus an additional 0.75 percentage point adjustment required by the Affordable Care Act (ACA). Hospitals that satisfactorily report quality data will qualify for the full update of 1.25 percent, while hospitals that do not will be subject to a statutory reduction of 2.0 percentage points. The reduction in payments for hospitals not meeting the quality reporting requirements is implemented by substituting a fee schedule increase factor of -0.75 percent (0.9925) for the 1.25 percent fee schedule increase factor that applies to hospitals meeting the quality reporting requirements. 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 outpatient department (OPD) fee schedule increase factor. One half of these hospitals (18 of 36), chose not to participate in the Hospital OQR Program for the 2018 payment determination.

Table 42 in the proposed rule (reproduced in the Appendix to this summary) includes the estimated impact of the proposed rule by provider type. It shows a projected change in expenditures of -0.1 percent for all facilities and -0.1 percent for all hospitals (all facilities except cancer and children’s hospitals, and CMHCs). The following table shows components of the -0.1 percent total:

	% Change All Facilities
All changes	-0.10
Fee schedule increase factor	+1.25
Difference in pass through estimates for 2018 and 2019	-0.13
Difference from 2018 outlier payments (1.02% vs. 1.0%)	-0.02
Site Neutral Payment for Clinic Visits	-1.20

Pass-through spending for drugs, biologicals and devices for 2019 are estimated to be \$126.7 million, or 0.17 percent of projected OPPS spending. The adjustment to the rates of -0.13 percent reflects the difference between this projection and the 0.04 percent estimate for 2018. The -0.13 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

³ The OPPS percentage update is based on the IPPS market basket, as provided by statute.

represent 1.02 percent of total OPSS payments compared to the 1.0 percent set aside, for an estimated decrease in 2018 payments of 0.02 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 OPSS payments because these adjustments are budget neutral. However, these factors have differential effects on individual facilities.

Although CMS projects an estimated decrease of -0.1 percent for all facilities, the proposed rule impacts vary depending on the type of facility. Impacts will differ for each hospital category based on the mix of services provided, location and other factors. As shown in the table below and in the full impact analysis included in the appendix to this summary, any significant variation in impacts are largely explained by the differential effect of CMS’ policy to apply a site neutral PFS relativity adjuster of 0.40 to clinic visits at off-campus PBDs that are otherwise paid under the OPSS.⁴ The site neutral policy appears to disadvantage larger hospitals (-1.6 percent) and major teaching hospitals (-1.8 percent) more than other hospitals (-1.2 percent average across all hospitals). Proprietary hospitals appear to be somewhat less affected by this policy than other hospitals (-0.4 percent compared to -1.2 percent across all hospitals).

Facility Type	Projected 2019 Impact
All Hospitals	-0.1%
All Facilities (includes CMHCs and cancer and children’s hospitals)	-0.1%
Urban	-0.1%
Large Urban	+0.1%
Other Urban	-0.2%
Rural	-0.1%
Beds	
0-99 (Urban)	+0.7%
0-99 (Rural)	+1.1%
500+ (Urban)	-0.6%
200+ (Rural)	-0.5%
Major Teaching	-0.8%
Type of ownership:	
Voluntary	-0.2%
Proprietary	0.7%
Government	-0.3%
CMHCs	-17.9%

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

⁴ With limited exceptions, off-campus PBDs that opened after November 2, 2015 are not paid under the OPSS under section 603 of the Bipartisan Budget Act of 2015. CMS pays for outpatient services in these PBDs using a “PFS relativity adjuster” of 0.4 that results in payment at 40 percent of OPSS rates. The PFS relativity adjuster does not apply to “excepted off-campus PBDs;” PBDs not subject to 603 that opened on or before November 2, 2015. CMS is proposing to apply the 40 percent PFS relativity adjuster in excepted off-campus PBDs.

By geographic region, the site neutral policy appears to have a larger impact in New England than elsewhere. For New England hospitals, the impact of the site neutral policy is -2.1 percent among urban New England hospitals and -4.1 percent among rural New England hospitals. For urban New England hospitals, much of this impact is offset by APC recalibration and wage index changes. Among the regions with the largest differences from the average are:

Region	Projected 2019 Impact
Urban New England	-0.4%
Rural New England	-3.4%
West South Central	+1.4%

For West South Central, the difference from the average increase for all hospitals is largely explained by the combined effects of an increase for recalibration, modest changes to the wage index, and less of a reduction from the site neutral policy.

B. Estimated Impact on Beneficiaries

CMS estimates that the aggregate beneficiary coinsurance percentage will be 18.5 percent for all services paid under the OPSS 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 OPSS Payments

A. Recalibration of APC Relative Payment Weights

As described below, CMS is largely continuing past policies unchanged. The only changes CMS proposes 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 proposed 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 December 31, 2017. For the final rule, CMS will use hospital final action claims from the same period of time processed on or before June 30, 2018. Cost data are from the most recently filed cost reports, in most cases for cost reporting periods beginning in 2016. Unless otherwise specified, in all circumstances, CMS uses these same data in the 2019 rate setting process. In a separate document available on the CMS website, CMS provides a detailed description of the claims preparation process and an accounting of claims used in the development of the proposed 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 proposed rule, CMS bypasses the 169 Healthcare Common Procedure Coding System (HCPCS) codes identified in Addendum N to the proposed rule. CMS indicates the list of bypass codes may include codes that were reported on claims in 2016 but were deleted for 2017. CMS is not proposing to delete any codes from the bypass list for 2019.

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

Table 1 of the proposed rule shows the relative effect on imaging APC payments after removing cost data for providers that report CT and MRI standard cost centers using "square feet" as the cost allocation method. Table 2 of the proposed 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	-3.6%
5522	Level 2 Imaging without Contrast	5.5%
5523	Level 3 Imaging without Contrast	4.3%
5524	Level 4 Imaging without Contrast	4.7%
5571	Level 1 Imaging with Contrast	7.7%
5572	Level 2 Imaging with Contrast	8.4%
5573	Level 3 Imaging with Contrast	2.8%
8005	CT and CTA without Contrast Composite	13.9%
8006	CT and CTA with Contrast Composite	11.4%
8007	MRI and MRA without Contrast Composite	6.6%
8008	MRI and MRA with Contrast Composite	7.4%

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

Cost Allocation Method	CT		MRI	
	Median CCR	Mean CCR	Median CCR	Mean CCR
All Providers	0.0377	0.0527	0.0780	0.1046
Square Feet Only	0.0309	0.0475	0.0701	0.0954
Direct Assign	0.0553	0.0645	0.1058	0.1227
Dollar Value	0.0446	0.0592	0.0866	0.1166
Direct Assign and Dollar Value	0.0447	0.0592	0.0867	0.1163

The proposed rule indicates that the number of valid MRI CCRs has increased by 17.4 percent to 2,174 providers and the number of valid CT CCRs has increased by 14.8 percent to 2,244 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 OPSS 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. Even though the proposed rule indicates that CMS believes it has appropriate imaging CCRs to use for determining payment, it is extending its policy of not using providers that use the square foot cost allocation methodology in calculating the OPSS relative weights for one additional year until 2020. CMS does not believe another extension in 2020 will be warranted and 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 OPSS 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 OPSS. CMS is continuing to follow this basic process for the 2019 OPSS proposed rule. The 2017 claims data that CMS is using for the 2019 proposed rule includes data from off-campus PBDs paid at a PFS comparable amount under section 603 of the Bipartisan Budget Act. CMS is proposing to eliminate these claims from the relative weight calculation as they are not paid under the OPSS.

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 costs to charges 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 proposed 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 OPSS 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 claims methodology. For 2018, CMS is confident that the billing data are accurate for the temporary predecessor codes to P9073 and is using its normal methodology to develop its pricing. It is not clear from the rule how rapid bacterial testing is paid.

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 is proposing no changes to its brachytherapy policy for 2018. The proposed payment rates appear in Addendum B to the proposed rule and are identified with status indicator “U” (Paid under OPPS; separate APC payment).

If CMS does not have billing data to set the payment rates, it may use external data to set prices for brachytherapy sources. CMS is proposing to use external data to set the proposed APC payment rate for HCPCS code C2645 ((Brachytherapy planar source, palladium-103, per square millimeter) at \$4.99 per mm², the same payment rate that was in effect for 2017 and 2018. CMS is proposing 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.

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.

Proposed Additional C-APCs for 2019

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

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 OPSS and the ASC payment system, regardless of the costs of the drugs. The costs associated with packaged drugs that function as a supply are included in the rate setting methodology for the surgical procedures with which they are billed. The payment rate for the associated procedure reflects the costs of the packaged drugs and other packaged items and services to the extent they are billed with the procedure.

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..."⁵ 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.

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 hospital

⁵ 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

outpatient department for a majority of the drugs included in its analysis. CMS observed the opposite effect for several drugs that function as a supply.

The proposed rule provided a detailed analysis of 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 hospital outpatient department continued to increase beyond the period of pass-through payment even though payment for the drug was packaged with its associated surgical procedure.

CMS' findings in the ASC setting were different than the hospital outpatient department. During 2013 through 2017, CMS found a decrease in claims and utilization of Exparel after pass-through payments ended. CMS indicates that several variables may contribute to this difference including lower payments to ASCs than hospitals that may make ASCs more cost sensitive to use of packaged products. Alternatively, ASCs do not typically report packaged items and services and the proposed rule suggests that CMS' analysis may be undercounting the number of Exparel units utilized in the ASC setting.

As a result of declining utilization of Exparel in the ASC setting once the drug stopped receiving pass-through payment, CMS is proposing 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. While this proposal is a departure from CMS' current ASC packaging policy for drugs that function as a supply, CMS believes the proposed change will provide incentives to use non-opioid pain management drugs with surgical procedures in the ASC setting and is responsive to the Commission's recommendation. Payment for non-opioid pain management drugs in the ASC setting is presented in further detail in the ASC section of this summary.

CMS is also seeking 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. The reduction or avoidance of prescription opioids would be the criteria CMS would use to determine whether separate payment is warranted for 2019 in the hospital outpatient department.

Examples of evidence that may be relevant could include an indication on the product's FDA label or studies published in peer-reviewed literature that the product is a non-opioid alternative that aids in the management of acute or chronic pain. CMS would also be interested in evidence that such products have shown clinical improvement over other alternatives, such as a device that has been shown to provide a substantial clinical benefit over the standard of care for pain management. Spinal cord stimulators used to treat chronic pain were provided as potential examples.

CMS is also interested in 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. To the extent that commenters provide evidence to support this approach, CMS would consider a final rule policy that provides an exception to the

packaging of certain non-pass-through devices that represent non-opioid alternatives for acute or chronic pain that have evidence to demonstrate that their use leads to a decrease in opioid prescriptions or addictions.

Alternatively, CMS is interested in comments on reorganizing or establishing more granular APC groupings to provide incentives for increased use of non-opioid alternatives.

For example, CMS would consider finalizing a policy to establish new APCs for procedures involving non-opioid pain management packaged items or services if such APCs would better recognize the resources involved in furnishing such items and services and decrease or eliminate the need for prescription opioids. Because patients may receive opioid prescriptions following receipt of a non-opioid drug or implantation of a device, CMS is interested in identifying any cost implications for the patient and the Medicare program caused by this potential change in policy.

4. Calculation of OPPS Scaled Payment Weights

CMS proposes to continue its policy adopted in 2013 of calculating the relative payment weights for each APC using geometric mean-based APC costs. As in past years, CMS proposes to standardize the relative weights based on APC 5012 (Level 2 Examinations and Related Services) because that is the APC where HCPC code G0463 is assigned. G0463 (Hospital outpatient clinic visit for assessment and management of a patient) is the most commonly billed OPPS service. CMS is giving APC 5012 a relative weight of 1.0 and dividing the geometric mean costs of all other APCs by the geometric mean cost for APC 5012 to determine its associated relative payment weight. Even though CMS is proposing a policy to pay for clinic visits furnished in off-campus PBDs at a PFS equivalent rate, CMS is continuing to use visits in these settings in determining the relative weight scalar. The proposed rule notes that the PFS adjuster is applied to the payment, not the relative weight and that CMS' proposal is not budget neutral while changes to the weights are budget neutral.

CMS proposes to follow its past practice with respect to applying budget neutrality for changes in the OPPS relative weights. Holding all other variables constant, CMS multiplies the 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 scalar. Using this process, CMS is proposing a weight scalar of 1.4553. The unscaled 2019 relative payments are multiplied by 1.4553 to determine the proposed 2019 scaled relative weights that are shown in Addendum A and B.

B. Conversion Factor Update

CMS proposes an OPPS conversion factor for 2019 of \$79.546. CMS began with the 2018 conversion factor of \$78.636 and adjusted it by the fee schedule OPD increase factor and various budget neutrality factors. As discussed earlier, the fee schedule increase factor equals the hospital inpatient market basket percentage increase, which is 2.8 percent, reduced by a multifactor productivity adjustment of 0.8 percentage points as required by the ACA, and further reduced by an additional 0.75 percentage points as also required by the ACA. This provides for

a fee schedule increase factor of 1.25 percent. Hospitals that fail to meet the OQR requirements are subject to a reduction of 2.0 percentage points in the fee schedule increase factor or -0.75 percent.

In addition to the fee schedule increase factor, the proposed rule indicates that the following adjustments are applied in calculating the proposed 2019 conversion factor:

- A wage index budget neutrality factor of 1.0004.
- An adjustment for pass-through spending of -0.13 percent. CMS estimates that 2019 pass-through spending for drugs, biological and devices will be \$126.7 million, or 0.17 percent of projected OPSS spending, compared with CMS' estimate that pass-through spending in 2018 of 0.04 percent. The increase in projected pass-through spending for 2018 therefore results in a budget neutrality adjustment of -0.13 percent.

CMS is not proposing to make any changes to the rural or cancer hospital adjustment for 2019 compared to 2018. The proposed rule indicates that the combined effect of these factors yields a proposed 2019 conversion factor of \$79.546 for hospitals satisfying the requirements of the quality reporting program. For hospitals that do not meet OQR requirements, CMS indicates that substituting a fee schedule increase factor of -0.75 percent for the 1.25 fee schedule increase factor for other hospitals produces a conversion factor of \$77.955.⁶

C. Wage Index Changes

CMS proposes to continue its policy of adopting the final fiscal year IPPS post-reclassified wage index for urban and rural areas as the OPSS calendar year wage index for adjusting the OPSS standard payment amounts for labor market differences. The 2019 OPSS proposed rule wage index is based on the FY 2019 IPPS proposed post-reclassified wage index, and any adjustments for the FY 2019 IPPS final post-reclassified wage index would be reflected in the final 2019 OPSS wage index.

CMS proposes to retain the OPSS 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 proposes 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. 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. In the FY 2019 IPPS/LTCH proposed rule, CMS said that it lacked the time to include the change in computing the proposed FY 2019 wage index, rate setting, and Tables 2 and 3 of that proposed rule, but it will do so in the final rule. CMS notes that the new core-based statistical area (CBSA) may impact budget neutrality factors and wage indexes; for example, it

⁶ HPA calculates a CF of \$79.547 ($\$78.636 \times 1.0125 \times 1.0004 \times 0.9987 = \79.547) for hospitals receiving the full update. For hospitals receiving a reduced update, HPA calculates a CF of \$77.976 ($\$78.636 \times 0.9925 \times 1.0004 \times 0.9987 = \77.976). In the past, CMS multiplied the full CF by 0.98 to calculate the reduced CF for hospitals that do not submit quality data. HPA calculates that CF as \$77.956 ($\$79.547 \times 0.98 = \77.956).

may qualify for the rural floor. Currently, there is one hospital located in new CBSA 46300, and CMS estimates the area wage index for that CBSA based on that hospital as follows:

	Estimated Unadjusted Wage Index for New CBSA 46300	Estimated Occupational Mix Adjusted Wage Index for New CBSA 46300
Proposed National Average Hourly Wage	42.990625267	42.948428861
Estimated CBSA Average Hourly Wage	35.833564813	38.127590025
Estimated Wage Index	0.8335	0.8878

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) codes updates for the OPSS wage index because the Social Security Administration (SSA) codes are no longer maintained and updated. 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 proposes to continue its 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 would also apply for any associated HOPD.

In the FY 2019 IPPS/LTCH PPS proposed rule, CMS proposed to discontinue the imputed floor policy (both the original methodology and alternative methodology) for fiscal year 2019 and subsequent fiscal years. Thus, for purposes of the OPSS, CMS proposes in this rule to discontinue the application of the imputed floor policy to hospitals paid under the OPSS effective for 2019 and for subsequent years.

For non-IPPS hospitals paid under the OPSS, CMS proposes to continue its policy to assign the wage index that would be applicable if the hospital were paid under the IPPS, based on its geographic location and any applicable wage index adjustments. CMS also proposes to retain its policy of allowing non-IPPS hospitals paid under the OPSS 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 proposed rule contains information from Table 2 of the FY 2019 IPPS/LTCH PPS proposed rule which identifies counties eligible for the out-migration adjustment as well as IPPS hospitals that would receive the adjustment for FY 2019; it also contains information on non-IPPS hospitals that would receive the section 505 outmigration adjustment under the 2019 OPSS.

CMS reminds readers that, in the 2015 final OPSS rule, it adopted a 3-year transition period for hospitals paid under the OPSS 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 proposes to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. 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 proposes to discontinue), 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 OPSS. 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 proposing to update the default statewide average CCRs for 2019 using the most recent cost report data. Table 5 lists the proposed statewide average default CCRs for OPSS 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 OPSS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs. The adjustment is budget neutral and is applied before calculating outliers and copayments.

F. 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 OPSS, Medicare has paid these hospitals under the OPSS 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 with this additional 1.0 percentage point reduction excluded from OPSS budget neutrality.

The cancer hospital adjustment is applied at cost report settlement rather than on a claim by claim basis. For the 2019 proposed rule, CMS updated its calculations to determine the target PCR using the latest available cost data (which, in most cases, are hospital cost reports from

2016) and determined that 0.89 is the target PCR. Consistent with section 1833(t)(18)(C) of the Act, CMS is proposing to reduce the target PCR from 0.89 to 0.88 and to not make this reduction subject to OPSS budget neutrality.

Table 6 in the proposed rule shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals, with increases in OPSS 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 OPSS makes outlier payments on a service-by-service basis when the cost of a service exceeds the outlier threshold. For 2019, CMS is proposing to continue to set aside 1.0 percent of the estimated aggregate total payments under the OPSS 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.

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

CMS is again proposing that a portion of the 1.0 percent outlier pool, specifically an amount equal to less than 0.01 percent of outlier payments, be allocated to CMHCs for partial hospitalization program outlier payments. CMS is proposing to continue 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 OPSS annual payment update factor, resulting in reduced OPSS 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 proposed rule, CMS applied the hospital-specific overall ancillary CCRs available in the April, 2018 update to the Outpatient Provider-Specific File after adjustment (using a CCR inflation adjustment factor of 0.987842 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 (1.04205) for two years for a total increase factor of 1.085868 to approximate 2019 charges. The inflation adjustment factors for CCRs and charges are the same as were used for the FY 2019 IPSS proposed rule.

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

This section provides step by step instructions for calculating an adjusted Medicare payment from the national unadjusted Medicare payment amounts shown in Addenda A and B to the proposed 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 proposed 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 is \$1,340 in 2018. The inpatient hospital deductible limit is applied to the *actual* co-payment amount after adjusting for the wage index. For this reason, the co-insurance levels shown in the OPPS payment rate Addenda A and B to the proposed rule do not reflect application of the hospital deductible limit.

The proposed rule estimates that, in aggregate, the percentage of beneficiary liability for OPPS payments in 2018 will be 18.5 percent, the same percentage estimated for 2017.

III. OPPS APC Group Policies

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

Table 7 (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 7: 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

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
	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. Proposed Treatment of New HCPCS Codes That Were Effective April 1, 2018 - CMS Solicits Public Comments in this 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 (see Table 8). The proposed payment rates, where applicable, can be found in Addendum B to this proposed rule.

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 to include in the April 2018 OPPS Update CR and 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. The proposed payment rates, where applicable, can be found in Addendum B to this proposed rule.

2. Proposed Treatment of New HCPCS Codes That Were Effective July 1, 2018 - CMS Solicits Public Comments in this 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 (see Table 10). The proposed payment rates, where applicable, can be found in Addendum B to this proposed rule.

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 is proposing 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.

In addition, there were seventeen new (PLA) codes (U codes) that were effective July 1, 2018 but were too late to be included in the July 2018 OPSS Update. These codes will be included in the October 2018 OPSS Update with an effective date of July 1, 2018. The proposed payment rates, where applicable, can be found in Addendum B to this proposed rule.

3. Proposed Process for New Level II HCPCS Codes That Will Be Effective October 1, 2018 and January 1, 2019 - CMS Will Be Soliciting Public Comments in the 2019 Final Rule with Comment Period

CMS proposes to continue the practice of providing interim payment status indicators, APC assignments and payment rates, if applicable, for new Level II HCPCS codes that will be effective October 1, 2018 or January 1, 2019 in Addendum B to the 2019 final rule. These codes will be flagged with comment indicator “NI” in Addendum B, indicating that CMS has assigned the codes an interim OPSS payment status for 2019. CMS proposes that these status indicators and APC assignments would be applicable in 2019. **CMS will invite public comment in the 2019 OPSS/ASC final rule** about the status indicators, APC assignments, and payment rates for these codes and this information would be finalized in the 2020 OPSS/ASC final rule with comment period.

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

CMS received the new and revised 2019 Category I and III CPT codes from the AMA in time for inclusion in this proposed rule. The new and revised CPT codes are included in Addendum B to this proposed rule. CMS assigned a new comment indicator “NP” and is requesting 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 proposes to finalize the status indicators and APC assignments for these codes in the 2019 OPSS/ASC final rule.

Because the CPT code descriptors in Addendum B are short descriptors, CMS included the long descriptors for the new and revised CPT codes in Addendum O. CMS notes that these new and revised CPT procedure codes have a placeholder for the fifth character and the final CPT code numbers will be included in the 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 has identified the APC with violations of the 2 times rules and proposes changes to the procedure codes assigned to these APCs in Addendum B (identified with comment indicator "CH"). CMS notes that in many cases, the proposed procedure code reassignments and associated APC configurations for 2019 are related to changes in costs of services that were observed in the 2017 claims data.

2. Proposed 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 lists the sixteen APCs that CMS is proposing 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. For the final rule, CMS plans to use 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.

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 proposed payment rates for these New Technology APCs are included in Addendum A to this proposed 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 is 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 notes 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 proposes to establish a different payment methodology for these low-volume services using its equitable adjustment authority. CMS proposes 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.

3. Proposed Procedures Assigned to New Technology APC Groups for 2019

CMS proposes to continue their current policy to retain services within New Technology APC groups until they obtain sufficient claims data to justify reassignment of the service to a clinically appropriate APC. 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 13, there are 4 CPT/HCPCS codes that describe MRgFUS procedures. For 2019, CMS proposes to assign 3 of the codes to standard APCs and proposes 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 has only identified 3 paid claims (1 in 2016 and 2 in 2017). CMS is concerned that the reported geometric mean cost for 2017 is significantly lower than the reported cost of the 2016 claim.

Using the proposed methodology for low-volume services, based on the 3 claims, CMS calculates an arithmetic mean of \$12,849.11, a geometric mean of \$8,579.91, and a median of \$4,676.77. CMS believes that the arithmetic mean is the most appropriate representative cost of the procedures described by CPT code 0398T, which gives consideration to the payment rates for the procedures in 2017 and 2018. Using the arithmetic mean, CMS proposes 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)).

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 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 believes that the arithmetic mean is the most appropriate representative cost of this procedure, which gives consideration to the higher payment rates for the procedures in 2015 and 2017. Using the arithmetic mean, CMS proposes 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 would result in a proposed payment rate of \$137,500.50.

CMS also proposes 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 notes 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.

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 take into account 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 are not discussed in the proposed and final rules. Addendum B to the proposed rule identifies with a comment indicator “CH” those HCPCS codes for which CMS is proposing a change to the APC assignment or status indicator.

1. 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 OPPI 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 (Table 14). CMS discusses the input it received from stakeholders suggesting alternative structures, including a five-level structure (Table 15) and a six-level structure (Table 16).

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.

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 proposes to maintain the 7 Imaging APCs (Table 17) and to make minor reassignments to the HCPCS codes within this series to resolve any violations of the 2 times rule.

Musculoskeletal Procedures (APCs 5111 through 5116)

In 2016, CMS consolidated the APCs for musculoskeletal procedures to a six-level structure.

For 2019, CMS is not proposing any changes to the Musculoskeletal APCs (Table 18). **CMS solicits comments on the creation of a new APC level between the current Level 5 and Level 6 within the Musculoskeletal APC series.**

IV. OPSS Payment for Devices

A. Pass-Through Payments for Devices

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

CMS follows the statutory requirements that a category of devices is eligible for transitional pass-through payments for at least 2, but not more than 3 years. To allow a pass-through payment period that is as close to a full 3 years as possible, in the 2017 OPSS 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 OPSS a device must meet the following criteria:

1. If required by the FDA, the device must have received FDA premarket approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA), or meets another appropriate FDA exemption from premarket approval or clearance; and the pass-through application must be submitted within 3 years from the date of the initial FDA approval or clearance, if required, unless there is a documented, verifiable delay in the US market availability in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability;
2. The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury to improve the functioning of a malformed body part; and
3. The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion.

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

1. Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (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 subregulatory 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 (June 1, 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/HospitalOutpatientPPS/Downloads/catapp.pdf>.

The summary below provides a high-level discussion of each application; readers are advised to review the proposed rule for more detailed information. **CMS invites public comment on whether the three technologies in question meet the newness, cost, and substantial clinical improvement criteria.**

1. *AquaBeam System*

PROCEPT BioRobotics Corporation submitted an application 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.

Newness. The FDA granted the applicant's De Novo request on December 21, 2017. The device is classified as a class II device. CMS received the application for a transitional pass-through on March 1, 2018; this is 3 years of the date of the initial FDA approval or clearance.

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 wound 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. CMS notes that in the 2000 final rule (65 FR 67804 – 67805) it explained how it interpreted §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 also stated 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. 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 also addressed this issue in the 2006 final rule (70 FR 68329 – 68630). CMS adopted as final that the surgical insertion or implantation criteria included devices that are surgically inserted or implanted via a natural or surgically created orifice, as well as those devices that are inserted or implanted via a surgically created incision. **CMS reiterated that it maintains all the criteria in §419.66 and 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.** CMS invites public comment on whether the AquaBeam System meets the eligibility criteria at §419.66(b).

Criteria established at §419.66(c).

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

Substantial clinical improvement. The applicant submitted several articles that examined the use of current standard treatment for BPH to other modalities used to treat BPH, not including the AquaBeam System. The applicant did include a recent clinical study involving the AquaBeam System that was an accepted manuscript describing a double-blind trial comparing treatment with the AquaBeam System to traditional transurethral prostatectomy (TURP). CMS acknowledges there may be some evidence of the improved safety of the AquaBeam System over TURP but there are no studies comparing other treatment modalities that are likely to have a similar safety profile as the AquaBeam System. CMS believes it has insufficient evidence that the AquaBeam System provides substantial clinical improvement over other similar products.

Cost. CMS believes the AquaBeam System meets all the cost criteria.

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

BioMonde US, LLC submitted an application 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 OPPTS final rule (81 FR 79650). CMS notes that the only new information provided were additional studies addressing substantial clinical improvement.

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

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.

Eligibility. Although the applicant claims BioBag® is an integral part of wound debridement and is used for only one patient. In the 2017 OPPTS 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.

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 believes it has insufficient evidence that the BioBag[®] provides substantial clinical improvement over other treatments for wound care.

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

3. *BlastX[™] Antimicrobial Wound Gel*

Next Science submitted an application 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.

Newness. BlastX[™] received a 510(k) clearance from the FDA on March 6, 2017.

Eligibility. Based on the evidence in the application, CMS states that BlastX[™] is not a skin substitute and cannot be considered for transitional pass-through status as a device. Under the OPPS, CMS notes 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 notes the manufacturer stated that the product would be used in association with any currently available skin substitute product. CMS concludes 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.

CMS concludes that BlastX[™] does not meet the basic criterion of being an eligible device for transitional pass-through payment and thus, it does not evaluate the product on the other criteria.

4. *EpiCord[®]*

MiMedx submitted an application 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 asserts 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 notes 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.

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).

Criteria established at §419.66(c).

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

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

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

5. *remedē[®] System Transvenous Neurostimulator*

Respicardia, Inc submitted an application 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 summarizes the findings from the pivotal study, and although the applicant reported a reduction in AHI in the treatment group CMS is concerned the applicant did not

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

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

6. Restrata[®] Wound Matrix

Acera Surgical, Inc. submitted an application 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.

Newness. The applicant received FDA clearance for Restrata[®] Wound Matrix through the 510(k) process on April 26, 2017 and submitted its application for pass-through payment status on February 27, 2018.

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 notes 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 Restrata[®] Wound Matrix.

Substantial clinical improvement. CMS discusses the three clinical studies submitted by the applicant; the largest study was a non-randomized, non-blinded, uncontrolled single site retrospective analysis of 70 patients with 82 wounds and the other two studies were extremely small (one was performed on pigs and the other was a case series of six patients). CMS believes it has insufficient evidence that the Restrata[®] Wound Matrix provides substantial clinical improvement over other treatments for wound care.

Cost. CMS believes Restrata[®] Wound Matrix meets all the cost criteria.

6. SpaceOAR System[®]

Augmenix, Inc. submitted an application 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 notes 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 notes it is not evident that SpaceOAR System[®] is superior to existing alternative biodegradable biomaterials currently utilized for spacing during prostate radiotherapy. CMS believes it has insufficient evidence that the SpaceOAR System[®] provides substantial clinical improvement over other treatments for wound care.

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

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

In the 2018 OPPTS 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. Proposed Changes to the Device-Intensive Procedure Policy for 2019

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 proposes to modify the criteria for device-intensive procedures. CMS no longer believes 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 device-intensive CMS is proposing 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 states 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 proposes 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 proposes 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, 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).

CMS seeks comments on these proposed criteria including whether there are any devices that are not capital equipment that should be deemed part of device-intensive procedures that would not meet the proposed definition of single-use device.

CMS also seeks comments on the full list of proposed 2019 device-intensive procedures provided in Addendum P.⁷ CMS requests comments identifying any procedure proposed to receive device-intensive status and should not receive this status according to the proposed criteria, or any procedure it did not assign device-intensive status to and should receive device-intensive status.

For new HCPCS codes describing procedures requiring the implantation of medical devices that do not yet have associated claims data, in the 2017 OPPI final rule, CMS finalized a policy to apply a device-intensive status with a default device offset set at 41 percent until claims data are available to establish the HCPCS code-level device offset. CMS also finalized that in certain rare instances, such as in the case of a very expensive implantable device, CMS may temporarily assign a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer.

In accordance with the proposal to lower the device offset percentage threshold from 40 to 30 percent, for new HCPCS codes describing procedures requiring the implantation of medical devices that do not yet have associated claims data, CMS proposes to apply a 31-percent until claims data are available to establish the HCPCS code-level device offset. CMS proposes to continue its current policy of temporarily assigning a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer.

CMS also clarifies 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 proposes 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.

CMS states that clinically related and similar codes are codes that either currently or previously describes the procedures described by the new HCPCS code. Under this proposal, claims data from clinically related and similar codes will be included as associated claims data for a new code. CMS proposes to apply the device-offset percentage derived from the existing clinically

⁷ Addendum P is available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html>.

related or similar HCPCS code's claims data to the new HCPCS code for determining the device offset percentage. If a new HCPCS code has multiple predecessor codes, the claims data for the predecessor code that has the highest individual HCPCS-level device offset percentage will be used to determine whether the new HCPCS code qualifies for device-intensive status. This policy will also apply to clinically related or similar codes.

Additional information for CMS to use for its consideration of an offset percentage higher than the proposed default of 31 percent, such as pricing data or invoices from a device manufacturer, should be sent to the Division of Outpatient Care⁸ or electronically to outpatientpps@cms.hhs.gov. Additional information can also always be submitted in response to the OPPI/ASC proposed rule.

3. Device Edit Policy

In the 2017 OPPI 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 is not proposing any changes to the device edit policy.

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

CMS reduces OPPI 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 proposes 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. Proposed 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

⁸ Division of Outpatient Care, Mail Stop C4-01-26, CMS, 7500 Security Boulevard, Baltimore, MD 21244-1850

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 OPSS 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 proposes to continue this policy of establishing the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 claims for all procedures in the APC based on calculations using the median cost instead of the geometric mean cost. For 2019, there are no procedures to which this policy would apply. (CMS refers readers to section III.D.4. of this proposed rule for the discussion on the proposed APC assignment change for CPT code 0308T to APC 5493, which has more than 100 total claims.)

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

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

Section 1833(t)(6) of the Act provides for temporary additional payments or “transitional pass-through payments” for certain drugs and biologicals. For pass-through payment purposes, radiopharmaceuticals are “drugs.” As required by statute, transitional pass-through payments for a drug or biological can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the product as a hospital outpatient service under Medicare Part B. CMS makes transitional pass-through payment for drugs and biologicals using the average sales price (ASP)+6 percent methodology with quarterly updates to ASP. Proposed 2019 pass-through drugs and biologicals and their designated APCs are assigned status indicator “G” in Addenda A and B to the proposed rule.

CMS approves pass-through payments quarterly. Prior to 2017, CMS used the rulemaking process to expire pass-through payments at the end of a calendar year. However, beginning with pass-through applications approved in 2017, CMS will expire 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 proposing to end 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 19 of the proposed 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 packaged⁹ or paid separately if they have per day costs above the packaging threshold of \$125 proposed for 2019. If paid separately, CMS proposes to pay these drugs at ASP+6 percent unless acquired through the 340B program. If separately payable drugs are acquired through the 340B program, CMS is proposing to pay for the drugs at ASP-22.5 percent.

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

CMS is proposing to continue pass-through payment status in 2019 for 49 drugs and biologicals. All 49 of these drugs and biologicals are listed in Table 20 of the proposed 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). This provision of law required extending pass-through payment for any drug or biological receiving pass-through payment on December 31, 2017 for which payment was packaged on January 1, 2018. The products receiving extended pass-through payment are included among those listed in Table 20 and are separately listed in Table 21.

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 is addressing the 2018 payment for these products through program instruction. It is proposing to pay the most current ASP+6 percent for the first quarter of 2019 and update the price quarterly based on the latest ASP for the remainder of 2019. CMS notes that it is currently approving pass-through payments for skin substitutes as devices but one of these four products (Q4172 (PuraPly, and PuraPly Antimicrobial, any type, per square centimeter)) is a skin substitute that was approved as a biological under a prior policy. For this reason, CMS is extending pass-through payment for PuraPly and PuraPly Antimicrobial under the CAA provision.

If ASP data is not available, CMS is proposing to 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 proposal in the 2019 PFS proposed rule. In the 2019 PFS proposed rule, CMS

⁹ 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).

is proposing to pay at WAC+3 percent instead of WAC+6 percent for drugs and biologicals furnished in physicians' offices. If WAC information also is not available, CMS proposes to provide payment for the pass-through at 95 percent of its most recent average wholesale price (AWP).

3. 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 OPSS. 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 proposes to continue to apply the current offset policies for all of the policy-packaged drugs, biologicals, and radiopharmaceuticals. CMS refers readers to the discussion in the 2016 OPSS/ASC final rule with comment period (80 FR 70430 through 70432) for a full description of the payment offset policy. CMS will continue to post annually on its website a file with the APC offset amounts to be used for purposes of both evaluating cost significance for candidate pass-through device categories and drugs and biologicals and for establishing any appropriate APC offset amounts. The file is not currently available but will be after the final rule is published. Table 22 lists the proposed APCs to which an offset will be applicable.

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

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

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

Cost Threshold for Packaging of "Threshold-Packaged Drugs"

"Threshold-packaged drugs" under the OPSS 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 proposed rule 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 (\$126.03) to the nearest \$5 increment. Based on this calculation, CMS is proposing a packaging threshold for 2019 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 OPSS.

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 proposing to package 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 OPSS 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 OPSS 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 OPSS 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 proposes to continue its policy of making an annual packaging determination for a HCPCS code in the OPSS 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 proposing to continue to apply 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 is proposing 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 cm² (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 proposes 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 threshold and PDC threshold from year-to-year which can result in reassignment of a skin substitute from the high cost to the low-cost group and result in a payment difference of approximately \$1,000, CMS 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 presents 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.

CMS discussed the relative merits and its concerns for each option. In the interim until CMS establishes a permanent policy, it is proposing 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. Table 23 of the proposed 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 proposes to continue its policy of making packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, in the case of multiple HCPCS codes describing the same drug or biological but with different dosages. The codes to which this policy applies, and their packaging status, are listed in Table 24 of the proposed rule.

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

Except for separately payable, non-pass-through drugs acquired with a 340B discount, CMS proposes to continue paying separately payable drugs and biologicals at ASP+6 percent in 2019. CMS proposes 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 2018 PFS proposed rule, CMS is proposing to pay for drugs without an ASP that are paid based on WAC at WAC+3 percent instead of WAC+6 percent. 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 scalar). Following established policy, CMS does not, however, apply the budget neutral weight scalar 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 proposed 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 proposed rule for which there was no ASP information available for December 2017 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.

CMS received comments concerned about this policy. The concern is that 22.5 percent of a biosimilar's reference product ASP is higher than the 22.5 percent of the biosimilar's own ASP because the reference product will generally have a higher price than a biosimilar. The commenters believe it is unfair to subtract larger amount about from the biosimilar's ASP than 22.5 percent of its own ASP. CMS agrees and is proposing that when a biosimilar is acquired under the 340B program, Medicare will pay the hospital based on 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 biosimilar is paid on pass-through, it will continue to receive ASP+6 percent of the reference product's ASP.

3. Payment Policy for Therapeutic Radiopharmaceuticals

For 2019, CMS is proposing 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

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

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 proposes continuing to provide an additional \$10 payment for radioisotopes produced by non-HEU sources in 2019. 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 proposes to continue paying 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/index.html>.

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

CMS is proposing to continue the same payment policy 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 percent¹⁰ 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 proposed rule, which is available on the CMS website.

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

¹⁰The + 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 proposed rule and proposals elsewhere in the 2019 OPPS proposed rule.

priced using either WAC or AWP. The proposed rule indicates 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 is proposing 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.

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

The proposed rule estimate for total pass-through spending for drug and device pass-through payments during 2019 is approximately \$126.7 million, or 0.18 percent¹¹ of total OPSS projected payments for 2019, which is less than the applicable pass-through payment percentage statutory limit of 2.0 percent.

A. Devices

CMS projects \$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

For the proposed rule, CMS calculates a pass-through spending estimate of \$116.7 million in 2019 (\$61.5 million for drugs and biologicals recently eligible for pass-through payments that will continue for 2019 and \$55.2 million for drugs and biologicals CMS knows or projects could be approved for pass-through status in 2019).

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

CMS proposes no changes to the current clinic and emergency department hospital outpatient visits payment policies or to the payment policy for critical care services when these services are provided on the campus of a hospital. CMS seeks public comments on any changes to these codes that it will consider for future rulemaking cycles, encouraging commenters to provide the data and analysis necessary to justify any suggested changes. For off-campus PBDs, CMS is

¹¹ Elsewhere in the proposed rule for purposes of calculating a budget neutrality adjustment to the conversion factor and OPSS payments, CMS indicated that the percentage of total OPSS payments paid as pass-through is 0.17 percent.

proposing to pay for clinic visits only at 40 percent of the current OPPS rate. See section X. B. for details.

VIII. Payment for PHP Services

A. PHP APC Update for 2019

For 2019, CMS proposes 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. CMS would continue to use 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 proposes to use the methodology for 2019 and subsequent years.

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 proposed PHP geometric mean per diem costs. For 2019, CMS proposes to continue its policy to exclude 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 proposes to default any CMHC CCR that is greater than 1 to the statewide hospital ancillary CCR.

CMS excluded 8 CMHCs, adjusted the CCR for 3 CMHCs, and removed 645 CMHC claims. CMS excluded 20 hospital-based PHP providers as follows: three with CCRs greater than 5, 16 with zero daily costs, and one after applying a ± 3 standard deviation trim on costs per day. Five hospital-based PHPs were defaulted to using their overall hospital ancillary CCRs due to outlier cost center CCR values.

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

2018 APC	Group Title	Proposed PHP APC Geometric Mean Per Diem Costs*	Proposed Payment Rates**
5853	Partial Hospitalization (3 or more services per day) for CMHCs	\$119.51	\$117.35
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	\$220.52	\$216.55

* Table 25 of the proposed rule shows the proposed PHP APC geometric mean per diem costs.

** The proposed payment rates are from Addendum A to the proposed 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, 2017.¹² 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 OPSS Revenue-Code-to-Cost Center crosswalk. Thus, CMS proposes to create a separate PHP-only Revenue-Code-to-Cost Center crosswalk for 2019 and subsequent years. CMS notes the proposal would not apply to CMHCs because they do not have a crosswalk.

Specifically, the new PHP-only Revenue-Code-to-Cost Center crosswalk would consist of the existing PHP allowable revenue codes and would map each of those codes to the new PHP cost center line 93.99 as the primary cost center source for the CCR. The new secondary cost center would be the current primary cost center, and the new tertiary cost center would be the current secondary cost center. However, CMS proposes a special rule for revenue code 0904: the current secondary cost center [3550 (“Psychiatric/Psychological Services”)] and the current tertiary cost center [9000 (“Clinic”)] would continue to apply for revenue code 0904. Table 26 in the proposed rule shows the current and proposed 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 27 of the proposed rule shows claims data from 2015 through 2017.

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 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.

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

D. Outlier Policy for CMHCs

For 2019, CMS proposes to 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 proposes to 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 proposes to 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.

In the 2017 OPPTS/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 proposes to continue this policy for 2019. This payment cap only impacts CMHCs.

CMS does not propose to set a dollar threshold for CMHC outlier payments that it proposes to apply to other OPPTS 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 17.9 percent in 2019. The estimate includes the impact of the trimming methodology, wage index, and other adjustments.

IX. Changes to the IPO 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 outpatient departments are equipped to provide the services to the Medicare population.
2. The simplest procedure described by the code may be performed in most outpatient departments.
3. The procedure is related to codes that CMS has already removed from the IPO list.
4. A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.

5. A determination is made that the procedure can be appropriately and safely performed in an ASC and is on the list of approved ASC procedures or has been proposed for addition to the ASC list.

The proposed rule indicates that not all of the established criteria need to be met for a procedure to be removed from the IPO list. CMS is proposing to remove the following codes from the IPO list:

- CPT code 31241 (Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery) 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 proposes to designate the service as a primary procedure that would trigger a C-APC assignment to APC to 5153 (Level 3 Airway Endoscopy).
- CPT code 01402 (Anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty) 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 is designating the service as unconditionally packaged.

CMS proposes to add HCPCS code C9606 (Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel) because this procedure is performed during acute myocardial infarction and is similar to CPT code 92941 (Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel), which was added to the IPO list for 2018.

CMS is soliciting 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; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed). Similar services already removed from the IPO list are: CPT code 0267T (Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)) and CPT code 0268T (Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)). CMS does not believe it has adequate information to determine whether CPT code 0266T should be removed from the IPO list which is why it is soliciting comments and not proposing to remove the procedure from the IPO list.

X. Nonrecurring Policy Changes

A. Collecting Data on Services Furnished in Off-Campus PBDs

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 OPSS services are shifting to off-campus provider-based emergency departments.

Effective January 1, 2019, CMS will implement a new modifier (ER-Items and services furnished by a provider-based off-campus emergency department) for this purpose through the subregulatory HCPCS modifier process. The modifier must be reported with every claim line for outpatient hospital services furnished in off-campus provider-based emergency departments. The modifier would be reported on the UB-04 form (CMS Form 1450) for hospital outpatient services.

Critical access hospitals would not have to report this modifier.

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

CMS goes through the history of Medicare inpatient and outpatient hospital payment systems and concerns about expenditure growth in the outpatient department. The proposed rule references the Secretary’s authority under section 1833(t)(2)(F) of the Act to develop a method for controlling unnecessary increases in the volume of covered OPD services. To date, CMS has not established policy under this authority and has attempted to address expenditure growth through such policies as increased packaging and the development of C-APCs. Despite these policies, the proposed rule expresses concern about continued growth in program expenditures for hospital outpatient services as illustrated in the two tables below:

**TABLE 30.—GROWTH IN EXPENDITURES UNDER OPSS
FROM CY 2010 THROUGH CY 2019*
(in millions)**

Calendar Year	Incurred Cost	Percent Increase
2010	\$36,774	-
2011	\$39,781	8.2%
2012	\$43,154	8.5%
2013	\$46,462	7.7%
2014	\$52,425	12.8%
2015	\$56,274	7.3%

Calendar Year	Incurred Cost	Percent Increase
2016	\$59,896	6.4%
2017	\$64,770	8.1%
2018	\$69,642	7.5%
2019 (Estimated)	\$75,315	8.1%

*Includes Medicare Part B Drug Expenditures.

TABLE 31.—PERCENTAGE INCREASE IN VOLUME AND INTENSITY OF HOSPITAL OUTPATIENT SERVICES*

Calendar Year	Percentage Increase
2011	3.7%
2012	5.1%
2013	5.5%
2014	8.0%
2015	3.5%
2016	6.5%
2017	5.8%
2018	5.4%
2019 (Estimated)	5.3%

*Includes Medicare Part B Drug Expenditures.

The proposed rule argues that spending growth is a result of higher payments under the OPSS than the PFS for comparable services. CMS cites MedPAC’s March 2018 Report to Congress that states “A large source of growth in spending on services furnished in hospital outpatient departments (HOPDs) appears to be the result of the unnecessary shift of services from (lower cost) physician offices to (higher cost) HOPDs.”¹³

CMS considers these shifts in the sites of service unnecessary if the beneficiary can safely receive the same services in a lower cost setting but instead receives care in a higher cost setting. In its 2012 Report to Congress, MedPAC recommended that the payment rates for E&M visits provided in hospital outpatient departments be reduced so that total payment rates for these visits are the same, whether the service is provided in a hospital outpatient department or a physician office.

CMS expresses further concern about the implications of the higher payments in the hospital outpatient department for beneficiary cost-sharing. For example, MedPAC estimates that “beneficiaries’ cost-sharing was \$260 million higher in 2009, \$325 million higher in 2014, and \$400 million higher in 2015 than it would have been because of the higher rates paid in HOPD settings.” CMS believes this volume growth and the resulting increase in beneficiary cost-sharing is unnecessary because it appears due to the difference in payment for each setting rather than patient acuity.

¹³ http://www.medpac.gov/docs/default-source/reports/mar18_medpac_entirereport_sec.pdf?sfvrsn=0

Section 603 of the Bipartisan Budget Act (BBA) of 2015 partially addressed these concerns by precluding payment under the OPSS effective January 1, 2017 for new off-campus PBDs that opened after November 2, 2015 (with limited exceptions). However, CMS indicates that the majority of hospital off-campus departments continue to receive full OPSS payment which is often higher than the payment that would have been made if a similar service had been furnished in the physician office setting. CMS provides a comparison of payment for a clinic visit between the hospital outpatient department (G0463) and a physician office (Level 3 office visit, 99203 for new patients and 99213 for established patient) in 2017:

	OPD	Physician Office
OPSS	\$106.56	\$0
PFS	\$77.88 (New Patient) \$51.68 (Established Patient)	\$109.46 (New Patient) \$73.93 (Established Patient)
Total	\$184.44 (New Patient) \$158.24 (Established Patient)	\$109.46 (New Patient) \$73.93 (Established Patient)

In these examples, the payment rate was approximately \$75 to \$85 more for the same service when furnished in the hospital outpatient department instead of a physician’s office, 20 percent of which was the responsibility of the beneficiary.

CMS believes capping the OPSS payment at the PFS-equivalent rate would remove the payment incentive that is increasing utilization in the OPD and be an effective method to control the volume of unnecessary services. Therefore, beginning with 2019, CMS is proposing to use its authority for controlling unnecessary increase in the volume of covered OPD services under section 1833(t)(2)(F) of the Act to pay the same amount for an outpatient clinic visit (G0463) at an off-campus PBD excepted from section 603 of the BBA that it currently pays for the same service in an off-campus PBD that is not excepted from section 603 of the BBA—40 percent of the OPSS rate. In 2019, the standard unadjusted Medicare OPSS proposed payment for the clinic visit is approximately \$116, with approximately \$23 being the average copayment. The proposed PFS equivalent rate for Medicare payment for a clinic visit would be approximately \$46 and the copayment would be approximately \$9. This proposal would save beneficiaries an average of \$14 per visit. No changes to hospital billing practices would be required to implement this proposal.¹⁴

The proposed rule provides CMS’ legal analysis for why budget neutrality does not apply to section 1833(t)(2)(F) of the Act. Because CMS does not believe that budget neutrality applies, it is implementing the proposal as a savings. The estimated payment impact is displayed in Column 5 of Table 42 of the proposed rule. The FY 2019 President’s budget approximates the savings including changes in enrollment, volume and case mix at \$760 million, with \$610 million of the savings accruing to Medicare, and \$150 million saved by Medicare beneficiaries.

¹⁴ Hospitals bill for services in off-campus PBDs subject to section 603 with a “PN” modifier which applies the PFS relatively adjuster of 0.4 to the OPSS payment amount. Excepted off-campus PBDs bill with modifier “PO” that indicates the service was provided in an off-campus PBD but the PFS relatively adjuster does not apply. Under this proposal, CMS will make the systems changes necessary to apply the PFS relativity adjuster when a clinic visit is billed in an excepted off-campus PBD with the “PO” modifier.

CMS is also soliciting 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 is soliciting 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 OPDS that may represent unnecessary increases in OPD utilization. Therefore, it is seeking public comment on the following:

- How might Medicare define the terms “unnecessary” and “increase” for services (other than the clinic visit) that can be performed in multiple settings of care? Should the method to control for unnecessary increases in the volume of covered OPD services include consideration of factors such as enrollment, severity of illness, and patient demographics?
- Should prior authorization be considered as a method for controlling overutilization of services?
- For what reasons might it ever be appropriate to pay a higher OPDS rate for services that can be performed in lower cost settings?
- How might Medicare use the authority at section 1833(t)(2)(F) of the Act to implement an evidence-based, clinical support process to assist physicians in evaluating the use of medical services based on medical necessity, appropriateness, and efficiency? Could utilization management help reduce the overuse of inappropriate or unnecessary services?
- With respect to rural providers, should there be exceptions from this policy, such as for providers who are at risk of hospital closure or that are sole community hospitals?
- What impact on beneficiaries and the health care market would such a method to control for unnecessary increases in the volume of covered OPD services have?
- What exceptions, if any, should be made if additional proposals to control for unnecessary increases in the volume of outpatient services are made?

C. Applying the 340B Drug Payment Policy to Nonexcepted Off-Campus PBDs

Under section 603 of the BBA, CMS is precluded from paying off-campus PBDs that opened after November 2, 2015 (with limited exceptions) under the OPDS. CMS pays for services in these “non-excepted off-campus PBDs”¹⁵ under a special PFS rate that pays 40 percent of the OPDS rate. However, Part B drugs furnished in non-excepted off-campus PBDs are paid at 106 percent of ASP and are not subject to any reduction in payment. CMS’ 340B policy which pays for drugs acquired under the 340B drug discount program at ASP-22.5 percent in hospital outpatient departments does not apply to non-excepted off-campus PBDs. However, CMS did indicate that it may consider applying its 340B payment policy in non-excepted off-campus PBDs through future notice and comment rulemaking.

Prior to CMS adopting its 340B drug policy, separately payable drugs and biologicals were paid at 106 percent of ASP in both excepted and non-excepted off-campus PBDs. Effective January 1, 2018, CMS pays at ASP-22.5 percent for drugs and biologicals acquired under the 340B

¹⁵ CMS generally refers to off-campus PBDs subject to section 603 as “non-excepted off-campus PBDs.” Off-campus PBD not subject to section 603 are referred to as “excepted off-campus PBDs.” PBDs on the campus of a hospital are not subject to section 603 and are simply referred to as “on-campus PBDs” or “on-campus departments of a hospital.”

program and paid under the OPSS in excepted off-campus PBDs and on-campus departments of a hospital. However, services furnished by non-excepted off-campus PBDs are not payable under the OPSS so the 340B payment changes do not apply. Drugs and biologicals furnished in non-excepted off-campus PBDs are currently paid in the same way Medicare Part B drugs are paid in the physician office and other nonhospital settings—typically at ASP+6 percent—regardless of whether they are acquired under the 340B Program.

In the 2018 OPSS final rule, CMS discussed concerns that not applying the 340B drug payment policy to non-excepted off-campus PBDs creates an incentive for hospitals to move drug administration services for 340B-acquired drugs to non-excepted off-campus PBDs to receive a higher payment amount for these drugs. 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 PBDs.

To address this concern, CMS is proposing 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 PBDs of a hospital effective January 1, 2019. CMS proposes 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 PBDs and excepted off-campus PBDs. CMS believes the proposed policy would better reflect the resources and acquisition costs that non-excepted off-campus PBDs incur for drugs and biologicals acquired under the 340B program.

CMS notes that its payment at ASP-22.5 percent for separately payable drugs and biologicals acquired under the 340B program in non-excepted off-campus departments will differ from the ASP+6 percent payment for drugs and biologicals made in physicians' offices and other non-hospital settings. The proposed rule further indicates that there are also circumstances where low-cost drugs are paid separately in physician offices but packaged into the special PFS payment made to non-excepted off-campus PBDs. When these low-cost drugs are packaged under the special PFS rate that applies to services in non-excepted off-campus PBDs, Medicare's payment reflects the 40 percent relativity adjuster that would not apply to drugs and biologicals that are separately paid in physician offices and other non-hospital settings. CMS provides this information as part of a legal justification for why it believes it has the authority to apply the 340B policy in non-excepted off-campus PBDs despite these sites not being paid under the OPSS.

In summary, CMS cites section 1833(t)(21)(C) of the Act as its authority for applying the 340B policy to non-excepted off-campus PBDs. This section of the law authorizes the Secretary to identify the "applicable payment system" (other than OPSS) to pay for services provided in non-excepted off-campus PBDs. CMS has designated the PFS as the applicable payment system for payment of services in non-excepted off-campus PBDs using the section 1833(t)(21)(C) of the Act authority. CMS believes this same section provides it with authority to pay for 340B acquired drugs and biologicals under a special PFS rate instead of under section 1847A/1842(o) of the Act—the statutory provisions that require CMS to pay ASP+6

percent for drugs and biologicals furnished in non-hospital settings—an amount equal to ASP minus 22.5 percent for drugs and biologicals acquired under the 340B Program that are furnished by non-excepted off-campus PBDs. CMS believes the proposed change in policy would eliminate the significant incongruity between the payment amounts for these drugs, depending upon whether they are furnished by excepted off-campus PBDs or non-excepted off-campus PBDs, which CMS believes is an unnecessary difference in payment where the 340B Program does not differentiate between PBDs paid under the OPSS and PBDs paid under the PFS using the PFS relativity adjuster.

D. Expansion of Clinical Families of Services at Excepted Off-Campus PBDs

Background

As noted earlier, section 603 of the BBA 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 OPSS 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

Citing its previous concerns about expansion of services in excepted off-campus PBDs, CMS proposes 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 listed in Table 32 of the rule (which is reproduced below) from which the excepted off-campus PBD furnished an item or service (and subsequently billed for that item or service under the OPSS) during certain baseline periods (generally from November 1, 2014 through November 1, 2015).

Thus, beginning January 1, 2019, excepted items and services only include items and services furnished and billed by an excepted off-campus PBD from the clinical families of services for which the excepted off-campus PBD furnished (and subsequently billed the OPSS) at least one item or service during the baseline period. CMS also proposes that if an excepted off-campus PBD furnishes a new item or service from a clinical family of services from which it furnished a service during the baseline period, this would not be treated as a service expansion and would be

paid under the OPPS. However, if an excepted off-campus PBD furnishes items or services from any clinical family of services from which it did not furnish an item or service during the baseline period (and subsequently bill the OPPS), these items and services would be paid under the PFS because they would be from a new clinical family of services and would no longer be considered excepted items or services.

CMS proposes a baseline period of November 1, 2014 through November 1, 2015 because it is the most recent 12-month period that precedes the enactment of section 603 and CMS believes a full 12-month period would adequately reflect the types of service lines furnished and billed by excepted off-campus PBDs. For excepted off-campus PBDs that did not furnish OPPS services until after November 1, 2014, CMS proposes that the 12-month baseline period begin on the first date the PBDs furnished covered OPD services before November 2, 2015. For providers that met the mid-build requirements, the baseline period would begin on the first date the excepted off-campus PBD furnished a service billed under the OPPS. CMS seeks comments on whether it should shorten the baseline period (e.g., to 3 or 6 months) for facilities that first began billing after November 1, 2014 or met the mid-build requirement.

To comply with this proposed policy, excepted off-campus PBDs must ascertain the clinical families of services from which they furnished services during the baseline period. CMS also notes that items and services not identified in Table 32 that are furnished by excepted off-campus PBDs must be reported with modifier “PN”.

CMS acknowledges stakeholder concerns with limiting service line expansion using the 19 clinical families listed in Table 32. CMS believes that these families recognize all clinically distinct service lines for which a PBD may bill under the OPPS and that the ability to furnish new services within a clinical family affords providers the ability to furnish services, including those using new or innovative technologies. CMS seeks comments on the proposed clinical families.

TABLE 32.—PROPOSED CLINICAL FAMILIES OF SERVICES FOR PURPOSES OF SECTION 603 IMPLEMENTATION

Clinical Families	APCs
Airway Endoscopy	5151-5155
Blood Product Exchange	5241-5244
Cardiac/Pulmonary Rehabilitation	5771; 5791
Diagnostic/Screening Test and Related Procedures	5721-5724, 5731-5735, 5741-5743
Drug Administration and Clinical Oncology	5691-5694
Ear, Nose, Throat (ENT)	5161-5166
General Surgery and Related Procedures	5051-5055; 5061; 5071-5073; 5091-5094; 5361-5362
Gastrointestinal (GI)	5301-5303; 5311-5313; 5331; 5341
Gynecology	5411-5416
Major Imaging	5523-5525; 5571-5573; 5593-5594
Minor Imaging	5521-5522; 5591-5592
Musculoskeletal Surgery	5111-16; 5101-02
Nervous System Procedures	5431-5432; 5441-5443; 5461-5464; 5471

Clinical Families	APCs
Ophthalmology	5481; 5491-5495; 5501-5504
Pathology	5671-5674
Radiation Oncology	5611-5613; 5621-5627; 5661
Urology	5371-5377
Vascular/Endovascular/Cardiovascular	5181-5184; 5191-5194; 5200; 5211-5213, 5221-5224; 5231-5232
Visits and Related Services	5012; 5021-5025; 5031-5035; 5041; 5045, 5821-5823

CMS seeks comment on whether specific groups of hospitals (such as rural hospitals) should be excluded from its proposal. CMS also seeks comment on alternative methodologies to limit the expansion of excepted services. The agency is particularly interested in comment on the adoption and implementation of MedPAC’s proposal to cap the amount of OPSS payments made to an excepted off-campus PBDs in a year based on payment for OPSS services furnished by the PBD during the 12-month baseline period that preceded the enactment of section 603. CMS notes that under this methodology, hospitals would have to report service volume for each excepted off-campus PBD for the applicable baseline period.

XI. 2019 OPSS Payment Status and Comment Indicators

A. 2019 OPSS Payment Status Indicator Definitions

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

B. 2019 Comment Indicator Definitions

For 2019, CMS proposes 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.

The definitions of the proposed OPPS comment indicators for 2019 are listed in Addendum D2 of proposed rule. (Each of the definitions above is excerpted from the proposed rule exactly as written.)

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

Summary of Selected Key Elements of Proposed 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	1.0003	
Proposed 2019 Update		
Hospital market basket update*	2.8%	
Multi-factor productivity adjustment (MFP)	-0.8%	
Net MFP adjusted update	2.0%	
Penalty for not reporting quality data	0.0%	-2.0%
Net MFP and quality adjusted update	2.0%	0.0%
Proposed 2019 ASC Conversion Factor	\$46.500	\$45.589
*CMS proposes to change from the CPI-U to the hospital market basket to determine the update factor.		

CMS notes that the projections may be updated in the final rule based on more recent data. As with the rest of the OPPS proposed rule and other CMS rules, addenda related to the ASC section (and referenced in this summary) are available only on the CMS website, at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html>; select “1695-P” from the list of regulations. All ASC Addenda to the proposed rule are contained in the zipped folders entitled Addendum AA, BB, DD1, DD2, and EE.

A. 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 OPFS.

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 proposes 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 proposes that these newly-eligible "surgery-like" procedures are 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 OPFS.

CMS invites comments on its proposal to revise the definition of surgery for the ASC prospective payment system. It also seeks comments on whether it should expand its definition of "surgery" to include procedures that fall outside the CPT surgical range but fall within the definition of "surgery" developed by the AMA Specialty Society Relative Value Scale Update Society for use in the agency's PFS professional liability insurance relative values and that meet the ASC setting criteria.¹⁶

¹⁶CMS refers readers to this list, which is available on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2018-PFS-FR-Invasive-Cardiology.zip>

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 33 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 33)				
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

Comment and Finalization Timeframes for New or Revised HCPCS Codes (from CMS Table 33)				
ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
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

Proposed Treatment of New and Revised Level II HCPCS Codes and Category III CPT Codes Implemented in April and July of 2018 for Which CMS is Soliciting Public Comments in this Proposed Rule

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 34-36, copied below, set out the codes, descriptors, and proposed 2019 payment indicators.

New Level II HCPCS Codes for Covered Surgical Procedures and Ancillary Services Effective on April 1, 2018 (Table 34)		
2018 HCPCS Code	Long Descriptor	Proposed 2019 Payment Indicator
C9462	Injection, delafloxacin, 1 mg	K2
C9463	Injection, aprepitant, 1 mg	K2
C9464	Injection, rolapitant, 0.5 mg	K2
C9465	Hyaluronan or derivative, Durolane, for intra-articular injection, per dose	K2
C9466	Injection, benralizumab, 1 mg	K2
C9467	Injection, rituximab and hyaluronidase, 10 mg	K2
C9468	Injection, factor ix (antihemophilic factor, recombinant), glycopegylated, Rebinyn, 1 i.u.	K2
C9469*	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	K2
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 effective July 1, 2018.

New Level II HCPCS Codes for Ancillary Services Effective on July 1, 2018 (Table 35)		
2018 HCPCS Code	Long Descriptor	Proposed 2019 Payment Indicator
C9030	Injection, copanlisib, 1 mg	K2
C9032	Injection, voretigene neparvovec-rzyl, 1 billion vector genome	K2

New Level II HCPCS Codes for Ancillary Services Effective on July 1, 2018 (Table 35)		
2018 HCPCS Code	Long Descriptor	Proposed 2019 Payment Indicator
Q5105	Injection, epoetin alfa, biosimilar, (Retacrit) (for esrd on dialysis), 100 units	K2
Q5106	Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units	K2
Q9991	Injection, buprenorphine extended-release (Sublocade), less than or equal to 100 mg	K2
Q9992	Injection, buprenorphine extended-release (Sublocade), greater than 100 mg	K2
Q9993*	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	K2
Q9995	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.		

New Category III CPT Code For Covered Ancillary Service Effective on July 1, 2018 (CMS Table 36)		
2018 CPT Code	Long Descriptor	Proposed 2019 Payment Indicator
0508T	Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia	Z2

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

Proposed Process for New and Revised Level II HCPCS Codes That Will Be Effective October 1, 2018 and January 1, 2019 for Which CMS Will Solicit Comments in the 2019 OPPS/ASC Final Rule

CMS proposes 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 will invite public comments in that 2019 final rule on the interim status indicators, APC assignments and payment rates that will be finalized in the 2020 OPPS/ASC final rule.

Proposed Process for Recognizing New and Revised Category I and Category III CPT Codes That Will Be Effective January 1, 2019 for Which CMS Will Solicit Comments in the 2019 OPPS/ASC Final Rule

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 Ambulatory Payment Classification

(APC) and status indicator assignments, as well as proposed payment rates. Such codes are assigned new comment indicator “NP”. Those new and revised codes are listed in Addendums AA and BB, and the long descriptors are in Addendum O at the ASC website. **CMS seeks comments and proposes to finalize the payment indicators in the 2019 final rule.**

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 proposes to permanently designate four additional procedures as office-based. Table 37 in the proposed rule (and reproduced below) shows the codes, descriptors, and proposed 2019 payment indicators.

ASC Covered Surgical Procedures Proposed to be Newly Designated As Permanently Office-Based for 2019 (CMS Table 37)			
2019 CPT Code	Long Descriptor	2018 Payment Indicator	Proposed 2019 Payment Indicator
31573	Laryngoscopy, flexible; with therapeutic injection(s) (eg, chemodervation agent or corticosteroid, injected percutaneous, transoral, or via endoscope channel), unilateral	G2	P3
36513	Therapeutic apheresis; for platelets	G2	R2
36902	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; with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty	G2	P3
36905	Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s); with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty	G2	P3

Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard rate setting methodology and the Medicare Physician Fee Schedule proposed rates. Current law specifies a 0.25 percent update to the Medicare Physician Fee Schedule payment rates for CY 2019. **CMS invites comment on the proposal.**

CMS also reviews 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 proposes 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 physician’s offices and thus CMS proposes 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.

CMS proposes 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.

2019 Payment Indicators for New 2019 CPT Codes for ASC Covered Surgical Procedures Designated as Temporary Office-Based (CMS Table 39)		
2019 CMS Placeholder Code	Long Descriptor	Proposed 2019 ASC Payment Indicator**
06X1T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	R2*
10X12	Fine needle aspiration biopsy, including ultrasound guidance; first lesion	P3*
10X14	Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion	P3*
10X16	Fine needle aspiration biopsy, including CT guidance; first lesion	P2*
10X18	Fine needle aspiration biopsy, including MR guidance; first lesion	R2*
11X02	Tangential biopsy of skin (eg, shave, scoop, saucerize, curette); single lesion	P3*
11X04	Punch biopsy of skin (including simple closure, when performed); single lesion	P3*
11X06	Incisional biopsy of skin (eg, wedge) (including simple closure, when performed); single lesion	P3*
*If designation is temporary.		
** Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the Medicare PFS proposed rates.		

CMS invites comment on the proposals.

Proposed 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 proposed rule and summary, CMS is proposing to modify its criteria for device-intensive procedures. CMS proposes to allow procedures that involve surgically inserted or implanted, high-cost, single use devices to qualify as device-intensive procedures. In addition, CMS proposes 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 proposes 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. The procedures are assigned the payment indicator "J8" and are included in Addendum AA (at the CMS ASC website) which lists the procedures, the CPT code and short-descriptor, the device offset percentage, and an indication of the full credit/partial credit device adjustment policy that would apply.

In addition, for 2019, CMS proposes 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 explains that under this proposal, 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.

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

CMS finalized a modification in payment for devices furnished with full or partial credit under the OPSS in the 2014 final rule, but there is no mechanism in the ASC claims processing system for ASCs to submit the actual amount received when furnishing a device without cost or with full or partial credit. CMS proposes to continue its policy for ASCs for 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 proposes to update the list of ASC covered device-intensive procedures which would be subject to the full credit/partial credit policy to all device-intensive procedures in 2019.

Proposed Additions to the List of ASC Covered Surgical Procedures

As discussed earlier, CMS proposes to revised 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 OPSS but not included on the list of covered ASC procedures.

CMS proposes 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 notes that even though these procedures involve blood vessels that could be considered major, CMS believes 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.

CMS requests comments about whether these procedures may be safely performed in an ASC.

Proposal to Review Recently-Added Procedures to the ASC Covered Procedures List

Historically, CMS has evaluated the ASC covered procedures list (ASC 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 proposes 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 CYs 2015, 2016, and 2017, and assess whether newly-added procedures continue to meet its criteria. CMS proposes to review all 38 procedures that were added to the ASC CPL for CYs 2015, 2016, and 2017. These are shown in Table 41 in the proposed rule.

CMS seeks comments about whether these recently-added procedures continue to meet the criteria to remain on the ASC CPL. CMS states that it intends to evaluate each of these 38 procedures using all available data, including clinical characteristics, utilization reflected in ASC claims and pricing data, prevailing medical practice, and any comments it receives to determine whether they continue to meet the criteria to be covered surgical procedures.

CMS solicits 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.

Covered Ancillary Services

CMS proposes to update the ASC list of covered ancillary services to reflect the payment status for the services under the OPSS. 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 OPSS. CMS proposes to continue this reconciliation of packaged status for subsequent years. All ASC covered ancillary services and their proposed 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; Proposed Update to ASC Covered Surgical Procedure Payment Rates for 2019

CMS proposes to update payments for office-based procedures and device-intensive procedures using its established methodology and using its proposed modified definition for device-intensive

procedures. CMS notes that because the proposed OPPS relative payment weights are based on geometric mean costs, the ASC system would use geometric means to determine the proposed relative payment weights under the ASC standard methodology. CMS would 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 proposed 2019 OPPS device offset percentages. CMS would make payment for office-based procedures at the lesser of the proposed 2019 Medicare Physician Fee Schedule non-facility PE RVU-based amount, or the proposed 2019 ASC payment amount calculated according to the standard methodology. CMS proposes to continue its policy for device removal procedures – such procedures that are conditionally packaged in the OPPS would be assigned the current ASC payment indicators and continue to be paid separately under the ASC payment system.

Payment for Covered Ancillary Services

CMS proposes to update payments and make changes necessary to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services. CMS also proposes to continue to set payment methodologies for brachytherapy services and separately payable drugs and biologicals equal to the proposed 2019 OPPS rates. CMS proposes to continue to base payment for separately payable covered radiology services based on the lower of the 2019 Medicare Physician Fee Schedule non-facility PE RVU-based amounts and the proposed 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 proposes to continue to set payments based on the OPPS relative payment weights, and therefore would include the cost of the diagnostic radiopharmaceutical. In the case of radiology services that use contrast agents, CMS proposes to continue to set payment based on the OPPS relative payment rate, and will, therefore, include the cost of the contrast agent. CMS proposes to continue to not make separate payment for procurement of corneal tissue when used in any noncorneal transplant procedure.

With regards to contractor-priced codes, CMS proposes to continue to designate hepatitis B vaccines as contractor-priced based on the invoiced costs for the vaccine, and corneal tissue acquisition as contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplant. In addition, consistent with its established ASC payment policy, CMS proposes that the 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 proposes that certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS be covered ancillary services when they are integral to an ASC covered surgical procedure. CMS proposes to pay for the tests at the lower of the Medicare Physician Fee Schedule non-facility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard rate-setting methodology. CMS identifies no new codes that meet this criterion for 2019.

CMS makes 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 proposes 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 proposes 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 proposes conforming changes to its regulations at 42 CFR 416.164(a)(4) and to 42 CFR 416.164 (b)(6).

CMS seeks comments on a number of issues in this section:

- Whether the proposed policy would decrease the dose, duration and/or number of opioid prescriptions beneficiaries receive during and following an outpatient visit or procedure (especially for beneficiaries at high-risk for opioid addiction) as well as whether there are other non-opioid pain management alternatives that would have similar effects and may, therefore, warrant separate payment.
- Ideas on regulatory, subregulatory, policy, practice, and procedural changes to help prevent opioid use disorder and improve access to treatment under the Medicare program.
- Barriers that may inhibit access to non-opioid alternatives for pain treatment and management or access to opioid use disorder treatment, including those barriers related to payment methodologies or coverage.
- Consistent with its “Patients Over Paperwork” Initiative, suggestions to improve existing requirements in order to more effectively address the opioid epidemic.
- Other non-opioid treatments for acute or chronic pain besides Exparel that might be affected by OPPS and ASC packaging policies including alternative, non-opioid pain treatments, such as devices or therapy services that are not currently separable payable.
- Whether CMS should consider separate payment for such items and services for which payment is currently packaged under the OPPS and ASC payment systems that are effective non-opioid alternatives as well as evidence that demonstrates such items and services lead to a decrease in prescription opioid use during or after an outpatient visit or procedure.
- Evidence relating to products that have shown clinical improvement over other alternatives, such as a device that has been shown to provide a substantial clinical benefit over the standard of care for pain management.
- Whether a policy of providing separate payment (rather than packaged payment) for these products, indefinitely or for a specified period of time would also incentivize the use of alternative non-opioid pain management treatments and improve access to care for non-opioid alternatives, particularly for innovative and low-volume items and services.
- Whether CMS should provide separate payment for non-opioid pain management treatments or products using a mechanism such as an equitable payment adjustment under its authority at section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments.

CMS also states that it is interested in comments on whether a reorganization of the APC structure for procedures involving these products or establishing more granular APC groupings for specific procedure and device combinations would better achieve its goal of non-opioid alternatives. For example, CMS states that it would consider finalizing a policy to establish new APCs for procedures involving non-opioid pain management packaged items or services if such APC would better recognize the resources involved in furnishing such items and services and decrease or eliminate the need for prescription opioids. CMS seeks comment on how such alternative payment structures would continue to balance the goals of incentivizing provider efficiencies with encouraging the use of non-opioid alternatives to pain management and any cost implications.

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

F. ASC Payment and Comment Indicators

CMS proposes to continue using the current comment indicators “NP” and “CH.” CMS proposes that Category I and III CPT codes that are new and revised for 2018 and any new and existing Level II HCPCS codes with substantial revisions would be labeled with the proposed new comment indicator ‘NP’ to indicate that these codes are open for comment as part of this 2019 proposed rule.

Addenda DD1 and DD2 provide a complete list of the ASC payment and comment indicators proposed for 2019. CMS will respond to public comment on the proposed payment and comment indicators and finalize their ASC assignment in the final rule.

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

Updating the ASC Relative Payment Rates for 2019 and Future Years

CMS proposes to continue to update relative weights using the national OPPS relative weights and the Medicare Physician Fee Schedule non-facility PE RVU-based amounts when applicable. CMS proposes to scale 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, 0.8854, is the proposed 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). CMS notes that as of the proposed rule, it had 98 percent of 2017 ASC claims data; 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 proposes 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 proposed 2019 national payment rates after application of the weight scalar, CMS proposes to compute the ratio of:

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

The resulting ratio, 1.0003, is the proposed 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 proposes 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 payment and the 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 seeks comments on ASC costs to assess whether the hospital market basket is an appropriate proxy for ASC costs. In addition, CMS indicates that it plans to assess changes in the migration of services from the hospital setting to the ASC setting. CMS welcomes comments on how best to evaluate the impacts of this payment change. Moreover, CMS seeks comment on an alternative proposal to maintain CPI-U while collecting evidence to justify a different payment update. CMS plans to revise its regulations at 42 CFR 416.171(a)9(2) to reflect this proposal.

CMS proposes to utilize the hospital market basket update of 2.8 percent minus the multifactor productivity adjustment (MFP) of 0.8 percent. This yields a proposed update of 2.0 percent for ASCs meeting quality reporting requirements. If the CPI-U had been used the proposed update would have been 1.3 percent.

CMS proposes to continue its policy of reducing the update by 2.0 percentage points for ASCs not meeting the quality reporting requirements, yielding an update of 0.0 percent (or no update) for such ASCs. CMS notes that it proposes to revise the updates if more current estimates of the hospital market basket update and MFP are available when the final rule is issued. The resulting 2019 ASC conversion factor proposed by CMS is \$46,500 for ASCs reporting quality data, and

\$45.589 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 1.0003	
Net MFP-adjusted update	<u>x 1.02</u>	<u>x 1.00</u>
Proposed 2019 ASC conversion factor	\$46.500	\$45.589

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 43 of the proposed rule and reproduced below). The eye and ocular adnexa group remains the largest source of payments, with no change in payments attributable to the proposed changes in 2019. CMS notes that this is due to a reduction in hospital reported costs for this category which lowers the payment weight for this group offsetting the proposed 2 percent ASC rate update. The second largest group, nervous system, is estimated to see a 4 percent increase. Payments for ancillary items and services are estimated to see a 2 percent increase.

Summary of Table 43: Aggregate Proposed 2019 Medicare Program Payments by Surgical Specialty or Ancillary Items and Services Group		
Surgical Specialty Group	Estimated 2018 ASC Payments (in Millions)	Estimated Proposed 2019 Percent Change
Total	\$4,772	2%
Eye and ocular adnexa	\$1,737	0%
Nervous system	\$993	4%
Digestive system	\$873	3%
Musculoskeletal system	\$574	4%
Genitourinary system	\$188	2%
Integumentary system	\$145	1%
Ancillary items and services	\$64	2%

CMS sets out estimated increases for 30 selected procedures in Table 44 in the proposed rule; the top 10 procedures are replicated below. CPT code 66984 (Cataract surgery with intraocular lens, 1 stage) is the largest aggregate payment procedure by far and is estimated to have no change in payment. The second largest aggregate payment procedures, CPT code 45380, is expected to see a 4 percent increase.

Excerpt from Table 44: Estimated Impact of the Proposed 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	0%
45380	Colonoscopy and biopsy	\$228	4%
63685	Insert/redo spine n generator	\$221	-2%
43239	Egd biopsy single/multiple	\$180	2%
63650	Implant neuroelectrodes	\$166	0%
45385	Colonoscopy w/lesion removal	\$156	4%
64483	Inj foramen epidural l/s	\$101	14%
0191T	Insert ant segment drain int	\$96	4%
66982	Cataract surgery complex	\$89	0%
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-P.html>. They include:

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

XIII. Requirements for the Hospital OQR Program

In this section, CMS proposes to modify the factors it considers with respect to removing measures from the OQR Program and to remove 10 measures, one beginning with the 2020 payment determination and the others beginning with 2021 payment. One of the measures proposed for removal is currently a voluntary measure. The total number of mandatory measures would be reduced from 21 previously adopted for the 2020 and 2021 payment determinations to 20 measures for 2020 and 12 measures for 2021 payment. Other proposed changes would 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 are 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 proposed 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. The proposals were developed to be

consistent with the Meaningful Measures Initiative¹⁷, 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.

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 now proposes to codify measure retention and removal policies at a new 42 CFR 419.46(h).

Currently, CMS uses a set of seven factors to determine whether to remove a measure from the OQR Program. Removals of measures meeting any of the criteria are not automatic and are made on a case-by-case basis.

In this rule, CMS proposes to modify the wording of one of the current seven factors, clarify another of them, and to add an eighth factor. These changes would be reflected in the proposed new regulatory text regarding measure retention and removal. The current seven factors consider

¹⁷ See <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativevGenInfo/MMF/General-info-Sub-Page.html>.

whether 1) performance on the measure is so high and unvarying that meaningful distinctions 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 measure is available; 5) a measure that is more proximal in time to desired patient outcomes on the topic is available; 6) another available measure is more strongly associated with the desired patient outcomes; and 7) collection or public reporting of the measure leads to negative unintended consequences such as patient harm.

CMS proposes that the wording of factor 7 be changed to align with the ASC QRP, to state: 7) collection or public reporting of a measure leads to negative unintended consequences *other than* patient harm. CMS believes this language is more appropriate because a measure that leads to patient harm would not be considered for removal using these factors. Instead, it would be removed under the previously adopted policy to immediately remove measures when patient safety is concerned.

The proposed new removal factor 8 would be that the costs associated with a measure outweigh the benefit of its continued use in the program. CMS notes that there are different types of costs associated with measures. These include the facility cost of information collection and submission of quality measures to CMS; the facility cost associated with complying with quality program requirements; the facility cost associated with participating in multiple quality programs and tracking similar or duplicative measures across programs; the CMS cost associated with program oversight of the measure; and the facility cost associated with compliance with other federal or state regulations (if applicable). CMS notes that it has proposed adding this factor to other quality reporting programs for 2019 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 considering the case-by-case application of the proposed Factor 8, CMS notes that a measure might be of limited use because publicly reported data cannot be easily interpreted by beneficiaries. In contrast, it might retain a measure that is burdensome for health care facilities to report if the benefit to beneficiaries justifies the reporting burden. CMS’ stated goal is to move the program forward in the least burdensome way possible while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize quality improvement.

CMS further 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 75th and 90th 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 proposed for removal 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 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 Beginning with 2020 and 2021 Payment Determinations

Applying the current and proposed measure removal criteria, and considering the goals of the Meaningful Measures Initiative, CMS proposes to remove 10 measures from the OQR Program. One measure would be removed beginning with 2020 payment and the others beginning with 2021 payment. CMS considered removal of the latter measures beginning with 2020 payment but elected to propose a delay to be sensitive to facilities' planning and operational procedures given that data collection for 2020 payment for these measures begins during 2018. Measures proposed for removal based on the proposed costs/benefits factor 8 would not be finalized for removal if that factor is not adopted in the final rule.

- OP-27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) would be removed beginning with the 2020 payment determination based on the proposed new factor 8, costs outweigh the benefits. CMS notes that some HOPDs are only required to participate in the Centers for Disease Control and Prevention National Healthcare Safety Network (NHSN) reporting system for the purpose of reporting this measure. (Acute care hospitals that participate in the IQR Program and the Hospital Acquired Condition Reduction Program must report other measures via the NHSN.) However, the vast majority of OQR Program participating facilities report this measure for these other programs, and the inpatient version of the measure captures the vast majority of hospital personnel. CMS also believes that some clinicians participating in the Merit-based Incentive Payment System (MIPS) will also choose to report this measure. As discussed in section XIV.C below, CMS also proposes to remove this measure from the ASC quality reporting program for the same reasons.
- OP-5: Median Time to ECG (NQF #0289) is a chart-abstracted measure proposed for removal under factor 8. While chart-abstraction is resource-intensive for facilities to conduct, CMS says this alone would not be sufficient to justify removal. In this case it has determined that the measure shows minimal performance variation despite not meeting the definition of topped out. The median time to ECG differs from the 75th and 90th percentile times by less than 2 minutes, and the difference between the 25th and 75th percentiles is only 5.5 minutes. CMS does not consider these differences to be meaningful in helping beneficiaries make informed care decisions.
- OP 31: Cataracts – Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery (NQF #1536) would be removed based on proposed factor 8, with CMS concluding that the high technical and administrative costs and burden outweigh the limited benefit of the measure. CMS says that it can be operationally difficult for facilities to collect and report the measure, as they might not have access to the pre-operative and post-operative patient surveys of visual function from clinicians. In addition, CMS is concerned that different surveys can be used and may not be comparable and that data validation is difficult. After initially adopting OP-31 as a

mandatory OQR Program measure for the 2016 payment determination, CMS subsequently delayed data collection and then made the measure voluntary. It reports that only 59 facilities (1.2 percent) reported this voluntary measure.

- OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) and OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use (NQF #0659) are chart-abstracted measures each proposed for removal under the proposed new costs/benefits factor 8. CMS bases its proposal on the combination of the cost of chart-abstraction, availability of both these measures for reporting in the MIPS, and preference for outcome measures in the OQR Program. With respect to the latter, the claims-based outcome measure, OP-32: Facility 7-Day Risk Standardized Hospital Visit Rate After Outpatient Colonoscopy (NQF #2539) would continue to be included in the OQR Program. As discussed in section XIV.C below, similar measures are proposed for removal from the ASCQR Program.
- OP-9: Mammography Follow-up Rates, which was developed in 2008, is proposed for removal under factor 3, measure does not align with current clinical guidelines or practice. Specifically, the measure does not take into account more recent guidelines and literature on the clinical benefits of diagnostic digital breast tomosynthesis (DBT), for which CMS cites various studies and the American College of Radiology breast cancer screening appropriateness criteria. CMS will investigate respecification of this measure to capture a broader spectrum of mammography services including DBT.
- 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 each proposed for removal on the basis of being topped out (factor 1). As noted above, CMS clarifies how it calculated the relevant statistics for these measures which address rare, undesired events for which a lower rate is preferred. Using this adapted methodology, each of these measures is found to have a TCOV less than the threshold of 0.10 since 2012.
- 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 proposed for removal 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. CMS does not believe the measure is consistent with the goals of its Meaningful Measures Initiative.

In the Collection of Information Requirements section of the proposed rule, CMS estimates that the removal of one chart abstracted measure (OP-5) and five measures submitted by HOPDs using a web-based tool (OP-12, OP-17, OP-29, OP-30 and OP-31) would lead to burden reduction and savings totaling and estimated \$48.2 million nationally for 2021. Burden associated with the proposal to remove OP-27 is not included in this estimate.

D. Summary Table of OQR Program Measures

The table below shows proposed measure removals for the 2020 and 2021 payment determinations along with OQR measures previously adopted for payment determinations

beginning in 2015. (In some cases, measures were adopted but data collection suspended prior to the measure being removed. 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 (<i>Proposals in Italics</i>)								
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	<i>Remove</i>
	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	<i>Remove</i>
	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	<i>Remove</i>
	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	<i>Remove</i>
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	<i>Remove</i>
0491 ⁺	OP-17: Tracking Clinical Results between Visits	X	X	X	X	X	X	<i>Remove</i>
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	

Summary Table—OQR Measures for Payment Determination Years 2015-2021 (*Proposals in Italics*)

NQF		2015	2016	2017	2018	2019	2020	2021
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	<i>Remove</i>	
0658	OP-29: Appropriate Follow- up Interval for Normal Colonoscopy in Average Risk Patients		X	X	X	X	X	<i>Remove</i>
0659	OP-30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use		X	X	X	X	X	<i>Remove</i>
1536	OP-31: Cataracts – Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery		Adopted, then excluded	Voluntary				<i>Remove</i>
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 requests public comment on future measure topics for the OQR Program. Across all the Medicare quality reporting and value-based purchasing programs, CMS is moving toward greater use of outcome measures and away from use of clinical process measures, and comments are specifically sought on any outcome measures that should be added and process measures that should be removed from the program.

F. Notice of Participation Form

CMS proposes to remove the requirement that hospitals submit a notice of participation form for participation in the OQR Program. Submission of any OQR Program data would indicate a hospital's status as a program participant. Under the proposal, a hospital would still need to (1) register on the QualityNet website before beginning to report data; (2) identify and register a QualityNet security administrator and (3) submit data. The regulatory text would be amended to reflect this proposal.

G. Frequency of OQR Program Specifications Manual Release

CMS proposes that beginning with 2019, instead of continuing to update the OQR Program measure specifications manual every 6 months (and addenda as necessary), it would update the manual every 6 to 12 months, depending on the need for an updated release. CMS believes that unnecessarily maintaining a twice-a-year schedule may be confusing to program participants. The schedule would consider the CMS policy of providing at least 6 months' notice for substantive changes in measure specifications. (The proposed rule does not mention how the proposal might affect the policy of providing 3 months' notice for subregulatory nonsubstantive changes, such as changes to ICD-10, CPT, NUBC and HCPCS codes.)

H. Extension of Reporting Period for OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy

CMS proposes to change 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.

Under the proposal, the reporting period for OP-32 would be changed beginning with the 2020 payment determination, which would use claims from calendar years 2016, 2017 and 2018 instead of 2018 alone. A similar pattern would occur for later payment determinations. Because CMS proposes to add prior years, it says payment determinations and public display of the measure would not be disrupted. For example, public display for the 2020 payment determination would occur in January 2020.

I. Payment Reduction for Hospitals that Fail to Meet the OQR Program Requirements for 2019 Payment

Existing policies with respect to computing and applying the payment reduction for hospitals that fail to meet the Hospital OQR Program requirements would be 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 \$77.955 by the final full conversion factor of \$79.546. Continuing previous policies, when applicable the reporting ratio is applied to all services calculated using the OPSS 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 would continue 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 OPSS national unadjusted payment rates would apply, and OPSS outlier eligibility and outlier payment would be 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

Similar to the OQR Program proposals discussed in section XIII, CMS would modify the factors it uses when considering removal of measures from the ASCQR Program and remove 8 measures from the program, one of which is voluntary. The total number of mandatory measures would be reduced from what is currently 10 for the 2020 and 2021 payment determinations to 9 measures in 2020 and 3 measures in 2021. (Two measures were previously finalized for addition to the program beginning with the 2022 payment determination.) Under the proposed rule, the reporting period for one claims-based measure would be lengthened. For the future, CMS seeks comments on beginning a validation process for chart-abstracted measures in the ASCQR Program.

No changes are 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 proposed rule is identical to the one described in XIII.A above regarding the OQR Program.

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

Currently, CMS uses a set of seven factors in determine whether to remove a measure from the ASCQR Program. Removals of measures meeting any of the criteria are not automatic and are made on a case-by-case basis. The current seven factors consider whether 1) performance on the measure is so high and unvarying that meaningful distinctions can no longer be made (the measure is “topped out”); 2) another measure with a stronger relationship to patient outcomes is available; 3) the measure does not align with current clinical guidelines or practice; 4) another more broadly applicable measure is available; 5) a measure that is more proximal in time to desired patient outcomes on the topic is available; 6) another available measure is more strongly associated with the desired patient outcomes for a particular topic; and 7) collection or public reporting of the measure leads to negative unintended consequences other than patient harm.

In this rule, CMS proposes to remove one of the current factors, clarify another, and add two new factors. The regulatory text at 42 CFR 416.320(c) would be revised to reflect these proposals.

- Effective with the 2019 OPPS/ASC final rule, current factor 2 (availability of alternative measures with a stronger relationship to patient outcomes) would be removed because it is duplicative with current factor 6 (another available measure is more strongly associated with desired patient outcomes for a particular topic).
- CMS clarifies its calculations for “topped out” measures (factor 1); the discussion is identical to that with respect to the OQR Program section XIII.B above. In this rule this calculation would apply to the proposed removal of four ASCQR Program measures (ASC-1, ASC-2, ASC-3, and ASC-4), discussed below, because they assess the rate of rare undesired events for which a lower rate is preferred.
- In order to align the removal factors with those of the OQR Program, CMS proposes a new factor 2, performance or improvement on the measure does not result in better patient outcomes.
- Also proposed is a new removal factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. The discussion of this proposed new factor 8 is identical to the discussion in section XIII.B above regarding the OQR Program removal factors.

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

Applying the current and proposed measure removal criteria, and considering the goals of the Meaningful Measures Initiative, CMS proposes to remove 8 measures from the ASCQR Program. One measure (ASC-8) would be removed beginning with 2020 payment and the others beginning with 2021 payment. CMS considered removal of the latter measures beginning with 2020 payment but elected to propose a delay to be sensitive to facilities’ planning and operational procedures given that data collection for 2020 payment for these measures begins during 2018. Measures proposed for removal based on the proposed new costs/benefits factor 8 would not be finalized for removal if that factor is not adopted in the final rule.

- ASC-8: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) would be removed from the ASCQR Program beginning with the 2020 payment determination based on the proposed new factor 8, costs outweigh the benefits. The proposal parallels that in section XIII.C above for the proposed 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. CMS also believes that some MIPS-eligible clinicians will choose to report this measure.
- 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) would be removed because in each case CMS has determined that these measures are topped out (factor 1). As discussed above, CMS clarifies the methodology it used for these measures because unlike most measures they assess the rate of rare, undesired events for which a lower rate is preferred. Using this adapted methodology, each of these measures is found to have a truncated coefficient of variation that is less than the threshold of 0.10 since 2013. In addition, CMS notes that in 2016 NQF endorsement was removed for measures ASC-1, ASC-3, and ASC-4.
- ASC-9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) and ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use (NQF #0659) would be removed based on newly proposed factor 8, costs outweigh benefits. The rationale for removal of these chart-abstracted process measures parallels that of the proposed removal of similar measures (OP-29 and OP-30) from the OQR Program as discussed in section XIII.C above. That is, CMS concludes that the measures should be removed because of a combination of the cost of chart- abstraction, availability of both these measures for reporting in the MIPS, and preference for outcome measures in the ASCQR Program. With respect to the latter, the claims-based outcome measure, ASC-12: Facility 7-Day Risk Standardized Hospital Visit Rate After Outpatient Colonoscopy (NQF #2539) would continue in the ASCQR Program.
- ASC-11: Cataracts – Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery (NQF #1536) would also be removed based on proposed factor 8, and the rationale is similar to that for the proposed removal of this measure (OP-31) from the OQR Program. In this case, CMS reports that only 118 facilities (2.3 percent) reported this currently voluntary measure.

In the Collection of Information section of the proposed rule, CMS estimates that its proposals to remove seven measures from the ASCQR Program would lead to a total annual reduction in information collection burden of \$5.1 million in 2021. Burden associated with the proposal to remove ASC-8 is not included in this estimate.

D. Table of ASCQR Program Measures

The table below shows proposed measure removals for the 2020 and 2021 payment determinations along with ASCQR Program 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>.

ASCQR Program Measures by Payment Determination Year (<i>Proposals in Italics</i>)								
	2015	2016	2017	2018	2019	2020	2021	2022
ASC-1: Patient Burn (NQF #0263)+	X	X	X	X	X	X	<i>Remove</i>	
ASC-2: Patient Fall (NQF #0266)	X	X	X	X	X	X	<i>Remove</i>	
ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267)+	X	X	X	X	X	X	<i>Remove</i>	
ASC-4: All-Cause Hospital Transfer/Admission (NQF #0265)+	X	X	X	X	X	X	<i>Remove</i>	
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	<i>Remove</i>		
ASC-9 Endoscopy/Poly Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658)		X	X	X	X	X	<i>Remove</i>	
ASC-10 Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use (NQF #0659)		X	X	X	X	X	<i>Remove</i>	
ASC-11 Cataracts – Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery (NQF #1536)		Adopted then excluded	Voluntary				<i>Remove</i>	
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						<i>Delay until further action</i>		
ASC 15b: OAS CAHPS – Communication About Procedure						<i>Delay until further action</i>		
ASC 15c: OAS CAHPS – Preparation for Discharge and Recovery						<i>Delay until further action</i>		
ASC 15d: OAS CAHPS – Overall Rating of Facility						<i>Delay until further action</i>		
ASC 15e: OAS CAHPS – Recommendation of Facility						<i>Delay until further action</i>		
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.								

E. Possible Future Validation of ASCQR Program Measures

CMS seeks 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.

Comments are sought on whether the OQR Program process is an appropriate model, the possibility of beginning with validation of ASC-13, the possible ASC sample size, sampling methodology, number of cases to sample, validation scores methodology, and reduced annual payment updates to facilities that do not pass validation requirements.

F. Extension of Reporting Period for ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy

CMS proposes 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 proposal for the parallel measure OP-32 is discussed above in section XIII.H. In this case, CMS estimates that the longer reporting period would increase the number of ASCs with eligible cases for this measure by 10 percent, adding 235 ASCs to the measure calculation.¹⁸

Under the proposal, the reporting period for ASC-12 would be changed beginning with the 2020 payment determination, which would use claims from calendar years 2016, 2017 and 2018 instead of 2018 alone. A similar pattern would occur for later payment determinations. Because CMS proposes to add prior years, it says payment determinations and public display of the measure would not be disrupted. For example, public display for the 2020 payment determination would occur in January 2020.

¹⁸ The proposed rule states that in the case of both HOPDs 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.

G. Payment Reduction for ASCs that Fail to Meet the ASCQR Program Requirements

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

CMS reports that for the 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 Electronic Interoperability

CMS discusses the status of adoption of health IT among Medicare and Medicaid participating providers. It says that as of 2015, 96 percent of hospitals had adopted certified EHRs with the capability to electronically export a summary of clinical care, yet significant obstacles to electronic exchange of health information remain. It reviews CMS and Office of National Coordinator (ONC) initiatives and regulatory activities aimed at advancing health information exchange. The January 2018 ONC draft Trusted Exchange Framework and Common Agreement (TEFCA)¹⁹ is highlighted.

CMS is interested in feedback from stakeholders on how it could use the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long-Term Care (LTC) Facilities to advance electronic exchange of health information in support of care transitions between hospitals and community providers. As an example, CMS says it might consider revising the hospital CoPs to require that hospitals electronically transfer medically necessary patient information to the other facility when a patient is transferred. Similarly, it might require that hospitals electronically send discharge information to a patient's community provider when possible, and to provide discharge instructions electronically to patients or a third-party application, if requested.

Relevant provisions of proposed CoP regulations are discussed including the November 3, 2015 proposed rule to implement provisions of the IMPACT Act (80 FR 68126), June 16, 2016 proposed changes to CoPs for hospitals and CAHs (81 FR 39448), and an October 4, 2016 final rule on requirements for LTC facilities (81 FR 68688).

¹⁹ The draft is available at <https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement>

In this rule, CMS requests stakeholder feedback on the following questions:

- If CMS were to propose a new CoP/CfC/RfP standard to require electronic exchange of medically necessary information, would this help to reduce information blocking as defined in section 4004 of the 21st Century Cures Act?
- Should CMS propose new CoPs/CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient's or resident's (or his or her caregiver's or representative's) right and ability to electronically access his or her health information without undue burden? Would existing portals or other electronic means currently in use by many hospitals satisfy such a requirement regarding patient/resident access as well as interoperability?
- Are new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information necessary to ensure patients/residents and their treating providers routinely receive relevant electronic health information from hospitals on a timely basis or will this be achieved in the next few years through existing Medicare and Medicaid policies, HIPAA, and implementation of relevant policies in the 21st Century Cures Act?
- What would be a reasonable implementation timeframe for compliance with new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information if CMS were to propose and finalize such requirements? Should these requirements have delayed implementation dates for specific participating providers and suppliers, or types of participating providers and suppliers (for example, participating providers and suppliers that are not eligible for the Medicare and Medicaid EHR Incentive Programs)?
- Do stakeholders believe that new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety?
- Under new or revised CoPs/CfCs/RfPs, should non-electronic forms of sharing medically necessary information (for example, printed copies of patient/resident discharge/transfer summaries shared directly with the patient/resident or with the receiving provider or supplier, either directly transferred with the patient/resident or by mail or fax to the receiving provider or supplier) be permitted to continue if the receiving provider, supplier, or patient/resident cannot receive the information electronically?
- Are there any other operational or legal considerations (for example, HIPAA), obstacles, or barriers that hospitals and other providers and suppliers would face in implementing changes to meet new or revised interoperability and health information exchange requirements under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future?
- What types of exceptions, if any, to meeting new or revised interoperability and health information exchange requirements, should be allowed under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future? Should exceptions under the QPP including CEHRT hardship or small practices be extended to new requirements? Would extending such exceptions impact the effectiveness of these requirements?

In addition, CMS discusses the MyHealthEData initiative to promote patient access to their medical records and the Blue Button 2.0 initiative for beneficiary access to Medicare claims information through API technology.

CMS seeks ideas from the public on how best to accomplish the goal of fully interoperable health IT and EHR systems for providers and suppliers and how to advance the MyHealthEData

initiative for patients. In particular, it would like to identify fundamental barriers to interoperability and patient access and how they might be reduced through revisions to the CoPs, CfCs, and RfPs for hospitals and other Medicare providers and suppliers. CMS has a particular interest in hearing about issues for providers and suppliers who are ineligible for the Medicare and Medicaid EHR Incentives program, such as long-term care and post-acute care providers, behavioral health providers, clinical laboratories and social service providers.

B. Improving Beneficiary Access to Provider and Supplier Charge Information

CMS repeats the comment solicitation that it included in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20548 and 20549). In general, CMS encourages all providers and suppliers of health care services to undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain, and to enable patients to compare charges for similar services.

CMS is concerned that challenges continue to exist for patients due to insufficient price transparency, including patients being surprised by out-of-network bills that the beneficiary might consider to be a part of an episode of care involving a hospitalization but that are not services furnished by the hospital. CMS is further concerned standard charges are not helpful to patients for determining what they are likely to pay for a particular service or facility encounter. In order to promote greater price transparency for patients, CMS is considering ways to improve the accessibility and usability of current charge information. A selection of the questions on which CMS seeks comment is provided below:

- How should it define “standard charges” in provider and supplier settings?
- What types of information would be most beneficial to patient? Should providers and suppliers be required to inform patients how much their out-of-pocket costs will be for a service?
- How can information on out-of-pocket costs be provided to better support patient choice and decision-making?
- Can CMS require providers and suppliers to provide patients with information on what Medicare pays for a particular service performed by that provider or supplier? What burden would be added as a result of such a requirement?
- CMS seeks public comment on improving a Medigap patient’s understanding of his or her out-of-pocket costs prior to receiving services, especially with respect to the following particular questions:
 - How does Medigap coverage affect patients’ understanding of their out-of-pocket costs before they receive care?
 - What challenges do providers and suppliers face in providing information about out-of-pocket costs to patients with Medigap?
 - What changes can Medicare make to support providers and suppliers that share out-of-pocket cost information with patients that reflects the patient’s Medigap coverage?
 - Who is best situated to provide patients with clear Medigap coverage information on their out-of-pocket costs prior to receipt of care?

- What role can Medigap plans play in providing information to patients on their expected out-of-pocket costs for a service?
- What State-specific requirements or programs help educate Medigap patients about their out-of-pocket costs prior to receipt of care?

C. Competitive Acquisition Program (CAP) for Part B Drugs Innovation Center Model

CMS is engaging in a comment solicitation on design of a Center for Medicare and Medicaid Innovation Center (Innovation Center) model that would build upon the CAP established under section 1847B of the Act, including but not limited to:

- The potential model’s scope;
- Which providers and suppliers should be included or excluded from the model;
- The types of Medicare Part B drugs and biologicals that should be included or excluded;
- The role of private-sector vendors (“model vendors”);
- A defined population of beneficiaries to be addressed by the potential model and appropriate beneficiary protections;
- Possible inclusion of other payers; and
- Options for model payments.

The proposed rule expresses interest in how to handle Medicare payment for new high-cost Part B drug therapies, and whether a potential CAP-like model could be an appropriate payment and delivery structure for these drugs and biologicals. The goals of this model are the same as those in the President Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs²⁰: increase competition, strengthen negotiation, create incentives for lower list prices, and lower out-of-pocket costs.

1. Current Medicare Payments for Part B Drugs

The proposed rule reviews the current benefit categories under which Medicare Part B pays for drugs:

Drugs Furnished Incident to a Physician’s Service: Drugs that are not usually self-administered and are furnished in physicians’ offices or hospital outpatient departments.

Durable Medical Equipment (DME) Drugs: Drugs infused through a covered item of DME, such as drugs administered with an infusion pump and inhalation drugs administered through a nebulizer.

Drugs with Specific Benefit Categories: Immunosuppressive drugs; hemophilia blood clotting factors; certain oral anticancer drugs; certain oral antiemetic drugs; pneumococcal pneumonia, influenza and hepatitis B vaccines; erythropoietin for trained home dialysis patients; and certain osteoporosis drugs.

²⁰ President Blueprint to Lower Drug Prices, <https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-blueprint-lower-drug-prices/>.

These drugs are generally paid at ASP+6 percent. As the 6 percent add-on is a function of the drug's ASP, CMS is concerned that this methodology creates a financial incentive to furnish higher cost drugs increasing Medicare spending and beneficiary liability. CMS further indicates that the ASP-based methodology creates no direct incentives for furnishing high-value drug therapies, does not directly take into account the effectiveness of a particular drug or does not consider the cost of clinically comparable drugs that are billed for and paid under other HCPCS codes.

The proposed rule presents statistics on the growth of Medicare Part B drug expenditures and attributes the increase to price growth rather than increases in enrollment and utilization.

2. CAP for Part B Drugs

Section 1847B of the Act authorizes CAP for Medicare Part B drugs and biologicals. Instead of buying drugs for use in the office, CAP allows physicians that volunteer to participate to place patient specific drug orders with an approved CAP vendor; the CAP vendor would acquire and distribute (or supply) the drugs to the physician's office and then bill Medicare and collect cost-sharing amounts from the beneficiary.

The CAP program operated from 2006 until 2008 with one vendor furnishing drugs for approximately 180 HCPCS billing codes to physicians across the U.S. and certain U.S. territories. Physicians in CAP did not buy or take title to the drug. The CAP vendor supplied drugs in unopened containers (not pharmacy-prepared individualized doses like syringes containing a patient's prescribed dose). The CAP vendor's drug claims were processed by a designated Medicare claims processing contractor selected by CMS.

Absent a willing vendor for the 2nd contract period, CAP was suspended on January 1, 2009. CMS indicates that it could not address the following concerns about CAP under existing statutory requirements:

- Uncertainty about the participation of non-pharmacy entities like wholesalers as approved CAP vendors.
- The requirement for a beneficiary-specific drug order, which impacts use of a consignment approach to facilitate emergency/urgent access to drugs, and to manage inventory through automated dispensing systems in the office.

Additional concerns included:

- Financial risks for vendors from unpaid beneficiary cost sharing, lost or damaged drugs, and unverified drug administrations (which prevented payment).
- Physician and vendor perception of burden associated with participation including ordering, billing, and post pay documentation.
- An evaluation of the CAP found that it was not associated with savings.

3. MedPAC Part B Drug Value Program (DVP) Proposal

In June 2017, MedPAC recommended the development of a voluntary alternative to the ASP payment system; the Part B Drug Value Program (DVP).²¹ The DVP would be permitted to use tools (such as a formulary, step therapy, prior authorization, indication-based pricing, risk-based contracting with savings passed back to the Medicare program, and, in certain circumstances, binding arbitration) to give DVP vendors greater negotiating leverage with manufacturers. Under the DVP, private vendors would negotiate prices for Medicare Part B drugs. Participating health care providers would continue to buy drugs from established distribution channels, but at the DVP-negotiated prices, and the Medicare payment to participating health care providers would be at the same negotiated price.

To encourage voluntary enrollment in the DVP, participating health care providers would have shared savings opportunities. Savings would also be shared with beneficiaries (through lower cost sharing), the DVP vendors, and the Medicare program. Nonparticipating health care providers would continue to buy drugs from traditional distribution channels and Medicare would pay based on the ASP system, although the ASP add-on would be reduced gradually to provide incentives to participate in the DVP. Other key elements of the DVP include its vendor structure, a shared savings component, tools to increase vendors' negotiating leverage, a reduction of the add-on in the ASP system, and exclusion of DVP prices from the ASP calculations.

4. Innovation Center Model Goals and Considerations

The Innovation Center is exploring improvements to the CAP. Such a CAP-like model would test an alternative to the current system, under which health care providers (physicians, hospital outpatient departments, and potentially other providers and suppliers) would acquire drugs through value-based agreements with manufacturers administered by CAP-like model vendors ("vendor-administered payment arrangements"), building on lessons learned from CMS' experience with the CAP.

CMS is considering requiring the vendor to include value-based pricing strategies, such as outcomes-based agreements, indication-based pricing, payment over time, shared savings or performance-based payments based on the impact on total cost of care, and reduced beneficiary cost-sharing. Such a model could start with a subset of therapies, with an increasing number of drugs and biologicals over time.

The proposed rule seeks comments on how to structure a model vendor role: a CAP- or DVP-like role or a hybrid where one of these approaches is tested for certain drugs and biologicals, such as high-cost drugs and biologicals, single source drugs and biologicals, or certain drug classes, and testing another approach for other types of drugs and biologicals. CMS is further considering whether vendors could take title to, but not possession of, drugs that are distributed directly to the providers and suppliers. The proposed rule describes a variety of other model approaches for custody and title of the drugs. CMS is also considering how a potential CAP-like

²¹ The MedPAC June 2017 *Report to the Congress: Medicare and the Health Care Delivery System*. http://medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf?sfvrsn=0

model could include other payers.

CMS solicits comments through a large number of questions that are selectively presented below:

Included Providers and Suppliers

- Are there types of Part B providers and suppliers that should be included or excluded from a potential CAP-like model and, if so, why?
- Should a potential CAP-like model address concerns about a potential reduction in overall payments for physicians that currently rely on revenue from Part B drugs and, if so, how?
- What protections or incentives would be necessary for providers and suppliers to participate in a potential model that would require that drugs and biologicals be acquired under a vendor-administered payment arrangement?

Included Drugs and Biologicals

- Which separately payable Part B drugs and biologicals, or drug classes, would be appropriate to include in a potential CAP-like model?
- Which specific drugs, drug classes, groups of drugs, or indications would be appropriate candidates for specific types of value-based pricing strategies or modifying beneficiary coinsurance?
- How could CMS ensure that payment arrangements are site neutral, where applicable? What current experience in the commercial or other markets should CMS consider?
- What information systems and infrastructure would be necessary for collection of outcomes data?

Beneficiary Cost Sharing, Protections and Fiscal Considerations

- How could a potential CAP-like model be structured to improve beneficiaries' access to Part B drugs and biologicals and quality of care?
- How could the sharing of value with beneficiaries be structured?
- What tools and strategies should a potential model include to ensure program integrity and to minimize the potential for fraud, waste and abuse?

Model Vendors

- How could the role of the CAP vendor be improved such that model vendors, and providers and suppliers, would not face unsurmountable challenges to participation? What types of organizations should CMS consider as candidates to serve as the model vendors?
- What methods should CMS consider for evaluation of submitted bids to obtain the best value for the Medicare program?
- What factors should CMS consider in setting the geographic areas that model vendors would serve?

- Should there be more than one model vendor that covers a specific geographic area? Are there unique challenges that should be addressed for certain geographic areas, such as rural areas or the U.S. territories, or for providers and suppliers in those areas?
- What are the potential risks with testing a consignment approach for model vendor-owned drugs and biologicals, including high-cost therapies? What would be possible approaches for mitigating these risks?
- What types of structures (such as group purchasing organizations, single or affiliated entities) could support a model vendor role for a potential CAP-like model for drugs and biologicals?
- What financial protection(s) may be necessary to encourage private-sector vendor participation in a potential CAP-like model?
- How should CMS structure the payment arrangement between CMS and selected model vendors?

Regulatory Barriers and Transparency Issues

- What specific regulatory barriers currently exist under either the Medicare or Medicaid programs to value-based pricing strategies? How could CMS best address these barriers?
- What waivers of statutory and other requirements would need to be considered for purposes of testing a potential CAP-like model?
- What specific engagement strategies, information sharing, and transparency would be necessary in order to encourage participation and provide important information to make health care decisions?
- What are specific barriers that limit sharing data with model vendors or manufacturers? What safeguards should be in place regarding sharing data with potential model participants?
- How should the potential model be evaluated?

Manufacturer Participation

- What features should CMS consider to provide incentives for manufacturers to participate? Should participation by manufacturers be mandatory?
- How would drug prices and manufacturer price reporting for drugs and biologicals be impacted by the potential CAP-like model test?

Model Scope

- What features should CMS consider to ensure a potential CAP-like model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures?
- Under a potential CAP-like model, how geographically broad should a model be in order to allow for a robust model test and evaluation?
- Under what circumstances would it not be appropriate to allow Medicare Advantage organizations, State Medicaid agencies, and Medicaid Managed Care Organizations to pay for drugs and biologicals for their enrollees through a model vendor's vendor-

- administered arrangement with a manufacturer?
- What are the potential interactions of a potential CAP-like model with existing CMS Innovation Center models? What steps should CMS consider to minimize potential overlap or impacts on existing models?

XVI. Additional IQR Program Policies

CMS proposes a change to the IQR Program in addition to those that were proposed as part of the FY 2019 inpatient prospective payment system (IPPS) proposed rule issued in April 2018. Specifically, in this rule, CMS proposes to remove the 3 communication about pain questions from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) measure beginning with 2022 discharges (for FY 2024 payment).²²

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 proposed for removal. The communication about pain questions were finalized for addition to the survey beginning with 2018 discharges (FY 2020 payment). The first public reporting of these new questions is scheduled for October 2020 (data for 2019 discharges). Confidential preview reports on 2018 data are expected to be provided to hospitals as early as July 2019. 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

CMS proposes to remove these questions from the survey because it says that some stakeholders remain concerned that the revised questions could potentially impose pressure on hospital staff to prescribe more opioids in order to achieve higher scores on the HCAHPS survey. In addition, the President’s Commission on Combating Drug Addiction and the Opioid Crisis recommended in its final report that CMS remove pain survey questions entirely on patient satisfaction surveys, so that providers are never incentivized for offering opioids to raise their survey score. In addition,

²² The HCAHPS requirements are available <http://www.hcahponline.org/>

the report recommended that HHS establish a policy to prevent hospital administrators from using patient ratings from CMS surveys improperly.²³

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. Under the proposal, the questions would be removed effective with January 2022 discharges, for the FY 2024 payment determination and subsequent years. The final public reporting of performance on these questions would be made on October 2022 for 2021 discharges. CMS would not change the scoring of the remaining 29 HCAHPS questions because of this proposal.

CMS says that it considered proposing earlier removal of the questions but is proposing January 2022 to allow sufficient time to make needed updates to the data collection tools, including the CMS data submission warehouse and related reporting tools, as well as time for updating the survey instrument itself. In addition, CMS believes the later data would allow time to assess the impact of using the questions while monitoring unintended consequences and empirical testing of how removal of these questions might affect responses on other survey items.

Factors that CMS identifies as possibly contributing to the perception of a link between the communication about pain questions and opioid prescribing practices include: misuse of the HCAHPS survey (such as using it for outpatient emergency room care instead of inpatient care, or using it for determining individual physician performance); failure to recognize that the HCAHPS survey excludes certain populations from the sampling frame (such as those with a primary substance use disorder diagnosis); and the addition of supplemental pain-related survey questions by the hospital that are not formally part of the HCAHPS survey or required by CMS.

CMS says it has heard from stakeholders that some hospitals are using raw HCAHPS survey data to compare, assess, and incentivize individual physicians, nurses, and other hospital staff or to assess emergency and outpatient departments. CMS emphasizes that the HCAHPS survey was never designed or intended to be used in these ways, and notes that the survey administration protocols²⁴ strongly discourage the unofficial use of HCAHPS scores for within-hospital comparisons, such as for comparisons of particular wards, floors, and individual staff hospital members.

Stating that pain management is a critical part of routine patient care on which hospitals should focus, CMS reiterates that the survey does not specify any particular type of pain control method, and the current questions focus on communication about pain with patients and do not recommend or imply that any particular type of treatment is appropriate. CMS believes that appropriate pain management includes communication with patients about pain-related issues, setting expectations about pain, shared decision-making, proper prescription practices, and alternative treatments for pain management.

²³ The report is available at https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf.

²⁴ See *HCAHPS Quality Assurance Guidelines* at <http://www.hcahpsonline.org/en/quality-assurance/>.

In addition to comments on the proposal to remove the questions, CMS seeks feedback on whether the communication about pain questions should be retained but with a further delay in public reporting. For example, public reporting could be delayed one year until October 2021. This would allow further time for CMS to engage a broad range of stakeholders and to assess the impact of the new communication about pain questions.

Comments are also sought on any potential implications of removing the questions for patient care and on: (1) the importance of receiving feedback from patients related to communication about pain management and the importance of publicly reporting this information for use both by patients in healthcare decision-making and by hospitals in focusing their quality improvement efforts; (2) additional analyses demonstrating a relationship between the use of pain questions in patient surveys and prescribing behavior, including unpublished data, if available; (3) input from clinicians and other providers concerning whether it would be valuable for CMS to issue guidance suggesting that hospitals not administer any surveys with pain-related questions, including adding hospital-specific supplemental items to HCAHPS, as well as the implementation of a third-party quality assurance program to assure that hospitals are not misusing survey data by creating pressure on individual clinicians to provide inappropriate clinical care; (4) information from clinicians and other providers concerning instances of hospital administrators using results from the HCAHPS survey to compare individual clinician performance directly to other clinicians at the same facility or institution and examples where, as a result, clinicians have felt pressured to prescribe opioids inappropriately (in terms of either quantity or appropriateness for particular patients); (5) suggestions for other measures that would capture facets of pain management and related patient education, for instance, for collecting data about a hospital's pain management plan, and provide that information back to consumers; and (6) how other measures could take into account provider-supplied information on appropriate pain management and whether patients are informed about the risks of opioid use and about non-opioid pain management alternatives.

In the Collection of Information section of the proposed rule, CMS estimates that removal of the 3 communication about pain questions from the HCAHPS survey would result in a burden reduction of \$1.0 million nationally.

XVII. Files Available to the Public via the Internet

Addenda for this 2019 OPPS/ASC proposed rule are available on the following CMS website:

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

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

APPENDIX: Table 42—OPPS Impact Table

	(1)	(2)	(3)	(4)	(5)	(6)
	Number of Hospitals	Proposed APC Recalibration (all proposed changes)	Proposed New Wage Index and Provider Adjustment	All Proposed Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update	Proposed Off- Campus Provider- Based Department Visits Policy	All Proposed Changes
ALL FACILITIES *	3,806	0.0	0.0	1.3	-1.2	-0.1
ALL HOSPITALS (excludes hospitals permanently held harmless and CMHCs)	3,695	0.0	0.0	1.3	-1.2	-0.1
URBAN HOSPITALS	2,900	0.0	0.0	1.3	-1.2	-0.1
LARGE URBAN (GT 1 MILL.)	1,534	0.0	-0.1	1.2	-1.0	0.1
OTHER URBAN (LE 1 MILL.)	1,366	0.0	0.1	1.3	-1.4	-0.2
RURAL HOSPITALS	795	0.3	0.0	1.5	-1.3	-0.1
SOLE COMMUNITY	367	0.2	-0.1	1.3	-1.5	-0.4
OTHER RURAL	428	0.4	0.0	1.7	-1.2	0.3
BEDS (URBAN)						
0 - 99 BEDS	980	0.5	-0.2	1.6	-0.8	0.7
100-199 BEDS	844	0.2	-0.2	1.3	-1.0	0.1
200-299 BEDS	463	0.1	0.1	1.4	-0.9	0.3
300-499 BEDS	399	-0.1	0.0	1.2	-1.2	-0.2
500 + BEDS	214	-0.3	0.1	1.1	-1.6	-0.6
BEDS (RURAL)						
0 - 49 BEDS	326	0.5	0.1	1.8	-0.5	1.1
50- 100 BEDS	287	0.3	0.0	1.6	-1.6	-0.2

		(1)	(2)	(3)	(4)	(5)	(6)
		Number of Hospitals	Proposed APC Recalibration (all proposed changes)	Proposed New Wage Index and Provider Adjustment	All Proposed Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update	Proposed Off-Campus Provider-Based Department Visits Policy	All Proposed Changes
	101- 149 BEDS	96	0.3	0.0	1.6	-1.0	0.4
	150- 199 BEDS	48	0.3	-0.2	1.4	-2.1	-1.0
	200 + BEDS	38	-0.2	-0.2	0.9	-1.2	-0.5
REGION (URBAN)							
	NEW ENGLAND	140	0.2	0.3	1.7	-2.1	-0.4
	MIDDLE ATLANTIC	336	0.0	-0.2	1.0	-0.9	0.0
	SOUTH ATLANTIC	463	0.0	-0.2	1.1	-1.1	-0.1
	EAST NORTH CENT.	468	0.0	-0.2	1.1	-1.6	-0.7
	EAST SOUTH CENT.	175	-0.1	0.1	1.2	-0.4	0.6
	WEST NORTH CENT.	180	-0.2	0.1	1.1	-1.3	-0.5
	WEST SOUTH CENT.	501	0.1	0.2	1.5	-1.0	0.3
	MOUNTAIN	207	0.0	-0.6	0.7	-1.2	-0.6
	PACIFIC	384	0.0	0.6	1.9	-1.1	0.5
	PUERTO RICO	46	-0.8	-1.0	-0.5	0.0	-0.6
REGION (RURAL)							
	NEW ENGLAND	21	0.0	-0.4	0.9	-4.1	-3.4
	MIDDLE ATLANTIC						
	SOUTH ATLANTIC	121	0.2	-0.1	1.4	-0.4	0.9
	EAST NORTH CENT.						
	EAST SOUTH CENT.						
	WEST NORTH CENT.						
	WEST SOUTH CENT.						
	MOUNTAIN	53	0.1	-0.3	1.1	-0.8	0.7

	(1)	(2)	(3)	(4)	(5)	(6)
	Number of Hospitals	Proposed APC Recalibration (all proposed changes)	Proposed New Wage Index and Provider Adjustment	All Proposed Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update	Proposed Off-Campus Provider-Based Department Visits Policy	All Proposed Changes
PACIFIC	23	0.3	-0.6	1.0	-2.1	-1.3
TEACHING STATUS						
NON-TEACHING	2,578	0.3	-0.1	1.4	-0.8	0.5
MINOR	769	0.0	0.1	1.3	-1.3	-0.2
MAJOR	348	-0.3	0.1	1.1	-1.8	-0.8
DSH PATIENT PERCENT						
0	10	-0.9	0.2	0.5	0.0	0.9
GT 0 - 0.10	258	0.4	-0.2	1.4	-0.8	0.5
0.10 - 0.16	244	0.2	-0.3	1.1	-0.7	0.4
0.16 - 0.23	574	0.1	-0.1	1.2	-1.2	-0.1
0.23 - 0.35	1,110	0.0	0.1	1.4	-1.4	-0.2
GE 0.35	958	-0.1	0.0	1.2	-1.2	-0.2
DSH NOT AVAILABLE **						
URBAN TEACHING/DSH						
TEACHING & DSH	1,009	-0.1	0.1	1.2	-1.5	-0.4
NO TEACHING/DSH						
NO TEACHING/NO DSH						
DSH NOT AVAILABLE**						
TYPE OF OWNERSHIP						
VOLUNTARY	1,970	0.0	0.0	1.3	-1.3	-0.2
PROPRIETARY	1,248	0.3	-0.2	1.4	-0.4	0.7
GOVERNMENT	477	-0.2	0.2	1.3	-1.4	-0.3
CMHCs	44	-19.1	0.3	-17.8	0.0	-17.9

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

Column (2) includes all proposed 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 proposed FY 2019 hospital inpatient wage index. The proposed rural SCH adjustment would continue our current policy of 7.1 percent so the budget neutrality factor is 1. The proposed budget neutrality adjustment for the cancer hospital adjustment is 1 because in CY 2019 the target payment-to-cost ratio is the same as it was in CY 2018 (0.88).

Column (4) shows the impact of all budget neutrality adjustments and the addition of the proposed 1.25 percent OPD fee schedule update factor (2.8 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 impact of the proposal to pay for the visit service furnished at excepted off-campus provider-based departments at an MPFS equivalent rate.

Column (6) shows the additional proposed adjustments to the conversion factor resulting from the frontier adjustment, a change in the pass-through estimate, and adding estimated outlier payments.

* These 3,806 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.