

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

The Centers for Medicare & Medicaid Services (CMS) released the calendar year 2020¹ final rule for Medicare's hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system on November 1, 2019. Policies in the final rule will generally go into effect on January 1, 2020 unless otherwise specified. The final rule will be published in the November 12th issue of the *Federal Register*.

There is a public comment period on the ambulatory payment classifications (APC) and/or status indicators of new or replacement Level II Health Care Common Procedure Coding System (HCPCS) codes. The public comment period closes on December 2, 2019.

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

Addenda containing relative weights, payment rates, wage indices and other payment information are available only on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1717-FC.html>. Unless otherwise noted, this weblink can be used to access any information specified as being available on the CMS website.

Table of Contents

TOPIC	Page
I. Overview	
A. Estimated Impact on Hospitals	3
B. Estimated Impact on Beneficiaries	5
II. Updates Affecting OPPS Payments	
A. Recalibration of APC Relative Payment Weights	6
B. Conversion Factor Update	14
C. Wage Index Changes	15
D. Statewide Average Default Cost-to-Charge Ratios	
E. Sole Community Hospital Adjustment	16
F. Cancer Hospital Adjustment	
G. Outpatient Outlier Payments	16
H. Calculation of an Adjusted Medicare Payment	
I. Beneficiary Coinsurance	17
III. OPPS APC Group Policies	
A. Treatment of New and Revised Codes	18

TOPIC	Page
B. Variations within APCs	20
C. New Technology APCs	21
D. APC-Specific Policies	25
IV. OPPS Payment for Devices	
A. Pass-Through Payments for Devices	37
B. Device-Intensive Procedures	51
V. OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals	
A. Transitional Pass-Through Payments	53
B. Payment for Non-Pass-Through Drugs, Biologicals, and Radiopharmaceuticals	55
VI. Estimate of OPPS Transitional Pass-Through Spending	
VII. Payment for Hospital Outpatient Visits and Critical Care Services	
VIII. Payment for Partial Hospitalization Program (PHP) Services	65
A. PHP APC Update for 2020	
B. PHP Service Utilization	67
C. Outlier Policy for Community Mental Health Centers (CMHC)	
D. Update to PHP Allowable HCPCS Codes	68
E. Regulatory Impact	
IX. Changes to the Inpatient Only List	69
X. Nonrecurring Policy Changes	
A. Supervision Level for Outpatient Therapeutic Services	72
B. Short Inpatient Hospital Stays	74
C. Controlling Unnecessary Increases in the Volume of Outpatient Services	75
XI. OPPS Payment Status and Comment Indicators	77
XII. MedPAC Recommendations	78
XIII. Updates to the ASC Payment System	
A. Background	79
B. Treatment of New and Revised Codes	80
C. Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services	82
D. Update to ASC Covered Surgical Procedures and Covered Ancillary Services	89
E. New Technology Intraocular Lenses (NTIOL)	
F. ASC Payment and Comment Indicators	90
G. Calculation of the ASC Payment Rates and Conversion Factor	
H. Impact	91
XIV. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program	
A. Measure Removal	93
B. OQR Program Measures and Topics for Future Consideration	
C. Summary Table of OQR Program Measures	94
D. Payment Reduction for Hospitals that Fail to Meet the OQR Program Requirements	96
XV. Ambulatory Surgical Center Quality Reporting (ASCQR) Program	
A. New Measure	97
B. ASCQR Program Measures and Topics for Future Consideration	
C. Summary Table of ASCQR Program Measures	98

TOPIC	Page
D. Payment Reduction for ASCs That Fail to Meet the ASCQR Program Requirements	99
XVI. Public List of Hospital Standard Charges & Price Transparency Quality Measurement	100
XVII. Organ Procurement Organizations (OPO): “Expected Donation Rate”	
A. Definition of “Expected Donation Rate” and Measure Data Collection Timeline	
B. Potential Changes to the OPO and Transplant Center Regulations	101
XVIII. Clinical Laboratory Fee Schedule: Revisions to Date of Service Policy	
XIX. Prior Authorization for Certain Hospital Outpatient Department Services	
A. Background	106
B. Prior Authorization Process	107
C. List of Outpatient Department Services Requiring Prior Authorization	
D. Regulatory Impact	110
XX. Cost Reporting, Hospital Chargemasters and Related Medicare Payment Issues	
XXI. Grandfathered Children’s Hospitals-within-Hospitals (HwHs)	
XXII. Opportunity to Apply for Resident Slots from Two Closed Teaching Hospitals	111
XXIII. Files Available to the Public Via the Internet	112
APPENDIX: Impact Table	114

I. Overview

A. Estimated Impact on Hospitals

The total 2020 increase in OPPS spending due only to changes in the 2020 OPPS rule is estimated to be approximately \$1.21 billion. Including estimated changes in enrollment, utilization, beneficiary cost-sharing and case-mix, the 2020 increase in OPPS spending will be approximately \$6.3 billion. Total OPPS spending is estimated to be \$79.0 billion in 2020. These spending estimates include the 2nd year phase-in of a policy adopted in the 2019 final rule to control for unnecessary increases in the volume of covered hospital outpatient department (HOPD) services. In 2019, CMS is paying 70 percent of the OPPS rate for a clinic visit service that is performed in an off-campus provider-based department (PBD) excepted from section 603 of the Bipartisan Budget Act of 2015. For 2020, CMS plans to adopt the remainder of the phase-in and pay 40 percent of the OPPS rate for a clinic visit furnished at an excepted off campus PBD.² Medicare makes payments under the OPPS to approximately 3,732 facilities (3,625 hospitals excluding CMHCs and cancer and children’s hospitals held harmless to their pre-OPPS payment to cost ratios).

CMS estimates that the update to the conversion factor and the multifactor productivity adjustment (not including the effects of outlier payments, pass-through payment estimates, the application of the frontier state wage adjustment, and controlling for unnecessary increases in the volume of covered HOPD services) will increase total OPPS payments by 2.6 percent in 2020.

² CMS’ authority to undertake this policy was challenged in a United States district court. On September 17, 2019, the District Court for the District of Columbia ruled in favor of the plaintiffs and vacated applicable portions of the final rule—a ruling that the agency asked the court to stay while the agency contemplates appeal. On October 21, 2019, the district court declined to stay its prior order. CMS is able to continue this policy because the district court’s decision applies to 2019 and the policy being undertaken in the final rule applies to 2020.

Considering all other factors, CMS estimates a 1.3 percent increase in payments between 2019 and 2020.

The update equals the market basket of 3.0 percent reduced by a multifactor productivity adjustment of 0.4 percentage points. The net update is 2.6 percent. Hospitals that satisfactorily report quality data will qualify for the full update of 2.7 percent, while hospitals that do not will be subject to a statutory reduction of 2.0 percentage points. All other adjustments are the same for the two sets of hospitals. Of the approximately 3,300 hospitals that met eligibility requirements to report quality data, CMS determined that 14 hospitals will not receive the full OPPS increase factor.

Table 68 in the final rule (reproduced in the Appendix to this summary) includes the estimated impact of the final rule by provider type. It shows an estimated increase in expenditures of 1.3 percent for all facilities and 1.3 percent for all hospitals (all facilities except cancer and children's hospitals, and CMHCs). The following table shows components of the 1.3 percent total:

	% Change All Facilities
All changes	1.3
Fee schedule increase factor	2.6
Site Neutral Payment for Clinic Visits	-0.6
Difference in pass through estimates for 2019 and 2020	-0.7
Difference from 2019 outlier payments (1.00% vs. 1.0%)	0.0

The fee schedule increase factor is 2.6 percent (3.0 percent for the hospital market basket less 0.4 percentage points for multifactor productivity). The site neutral policy is expected to result in savings of -0.6 percent. CMS estimates that pass-through spending for drugs, biologicals and devices for 2020 will be \$698.4 million, or 0.88 percent of OPPS spending. For 2019, CMS estimates pass-through spending would be 0.14 percent of OPPS spending. The -0.74 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 2019 will represent 1.00 percent of total OPPS payments compared to the 1.0 percent set aside, for no net change in 2020 payments.

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

Although CMS projects an estimated increase of 1.3 percent for all facilities, the final rule impacts vary depending on the type of facility. Impacts will differ for each hospital category based on the mix of services provided, location and other factors. Impacts for selected categories of hospitals are shown in the table below:

Facility Type	2020 Impact
All Hospitals	1.3
All Facilities (includes CMHCs and cancer and children's hospitals)	1.3
Urban	1.3
Large Urban	1.2
Other Urban	1.4
Rural	1.1
Beds	
0-99 (Urban)	1.9
0-49 (Rural)	1.5
500+ (Urban)	1.1
200+ (Rural)	0.6
Major Teaching	0.9
Type of ownership:	
Voluntary	1.1
Proprietary	2.1
Government	1.3
Puerto Rico	20.9

The larger increase for proprietary hospitals is accounted for by recalibration (+0.6) and a lesser reduction from the site neutral policy (-0.2 percent) than the average for all hospitals.

The larger increase in Puerto Rico is accounted for by changes to the wage index. The OPPS uses the same wage index as is used for the IPPS. In the FY 2020 IPPS final rule, CMS adopted a policy to uniformly adjust the lowest quartile wage indexes by $\frac{1}{2}$ of the difference between the hospital's wage index and the 25th percentile wage index. CMS is adopting the same policy for the OPPS wage index and making the change budget neutral with an adjustment to the OPPS conversion factor. As Puerto Rico has the lowest wage indexes among all OPPS hospitals, it would experience the highest overall benefit from this proposal.

B. Estimated Impact on Beneficiaries

CMS estimates that the aggregate beneficiary coinsurance percentage will be 18.1 percent for all services paid under the OPPS in 2020. 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 (\$1,364 in 2019) which accounts for the aggregate coinsurance percentage being less than 20 percent.

II. Updates Affecting OPPS Payments

A. Recalibration of APC Relative Payment Weights

As described below, CMS is largely continuing past policies unchanged.

1. Database Construction

a. Database Source and Methodology

For the 2020 rule, CMS uses hospital final action claims for services furnished from January 1, 2018 through December 31, 2018 processed through the Common Working File as of June 30, 2019. Cost data are from the most recently filed cost reports which, in most cases, are from 2017. In a separate document available on the CMS website, CMS provides a detailed description of the claims preparation process and an accounting of claims used in the development of the final rule payment rates, including the number of claims available at each stage of the process. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1717-FC.html> (click on 2020 NFRM OPPS Claims Accounting).

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

For the 2020 final rule, CMS bypasses the 170 Healthcare Common Procedure Coding System (HCPCS) codes identified in Addendum N. CMS indicates the list of bypass codes may include codes that were reported on claims in 2018 but were deleted for 2019. CMS is deleting 5 codes from the bypass list for 2020 (G0436, 71010, 71015, 71020 and 93965).

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

To convert billed charges on outpatient claims to estimated costs, CMS multiplies the charges by a hospital-specific CCR associated with each revenue code and cost center. To calculate CCRs for 2020, CMS is employing the same basic approach used for APC rate construction since 2007. CMS applies the relevant hospital-specific CCR to the hospital's charges at the most detailed level possible based on a revenue code-to-cost center crosswalk containing a hierarchy 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. No new revenue codes were added for 2018, the year of claims data used for deriving the 2020 payment rates. CCRs are calculated for the standard and nonstandard cost centers accepted by the electronic cost report data at its most detailed level. Generally, the most detailed level will be the hospital-specific departmental level.

In the 2014 OPPS/ASC final rule with comment period (78 FR 74840 through 74847), CMS created distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. However, in response to public comment, CMS removed claims from providers that use a cost allocation method of “square feet” to calculate CCRs used to estimate costs associated with the CT and MRI APCs (78 FR 74847) because of concerns about the accuracy of this cost allocation method. CMS indicated that it would provide hospitals with 4 years to transition to a more accurate cost allocation method and would use cost data from all providers, regardless of the cost allocation statistic employed, beginning in 2018. CMS later extended the transition policy through 2018 and 2019.

Table 2 of the final rule shows the relative effect on imaging APC payments after removing cost data for providers that report CT and MRI standard cost centers using square feet as the cost allocation method. Table 3 of the final rule provides statistical values based on the CT and MRI standard cost center CCRs using the different cost allocation methods. Tables 2 and 4 are combined below to show the full impact of continuing to exclude square feet CCRs from the methodology and CMS’ final rule policy to create a transition to fully using all CCRs regardless of the cost allocation methodology used.

The final rule indicates that the number of valid MRI CCRs has increased by 18.8 percent to 2,207 providers and the number of valid CT CCRs has increased by 16.0 percent to 2,291 providers since CMS adopted its policy in 2014 of excluding providers that use the square foot cost allocation method. As shown in combined Table 2/4 below, eliminating these hospitals from the OPPS rate setting methodology increases the payment for all but one of the imaging APCs because hospitals that use the square foot allocation have lower CCRs for their imaging cost centers.

CMS indicates that many providers continue to use the “square feet” cost allocation methodology, which indicates that these providers believe it is valid for attributing costs. Therefore, CMS proposed to include those providers that use a “square feet” cost allocation method to estimate costs for CT and MRI beginning with 2020.

Public commenters raised concerns about CMS’ proposal noting a significant number of CCRs are close to zero regardless of the cost allocation method used. Several commenters requested that CMS not use the CT and MRI-specific cost centers and instead estimate cost using the single diagnostic radiology cost center believing this will solve the inaccurate reporting of costs for CT and MRI services. Other commenters requested that CMS extend the transition or phase-in any reductions that result from using all hospitals’ CT and MRI CCRs. A number of commenters expressed concern about the impact of the reduced rates on physician fee schedule (PFS) payments because the Deficit Reduction Act of 2005 caps the PFS rate at the OPPS rate.

CMS responded that it will apply 50 percent of the payment impact from ending the transition in 2020 and 100 percent of the payment impact from ending the transition in 2021. For 2020, CMS will calculate the imaging payment rates based on 50 percent of the transition methodology (excluding square feet CCRs) and 50 percent of the standard methodology (including square feet CCRs). Beginning in 2021, CMS will set the imaging APC payment rates at 100 percent of the

payment rate using the standard payment methodology. Combined Table 2/4 below illustrates the estimated impact on geometric mean costs for CT and MRI APCs under the blended approach.

Table 2/4—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	% Change Excluding Sq. Ft. CCRs	% Change 50% Blend
5521	Level 1 Imaging without Contrast	-2.5%	-1.3%
5522	Level 2 Imaging without Contrast	5.8%	2.9%
5523	Level 3 Imaging without Contrast	4.0%	2.0%
5524	Level 4 Imaging without Contrast	4.9%	2.5%
5571	Level 1 Imaging with Contrast	6.6%	3.3%
5572	Level 2 Imaging with Contrast	7.9%	3.9%
5573	Level 3 Imaging with Contrast	1.8%	0.9%
8005	CT and CTA without Contrast Composite	14.1%	7.0%
8006	CT and CTA with Contrast Composite	10.9%	5.4%
8007	MRI and MRA without Contrast Composite	6.5%	3.2%
8008	MRI and MRA with Contrast Composite	6.5%	3.2%

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

Cost Allocation Method	CT		MRI	
	Median CCR	Mean CCR	Median CCR	Mean CCR
All Providers	0.0356	0.0496	0.0772	0.1026
Square Feet Only	0.0288	0.0445	0.0674	0.0930
Direct Assign	0.0506	0.0585	0.0978	0.1186
Dollar Value	0.0424	0.0560	0.0875	0.1146
Direct Assign and Dollar Value	0.0425	0.0562	0.0879	0.1147

Recognizing the potential impact that the CT and MRI CCRs may have on other payment systems, CMS will continue to monitor OPPS imaging payments and consider the potential impacts of payment changes on the physician fee schedule and ambulatory surgical center payment systems.

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

To determine each APC’s relative weight, 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. CMS standardizes the relative weights to the APC for G0463, an outpatient hospital visit—the most commonly furnished service billed under the OPPS. CMS is continuing to follow this basic process for 2020. The 2018 claims data that CMS is using for 2020 includes data from off-campus PBDs paid at a PFS comparable amount under section 603 of the Bipartisan Budget Act (BBA) of 2015. As these claims are not paid under the OPPS, CMS eliminates these claims from the relative weight calculation.

Several commenters noted about 400,000 fewer lines with PN modifier on the limited data set for 2020 than 2019 and requested an explanation for the discrepancy. CMS explains the discrepancy

is due to a programming change to eliminate claim lines with the PN modifier earlier in the process so they did not appear on the proposed rule limited data set. For the final rule, CMS is including these data on the limited data set but continuing to exclude them from setting the relative weights.

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

The relative weights for blood and blood product APCs are determined by converting charges to costs using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center. CMS is also continuing to include blood and blood products in the comprehensive APCs, which provide all-inclusive payments covering all services on the claim. HCPCS codes and their associated APCs for blood and blood products are identified with a status indicator of “R” (Blood and Blood Products) in Addendum B of the final rule.

Pathogen-Reduced Platelets and Rapid Bacterial Testing for Platelets

Pathogen reduction is a costlier service than rapid bacterial testing; however, a single code was created for both services. As a result, CMS was concerned that the OPPS relative weight for pathogen reduction would be too low as evidence suggested a single code was being used to bill for two different services which vary significantly in costs. Until this concern could be addressed, CMS created a code for pathogen reduction only and crosswalked its relative weight until claims data were available to price code P9073 under the normal methodology. This policy was continued for 2019. For 2020, CMS indicates that it now has 4,700 claims for code P9073 (pathogen reduction) and the rate based on claims data will be \$585 or \$60 less than the crosswalked payment rate to P9037 (irradiated platelets). Therefore, CMS proposed to price code P9073 under its normal methodology rather than through a crosswalk to code P9037.

Public comments asked CMS to continue to use the crosswalk methodology to price code P9073 for 2020 and 2021 arguing that approximately 30 percent of the 2018 claims contain costs that are at least \$100 lower and representative of a less expensive technology than pathogen reduction. CMS continues to believe that, beginning in 2020, it is appropriate to calculate the payment rate for services described by HCPCS code P9073 using the standard methodology (which involves using data from 2018 claims for the code). As coding issues were resolved in January 2018, CMS has no reason to believe that the data may reflect the costs for services other than those described by P9073.

Brachytherapy sources

The statute requires the Secretary to create APCs for brachytherapy consisting of a seed or seeds (or radioactive source) – i.e., “brachytherapy sources” – separately from other services or groups of services, in order to reflect the number, isotope, and radioactive intensity of the brachytherapy sources furnished. Since 2010, CMS has used the standard OPPS payment methodology for brachytherapy sources, with payment rates based on source-specific costs as required by statute. CMS proposed no changes to its brachytherapy policy for 2020.

If CMS does not have billing data to set the payment rates, it may use external data to set prices for brachytherapy sources. For 2019, CMS used external data to set a payment rate for HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) at \$4.69 per mm². For 2020, CMS proposed to set the payment rate for HCPCS code C2645 at 1.02 per mm² based on 2018 claims data.

One commenter objected to setting the payment for HCPCS code C2645 at 1.0 per mm² arguing that two claims is insufficient volume for rate setting. While CMS maintains that it is appropriate to use claims data to price this product under the OPPS, it is using its equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the \$4.69 per mm² rate for HCPCS code C2645.

Other commenters were concerned about the accuracy of the proposed rule payment rate for HCPCS code C2642 (Brachytherapy source, stranded, cesium-131, per source) of \$67.29 per source. One provider commented that it underreported the actual costs in the 2018 data that are being used to set 2020 payments. CMS responded that the geometric mean costs for HCPCS code C2642 are based on 85 claims from 2018. The final rule geometric mean cost is \$75.06 per source compared to a 2019 payment rate of \$79.94 per source. As the final rule rate does not appear unusual or erroneous, CMS is finalizing the \$79.94 per source rate for HCPCS code C2642.

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 2020

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 integral, ancillary, supportive, dependent, and adjunctive to the primary 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 are higher than the highest cost C-APC in a clinical family just to accommodate potential complexity adjustments.

Commenters requested a number of changes to the complexity adjustment criteria that would result in more procedures being assigned to a higher weighted C-APC. These requests included various combinations of procedures or removing the minimum number of claims required for a specific technology to receive a complexity adjustment. CMS believes requiring a minimum frequency of 25 claims and the other criteria are adequate to determine if a combination of procedures represents a complex, costly subset of the primary service. Lowering the minimum of 25 claims further could lead to unnecessary complexity adjustments for service combinations that are rarely performed.

Additional C-APCs for 2020

CMS proposed to add two C-APCs beginning in 2020: C-APC 5182 (Level 2 Vascular Procedures) and C-APC 5461 (Level 1 Neurostimulator and Related Procedures). Similar to other C-APCs, these APCs include primary, comprehensive services, such as major surgical procedures, that are typically reported with other ancillary and adjunctive services. Also, there are higher APC levels within the clinical family or related clinical family of these APCs that have previously been assigned to a C-APC. Public commenters supported the creation of these C-APCs that CMS is finalizing without change.

Other comments requested CMS either create new C-APCs or discontinue current ones. CMS declined to do either for various reasons. Device manufacturer associations raised broader concerns that C-APC payment rates may not adequately reflect hospital costs. Some commenters urged CMS to invest in policies and education for hospitals to bill correctly to ensure that costs are captured in C-APC rates. CMS responded by referencing its 2018 analysis of the C-APCs showing that its payment policy did not adversely affect access to care or reduce payments to hospitals.

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

For the 2019 OPPS, CMS excluded 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. Commenters asked whether CMS' policy applies to the "Comprehensive Observation Services" C-APC just as it would to a procedural C-APC. CMS considered the issue and did not believe the policy needs to be extended because the criteria for billing the "Comprehensive Observations Services" C-APC make it highly unlikely that a new technology service will be billed in conjunction with it.

Several commenters objected to CMS packaging payment for procedures assigned to a New Technology APC into the C-APC for “Comprehensive Observation Services.” The commenters stated that there were instances where beneficiaries receiving observation services may require the types of procedures that are assigned to new technology APCs. CMS agreed with these comments and is modifying its policy to exclude procedures assigned to New Technology APCs from being packaged under the C-APC policy including for the “Comprehensive Observation Services” C-APC.

The full list of C-APCs, the data CMS used to evaluate APCs for being a C-APC and C-APC complexity adjustments are found in Addendum J. C-APCs with a status indicator of “J1” or “J2” (only for the Comprehensive Observation Services C-APC) can be found in other Addenda as well.

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 2020.

3. Changes to Packaged Items and Services

Drugs that function as a supply are packaged under the OPPS and the ASC payment system, regardless of the costs of the drugs. CMS examined this policy for 2019 in response to the President’s Commission on Combating Drug Addiction and the Opioid Crisis (the Commission). As a result of this review, CMS decided to pay separately for one product (Exparel—a postsurgical analgesia injection) in the ASC setting only rather than as packaged. It remains a packaged product in the OPPS.

In the 2020 proposed rule, CMS reevaluates this issue under section 6082 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act enacted on October 24, 2018. Section 6082(a) of the SUPPORT Act requires the Secretary to review payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with the goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. CMS reiterates its prior analysis and is not proposing any changes to its packaging policies for 2020. It will continue to package all drugs that function as supplies under the OPPS and pay separately for the cost of non-opioid pain management drugs that function as surgical supplies in the ASC setting.

CMS further reviewed external data from stakeholders and concluded that there is no compelling evidence to make revisions to its OPPS payment policies for 2020. The proposed rule indicated that this conclusion is supported by MedPAC in its March 2019 Report to Congress. Nevertheless, CMS invited public comments on whether there were other non-opioid pain management alternatives for which payment policy should be revised to allow separate payment. To qualify for separate payment, public comments must provide evidence-based support, such as

published peer-reviewed literature, that CMS could use to determine whether these products help to deter or avoid prescription opioid use and addiction as well as evidence that the current packaged payment for such non-opioid alternatives presents a barrier to access to care warranting revised, including possibly separate, payment under the OPPS. Evidence that current payment policy provides a payment incentive for using opioids instead of non-opioid alternatives should align with available Medicare claims data.

Public commenters requested that CMS pay separately for Exparel, Omidria, MKO Melt, continuous peripheral nerve blocks, spinal cord stimulators and other products that function as a surgical supply in the hospital outpatient setting. CMS disagreed with paying separately for any of these products under the OPPS largely because it observed increasing utilization despite its packaging policies or studies provided did not demonstrate a reduction in opioid use.

There were public comments supporting CMS' proposal to pay separately for Prialt (HCPCS J2278, injection, ziconotide), a non-narcotic pain reliever administered via intrathecal injection. Commenters provided data indicating that Prialt potentially could lower opioid use, including opioids such as morphine. In addition to continued separate payment, several commenters recommended CMS reduce or eliminate the coinsurance for the drug in order to increase beneficiary access. CMS responded that there is no provision of law that would allow CMS to waive beneficiary coinsurance.

The final rule does not approve separate payment for any additional drugs (or other products) that function as a supply in the final rule. CMS will continue to analyze the issue of access to non-opioid alternatives in the OPPS and the ASC settings under section 6082 of the SUPPORT Act.

4. Calculation of OPPS Scaled Payment Weights.

As in past years, CMS will standardize the relative weights based on APC 5012 and HCPCS code G0463 (a hospital outpatient clinic visit) which is the most commonly billed OPPS service. CMS is giving APC 5012 a relative weight of 1.0 and dividing the geometric mean costs of all other APCs by the geometric mean cost for APC 5012 to determine its associated relative payment weight. Even though CMS is paying for clinic visits furnished in off-campus PBDs at a PFS equivalent rate under a site neutral policy, CMS is continuing to use visits in these settings to determine the relative weight scaler because the PFS adjuster is applied to the payment, not the relative weight. CMS' site neutral policy is not budget neutral while changes to the weights are budget neutral.

Specified covered outpatient drugs (SCODs) are included in the budget neutrality calculation to ensure that the relative weight changes between 2019 and 2020 do not increase or decrease expenditures. However, SCODs are not affected by the budget neutrality adjustment.

CMS is following its past practice to determine budget neutrality for changes in the OPPS relative weights. Holding all other variables constant, CMS multiplies the 2019 and 2020 relative weights respectively for each APC by its associated volume from 2018. It sums the 2019 and 2020 relative weights respectively, and then divides the 2019 aggregate relative weights by the

2020 aggregate relative weights to determine the weight scaler. Using this process, CMS is adopting a weight scaler of 1.4349. The unscaled 2020 relative payments are multiplied by 1.4349 to determine the 2020 scaled relative weights that are shown in Addendum A and B.

B. Conversion Factor Update

For CY20, in a December 31, 2019, final rule correction notice, CMS updated the conversion factor from \$80.784 to \$80.793. Hospitals failing to meet the Outpatient Quality Reporting Program requirements will see a reduced CY20 conversion factor of \$79.250, as these facilities are subject to a 2.0 percentage point update reduction. CMS does not show the details of this calculation in the final rule, but it can be found on page 24 of the claims accounting at the weblink shown at the beginning of the summary and is shown in the below table:

2019 Conversion Factor	\$79.490
Remove pass-through and outliers from prior year CF	1.0115
Wage Index Budget Neutrality (changes to wage data as well as the 25 th percentile policy)	0.9990
Budget Neutrality Wage Index Cap	0.9991
Cancer Hospital Adjustment	0.9999
Update	1.0260
Pass-Through and Outlier Adjustment	0.9812
2020 Conversion Factor	\$80.784

CMS removes the prior year's pass-through and outlier adjustment from the 2019 conversion factor which increases it by 1.15 percent. Standard wage index budget neutrality is 0.9990 (-0.1 percent) for changes to the wage data. While CMS describes this as the standard wage index budget neutrality adjustment, it appears to also include budget neutrality for increases in wage indexes below the 25th percentile which would explain why this adjustment changed from +0.05 percent in the proposed rule to -0.1 percent in the final rule. The budget neutrality adjustment for CMS' policy of capping any reductions in the wage index at 5 percent is 0.9991 (-0.09 percent). The cancer hospital adjustment is 0.9999 (-0.01 percent). The update of 1.026 (2.6 percent) equals the market basket of 3.0 percent less 0.4 percentage points for multifactor productivity. CMS estimates that pass-through spending for drugs, biologicals and devices for 2020 will be \$698.4 million or 0.88 percent of OPPS spending.³ The outlier adjustment is 0.99 (-1.0 percent). The combined adjustment for pass-through and outliers is 0.9812 (-1.88 percent).

CMS reports that the reduced conversion factor for hospitals not meeting the OQR requirements will be \$79.249 which equals 98.1 percent of the full conversion factor. CMS describes this as the "reporting ratio" that is applied to hospitals that do not qualify for the full update because they failed the OQR requirements. The rule does not explain how the reporting ratio was derived. However, substituting an update of 1.006 (2.6 percent less 2.0 percentage points) into the above formula produces a lower conversion factor (\$79.210).

³ This figure may be erroneous. In the section on spending for pass-through drugs and devices, CMS says total spending will be \$698.4 million. However, the numbers CMS provides in the text add to \$672.37 million.

C. Wage Index Changes

CMS is continuing its policy of using the fiscal year IPPS post-reclassified wage index for urban and rural areas as the OPPS calendar year wage index. The 2020 OPPS rule wage index is based on the FY 2020 IPPS post-reclassified wage index; any adjustments for the FY 2020 IPPS post-reclassified wage index are reflected in the 2020 OPPS wage index including the following FY 2020 IPPS rule:

1. Calculate the rural floor without including the wage data of urban hospitals that have been reclassified as rural;
2. Remove the wage data of urban hospitals that have been reclassified as rural from the calculation of “the wage index for rural areas in the state”;⁴
3. Increase the wage index values below the 25th percentile by half the difference between the otherwise applicable final wage index value and the 25th percentile wage index value; and
4. Apply a budget neutrality adjustment for the increase in the 25th percentile wage indexes as well as a 5 percent cap on reductions in the wage index.

There are two differences between the proposed and final rule adjustments. In the proposed rule, CMS applied a uniform adjustment for budget neutrality to hospitals with wage indexes in the top quartile to offset the costs for increasing the wage indexes for hospitals in the bottom quartile. For the final rule, CMS is not applying the reduction in the wage indexes for hospitals in the top quartile. Budget neutrality for the increase in the lowest 25th percentile wage indexes will be achieved through a uniform reduction to all OPPS rates.

Comments on the increase to the 25th percentile wage indexes were similar to those provided on the FY 2020 IPPS rule. There were comments supporting the policy, opposing it and suggestions that it should be adopted but not be made budget neutral as well as suggestions that the budget neutrality adjustment should not apply to the hospitals with wage indexes among the bottom 25th percentile. There were comments suggesting that CMS does not have the legal authority for the policy.

CMS reiterated the same responses from the FY 2020 IPPS that its policy increases the accuracy of the wage index as a relative measure because it allows low wage index hospitals to increase their employee compensation in ways that would be expected if there were not a lag in reflecting compensation adjustments in the wage index. CMS opposes using the wage index to increase or decrease overall spending and is applying a budget neutrality adjustment consistent with 1886(t)(2)(D) and (9)(B) of the Act.

Similarly, there were comments both in support of and opposed to excluding the wage data of urban hospitals that reclassify as rural in calculating the rural floor. One commenter said that CMS’ policy to remove the wage data of hospitals that have been reclassified from urban to rural

⁴This provision will prevent an urban hospital not reclassified as rural from having its wage index increased when another hospital reclassifies as rural. CMS is modifying its implementation of section 1886(d)(8)(C)(iii) of the Act which raises the urban wage index for hospitals not reclassified as rural when a hospital reclassified as rural raises the rural wage index. It is separate from the rural floor provision which is a freestanding provision of the Balanced Budget Act of 1997.

from calculation of the rural floor reflects a misreading of section 1886(d)(8)(E) of the Act. Again, CMS responded as it did in the IPPS rule indicating that in the absence of broader wage index reform from Congress, it is appropriate to revise the rural floor calculation as part of an effort to reduce wage index disparities. It disputed the legal objection to this policy but did not address the legal concerns in any detail.

CMS retains the OPPS labor-related share of 60 percent for purposes of applying the wage index for 2020 and notes that the wage index adjustment is made in a budget neutral manner. It also uses the latest OMB statistical area delineations and continues past adjustments required by the ACA (the “frontier state” adjustment that requires a wage index floor of 1.0).

For non-IPPS hospitals paid under the OPPS for 2020, CMS is continuing past policies of assigning the wage index that would be applicable if the hospital were paid under the IPPS and allowing the hospital to qualify for the out-migration adjustment.

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

D. Statewide Average Default Cost-to-Charge Ratios

In cases where there is no data to calculate a hospital’s CCR, CMS uses the statewide average CCR to determine outlier payments, payments for pass-through devices, and other purposes. The statewide average is used for hospitals that are new, hospitals that have not accepted assignment of an existing hospital’s provider agreement, and hospitals that have not yet submitted a cost report. CMS also uses the statewide average default CCRs to determine payments for hospitals that appear to have a CCR falling outside the predetermined ceiling threshold for a valid CCR or for hospitals in which the most recent cost report reflects an all-inclusive rate status. CMS is updating the default statewide average CCRs for 2020 using the most recent cost report data. The table of statewide average CCRs is no longer being included in the OPPS rule. CMS says it is available at the link provided at the beginning of this summary but HPA could not locate it.

E. Sole Community Hospital Adjustment

For 2020, CMS is continuing to apply a 7.1 percent payment adjustment under section 1833(t)(13)(B) of the Act for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs. The adjustment is budget neutral and is applied before calculating outliers and copayments.

F. Cancer Hospital Adjustment

Eleven cancer hospitals meeting specific statutory classification criteria are exempt from the IPPS. Medicare pays these hospitals under the OPPS for covered outpatient hospital services. The ACA requires an adjustment to cancer hospitals’ outpatient payments sufficient to bring

each hospital's payment-to-cost ratio (PCR) up to the level of the PCR for all other hospitals—the target PCR. The change in these additional payments from year to year is budget neutral. The 21st Century Cures Act reduced the target PCR by 1.0 percentage point and excludes the reduction from OPPS budget neutrality.

The cancer hospital adjustment is applied at cost report settlement rather than on a claim by claim basis. For 2020, CMS updated its calculations using the latest available cost data and is using a target PCR of 0.90. Consistent with section 1833(t)(18)(C) of the Act, CMS is reducing the target PCR from 0.90 to 0.89.

Table 7 in the final rule shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals, with increases in OPPS payments for 2020 ranging from 7.1 percent to 50.2 percent. As indicated in the conversion factor update section, the revised cancer hospital adjustment requires a -0.01 percent adjustment to OPPS rates for budget neutrality.

G. Outpatient Outlier Payments

The OPPS makes outlier payments on a service-by-service basis when the cost of a service exceeds the outlier threshold. For 2020, CMS is continuing to set aside 1.0 percent of the estimated aggregate total payments under the OPPS for outlier payments. It is calculating the fixed-dollar threshold using the same methodology that was used to set the threshold for 2019 and previous years. CMS is continuing to set the outlier payment equal to 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount when both the 1.75 multiple threshold and the fixed-dollar threshold are met. For 2020, CMS calculates a fixed-dollar threshold of \$5,075 (compared to \$4,825 in 2019).

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

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

To model hospital outlier payments and set the outlier threshold for the final rule, CMS applied the hospital-specific overall ancillary CCRs available in the October, 2019 update to the Outpatient Provider-Specific File after adjustment using a CCR inflation adjustment factor of 0.97517 to approximate 2020 CCRs and a charge inflation factor of 1.11100 to approximate 2020 charges from 2018 claims.

K. Calculation of an Adjusted Medicare Payment

This section provides step by step instructions for calculating an adjusted Medicare payment from the national unadjusted Medicare payment amounts shown in Addenda A and B to the final rule. The steps show how to determine the APC payments that would be made under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: “J1,” “J2,” “P,” “Q1,” “Q2,” “Q3,” “Q4,” “R,” “S,” “T,” “U,” or “V” (as defined in Addendum D1 to the final rule), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of “Q1” and “Q2”) qualify for separate payment. CMS notes that, although blood and blood products with status indicator “R” and brachytherapy sources with status indicator “U” are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements.

L. Beneficiary Coinsurance

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 \$1,364 in 2019. The inpatient hospital deductible limit is applied to the *actual* co-payment amount after adjusting for the wage index. Addenda A and B to the final rule include a column with a “#” to designate those APC and HCPCS codes where the deductible limit applies.

III. OPPS APC Group Policies

A. Treatment of New and Revised Codes

Table 10 (copied below from the final 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 9: Comment Timeframe for New or Revised HCPCS codes

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2019	HCPCS (CPT and Level II Codes)	April 1, 2019	2020 OPPS/ASC proposed rule	2020 OPPS/ASC final rule with comment period
July 2019	HCPCS (CPT and Level II Codes)	July 1, 2019	2020 OPPS/ASC proposed rule	2020 OPPS/ASC final rule with comment period
October 2019	HCPCS (CPT and Level II Codes)	October 1, 2019	2020 OPPS/ASC final rule with comment period	2021 OPPS/ASC final rule with comment period

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
January 2020	CPT Codes	January 1, 2020	2020 OPPS/ASC proposed rule	2020 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2020	2020 OPPS/ASC final rule with comment period	2021 OPPS/ASC final rule with comment period

1. April 2019 Codes - CMS Solicited Public Comments in the Proposed Rule

For the April 2019 update, there were no new CPT codes. In the April 2019 OPPS quarterly update, CMS made effective eight new Level II HCPCS codes and assigned them interim OPPS status indicators and APCs. CMS did not receive any comments on the status indicators or APC assignments. The final payment rates, where applicable, can be found in Table 8 and Addendum B of final rule.

2. July 2019 HCPCS Codes - CMS Solicited Public Comments in the Proposed Rule

In the July 2019 OPPS quarterly update, CMS made effective 58 new codes and assigned them interim OPPS status indicators and APCs. CMS received comments on 8 of these codes. These comments are summarized in section III. B. below. No comments were received on the other 50 codes. Some of the temporary C-codes were replaced with permanent J-codes. The C-codes, replacement J codes, final payment rates, where applicable, can be found in Table 9 and Addendum B of the final rule.

3. October 2019 HCPCS Codes - CMS Soliciting Public Comments in the 2020 Final Rule with Comment Period

CMS is continuing the practice of providing interim payment status indicators, APC assignments and payment rates, if applicable, for HCPCS codes that were effective October 1, 2019 in Addendum B to the 2020 final rule. These codes are flagged with comment indicator “NI”, indicating that CMS has assigned the codes an interim OPPS payment status for 2020. **CMS invites public comment on the interim status indicators, APC assignments, and payment rates for these codes.** Final decisions on these codes in response to comments will be made in the 2021 OPPS/ASC final rule.

4. January 2020 HCPCS Codes

a. New Level II HCPCS Codes – CMS Soliciting Public Comments in the 2020 Final Rule with Comment Period

Unlike the CPT codes that are effective January 1 of the following year, most Level II HCPCS codes that are effective at that time are not known in time to be included in the proposed rule. CMS solicits comments on the new Level II HCPCS codes that will be effective January 1, 2020 in the 2020 OPPS/ASC final rule.

These codes will be flagged with comment indicator “NI” in Addendum B, indicating that CMS has assigned the codes an interim OPPS payment status for 2020. **CMS invites public comment in the 2020 OPPS/ASC final rule on the status indicators, APC assignments, and payment rates for these codes.** Final decisions on these codes in response to comments will be made in the 2021 OPPS/ASC final rule.

b. CPT Codes - CMS Solicited Public Comments in the Proposed Rule

For the 2020 OPPS update, CMS received CPT codes that will be effective January 1, 2020 in time to be included in the proposed rule. CMS assigned comment indicator “NP” to these codes indicating that it was requesting comments on the proposed APC assignment, payment rates and status indicators. (NP indicates that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year. CMS proposed an APC assignment and accepted comments on the proposed APC assignment and status indicator.) CMS finalized the status indicators and APC assignments for these codes in the final rule. Comments and responses on specific codes are summarized in section III. D. IV. B and XII. of this summary.

Because 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 had a placeholder for the fifth character in the proposed rule. The final CPT code numbers are 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 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 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 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 Hospital Outpatient Panel (HOP) recommendations for specific services for the 2020 OPPS and CMS’ responses are discussed throughout the final rule as applicable.

For the 2020 proposed rule, CMS identified the APC with violations of the 2 times rules and proposed changes to the procedure codes assigned to these APCs in Addendum B (identified with comment indicator “CH”). In many cases, the proposed procedure code reassessments and associated APC configurations for 2020 were related to changes in costs of services that were observed in the 2018 claims data.

2. APC Exceptions to the 2 Times Rule

CMS may make exceptions to the 2 times limit on the variation of costs within each APC group in unusual cases, such as low-volume items and services. CMS used the following criteria to decide whether to make exceptions:

- resource homogeneity;
- clinical homogeneity;
- hospital outpatient setting utilization; frequency of service (volume); and
- opportunity for upcoding and fragmenting and billing multiple codes.

CMS notes that in cases in which a recommendation by the HOP appears to result in or a violation of the 2 times rule, CMS generally accepts the HOP's recommendations because the HOP'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.

There were 18 APCs in the proposed rule with a 2 times violation where CMS made an exception. CMS did not receive any comments on the proposed rule 2 times violation exceptions.

Using the final rule claims data, two APCs with 2 times violations were remedied (APC 5672-Level 2 Pathology and APC 5733-Level 3 Minor Procedures) while an additional one was created (APC 5593-Level 3 Nuclear Medicine and Related Services). CMS finalized its proposal to except 16 of the 18 proposed APCs from the 2 times violations for 2020 and the additional one created in the final rule data.

C. New Technology APCs

1. New Technology APC Groups

Currently, there are 52 levels of New Technology APC groups with two parallel status indicators; one set with a status indicator of "S" (S = Significant procedure, not discounted when multiple) and the other set with a status indicator of "T" (T = Significant procedure, multiple reduction applies). The New Technology APC levels range from the cost band assigned to APC 1491 (New Technology – Level 1A (\$0 - \$10)) through the highest cost band assigned to APC 1908 (New Technology – Level 52 (\$145,001 - \$160,000)). Payment for each APC is made at the mid-point of the APC's assigned cost band.

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

One objective of establishing New Technology APCs is to generate sufficient claims data for a new procedure for assignment to a 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. 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 uses the following methodology from the 2019 OPPS final rule (83 FR 58892-58893):

- 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 a clinical 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 in the annual rule 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. Procedures Assigned to New Technology APC Groups for 2020

CMS is continuing its current policy of retaining services within New Technology APC groups until there are sufficient claims data to justify reassignment of the service to a clinical APC. In cases where CMS determines the assignment to the initial New Technology APC is no longer reflective of the technology's costs, CMS 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 to better recognize its costs and also retain a service in a New Technology APC for more than 2 years if there is not sufficient claims data for reassigning a service to a clinical APC.

A common public comment is that Medicare's data does not present accurate costs for procedures that CMS is using to assign a technology to a clinical APC or New Technology APC. In each of these instances, CMS responds it relies on hospitals to accurately report charges on claims and charges and costs on their Medicare hospital cost reports. CMS does not dictate hospital charging practices. This summary does not repeat this same response but readers can assume that CMS responded accordingly each time a concern was raised about hospitals reporting charges or costs inaccurately.

a. Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (APCs 1537, 5114 and 5414). There are 4 CPT/HCPSCS codes for MRgFUS procedures. For 2020, CMS proposed to assign 3 of the codes to clinical APCs and to maintain CPT code 0398T in a New Technology APC. CPT code 0398T was first assigned to a New Technology APC in 2016. CMS has only identified 37 paid claims (1 in 2016, 11 in 2017, and 25 claims in 2018). CMS is concerned about the relatively small number of claims and the fluctuation in the cost of the procedure.

Based on the 37 claims, CMS calculated a geometric mean cost of approximately \$8,829, an arithmetic mean cost of \$10,021, and a median cost of \$11,985. CMS used the arithmetic mean

as the representative cost of CPT code 0398T and proposed maintaining the procedure in APC 1575 (New Technology – Level 38 (\$10,0001-\$15,000)), with a payment rate of \$12,500.50.

Commenters stated that the claims data for CPT code 0398T continues to underestimate the resources used to perform the procedure even when using the low-volume payment policy to establish the payment rate. Costs for another service (HCPCS code C9734) went from \$5,222 in 2017 to \$11,675 in the 2020 proposed rule which commenters argue justifies a higher payment rate for CPT code 0398T. Commenters supported restoring the payment rate from 2018 of \$17,500.50 or raising it to \$22,000 or \$25,000.

CMS responded that the data for another code is not predictive of the change in costs for CPT code 0398T. There were 43 claims for code CPT 0398T for the 3-year period from 2016 through 2018 with a geometric mean cost of \$8,485; arithmetic mean cost of \$9,672, and median cost of \$11,182. Based on the median cost of \$11,182, CMS is assigning CPT code 0398T to New Technology APC 1575 (New Technology - Level 38 (\$10,001-\$15,000)) with a payment rate of \$12,500.50.

b. Retinal Prosthesis Implant Procedure. CPT code 0100T is for implantation of a retinal prosthesis. HCPCS code C1841 is for the retinal prosthesis device (the Argus II). For 2020, CMS has only 35 paid claims for the 4-year period of 2015 through 2018. CMS calculated a geometric mean cost of \$146,059, an arithmetic mean cost of \$152,123, and a median cost of \$151,267. All three estimates of the cost of the Argus II retinal prosthesis procedure fall within the cost band for New Technology APC 1908, with an estimated cost between \$145,001 and \$160,000. CMS proposed to maintain the assignment to APC 1908 (New Technology-Level 52 (\$145,0001-\$152,000)), with a payment rate of \$152.500.50. Public comments supported CMS' proposal. For the final rule, CMS had 41 claims from 2015 through 2018 with a geometric mean cost of \$146,042, arithmetic mean cost of \$151,453 and a median cost of \$151,426. As all of these estimates fall within the same range, CMS is finalizing its proposal of paying at \$152,500.50.

c. Bronchoscopy with Transbronchial Ablation of Lesion(s) by Microwave Energy. Effective January 1, 2019, CMS established HCPCS code C9751 for bronchoscopy with transbronchial microwave ablation for treatment of lung cancer. Based on review of the New Technology APC application and the service's clinical similarity to other services, CMS estimates the cost of the procedure between \$8,001 and \$8,500. CMS has not received any claims for this procedure. For 2020, CMS proposed continuing to assign C9751 to New Technology APC 1571 ((Level 34) (\$8,001 - \$8,500)), with a proposed rate of \$8,250.50. One commenter advised CMS that there will be clinical trials in 2020 and limited market release resulting in 2020 claims. One commenter supported CMS' proposal. CMS is finalizing its proposal without modification.

d. Pathogen Test for Platelets. HCPCS code P9100 is used to report any test that identifies bacterial or other pathogen contamination in platelets. For 2019, this code was assigned to New Technology APC 1493 (Level 1C (\$21 - \$30)), with a payment rate of \$25.50.

CMS has identified 1,100 claims with a geometric mean cost of approximately \$32 for setting the 2020 payment rate. CMS proposed to reassign code P9100 to New Technology APC 1494

(Level 1D (\$31 - \$40)), with a proposed payment of \$35.50. One commenter supported the proposal that CMS is finalizing without modification.

e. Fractional Flow Reserve Derived from Computed Tomography (FFRCT). FFRCT (trade name HeartFlow) is a noninvasive diagnostic service that measures coronary artery disease by CT scans (CPT code 0503T). Although payment for analytics performed after the main diagnostic/imaging procedures are packaged into the payment for the primary procedure, CMS determined in 2018 that HeartFlow should receive a separate payment because the procedure is performed by a separate entity. CMS explains that the provider performing the CT scan does not do the analysis; instead a HeartFlow technician conducts computer analysis offsite. CMS assigned CPT code 0503T to New Technology APC 1516 (Level 16 (\$1,401-\$1500)), with a payment rate of \$1,450.00. CMS notes the developer indicated the price of the procedure was approximately \$1,500.

CMS identified 840 claims with an estimated geometric mean cost of approximately \$788.19 for setting the 2020 payment rate. CMS proposed to reassign CPT code 0503T to New Technology APC 1509 (Level 9) (\$701 - \$800), with a proposed payment of \$750.50.

Commenters expressed concern that CMS proposed a 50 percent reduction for the HeartFlow technology based on a small number of claims from a single year that are unrepresentative of the cost of the technology because the data do not reflect normal charge mark-ups from hospitals. The rate reduction may discourage hospitals from using the service causing some beneficiaries to have unnecessary and costly invasive coronary angiograms. Commenters cited past precedents and asked CMS to use its equitable adjustment authority to use multiple years of claims for low-volume services and set a higher rate for HeartFlow.

With respect to rates in prior years, the rates were set based on data from the manufacturer, not claims data because the product was not yet marketed. The 2020 proposed rule APC assignment was based on 2018 claims data; the first year the service was payable in the OPPS. For the final rule, there are now 957 total claims billed with CPT code 0503T and 101 single frequency claims.

While the number of single frequency claims is just above the threshold to use the low-volume payment policy, CMS still has concerns about the normal cost distribution of the claims used to calculate the payment rate for Heartflow. For this reason, CMS will use the low claims volume methodology to price this technology for 2020. Using 2018 claims for the final rule, CPT code 0503T has a geometric mean cost of \$768.26, an arithmetic mean cost of \$960.12 and a median cost of \$900.28. Based on the arithmetic mean, CMS is assigning CPT code 0503T to Technology APC 1511 (New Technology - Level 11 (\$901 - \$1000)) with a payment rate of \$950.50.

f. Cardiac Positron Emission tomography (PET)/Computed Tomography (CT) Studies. Effective January 1, 2020, CMS proposed to assign CPT codes 78431, 78432, and 78433 for cardiac PET/CT studies to clinical APC 5594 (Level 4 Nuclear Medicine and Related Services). Commenters indicated that CMS has received new technology applications for these services that indicate higher costs than the APC 5594 proposed payment rate of \$1,466.16. Commenters

requested assignment of CPT codes 78431, 78432 and 78433 to APC 1522 (New Technology - Level 23 (\$2501-\$3000)) with a proposed payment rate of \$2,750.50. CMS agreed with these comments and is making the assignments as requested. More information about the APC assignments for these codes is included in section III. D. b.

g. *V-Wave Interatrial Shunt Procedure*. A randomized, double-blinded control IDE study is currently in progress for the V-Wave interatrial shunt procedure. The developer of V-Wave is concerned that the current coding of these services by Medicare would reveal to the study participants whether they have received the interatrial shunt because an additional procedure code, CPT code 93799 (Unlisted cardiovascular service or procedure) would be included on the claims for participants in both the experimental and control group of the study. CMS created a temporary HCPCS code to describe the V-wave interatrial shunt procedure for both the experimental group and the control group in the study (HCPCS code C9758) and assigned the service to New Technology APC 1589 (New Technology - Level 38 (\$10,001-\$15,000)).

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. In some cases, CMS did not have the final code number for the proposed rule and used a placeholder code with an “X” in one of the five positions for the code. For this final rule summary, the final code number rather than the placeholder code is being used to describe CMS’ proposed rule action.

1. *Barostim Neo™ System (APC 5464)*. A medical device company agreed with the reassignment for CPT codes 0266T and 0268T to APC 5464. Claims data show a geometric mean cost of approximately \$25,558 for CPT code 0268T based on 6 single claims (out of 6 total claims), which is consistent with the geometric mean cost of approximately \$28,491 for APC 5464, rather than the geometric mean cost of approximately \$18,864 for APC 5463 where these codes were previously assigned.

2. *Biomechanical Computed Tomography (BCT) Analysis (APCs 5521, 5523, and 5731)*. In the July 2019 OPPS quarterly update CR (Transmittal 4313, Change Request 11318, dated May 24, 2019), CMS assigned these new codes an interim SI and to the APCs shown in Table 17 of the final rule. A commenter agreed with these assignments.

3. *Cardiac Magnetic Resonance (CMR) Imaging (APC 5572)*. For 2020, CMS proposed to maintain the APC assignment for CPT code 75561 to APC 5572 (Level 2 Imaging with Contrast) with a proposed payment rate of \$373.45. Public commenters objected to this APC placement

contending that CMR is grouped with clinically dissimilar procedures like CT of the abdomen and MRI of the neck and spine. They requested a reassignment to APC 5573 with a proposed payment rate of \$682.96. Another commenter expressed concern about the declining rate for APC 5572 from \$426.52 in 2017 to \$373.45 proposed for 2020 that it attributed to faulty cost reporting methods used by hospitals.

CMS responded that claims data for CPT code 75561 show a geometric mean cost of approximately \$413 based on 14,350 single claims (from 18,118 total claims), which is within the range of costs for other procedures in this APC and more comparable to the geometric mean cost of \$359 for APC 5572, rather than \$660 for APC 5573. On the issue of clinical similarity, CMS states that all the procedures in APCs 5111 through 5116 are similar in that they involve some form of musculoskeletal procedure and the levels are differentiated by resource costs.

4. *CardioFlux™ Magnetocardiography (MCG) Myocardial Imaging (APC 5723)*. For 2020, CMS proposed to maintain the APC assignment for CPT code 0541T to APC 5722 (Level 2 Diagnostic Tests and Related Services) with a proposed payment rate of \$256.60. The code has a status indicator of “N” for unconditionally packaged because is an add-on. The code must always be performed with another service. Payment is packaged into the other service. One commenter requested the code be reassigned to APC 5593 (Level 3 Nuclear Medicine) or APC 5724 (Level 4 Diagnostic Tests and Related Services) as more clinically and resource similar arguing that the equipment for this technology is expensive and has a useful life of only 7 years as well on-site costs for implementation and ongoing operation.

CMS disagreed with the comment on the basis that the service is clinically dissimilar to the other services cited by the commenter. Nevertheless, CMS is changing the assignment from APC 5722 (Level 2 Diagnostic Tests and Related Services to APC 5723 (Level 3 Diagnostic Tests and Related Services) in the absence of OPPS claims data based on the anticipated operating costs per case derived from the public comment and publicly available information about the service. The final rule payment rate for APC 5723 is \$485.55.

5. *Cataract Removal with Endoscopic Cyclophotocoagulation (ECP) (APC 5492)*. For 2020, CMS proposed to assign two new codes (66987 and 66988) to APC 5491 (Level 1 Intraocular Procedures) with a proposed payment rate of \$2,053.39. One commenter asked CMS to assign the codes to APC 5492 (Level 2 Intraocular Procedures) while the four professional ophthalmology organizations requested that CMS establish the APC assignment based on the combined costs of CPT codes 66711 and 66982 (66987) and 66711 and 66984 (66988). CMS responded that it does not generally assign codes to APCs based on the combined costs of two services. Nevertheless, it did agree with the commenters to assign the new codes to APC 5492 with a payment rate of \$3,817.90.

6. *Chimeric Antigen Receptor T-Cell (CAR T) Therapy (APCs 5694, 9035, and 9194)*. Chimeric Antigen Receptor (CAR) T-cell therapy is a cell-based gene therapy in which T-cells are collected and genetically engineered to express a chimeric antigen receptor that will bind to a certain protein on a patient’s cancerous cells. The CAR T-cells are then administered to the patient to attack certain cancerous cells and the individual is observed for potential serious side

effects that would require medical intervention. The CAR T products are paid as drugs under Q codes using the average sales price methodology.

Effective January 1, 2019, the AMA created four Category III CPT codes for various steps required to collect and prepare the genetically modified T-cells for CAR T-cell therapy. CMS assigned CPT codes, 0537T, 0538T, and 0539T status indicator “B” to indicate that the services are not paid under the OPPS. CPT code 0540T for the administration of CAR T is separately paid as an outpatient service and assigned to APC 5694 (Level IV Drug Administration) for CY 2019. The HOP Panel recommended that CMS assign a status indicator of “Q1” (conditionally packaged) to the codes for collecting and modifying the patient’s T cells.

Public commenters recommended that CMS assign status indicator “N” (unconditionally packaged), “Q1” or “S” (separately payable) to the CAR-T collection and processing steps. Commenters arguing for the codes to be unconditionally packaged indicated the assignment would ease billing burden and confusion relative to current status indicator assignment of “B.” Those advocating for status indicator “S” believe that separate payment is warranted for distinct procedures ordered and performed by clinicians. Supporter of status indicator “Q1” indicated conditional packaging would be consistent with another service where a tissue sample is drawn from a patient (CPT code 0565T-Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; tissue harvesting and cellular implant creation). Other commenters said CMS should eliminate the language referencing leukapheresis and dose preparation procedures from the drug codes (Q0241 and Q0242).

CMS responded that the services at issue are associated with manufacturing the drug. Medicare does not separately recognize or pay for the steps used in manufacturing a drug. Additionally, CMS says CAR T-cell therapy is a biologic, with unique preparation procedures. It cannot be directly compared to other therapies or existing CPT codes. Although there is no payment associated with 0537T, 0538T, and 0539T, these codes can still be reported to CMS for tracking purposes.

7. Colonoscopy and Sigmoidoscopy with Endoscopic Mucosal Resection (EMR) (APC 5313). CMS proposed to continue to assign CPT codes 45349 and 45390 to APC 5312 (Level 2 Lower GI Procedures), with a proposed payment rate of \$1,024.08. A commenter stated that the two procedures are different from the other procedures currently assigned to APC 5312, and are more similar to procedures assigned to APC 5213. Based on final rule data that shows a geometric mean cost of approximately \$1,941 for CPT code 45349 based on 386 single claims (out of 387 total claims), and a geometric mean cost of about \$2,039 for CPT code 45390 based on 10,212 single claims (out of 10,246), CMS is reassigned these codes to APC 5313 with a payment rate of \$2,343.92. for 2020.

8. Coronary Computed Tomographic Angiography (CCTA) (APC 5571). For 2020, CMS proposed to continue to assign CPT codes 75572, 75573, and 75574 to APC 5571 (Level 1 Imaging with Contrast) with a proposed payment rate of \$179.91. Commenters expressed concern that 2020 is the third consecutive year of decreased reimbursement for cardiac CT. In addition, commenters said CPT codes 75572, 75573, and 75574 require more time than the contrast-enhanced studies in APC 5571, are performed by highly trained technologists, involve

higher risk patients, the administration of vasoactive medications, and close supervision of patients during and after the procedure. These commenters suggested an assignment to APC 5572 (Level 2 Imaging with Contrast) with a proposed payment rate of \$373.45, or APC 5573 (Level 3 Imaging with Contrast) with a proposed payment rate of \$682.96.

CMS declined to make the requested reassessments indicating that there are many years of claims data associated with these services. Claims data from 2018 show a geometric mean cost of approximately \$159 for CPT code 75572 based on 12,299 single claims (out of 23,902 total claims), \$185 for CPT code 75573 based on 323 single claims (out of 466 total claims) and \$196 for CPT code 75574 based on 25,434 single claims (out of 40,219 total claims).

9. Deep Brain Stimulation (DBS) Programming (APC 5742). In 2018, the DBS programming codes were CPT code 95978 (first 60 minutes), which was assigned to APC 5742, with a payment of \$115.18, and CPT code 95979 (each additional 30 minutes), which was packaged as an add-on. For 2019, the CPT deleted codes 95978 and 95979 and replaced them with CPT codes 95983 (first 15 minutes) and 95984 (each additional 15 minutes) effective January 1, 2019. As a result of the coding change, CMS assigned CPT code 95983 to APC 5741 (Level 1 Electronic Analysis of Devices) with a payment rate of \$37.16, and packaged CPT code 95984 as an add-on. This decision effectively reduced payment for 60 minutes of DBS programming from \$115.18 to \$37.16.

The HOP Panel recommended CMS reassign CPT code 95983 to APC 5742. A commenter stated that the reduced payment rate is not appropriate. The overall time and resources expended by a hospital when furnishing this service in the HOPD setting remains the same, even if the units are billed differently. CMS agreed with the commenters and is reassigning CPT code 95983 to APC 5742 and packaging CPT code 95984 as an add-on code. The final rule payment rate for 2020 for APC 5742 is \$113.41.

10. Extracorporeal Shock Wave Lithotripsy (ESWL) (APC 5374). CMS did not propose a change to the APC assignment for ESWL in the 2020 OPPS proposed rule. However, payment for CPT 50590 declined from \$4,055 in 2018 in APC 5375 to \$2,952 in 2019 in APC 5374. For 2020, the proposed payment rate for CPT code 50590 in APC 5374 was \$3,059.21.

Commenters requested that CMS restore the code to APC 5375 on the basis that it is similar to two ureteroscopy with lithotripsy (URSL) procedures that are assigned to APC 5375. The URSL codes require an indwelling ureteral stent that can lead to infection, visits to the emergency department and unplanned admissions. Commenters are concerned that CMS' payment for CPT 50590 being too low may lead to more use of URSL and an increase in inpatient admissions. There were further comments that the cost of capital equipment should result in a higher APC payment, CMS should add the cost of a ureteral stent to the payment amount and concerns that hospitals are reporting charges and costs for ESWL incorrectly.

CMS disagrees and said that its data supports the assignment of CPT code 50590 to APC 5374. The geometric mean cost for APC 5374 is about \$2,953 while APC 5375 shows a geometric mean cost of approximately \$4,140. URSL has costs (\$3,740 and \$4,361) that are more aligned with APC 5375 with geometric mean costs between \$3,575 and \$5,655. While all of the

procedures treat kidney stones, the clinical differences between URSL and ESWL may be accounting for differential resources costs that are shown in the Medicare cost data. CMS declined to add the cost of a ureteral stent to Medicare's payment as it believes this cost would be included in the cost data hospitals report to CMS to determine payment.

11. Extravascular Implantable Cardioverter Defibrillator (EV ICD). CMS assigned CPT codes 0571T through 0580T status indicator "E1" (not paid by Medicare) as these services are investigational. One commenter indicated that the device associated with these codes received FDA approval for an investigational device exemption (IDE) Category B designation. An application for national coverage for the clinical trial as a Category B IDE study is pending. The commenter requested that a crosswalk to comparable procedures involving ICD placement so that appropriate hospital outpatient payment may be made in the event the Category B IDE study is approved for Medicare coverage. CMS is finalizing its proposal without modification but will reconsider this decision if Medicare approves the clinical trial as a Category B IDE study.

12. Genicular and Sacroiliac Joint Nerve Injections/Procedures (APCs 5442 and 5431). For 2020, CPT established four new codes to describe genicular and sacroiliac joint nerve injections and procedures. CMS proposed to assign CPT codes 64451 and 64454 to APC 5442 (Level 2 Nerve Injections) with a proposed payment rate of \$627.39; CPT code 64624 to APC 5443 (Level 3 Nerve Injections) with a proposed payment rate of \$808.58; and CPT code 64625 to APC 5431 (Level 1 Nerve Procedures) with a proposed payment rate of \$1,747.26.

Commenters asked CMS to assign CPT code 64624 to APC 5431 with similar radiofrequency ablation procedures. CPT code 64624 involves the destruction of three nerve branches at three locations in the knee, and the destruction is typically done via radiofrequency ablation similar to the other procedures cited (CPT codes 64633 and 64635). CMS agrees that this new procedure shares similar characteristics with CPT codes 64633 and 64635 that are assigned to APC 5431. The proposed policy is being finalized with a modification to assign CPT code 64624 to APC 5431.

13. FemBloc® and FemChec®. CMS proposed to assign new codes for FemBloc (0567T) to APC 5414 (Level 4 Gynecologic Procedures) with a payment rate of \$2,564.60 and FemChec (0568T) to APC 5732 (Level 2 Minor Procedures) with a payment rate of \$34.33. One commenter requested that both codes be assigned to higher paying APCs. However, CMS states that it discovered both of these codes are associated with products that are not FDA approved and are in clinical trials. For this reason, CMS is assigning a status indicator of "E" and not allowing Medicare payment.

14. Hemodialysis Arteriovenous Fistula (AVF) Procedures (APC 5194). CMS established HCPCS code C9754 for the Ellipsys® System and C9755 for the WavelinQTM System effective January 1, 2019. Both HCPCS codes were assigned to APC 5193 (Level 3 Endovascular Procedures) with a payment rate of 9,669.04 for 2019. For 2020, CMS proposed to continue to assign HCPCS codes C9754 and C9755 to APC 5193 with a proposed payment rate of \$10,013.25.

A presenter at the HOP estimated conservatively that the procedure will cost estimate over \$12,500 and payment for 35 procedures at the presenter's hospital ranged from \$,3410 to \$11,247. One comment provided data from the 1st quarter of 2019 showing geometric mean costs of \$12,960. Several physicians stated that the current payment rate does not cover the cost of the procedure and requested the reassignment of both HCPCS code C9754 and C9755 to APC 5194 (Level 4 Endovascular Procedures) with a proposed payment rate of \$16,049.73. The HOP did not make a recommendation on the APC placement of these codes. CMS agreed with the commenters and is revising the APC assignment for HCPCS code C9754 and C9755 to APC 5194 for 2020. The final payment for 2020 will be \$15,938.20.

15. Hemodialysis Duplex Studies (APCs 5522 and 5523). For 2020, the CPT Editorial Panel established CPT codes 93985 and 93986 to replace HCPCS code G0365. CMS proposed to assign CPT code 93985 and 93986 to APC 5522 (Level 2 Imaging without Contrast) with a proposed payment rate of \$111.04. Several commenters recommended assigning CPT code 93985 from APC 5522 to APC 5523 (Level 3 Imaging without Contrast) with a proposed payment rate of \$231.28. The code represents a bilateral study that should be assigned to APC 5523 with similar bilateral/complete duplex studies. CMS agrees and is assigning the code to APC 5523. It received no comments on CPT code 93986.

16. Intraocular Procedures (APCs 5491 through 5494). In prior years, CPT code 0308T was assigned to APC 5495 (Level 5 Intraocular Procedures) based on its estimated costs. In addition, its payment has been based on its median cost under the payment policy for low volume device-intensive procedures. For 2019, CMS assigned CPT code 0308T to the APC 5494 (Level 4 Intraocular Procedures) based on data for a single claim. However, this decision resulted in the ASC payments being higher than the OPPS payment because of the intersection of the C-APC methodology under the OPPS and the device intensive methodology under the ASC payment system.

To fix this discrepancy, CMS proposed to reestablish recently eliminated APC 5495 (Level 5 Intraocular Procedures) to reflect the estimated costs of 0308T. CMS further proposed to assign the code to APC 5495 based on the median cost of the procedure given its very low volume of Medicare claims. Commenters supported the change. The final payment rate in 2020 for APC 5495 will be \$20,673.31

17. Long-Term Electroencephalogram (EEG) Monitoring Services (APCs 5722, 5723, and 5724). For 2020, the CPT deleted four long-term EEG monitoring service codes and replaced them with 23 new CPT codes (10 physician interpretation and 13 technical component codes). In the 2020 proposed rule, CMS assigned the 13 technical component codes (CPT codes 95700-95716), to either APC 5722 (Level 2 Diagnostic Tests and Related Services) with a proposed payment rate of \$256.60 or APC 5723 (Level 3 Diagnostic Tests and Related Services) with a proposed payment rate of \$486.65. The 10 physician interpretation codes are only paid under the PFS and not the OPPS.

Many commenters stated the proposed APC assignments for CPT codes 95712, 95713, 95715, and 95716 does not appropriately reflect the resources and time required to monitor complex

epilepsy patients. Several other commenters recommended the reassignment of CPT codes 95712 and 95713 to APC 5723 and stated they should be paid approximately half the rate of the 24-hour video EEG services. These same commenters requested that CPT codes 95715 and 95716 be assigned to APC 5724 with a proposed payment rate of \$920.66 since patients being tested may be receiving observation services and will not be admitted to the hospital.

CMS believes the resources and time associated with intermittent monitoring (CPT code 95712) every two hours are less than that of continuous monitoring (CPT code 95713). CMS believes it would be appropriate to modify the APC assignment for the continuous monitoring codes (CPT codes 95713 and 95716) to APC 5723 and APC 5724 respectively. CMS is finalizing its proposal with a modification to assign CPT 95713 to APC 5723 with a final payment rate of \$485.55 and CPT code 95716 to APC 5724 with a final payment rate of \$908.84.

18. Musculoskeletal Procedures (APCs 5111 through 5116). CMS is continuing to maintain a six-level structure for the Musculoskeletal APCs while continuing to review the structure of these APCs to determine whether additional granularity would be necessary. It did not propose any structural changes to the musculoskeletal APCs.

In 2018, CMS removed CPT code 27447 (total knee arthroscopy or TKA) from the IPO list. As 2018 claims are used to determine 2020 APC assignments, CMS reviewed data for the approximately 60,000 hospital outpatient claims reporting the procedure. The geometric mean cost was approximately \$12,472.05, which is similar to the geometric mean cost for APC 5115 (Level 5 Musculoskeletal Procedures) of \$11,879.66 where TKA is assigned. CMS did not propose a change to TKA's APC assignment.

For 2020, CMS is removing CPT code 27130 (Total hip arthroplasty or THA) from the IPO list. The 50th percentile IPPS payment for TKA/THA procedures without major complications or comorbidities (MS-DRG 470) is approximately \$11,900 for FY 2020 when the procedure is performed on an inpatient basis. Therefore, CMS proposed to assign CPT code 27130 to the Level 5 Musculoskeletal Procedures APC that has a geometric mean cost of \$11,879.66.

The only comment CMS received on the musculoskeletal APCs requested that CMS reconsider the assignment of CPT code 22869 to APC 5115 and instead allow the code to remain in APC 5116. Commenters believe CMS' proposal is based on inaccurate data and once hospital billing errors are resolved, costs for this code will return to historical levels. CMS is finalizing the proposed reassignment of CPT code 22869 to APC 5115 without change.

19. Nuclear Medicine Services

Cardiac Positron Emission tomography (PET)/Computed Tomography (CT) Studies (APCs 1522, 1523, and 5594). For 2020, CPT established six new codes (78429, 78430, 78431, 78432, 78433, and 78434) to describe cardiac PET/CT studies. Several commenters recommended that CPT code 78429 not be assigned to APC 5593 as CMS proposed but instead to APC 5594. They stated that APC 5593 does not recognize the additional cost associated with

the CT scan that is included in the service. CMS agrees and is assigning CPT code 78429 to APC 5594.

Several commenters indicated that CMS received a new technology application for CPT codes 78431, 78432, and 78433 that details the costs associated with providing these services. For CPT code 78431, 78432 and 78433, the commenters disagreed with the proposed APC placement and recommended changing its assignment from APC 5594 (Level 4 Nuclear Medicine and Related Services) with a proposed payment rate of \$1,466.16 to APC 1522 (New Technology - Level 23 (\$2501-\$3000)) with a proposed payment rate of \$2,750.50. CMS agrees and is revising the APC assignment for CPT codes 78431, 78432, and 78433 from APC 5594 to APC 1522, and reassigning CPT codes 78432 and 78433 from APC 5594 to APC 1523.

Single-Photon Emission Computed Tomography (SPECT) Studies (APCs 5591, 5593, and 5594). For 2020, CMS proposed to continue assigning CPT codes 78800 and 78801 to APC 5591 with a proposed payment rate of \$372.69, CPT codes 78802 and 78804 to APC 5593 with a proposed payment rate of \$1,293.33, and CPT code 78803 to APC 5592 with a proposed payment rate of \$482.38. CMS proposed to assign new CPT codes 78830 and 78831 to APC 5593, and 78832 to APC 5594. As new CPT code 78835 is an add-on code, it is unconditionally packaged with the primary care.

Several commenters disagreed with the assignment for CPT code 78803 and requested it be assigned to APC 5593 because this one code will replace seven SPECT codes that will be deleted on December 31, 2019. Several commenters indicated that APC 5592 would not account for the deleted SPECT codes and recommended using a weighted average of the prior codes to determine an appropriate geometric mean cost for 78803. Based on their calculation, the geometric mean cost for the code should be \$784.18, which is higher than the approximately \$462 geometric mean cost for APC 5592, and more consistent with the geometric mean cost for APC 5593.

CMS responded that its analysis showed that the range of geometric mean costs for CPT code 78803 and the seven deleted codes is between \$433 and \$1,417. Several of the deleted codes were assigned to APC 5593. Based on its review of these codes, CMS believes it would be appropriate to assign CPT code 78803 to APC 5593.

Some commenters disagreed with the assignment of CPT code 78804 to APC 5593, and stated that the APC assignment does not adequately capture the cost of multiple SPECTs provided. The commenters indicated that it would not make sense to continue to assign single and full sets of studies to the same APC and urged CMS to reassign the code to APC 5594. CMS disagreed indicating that its claims data show a geometric mean cost of approximately \$1,298 for CPT code 78804 based on 1,656 single claims (out of 2,961 total claims). The more accurate assignment is to APC 5593 that has a geometric mean cost of \$1,245 compared to the geometric mean cost of approximately \$1,412 for APC 5594.

Several commenters opposed the APC assignment for CPT code 78831 to APC 5593. They indicated that the proposed APC assignment for CPT code 78831 does not adequately reflect the resources required to perform the procedure and it should be reassigned to APC 5594. CMS

responded that CPT code 78831 shares similar characteristics and resources to existing CPT code 78804. Consequently, it assigned the new code to APC 5593, which is the same APC assignment for CPT 78804.

In summary, CMS is finalizing its proposal without modification for CPT codes 78800, 78801, 78802, 78804, 78830, 78831, 78832, and 78835. It is assigning CPT code 78803 to APC 5593 for 2020.

20. Radiofrequency Spectroscopy (MarginProbe). CMS proposed to assign CPT code 0546T status indicator "N" (unconditionally packaged) as it is an intraoperative service. Payment is packaged into the primary surgical procedure. Several commenters requested separate payment for CPT code 0546T. One commenter stated that CPT code 0546T is a distinct procedure with a beginning, middle, and end. The cost of the procedure is not included in the primary surgical procedure. According to the commenter, CMS has previously stated that it has the discretion not to package an intraoperative service:

To the extent that a service for which New Technology APC status is being requested is ancillary and supportive of another service, for example, a new intraoperative service or a new guidance service, we might not consider it to be a complete service because its value is as part of an independent service. However, if the entire, complete service, including the guidance component of the service, for example, is 'truly new,' as we explained that term at length . . . we would consider the new complete procedure for New Technology APC assignment." (72 FR 66621)

The commenter also indicated that, at its September 2018 meeting, the CPT Editorial Panel determined that radiofrequency spectroscopy is a stand-alone service and, therefore, issued a unique code, specifically, CPT code 0546T to be effective July 1, 2019.

CMS responded that intraoperative items and services are packaged under the OPPS. Because intraoperative services support the performance of an independent procedure furnished at the same time, CMS packages the payment for the radiofrequency spectroscopy into the OPPS payment for the primary surgical procedure. It further adds that the establishment of a new CPT code does not indicate that a code is always a stand-alone procedure or service. The current CPT code set lists hundreds of add-on codes that do not describe stand-alone services. CMS is finalizing its proposal without modification.

21. Reflectance Confocal Microscopy (RCM). For CY 2020, CMS proposed to continue to assign CPT code 96932 status indicator "Q1" (conditionally packaged) and to APC 5731 (Level 1 Minor Procedures) with a proposed payment rate of \$23.57. CPT established six codes to describe the services associated with RCM. One commenter attributed the low payment rate for CPT code 96932 to misreporting of charges by one of two hospitals that bills for this service. The commenter stated that the cost of performing the imaging service is about \$128, which is more than the proposed payment rate of \$23.57. CMS should use its equitable adjustment authority to either:

- Reassign the code to APC 5522 (Level 1 Imaging without Contrast) with a proposed payment rate of \$111.04;
- Reassign the code to New Technology APC 1503 (New Technology - Level 3 (\$101 - \$200) with a proposed payment rate of \$150.50; or
- Assign an unconditionally packaged ("N") or non-payable status indicator to the code, similar to the other RCM codes.

The last option was suggested to avoid the PFS cap at the OPPS payment amount. Based on its review of the issue, CMS agrees with the commenter and is revising the OPPS status indicator assignment for CPT code 96932 from "Q1" to "N" consistent with the status indicator assignment for several other RCM codes. This change will result in services not being capped at the OPPS rate under the PFS based on the very low volume of services billed under the OPPS.

22. *remedē® System - Transvenous Phrenic Nerve Stimulation Therapy (APCs 5461 5464, 5724, and 5742)*. For the 2020 update, CMS proposed to reassign CPT codes 0426T and 0431T from APC 5463 (Level 3 Neurostimulator and Related Procedures) with a proposed payment rate of \$19,370.82 to APC 5464 (Level 4 Neurostimulator and Related Procedures) with a proposed payment rate of \$29,025.99. In addition, CMS proposed to continue to assign CPT code 0427T to APC 5463.

A commenter suggested maintaining the current assignment for CPT code 0426T rather than reassigning it from APC 5463 to APC 5464 because the resources required for the procedure are more closely aligned with the procedures in APC 5463. CMS agreed. CPT code 0426T describes the insertion or replacement of the stimulation lead associated with a neurostimulator system for the treatment of central sleep apnea, and APC 5463 includes other procedures that involve the insertion or replacement of a stimulation lead for a neurostimulator system.

The commenter also stated that CPT code 0427T is for the initial insertion of an implantable pulse generator when the full system cannot be implanted for a patient. The procedure does not occur frequently. The hospital resources associated with CPT code 0427T are very similar to CPT code 0431T, which is assigned to APC 5464. The commenter recommended the assignment of both procedures to APC 5464. CMS agreed. It is modifying the proposal and reassigning CPT code 0427T to APC 5464.

In summary, CMS is finalizing its proposal for to assign CPT code 0431T to APC 5464 but is maintaining the APC assignment for CPT code 0426T in APC 5463, and reassigning CPT code 0427T to APC 5464.

23. *Surgical Pathology Tissue Exam (APC 5673)*. In 2019, CMS assigned CPT code 88307 to APC 5673 (Level 3 Pathology) with a payment rate of \$274.22. For 2020, CMS proposed to reassign the code to APC 5672 (Level 2 Pathology) with a proposed payment rate of \$148.62. A commenter disagreed with the proposed reassignment and urged CMS to continue to assign CPT code 88307 to APC 5673 to avoid a resource cost rank order anomaly with other services. Further, the physician fee schedule technical component service is more than six times the proposed OPPS rate suggesting a problem with the cost data CMS is using to set the OPPS rate.

Based on the latest hospital outpatient claims data used for this final rule with comment period, we agree with the commenter that the code should continue to be assigned to APC 5673 for 2020. Specifically, CPT code 88307 shows a geometric mean cost of approximately \$219, which is more appropriate in APC 5673 that has a geometric cost of approximately \$277 compared to the geometric mean cost of about \$140 for APC 5672. Consequently, CMS is maintaining the APC assignment for CPT code 88307 in APC 5673 for 2020.

24. Urology Procedures.

a. HIFU Procedure - High-Intensity Focused Ultrasound of the Prostate (APC 5375). In 2017, CMS approved a new technology application and created a new code (HCPCS C9747) for prostate HIFU. Based on the estimated cost provided in the new technology application, CMS assigned the code to APC 5376 (Level 6 Urology and Related Services) with a payment rate of \$7,452.66 effective July 1, 2017. CMS first had claims for the procedure for the 2019 OPPS update and revised the APC assignment for HIFU to APC 5375 with a payment rate of \$4,020.54. For 2020, CMS proposed to continue to assign HCPCS code C9747 to APC 5375 with a proposed payment rate \$ 4,286.06.

Several commenters recommended a reclassification to APC 5376 because they believed the service is clinically similar and comparable in terms of resources to cryoablation of the prostate (CPT code 55873) with a proposed payment rate of \$8,193.30. The commenters believe that the geometric mean cost, and ultimately, the APC determination for the prostate HIFU procedure was based on inaccurate hospital costs. They believed that the average cost of the procedure should be approximately \$6,250.

CMS disagrees. The final rule data supports maintaining HCPCS code C9747 in APC 5375 as the geometric mean cost is approximately \$5,850 based on 264 single claims (out of 268 total claims). The geometric mean cost for APC 5375 is \$4,140 for APC 5375 compared to a geometric mean cost of approximately \$7,894 for APC 5376. Cryoablation of the prostate has a geometric mean cost of about \$8,152 based on 1,417 single claims (out of 1,429 total claims). CMS is finalizing its proposal without modification.

b. ProACT Procedure - Transperineal Periurethral Adjustable Balloon Continence Device Procedure (APCs 5371, 5374, 5375, and 5376). In 2017, CMS created HCPCS code C9745 under a new technology approval for the transperineal periurethral adjustable balloon continence device procedure (ProACT therapy). Based on the estimated cost for the bilateral placement of the balloon continence devices, CMS assigned the code to APC 5377 (Level 7 Urology and Related Services) with a payment rate of \$14,363.61 effective July 1, 2017.

In July 2019, CPT established codes 0548T, 0549T, 0550T, and 0551T to describe the transperineal periurethral adjustable balloon continence device procedure. For 2020, CMS proposed to assign CPT code 0548T (the successor code to HCPCS code C9746) to APC 5376. In addition, CMS proposed to assign CPT codes 0549T, 0550T, and 0551T to APCs 5375, 5374, and 5371, respectively.

One commenter suggested not changing the APC assignment for CPT code 0548T arguing that

the calculated geometric mean cost does not accurately reflect the actual cost of the procedure. The commenter noted there were only two claims in the 2018 charge data—one with a cost of \$16,250 and the other one with a cost of \$0. The commenter also requested a requested a reassignment from APC 5375 to APC 5376 for CPT code 0549T.

CMS responds that the 2020 data used for the final rule supports its reassignment of CPT code 0548T. Predecessor code C9746 has a geometric mean cost of approximately \$9,504 based on 7 single claims (out of 7 total claims), which is most comparable to the geometric mean cost of about \$7,894 for APC 5376, rather than the geometric mean cost of approximately \$17,195 for APC 5377. CMS further disagrees with comment opposing the revised APC assignment for CPT code 0549T (unilateral placement of the balloon continence device) from APC 5375 to APC 5376. The cost associated with CPT code 0549T should be less than that of CPT code 0548T since CPT code 0549T describes the use of only one device. CMS is finalizing its proposals without modification.

c. Rezum Procedure - Transurethral High Energy Water Vapor Thermal Therapy of the Prostate (APC 5373) Effective January 1, 2018, CMS created HCPCS code C9748 under a new technology for the transurethral radiofrequency generated water vapor thermal therapy of the prostate (the Rezum procedure), and established HCPCS code C9748. CMS assigned HCPCS code C9748 to APC 5373 (Level 3 Urology and Related Services) with a payment rate of \$1,695.68. CPT established code 53854 for the Rezum procedure effective January 1, 2019. CMS assigned CPT 53854 to APC 5373 with a 2019 payment rate of \$1,739.75. For 2020, CMS proposed to maintain the APC assignment for CPT code 53854 to APC 5373 with a proposed payment rate of \$1,797.97.

Several commenters requested a reclassification for CPT code 53854 from APC 5373 to APC 5374 (Level 4 Urology and Related Services) with a proposed payment rate of \$3,059.21. The commenters stated that the Rezum procedure is most clinically similar to CPT code 53850; the transurethral microwave therapy (TUMT) and 53852; transurethral needle (radiofrequency) ablation (TUNA). Some commenters reported that the primary difference between each of these codes is the energy source used to destroy or shrink the prostate tissue (microwave energy, radiofrequency energy or radiofrequency generated water vapor thermotherapy).

CMS responded that its claims data show a geometric mean cost of approximately \$1,899 for the predecessor HCPCS code C9748 based on 191 single claims (out of 192 total claims). The geometric mean cost for the Rezum procedure is more similar to the geometric mean cost of \$1,733 for APC 5373 rather than APC 5374 that has a geometric mean cost of approximately \$2,953. TUMT has a geometric mean cost of approximately \$2,851 based on 41 single claims (out of 41 total claims). TUNA has a geometric mean cost of about \$3,027 based on 513 single claims (out of 514 total claims). In both cases, the resource costs for the TUMT and TUNA procedures are much higher than those of the Rezum procedure.

CMS is finalizing its proposal without modification.

d. VaporBlate Procedure - Transurethral Radiofrequency Generated Water Vapor Thermal Therapy of the Prostate. CMS proposed to assign CPT code 0582T status indicator “E” (not payable) because the service is investigational and not covered by Medicare. One commenter indicated that the technology associated with this new code was designated by the FDA as a Category B IDE on August 29, 2019 and the manufacturer is in the process of applying for Medicare coverage of the Category B IDE clinical trial. In the event the clinical trial is approved by Medicare, the commenter argued that the technology has a higher cost than Rezum and should be assigned to either APC 5190 (New Technology - Level 39 (\$15,001-\$20,000)) with a proposed payment rate of \$ 17,500.50; or APC 5377 (Level 7 Urology and Related Services) with a proposed payment rate of \$17,465.94. CMS responded that the VaporBlate procedure does not yet meet its standards for coverage. It is finalizing its proposal to assign status indicator “B” that will not allow Medicare Part B payment for the technology.

IV. OPPS Payment for Devices

A. Pass-Through Payments for Devices

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

CMS follows the statutory requirements that a category of devices is eligible for transitional pass-through payments for at least 2, but not more than 3 years. To allow a pass-through payment period that is as close to a full 3 years as possible, in the 2017 OPPS final rule (81 FR 79655), CMS finalized a policy change to allow for quarterly expiration of pass-through payments status for devices. This policy began with pass-through devices approved in 2017. Except for brachytherapy sources, for devices that are no longer eligible for pass-through payments, CMS packages the costs of the devices into the procedures with which the devices are reported in the claims data used to set the payment rates.

Currently, there is one device category eligible for pass-through payment: HCPCS code C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), with an eligibility date of January 1, 2019. The pass-through status of the device category for C2624 expires on December 31, 2021 and C1822 will continue to receive device pass-through payments in 2020.

2. New Device Pass-Through Applications

a. Background

Criteria for New Device Pass-Through Applications.

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

- I.** 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.

As discussed below in section IV.A.4, CMS finalizes its proposal for an alternative pathway for OPPS device pass-through payment applications for devices approved under the FDA Breakthrough Device Program for OPPS device pass-through payment applications.

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 2020

CMS received seven applications by the March 1, 2019 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 2019 quarters (June 1, September 1, and December 1) will be discussed in the 2021 OPPS/ASC proposed rule. Detailed instructions for submission of an application are on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf>.

CMS approves device pass-through payment status beginning January 1, 2020 for the following:

- Surefire® Spark™ Infusion System
- Optimizer® System
- AquaBeam and
- AUGMENT® Bone Graft

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

1. Surefire® Spark™ Infusion System

TriSalus Life Sciences submitted an application for the Surefire® Spark™ Infusion System, a pliable microcatheter with a self-expanding, nonocclusive one-way microvalve at the distal end used to infuse a high dose of chemotherapy into liver tumors. According to the applicant, the system creates an increase in pressure during infusion, opening up collapsed vessels in tumors which enables perfusion and therapy delivery in areas otherwise inaccessible to the circulation. Real-time fluoroscopic guidance is used to navigate the device into the blood vessels to infuse a high dose of chemotherapy into liver tumors.

Newness. The Surefire® Spark™ Infusion System received FDA 510(k) premarket clearance on April 3, 2018. CMS received the application on November 29, 2018 which is within 3 years of the date of the initial FDA clearance.

Eligibility. According to the applicant, the Surefire® Spark™ Infusion System meets all the eligibility requirements. CMS agrees.

Criteria established at §419.66(c).

Existing payment category. CMS identified two existing pass-through payment categories that may be applicable to the Surefire® Spark™ Infusion System. HCPCS codes C1887 (Catheter, guiding (may include infusion/perfusion capability)) and C1751(Catheter, infusion, inserted peripherally, centrally or midline (other than hemodialysis)).

The manufacturer of the device did not believe there is an existing pass-through category applicable to the Surefire® Spark™ System because the existing categories do not appropriately describe catheters with a pressure-enabled drug delivery (PEDD) valve, a key mechanism of the system. According to the manufacturer the PEDD valve is closely associated with differential and improved outcomes as compared to catheters without PEDD valves. Based on this information, CMS believes the Surefire® Spark™ System meets the eligibility criterion.

Substantial clinical improvement. The applicant claimed that the Surefire® Spark™ Infusion System is a substantial clinical improvement over existing technologies because the pressurized delivery of therapy opens up collapsed vessels in tumors and enables therapy delivery into hypoxic areas of liver tumors. CMS summarized the findings from four studies: a pilot study of nine patients; a single center retrospective study of 22 patients; a case-control series of 19 patients; and a multi-center registry of 72 patients.

CMS was concerned that the studies have small sample size, follow-up is limited to 3 to 6-month timeframe, and outcomes are primarily focused on imaging (tumor response rates and lesion size) and not on mortality endpoints. The manufacturer responded to CMS' concerns and noted that the population size in the studies is normal for a new and innovative technology. The manufacturer stated that the studies are methodologically rigorous and show statistically significant differentiation from comparators. The manufacturer noted that overall survival is not

an appropriate endpoint for hepatocellular carcinoma and cited National Comprehensive Cancer Network (NCCN) guidelines, noting that tumor necrosis and pathological response are primary predictors of success in these cases. Multiple commenters stated that the Surefire® Spark™ System provided substantial clinical benefit over conventional therapy.

After consideration of the comments received, CMS determines that the Surefire® Spark™ System meets the substantial clinical improvement criterion.

Cost. CMS believes the Surefire® Spark™ Infusion System meets all the cost criteria. CMS approves the Surefire® Spark™ Infusion System for device pass-through payment status beginning January 1, 2020.

2. *TracPatch*

TracPatch is described as a 24/7 remote monitoring wearable device which utilizes an accelerometer, temperature sensor and a step counter. Bluetooth connectivity allows the device to be paired with any smartphone and the TracPatch cloud allows for unlimited data collection and storage. A web dashboard and computer application allow a health care provider to access the information and monitor a patient pre- and post- operative total knee surgery.

Newness. The applicant stated that TracPatch does not need FDA clearance because it is a Class I device that would be assigned to a generic category of devices described in the Code of Federal Regulations (21 CFR parts 862 through 892). Because TracPatch will be introduced into the market in 2019, the applicant stated it would be within 3 years of submission of the device pay-through payment application.

The manufacturer clarified that as of August 28, 2019, TracPatch was registered with FDA as a Class I Exempt goniometer. CMS determines that Trac Patch meets the newness criterion.

Eligibility. According to the applicant, TracPatch is an integral part of monitoring knee range of motion, is used for only one patient, and is placed on the skin by Velcro strips. The applicant also claims the device meets the requirements of §419.66(b)(4). CMS was concerned that TracPatch does not meet the eligibility criterion because the device is not surgically implanted or inserted into the patient or applied to a wound or other skin lesions.

CMS states the manufacturer provided more information about the device but did not provide any evidence that TracPatch is surgically implanted or inserted into a patient or is applied in a wound or on other skin lesions. CMS notes that the descriptor of the Class I Exempt goniometer on the FDA product classification webpage states that the goniometer is not an implantable device.

After consideration of the information, CMS determines that TracPatch does not meet the basic eligibility criterion for transitional pass-through status. Because of this determination, CMS did not evaluate the product to determine whether it meets the other criteria required for transitional pass-through payment for devices. CMS does not approve pass-through payment status for this device.

3. *Vagus Nerve Stimulation (VNS) Therapy® System for Treatment Resistant Depression (TRD)*

LivaNova USA Inc. submitted an application for the VNS Therapy® System, an implantable device used for the treatment of TRD. According to the applicant, the system consists of two implantable components: a programmable electronic pulse generator and a bipolar electrical lead that is connected to the programmable electronic pulse generator. A hand-held programmer programs the pulse generator simulation parameters. The applicant stated the system provides indirect modulation of brain activity through the stimulation of the vagus nerve which is believed to alter brain networks and treat psychiatric diseases.

Newness. The applicant received FDA clearance for the VNS Therapy® System for TRD through the PMA process on July 15, 2005 and the VNS Therapy® for TRD was introduced to the market in September 2005. A national coverage determination (NCD 160.18) released on May 4, 2007 prohibited Medicare coverage for the use of the device for TRD. On February 15, 2019, CMS approved coverage with evidence development (CED) studies for VNS Therapy® for TRD. CMS stated that the regulations require a pass-through payment application must be received within 3 years of when the device either received FDA approval or was introduced to the market; this is independent of Medicare coverage. CMS noted that the payment application would have needed to have been submitted to CMS by September 2008.

CMS was also concerned that the neurostimulator device for the VNS Therapy® is the same device that has been used since 1997 to treat epilepsy.⁵ Although the applicant discussed the differences between the two devices, CMS was concerned that these differences do not demonstrate that the actual device used to treat TRD is any different than the device used to treat epilepsy.

CMS summarizes the comments made by the manufacturer supporting why the VNS Therapy® System for TRD meets the newness criterion. CMS disagrees with the manufacturer's comments and does not believe the manufacturer provided evidence to demonstrate that the neurostimulator device for the VNS Therapy® is not similar to the neurostimulator device used since 1997 to treat epilepsy. Another commenter did not believe that the technical improvements with the VNS Therapy® System for TRD were not substantial enough to establish the device as a new device that meets the newness criterion.

CMS also disagrees with the manufacturer's comments that the intent of the newness criterion described in the 2016 OPPS final rule (80 FR 70418 - 70420) implies that the requirement for a device to be available in the market for less than three years would be suspended if the device was unavailable in the market due to national non-coverage. CMS states this comment does not align with the language of §419.66(b)(1) which requires the device pass-through application must be received within 3 years from the date of market availability and makes no exception for periods of national non-coverage. CMS determines that the VNS Therapy® System for TRD does not meet the newness criterion.

⁵ Current Behavioral Neuroscience Reports. 2014 June; 1(2): 64-73.

Eligibility. According to the applicant, the VNS Therapy® meets all the eligibility requirements. CMS agrees that the device meets the criterion described by §419.66(b)(4).

Criteria established at §419.66(c).

Existing payment category. The applicant suggested a category descriptor of “Generator, neurostimulator (implantable), TRD, non-rechargeable. CMS noted that the device category represented by HCPCS code C1767 is described as “Generator, neurostimulator (implantable), non-rechargeable” and includes the device category descriptor for VNS Therapy®. The applicant asserted that this device category descriptor for C1767 is too broad and the VNS Therapy® should have a separate code. In response to the applicants request for a new device category based on a beneficiary’s diagnosis, CMS stated the OPPS does not differentiate payment by diagnosis.

In comments, the applicant asserted that the VNS Therapy® for TRD is not described by any of the existing device categories in the OPPS. CMS disagrees and determines that the device does not meet the requirements of §419.66(c)(1) and the device eligibility criterion.

Because CMS determines that the VNS Therapy® System for TRD does not meet either the newness criterion or the device category eligibility criterion for transitional pass-through payment status, it did not evaluate this device to determine whether it meets the other criteria. CMS does not approve pass-through payment status for this device.

4. Optimizer® System

Impulse Dynamics submitted an application for the Optimizer® System, an implantable device used for treating patient with chronic, moderate-to-severe heart failure by restoring a normal timing pattern of the heartbeat. According to the applicant, the device is indicated for patients who are not suited for treatment with other heart failure devices.

Newness. The Optimizer® System received a Category B-3 Investigational Device Exemption (IDE) from the FDA on April 6, 2017 and received its PMA on March 21, 2019. CMS received the application for a transitional pass-through on February 26, 2019 which is within 3 years of the date of FDA approval.

Eligibility. According to the applicant, the Optimizer® System meets all the eligibility requirements. CMS agrees.

Criteria established at §419.66(c).

Existing payment category. CMS has not identified an existing pass-through payment category that describes the Optimizer® System and it meets the device category eligibility criterion.

Substantial clinical improvement. According to the applicant, the Optimizer® System improves clinical outcomes for patients with moderate-to-severe chronic heart failure by improving exercise tolerance, quality of life, and functional status of patients. The applicant claims that the

Optimizer® System meets an unmet need because there is no therapeutic medical device therapy for the 70 percent of heart failure patients with New York Heart Association (NYHA) Class III heart failure, normal QRS duration and reduced ejection fraction. CMS discussed the studies submitted to support these claims. CMS had several concerns with the studies including the mixed mortality outcomes presented, the generalizability to the Medicare population because the study populations were predominately white male with an average age under 65 years old, and the potential placebo effects and selection bias that may have impacted study results.

The manufacturer responded to CMS' concerns and asserted the Optimizer® System meets the substantial clinical improvement criterion. The manufacturer noted that based on currently published data the devices does not have a negative impact on mortality. The manufacturer acknowledged that white male patients were prevalent in their studies but noted that in heart failure clinical trials these groups are typically over-represented. The manufacturer conducted additional analyses on patients aged 65 and older which showed that the results for this population were not dissimilar to the average population. In addition, the manufacturer presented data demonstrating substantial clinical improvement in terms of functional status, quality of life, and exercise tolerance.

After reviewing the additional information, CMS agrees that for patients with NYHA Class III heart failure who remain symptomatic despite guideline directed medical therapy, who are in normal sinus rhythm, are not indicated for Cardiac Resynchronization Therapy, and have a left ventricular ejection fraction ranging from 25 to 45 percent, the Optimizer® System is a substantial clinical improvement over existing treatment options for this population.

CMS determines that the Optimizer® System has demonstrated substantial clinical improvement relative to existing treatment options for patients with moderate to severe CHF.

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

After consideration of comments, CMS approves the Optimizer® System for device pass-through payment status beginning January 1, 2020.

5. AquaBeam System

PROCEPT BioRobotics Corporation submitted an application for the AquaBeam System⁶, 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.

⁶In the 2019 IPPS final rule, CMS approved a new technology add-on payment for the AquaBeam System (83 FR 41355). This add-on payment will continue in FY 2020 (CMS-1716-F).

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.

The applicant resubmitted their application with additional information that they believe supports the eligibility of the device for a device pass-through payment. The applicant stated that the AquaBeam System's handpiece is temporarily surgically inserted into the urethra through the urinary meatus and does not create an incision or surgical opening but ablates prostate tissue. According to the applicant, the device only cuts the prostatic tissue after being inserted into the prostatic urethra. The prostatic urethra tissue is not cut to access the prostate tissue but the removal of the prostatic urethra is an important aspect of treating the obstruction that causes BPH symptoms.

CMS reiterated the comments it made in the 2019 OPPS proposed and final rule about the eligibility of the AquaBeam System, including CMS' discussion of this issue in the 2000 final rule (65 FR 67804 – 67805) and the 2006 final rule (70 FR 68329 – 68630). CMS adopted 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.

In comments, the applicant restated that the system does not cut or otherwise create a surgical opening and provided additional details in support of AquaBeam's eligibility. Several commenters agreed and stated that the AquaBeam System is not used to cut or otherwise create a surgical opening; the head piece is integral to the service provided and is a single use item that comes into contact with human tissue; and the insertion is through a natural orifice, the prostatic urethra.

After consideration of comments, including the additional clarifying information of the clinical details of the procedure, CMS understands that after being inserted into the urethra, the device ablates both the prostatic urethra and the prostate tissue to relieve and treat symptoms of BPH. CMS determines the AquaBeam system meets the eligibility criterion.

Criteria established at §419.66(c).

Existing payment category. CMS has not identified an existing pass-through payment category that describes the AquaBeam System. The applicant proposed a category descriptor "Probe, image guided, robotic resection of prostate."

Substantial clinical improvement. The applicant stated that the AquaBeam System is the first autonomous tissue resection robot for the treatment of lower urinary tract symptoms due to BPH.

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 acknowledged 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 believed it has insufficient evidence that the AquaBeam System provides substantial clinical improvement over other similar products.

In comments, the applicant noted that in the FY 2019 IPPS final rule, CMS concluded that the WATER study findings were statistically significant and showed AquaBeam superior to TURP in safety. The applicant provided literature and additional data demonstrating the AquaBeam System's superiority to other techniques, specifically for reducing operative time and complications, especially for large prostates. CMS appreciates this additional data and agrees with the comments about the results of the WATER study.

After review of the additional data and literature, CMS believes that the AquaBeam System provides a substantial clinical improvement.

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

After consideration of comments, CMS approves the AquaBeam System for device pass-through status beginning January 1, 2020.

6. Eluvia™ Drug-Eluting Vascular Stent System

Boston Scientific Corporation submitted an application for the Eluvia™ Drug-Eluting Vascular Stent System which is comprised of an implantable endoprosthesis and a stent delivery system (SDS). The drug-eluting stent system is indicated for improving luminal diameter in the treatment of peripheral artery disease (PAD) with symptomatic de novo or restenotic lesions in the native superficial femoral artery (SFA) and or proximal popliteal artery (PPA) with reference vessel diameters (RVD) ranging from 4.0 to 6.0 mm and total lesion lengths up to 190 mm. According to the applicant, the Eluvia™ stent is coated with the drug paclitaxel, which helps prevent the artery from restenosis, and the drug delivery system is designed to sustain the release of paclitaxel beyond 1 year to match the restenotic process in the SFA.

Newness. The Eluvia™ Drug-Eluting System received FDA approval (PMA) on September 18, 2018. CMS received the application on November 15, 2018 which is within 3 years of the initial FDA approval.

Eligibility. According to the applicant, the Eluvia™ System meets all the eligibility requirements.

Criteria established at §419.66(c).

Existing payment category. CMS has not identified an existing pass-through payment category that describes the Eluvia™ System. The applicant proposed a category descriptor of “Stent, non-coronary, polymer matrix, minimum 12-month sustained drug release, with delivery system.”

Substantial clinical improvement. The applicant asserted that the Eluvia™ stent is a substantial clinical improvement because it achieves superior primary patency; reduces the rate of subsequent therapeutic interventions; decreases the number of future hospitalizations or physician visits; reduces hospital readmissions; reduces the rate of device-related complications; and achieves similar functional outcomes and EQ-5D index values with only half the rate of target lesion revascularization (TLRs). The applicant submitted the results of the MAJESTIC study, a prospective, multi-center, single-arm, open-label study (57 patients) and the results of the IMPERIAL study which compared the Eluvia™ stent to the Zilver® Drug-Eluting Peripheral Stent in a global, multi-center randomized control study (465 subjects). CMS was concerned the IMPERIAL study, which showed significant differences in primary patency at 12 months, was designed for non-inferiority and not superiority.

CMS also noted the result of recent published meta-analysis of randomized controlled trials of the risk of death associated with the use of paclitaxel-coated balloons and stents in the femoropopliteal artery of the knee which found an increased death following application of paclitaxel-coated balloons and stents in the femoropopliteal artery of the lower limbs and urged that further investigations are warranted.⁷ Although the Eluvia™ stent was not included in the meta-analysis, CMS was concerned that the meta-analysis results prevent CMS from making a determination of substantial clinical improvement for the Eluvia stent.

CMS discusses the comments it received, including comments from the applicant about the application of the results of the meta-analysis to the Eluvia™ stent. CMS notes it continues to follow FDA's guidance and recommendations for the use of paclitaxel-coated balloons and paclitaxel-eluting stents for PAD. CMS discusses the June 19-20, 2019 meeting of the Circulatory Systems Device Panel of the Medical Devices Advisory Committee and notes the Panel and the FDA concluded that additional clinical study data are needed to fully evaluate the late mortality signal. As of August 7, 2019, FDA continues to actively work with the manufacturers and investigators on developing additional clinical evidence.⁸ CMS notes they continue to stress the importance of clinicians weighing the potential benefits of the paclitaxel-coated devices with the potential risks, including late mortality. CMS remains concerned that it does not have sufficient information to determine that the Eluvia™ device represents a substantial clinical improvement over existing devices. It will continue to monitor any new information and/or recommendations.

CMS is not approving the Eluvia™ device for 2020 device transition payment

⁷ Katsanos, K., et al. “Risk of Death Following Applications of Paclitaxel-Coated Balloons and Stents in the Femoropoliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trial,” *JAMA*, vol. 7(24).

⁸ <http://www.fda.gov/medical-devices/letters-health-care-providers/august-7-2019-update-treatment-peripheral-arterial-disease-paclitaxel-coated-balloons-and-paclitaxel>

7. AUGMENT® Bone Graft

Wright Medical submitted an application for the AUGMENT® Bone Graft which is used as an alternative to autograft in arthrodesis of the ankle and/or hindfoot where the need for supplemental graft material is required. The product has two components: recombinant human platelet-derived growth factor-BB (rhPDGF-BB) and Beta-tricalcium phosphate (β-TCP) granules that are combined at the point of use and applied to the surgical site, eliminating the need for an autologous bone graft.

Newness. The AUGMENT® Bone Graft received FDAPMA on September 1, 2015. The application was received May 31, 2018 which is within 3 years of the date of the initial FDA approval.

Eligibility. According to the applicant the AUGMENT® Bone Graft meets all the eligibility requirements. CMS agrees

Criteria established at §419.66(c).

Existing payment category. CMS has not identified an existing pass-through payment category that describes the AUGMENT® Bone Graft. The applicant proposed a category descriptor of “rhPDGF-BB and β-TCP as an alternative to autograft in arthrodesis of the ankle and/or hindfoot.”

Substantial clinical improvement. The applicant claims the AUGMENT® Bone Graft provides a substantial clinical improvement by reducing pain at the autograft donor site. CMS discussed the data examining the use of autograft arthrodesis of the ankle and/or hindfoot and arthrodesis with the use of AUGMENT® Bone Graft. CMS was concerned that it is unable to sufficiently determine substantial clinical improvement using the provided data. It noted that a long-term study of at least 60 months is currently underway to assess long-term safety and efficacy.

In comments, the applicant and other commenters, provided additional information and analysis addressing CMS concerns, including clarification of the difference between the device and the reamer-irrigator-aspirator (RIA) technique. The applicant also submitted data from the ongoing FDA required post-approval study. After reviewing the additional information provided, CMS agrees that AUGMENT® Bone Graft provides a substantial clinical improvement by reducing both chronic pain and complications.

Cost. CMS believes the AUGMENT® Bone Graft meets all the cost criteria.

After consideration of comments, CMS approves the AUGMENT® Bone Graft for device pass-through status beginning January 1, 2020.

3. Request for Information and Potential Revisions to the OPPS Device Pass-Through Substantial Clinical Improvement Criterion in the FY 2020 IPPS/LTCH PPS Proposed Rule

In the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19368 through 19371), CMS requested information on the substantial clinical improvement criterion for OPPS transitional pass-through

payments for devices for potential revisions. Specifically, CMS sought comments on the type of additional detail and guidance that would be useful. This request for comments was intended to be broad in scope and provide a foundation for potential rulemaking in future years.

In the FY 2020 IPPS/LTCH PPS, CMS also solicited comments on specific changes or clarifications to the IPPS and OPPS substantial clinical improvement criterion that CMS might consider making in the FY 2020 IPP/LTCH S PPS final rule to provide greater clarity and predictability.⁹

CMS invited comments on this topic in this proposed rule. CMS only received one comment which recommended that CMS demonstrate greater flexibility in considering what constitutes substantial clinical improvement, including evidence developed through data registries and evidence from markets outside the US. CMS notes that it accepts a wide range of data and other evidence to help determine whether a device meets the substantial clinical improvement criterion.

4. Proposed Alternative Pathway to the OPPS Device Pass-Through Substantial Clinical Improvement Criterion for Transformative New Devices

CMS discussed the FDA programs for expediting the development and review of transformative new technologies intended to treat serious conditions and address unmet medical needs. In 2001, when CMS first established the substantial clinical improvement criterion (66 FR 46913), the FDA had three expedited programs (Priority Review, Accelerated Approval, and Fast Track) for drugs and biologicals and no expedited programs for devices. There are now four expedited FDA programs for drugs (the three expedited FDA programs available in 2001 and Breakthrough Therapy, established in 2012) and one expedited FDA program for devices, the Breakthrough Devices Program.¹⁰ The 21st Century Cures Act (Pub. L. 144-255) established the Breakthrough Devices Program to expedite the development of, and provide for, priority review of medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. In addition, one of the following four criteria are also required: (1) represent breakthrough technologies; (2) no approved or cleared alternatives exist; (3) offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternative, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care, or establish long-term clinical efficiencies; or (4) the availability of which is in the best interest of patients.

For applications for pass-through payment on or after January 1, 2020, CMS proposed to revise §419.66(c)(2) to establish an alternative pathway for device pass-through payment applications for new medical devices received on or after January 1, 2020. If a medical device is part of the FDA's Breakthrough Devices Program and received marketing authorization (that is, the device has received PMA, 510(k) clearance, or the granting of a De Novo classification request), it will

⁹ In the 2020 IPPS final rule, CMS codifies at §412.87 aspects of how it evaluates substantial clinical improvement for purposes of new technology add-on payments under the IPPS (CMS-1716-F).

¹⁰ FDA guidance is available at <https://www.fda.gov/downloads/Drug/Guidance/UCM358301.pdf> and <https://www.fda.gov/downloads/MEdicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM581664.pdf>.

not be evaluated for substantial clinical improvement for the purposes of determining device pass-through payment status. The device will still need to meet the eligibility criteria under §419.66(b), the other criteria for establishing device categories under §419.66(c), and the cost criterion under §419.66(d).

MedPAC opposed this proposal; it was concerned that it would provide inappropriate incentives for providers to use new technology without proven safety or efficacy by providing increased payment for the new technology. CMS appreciates the concerns but it continues to believe that it is appropriate to facilitate beneficiary access to new medical devices by establishing an alternative pathway for devices that receive FDA marketing authorization through FDA's Breakthrough Devices Program.

Most commenters supported the proposal for an alternative pathway and recommended inclusion of other FDA programs, such as the Expedited Access Pathway, and also to New Technology APCs, drug pass-through payments, and non-opioid alternatives. CMS continues to believe that it is appropriate to distinguish between drugs and devices and notes the broader Administrative initiatives for drug access. CMS notes it will take into consideration the suggestions for expansion of the alternative pathway in future rulemaking. CMS agrees with commenters suggestions that the effective date of the policy be revised to include device pass-through applications received by the September 2019 quarterly application deadline.

After considering comments, CMS finalizes the proposed policy with modification, for an alternative pathway to the substantial clinical improvement criterion for devices that have FDA Breakthrough Devices Program designation and have received FDA marketing authorization (that is, the device has received PMA, 510(k) clearance, or the granting of a De Novo classification request) for devices approved for transitional pass-through status effective on or after January 1, 2020. CMS will include device pass-through applications received by the September 2019 quarterly application submission deadline.¹¹

Devices Approved for Pass-Through Status under the Breakthrough Device Alternative Pathway. CMS received two device pass-through applications by the September 2, 2019 quarterly application deadline that meet the requirements for the Breakthrough Device Alternative Pathway: The Optimizer® System and the ARTIFICIALIris®. These devices also meet the other criteria for device pass-through including the eligibility criteria under §419.66(b), the criteria for establishing device categories under §419.66(c), and the cost criterion under §419.66(d). CMS approves both of these devices for pass-through payment beginning on January 1, 2020; the Optimizer® System is also approved under the standard pathway.

ARTIFICIALIris is an iris prosthesis for the treatment of iris defects. The ARTIFICIALIris was received in June 2019 after the March 2019 quarterly deadline for applications included in the 2020 rulemaking. CMS approves ARTIFICIALIris for transitional pass-through payment under the alternative pathway for 2020. CMS notes that all applicants that are preliminary approved upon quarterly review, including ARTIFICIALIris, will automatically be included in the next

¹¹ In the 2020 IPPS final rule, CMS finalizes its alternative new technology add-on payment for medical devices that meet the proposed criteria. CMS also finalizes this alternative for Qualified Infectious Disease Products (QIDP) CMS-1716-F.

applicable OPPS rulemaking cycle. A discussion of the ARTIFICIALiris application will be included in the 2021 rulemaking.

B. Device-Intensive Procedures

1. HCPCS Code-Level Device-Intensive Determination

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

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

2. Device-Intensive Procedure Policy for 2019 and Subsequent Years

For 2019 and subsequent years, in the 2019 OPPS final rule (83 FR 58944 through 58948, CMS finalized 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 also finalized its proposal for 2019 and subsequent years, for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

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

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).

CMS also finalized lowering the default device offset from 41 to 31 percent until claims data are available to establish the HCPCS code-level device offset. CMS will continue its current policy of temporarily assigning a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer.¹² Once claims data are available for a new procedure requiring the implantation of a medical device, device-intensive status is applied to the code if the HCPCS code-level device offset is greater than 30 percent.

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

For 2020, CMS did not propose any changes to the device-intensive policy. Several commenters identified additional HCPCS codes not included in the proposed list that had device offset percentage greater than the 30 percent threshold. The full listing of 2020 device-intensive procedures is provided in Addendum P.¹³

3. Device Edit Policy

In the 2017 OPPS final rule, CMS finalized it would apply the device claims editing policy on a procedure level rather than APC level, consistent with its finalized policy to make device-intensive determinations at the HCPCS code level. For 2017 and subsequent years, CMS applies the device coding requirements to the newly defined device-intensive procedures. In addition, CMS created HCPCS code C1889 to recognize devices furnished during a device intensive procedure that are not described by a specific Level II HCPCS Category C-code. Any device code, including C1889, when reported on a claim with a device-intensive procedure, will satisfy the edit requiring a device code to be reported on a claim with a device-intensive procedure. For 2019, CMS the description of HCPCS code C1889 is: “Implantable/insertable device, not otherwise classified.

¹² Additional information for consideration of an offset percentage higher than the default can be submitted to outpatientpps@cms.hhs.gov. Additional information can be submitted prior to the issuance of an OPPS proposed rule or as a public comment to a proposed rule.

¹³ Addendum P is available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html>.

For 2020, CMS did not propose any changes to the device edit policy.

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

CMS reduces OPPS payments by the full or partial credit a provider receives for a replaced device for the applicable device-dependent APCs. Hospitals report the amount of the credit in the amount portion for value code “FD” (credit received from the manufacturer for a replaced medical device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. For 2019 and subsequent years, CMS finalized its proposal to apply the no cost/full credit and partial credit device policies to all procedures that qualify as device-intensive under the proposed modified criteria discussed above.

For 2020, CMS did not propose any changes to these policies.

5. Payment Policy for Low Volume Device-Intensive Procedures

In the 2017 OPPS final rule, CMS finalized that the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC be calculated using the median cost instead of the geometric mean cost. For 2019, CMS continued this policy.

For 2020, CMS finalizes its proposal to continue its current policy of establishing the payment rate for any device-intensive procedure assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC using the median cost instead of the geometric mean cost. For 2020, this policy would apply to CPT code 0308T (Insertion of ocular telescope prosthesis including removal or crystalline lens or intraocular lens prosthesis) which is assigned to APC 5495 (Level 5 Intraocular Procedures).

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

A. Transitional Pass-Through Payments

Section 1833(t)(6) of the Act provides for temporary additional payments or “transitional pass-through payments” for certain drugs and biologicals. For pass-through payment purposes, radiopharmaceuticals are “drugs.” As required by statute, transitional pass-through payments for a drug or biological can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made under the OPPS. CMS makes transitional pass-through payment for drugs and biologicals using the average sales price (ASP)+6 percent methodology with quarterly updates to ASP. Pass-through drugs and biologicals for 2020 and their designated APCs are assigned status indicator “G” in Addenda A and B of the final rule.

CMS approves pass-through payments quarterly. Prior to 2017, CMS used the rulemaking process to expire pass-through payments at the end of a calendar year. However, beginning with pass-through applications approved in 2017, CMS expires pass-through payments in the calendar quarter that is not more than 3 years after payment was first made for the hospital outpatient service under Medicare. The 2017 policy change eliminated the variability of the pass-through

payment eligibility period based on when a particular application was initially received and also ensures that new pass-through drugs receive as close to three years as possible of pass-through payment.

One commenter said that CMS should pay all drugs in a coverage with evidence development (CED) trial at the same rate rather than provide pass-through payment for some drugs and packaged payment for others. CMS declined to adopt this suggestion noting that pass-through payment expired for some drugs in the particular CED trial of concern to this commenter while it is continuing for other drugs. The final rule states that the policy is consistent with the statute.

Table 40 of the final rule lists 6 drugs and biologicals with expiring pass-through status on December 31, 2019. Each of the products will have received the full 3 years of pass-through payments once the additional payments expire.

Table 41 of the final rule lists 80 drugs and biologicals for which CMS is continuing pass-through payment status in 2020. Four of these drugs and biologicals (5 total codes as one product, PuraPly, has been split into two codes) have already had 3 years of pass-through payment. Pass-through payment for these products was extended by an additional two years effective October 1, 2018 by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018. Pass-through payment for these products will expire on September 30, 2020. Table 42 lists the codes that qualify for these additional 2 years of pass-through payments.

For 2020, CMS is continuing ASP+6 percent as payment for pass-through drugs and biologicals. As separately payable drugs and biologicals will be paid at ASP+6 percent with or without pass-through payment (except when acquired through the 340B drug discount program), no APC offset is required for the pass-through payment.

For policy packaged drugs¹⁴, the payment amount would be equal to ASP+6 percent for 2020 minus a payment offset for any predecessor drug products included in the APC. Table 43 lists the APCs where an offset will be applied for policy packaged drugs paid on pass-through.

Diagnostic and therapeutic radiopharmaceuticals receiving pass-through payment will also be paid ASP+6 percent. If ASP data are not available, CMS will provide pass-through payment at wholesale acquisition cost (WAC)+3 percent. If WAC information also is not available, CMS will provide payment for pass-through drugs and biologicals at 95 percent of their most recent average wholesale price (AWP).

CMS directs readers to the following link for a file of APC offset amounts used to evaluate cost significance for candidate pass-through device categories and drugs and biologicals and for

¹⁴ Except when paid on pass-through, payment for these drugs is always packaged with the APC. Policy packaged drugs include anesthesia; medical and surgical supplies and equipment; surgical dressings; devices used for external reduction of fractures and dislocations; 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.

establishing any appropriate APC offset amounts: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files.html>.

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

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

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

Cost Threshold for Packaging of “Threshold-Packaged Drugs”

“Threshold-packaged drugs” under the OPPS are drugs, non-implantable biologicals and therapeutic radiopharmaceuticals whose packaging status is determined by the packaging threshold. If a drug’s average cost per day exceeds the annually determined packaging threshold, it is separately payable and, if not, it is packaged. For 2019, the packaging threshold for drugs, biologicals, and radiopharmaceuticals that are not new and do not have pass-through status is \$125.

To calculate the 2020 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 CMS’ Office of the Actuary to trend the \$50 threshold forward from the third quarter of 2005 to the third quarter of 2020. CMS rounds the resulting dollar amount (\$128.11) to the nearest \$5 increment. Based on this calculation, CMS is adopting a packaging threshold for 2020 of \$130.

CMS used the following process to determine the 2020 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 2018 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 2018 and were paid (either as packaged or separate payment) under the OPPS.

To calculate the per day cost for the final rule, CMS uses ASP+6 percent for each HCPCS code. CMS used the manufacturer-submitted ASP data from the 2nd quarter of 2019 (data that were used for payment purposes in the physician’s office setting effective October 1, 2019). 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 2018 hospital claims data. CMS is packaging products with a per day cost of less than or equal to \$130 and paying separately for items with a per day cost greater than \$130 in 2020.

CMS continues to use quarterly ASP updates as follows:

- 4th quarter of 2018: Per day cost, budget neutrality estimates, packaging determinations, impact analyses, and Addenda A and B for the 2020 OPPS proposed rule;
- 2nd quarter of 2019: Per day cost, budget neutrality estimates, packaging determinations, impact analyses and Addenda A and B for the 2020 OPPS final rule; and
- 3rd quarter of 2019: payment rates effective January 1, 2020 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, 2020 for drugs and biologicals furnished in the physician office setting.

ASP-based payment rates for both the OPPS and physician office settings are updated quarterly using reported ASP data with a two-quarter lag, and these updates are available on the CMS website. CMS is continuing its policy of making an annual packaging determination for a HCPCS code in the OPPS final rule and not updating that code's packaging status during the year. Only HCPCS codes which are identified as separately payable in the 2020 final rule are subject to quarterly updates.

As in past years, CMS is applying the following policies to determine the 2020 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 2019 and were proposed for separate payment in 2020 are separately payable in 2020 even if the updated data used for the 2020 final rule indicate per day costs equal to or less than the \$130 threshold.
- HCPCS codes that were packaged in 2019, proposed for separate payment in 2020, and have per day costs equal to or less than \$130 based on the updated data used for the 2020 final rule are packaged in 2020.
- HCPCS codes for which CMS proposed packaged payment in 2020 and have per day costs greater than \$130 based on the updated data used for the 2020 final rule are separately payable in 2020.

CMS received one comment asking it not package drugs that are in short supply even though their per day costs are below the packaging threshold. Another comment asked CMS to stop packaging one drug used in an intrathecal infusion pump as another drug used in the same pump is paid separately. CMS declined to change its policy in either of these circumstances. In the first circumstance, CMS indicated the packaging threshold is intended to package relatively low-cost drugs whether or not they are in short supply. In the second circumstance, CMS indicated that its packaging decisions on each of the drugs is consistent with its policies.

Policy Packaged Drugs, Biologicals, and Radiopharmaceuticals

CMS did not propose any changes for policy packaged drugs, biologicals and radiopharmaceuticals. However, CMS did receive comments requesting that it reinstate claims edits that require nuclear medicine procedures to be billed with a radiopharmaceutical. These edits were in place from 2008 to 2014 to ensure that all packaged costs are included on nuclear

medicine claims. CMS declined to act on this comment indicating that it expects hospitals to code and report their costs accurately regardless of whether there are payment edits requiring reporting of specific costs.

Other comments asked radiopharmaceuticals always be paid separately or subject to a different packaging threshold than separately payable drugs. CMS declined to act on this comment saying that the APCs for which the diagnostic radiopharmaceuticals are used reflect the average costs of these products.

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

For 2020, CMS is continuing its policy of making packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis in the case of multiple HCPCS codes describing the same drug or biological but with different dosages. The codes to which this policy applies, and their packaging status, are listed in Table 44 of the final rule.

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

Except for separately payable, non-pass-through drugs acquired with a 340B discount, CMS will continue paying for separately payable drugs and biologicals at ASP+6 percent in 2020. CMS is continuing its policy to pay for drugs acquired with a 340B discount at ASP-22.5 percent in 2020 (see section V.B.6 below for more detail about CMS' policy in the context of ongoing litigation). Medicare's payment represents the combined acquisition and pharmacy overhead payment for drugs and biologicals.

Consistent with policy in the PFS, CMS is paying for drugs during an initial sales period (2 quarters) in which ASP pricing data are not yet available from the manufacturer at WAC+3 percent. Consistent with the statute, CMS is limiting its WAC+3 policy only to new drugs in an initial sales period. Other drugs and biologicals where ASP data are not available will continue to be paid at WAC+6 percent. Drugs that are paid using WAC and that are acquired under the 340B program would be paid at WAC-22.5 percent. If ASP and WAC are unavailable, Medicare will pay 95 percent of average wholesale price (AWP) or 69.46 percent of AWP if the drug is acquired under the 340B program.

Even though CMS' policy is unchanged, commenters continue to object to the 3 percent add-on for new drugs and biologicals where ASP is unavailable arguing that it discourages use of new or innovative products. CMS reiterated its prior response that its policy is consistent with MedPAC's recommendation, lowers beneficiary coinsurance and addresses pricing issues for WAC-based payment of Part B drugs.

CMS also will continue to include payments for separately payable drugs and biologicals in determining budget neutrality adjustments (i.e., the budget neutral weight scaler). Following established policy, CMS does not, however, apply the budget neutral weight scaler in determining payments for these separately paid drugs and biologicals due to the statutory

requirement that their payments be based on acquisition costs or the amount required by statute in physician's offices when acquisition costs are unavailable for outpatient department costs.

The payment rates shown for drugs and biologicals in Addenda A and B of the final rule are not the payment rates that Medicare will pay on January 1, 2020. Payment rates effective January 2020 will be released near the end of December 2019 and will be based on ASP data submitted by manufacturers for the third quarter of 2019 (July 1, 2019 through September 30, 2019). Payment rates will be updated quarterly throughout 2020.

Payment rates for drugs and biologicals in Addenda A and B of the final rule for which there was no ASP information available for the 2nd quarter of 2018 are based on mean unit cost in the available 2018 claims data. If ASP information becomes available for the quarter beginning in January 2020, CMS will pay for these drugs and biologicals based on the newly available ASP information.

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 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. If a biosimilar is acquired under the 340B program, CMS' policy is to pay for the biosimilar at ASP minus 22.5 percent of its own ASP rather than doing the subtraction from the reference product ASP. If WAC is used for pricing, the add-on will be +3 percent or +6 percent of its own WAC depending on whether the biosimilar is in an initial sales period or -22.5 percent of its own WAC if acquired under the 340B drug discount program.

Biosimilars are eligible for pass-through payment like any other drug or biological. Pass-through would apply to each new biosimilar irrespective of whether the product is biosimilar to the same reference product. While CMS did not propose any changes to this policy, it still received comments supporting and opposing this policy. Supporters believe the policy will encourage use of biosimilars and result in long term savings to Medicare. Opponents believe only the originator product is new and innovative and should receive pass-through payment. CMS is not making any changes in response to these comments.

3. Payment Policy for Therapeutic Radiopharmaceuticals

For 2020, CMS will continue paying for therapeutic radiopharmaceuticals at ASP+6 percent. For therapeutic radiopharmaceuticals for which ASP data are unavailable, CMS will determine 2020 payment rates based on 2018 geometric mean unit cost.

4. Payment for Blood Clotting Factors

For 2020, CMS will 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 2020 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>.

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

CMS is continuing the same payment policy in 2020 for non-pass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data. In priority order, CMS will pay for these products using ASP+6 percent if ASP is reported, WAC+6 percent if a WAC is available and at 95 percent of AWP if ASP and WAC are unavailable. The 2020 payment status of each of the non-pass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data is listed in Addendum B of the final rule.

6. 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 continued this policy for 2019. For 2020, CMS proposed to continue to pay ASP-22.5 percent for 340B-acquired drugs.

On December 27, 2018, United States District Court for the District of Columbia concluded the Secretary exceeded his statutory authority by adjusting the Medicare payment rates for drugs acquired under the 340B Program to ASP-22.5 percent for 2018 (see *American Hospital Association et al. v. Azar et al.*). On May 6, 2019, the district court ruled that the rate reduction for 2019 also exceeded his authority. The district court remanded the issue to the Secretary to devise an appropriate remedy while also retaining jurisdiction. CMS asked the district court to enter final judgment so as to permit an immediate appeal. On July 10, 2019, the district court granted the government's request and entered a final judgment. The agency has now appealed the district court decision.

CMS is taking the steps necessary to craft an appropriate remedy in the event of an unfavorable decision on appeal. The final rule notes CMS' intent to conduct a 340B hospital survey to collect drug acquisition costs for 2018 and 2019. The survey data may be used in setting the Medicare payment amount for drugs acquired under the 340B program going forward and as a remedy for prior years if the district court decision is upheld on appeal.

The final rule states that devising a remedy will be complex because of the OPPS budget neutrality requirements and the transfer of payments between separately payable drugs acquired under the 340B program and all other services—an estimated \$1.6 billion for 2018 only. The payment transfer will affect approximately 3,900 facilities that are reimbursed for outpatient items and services covered under the OPPS as well as the 20 percent coinsurance paid by millions of different Medicare beneficiaries.

In the proposed rule, CMS solicited public comments on a remedy for 2018 and 2019 if the district court decision is upheld on appeal. In the final rule, CMS states that it will consider this public input in the event the 340B hospital survey data are not used to devise a remedy. Public input will inform the steps that are required under the Administrative Procedure Act (e.g. hospitals will need to be provided with sufficient notice of the impact of the remedy on their rates to enable them to comment meaningfully on a proposed rule). CMS anticipates proposing the specific remedy for 2018 and 2019, as well as changes to the 2020 rates, in the 2021 OPPS/ASC proposed rule in the event the agency loses on appeal and it does not use 340B hospital survey data to craft the remedy.

CMS sought public comment in the proposed rule on the OPPS payment rate for 340B acquired drugs, including whether a rate of ASP+3 percent could be an appropriate remedial payment amount both for 2020 and determining the remedy for 2018 and 2019. The agency argues that this payment would be significantly above a 340B hospital's cost to acquire drugs but believes it would be consistent with the District Court's decision to limit the size of the payment reduction the agency can permissibly apply.¹⁵

The final rule categorizes the comments as follows:

Appropriate Payment Rate for 340B-Acquired Drugs in 2020

Public commenters both supporting and opposing CMS' policies reiterated prior public comments and did not suggest an alternative payment rate for 340B drugs. As CMS hopes to prevail on appeal and have its 340B policy upheld, it is finalizing the proposal to continue paying for 340B acquired drugs in the hospital outpatient department at ASP minus 22.5 percent rather than an alternative payment amount of either ASP+3 percent or ASP+6 percent.

2020 Payment Policy for 340B-Acquired Drugs to Non-Excepted Off Campus Provider Based Departments (PBDs)

Under section 603 of the Bipartisan Budget Act of 2015, off-campus provider-based departments that first furnish services on or after November 2, 2015 are not paid under the OPPS. These provider-based departments are known as "non-exceptioned." Other off-campus provider-based departments are grandfathered from section 603 and continue to be paid under the OPPS. These provider-based departments are known as "exceptioned." CMS initially applied its policy of paying for 340B drugs at ASP-22.5 percent only in exceptioned off-campus provider-based departments. In 2019, CMS expanded the policy to non-exceptioned departments.

Public comments on this issue reiterated prior comments disputing CMS' assertion that if exceptioned off-campus provider-based departments were not subject to the 340B acquired drugs policy, hospitals would furnish services in these sites to avoid the payment reduction. Other comments challenged whether CMS has the legal authority to apply its policy in these sites that

¹⁵ See page 27 of the Court's ruling in *American Hospital Association et al. v. Azar et al* "...in other cases, courts have found that payment reductions of 0.2% and 2.9% were not significant enough to warrant a finding that the Secretary exceeded his adjustment authority." See *Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 260 (D.D.C. 2015) (citing *Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 700 (D.C. Cir. 2014)).

are not paid under the OPPS and instead are paid under the “applicable payment system.” There is no “applicable payment system” that pays ASP-22.5 percent in the statute.

CMS reiterated its prior response that not adjusting payment exclusively for these departments would present a significant incongruity between the payment amounts for these drugs depending on where they are furnished. In order to avoid perverse incentives and the potential resulting distortions in drug payment, CMS identified the PFS as the “applicable payment system” for 340B-acquired drugs and biologicals. Accordingly, it is paying ASP-22.5 percent under the PFS instead of ASP+6 percent under section 1847A of the Act in nonexcepted off-campus PBDs.

Comments on Use of ASP plus 3 Percent for CY 2020

Many commenters opposed a payment amount of ASP+3 percent as a potential remedial payment for 340B-acquired drugs arguing both that there is no statutory authority for such a policy and CMS did not provide a rationale to support it. A few commenters supported the proposal to pay ASP+3 percent for 340B-acquired drugs in 2020, rather than continue to pay ASP minus 22.5 percent. One commenter supported ASP+3 percent to lessen the amount CMS would need to refund if its appeal fails. CMS is finalizing its proposal to continue to pay for 340B-acquired drugs at ASP minus 22.5 but will consider these comments if it loses the 340B case on appeal.

Use of Hospital Acquisition Costs:

Several commenters supported CMS basing its payment on hospitals' acquisition costs for drugs as there is authority in the statute to base payment for Part B drugs in the outpatient department on hospital acquisition costs. CMS noted its intent to conduct a 340B hospital survey to collect drug acquisition cost data for 2018 and 2019.

Potential Remedy for 2018 and 2019

In the proposed rule, CMS requested comments on the following options for applying a remedy in 2018 and 2019:

- On a claim-by-claim basis;
- Through an upward adjustment to 340B claims in the future to account for any past underpayments; or
- Through additional payments outside the normal claims process (e.g. a lump sum payment to each hospital claiming harm from the 340B policy) that are then made budget neutral in a future year (e.g. 2021);

CMS also sought public comments on the best, most appropriate treatment of budget neutrality and Medicare beneficiary cost-sharing responsibilities under any remedy.

On making a refund payment to hospitals, commenters both supported a retrospective claims analysis to determine amounts owed to hospitals and making a single lump sum payment or segmented multiple payments to refund amounts owed to hospitals for 340B acquired drugs.

Several comments indicated that CMS could identify past drug payments made in 2018 and 2019 at ASP-22.5 percent and provide payment based on 1.36 percent of that amount (ASP+6 percent / ASP minus 22.5 percent = 1.06/0.775). One commenter said the amount owned to hospitals should only be distributed to hospitals that demonstrate “responsible program integrity.” Unused funds would be spent to identify and implement solutions for duplicate discount prevention. Some commenters believe that the remedial payment methodology should be the subject of notice and comment rulemaking while others believe the remedy does not necessitate rulemaking.

On budget neutrality, many commenters asserted that there are prior court precedents that make budget neutrality unnecessary: Cape Cod Hospital v. Sebelius (D.C. Cir. 2011), H. Lee Moffitt Cancer Center & Research Institute, Inc. vs. Azar, (D.D.C. 2018), Shands Jacksonville Medical Center v. Burwell, (D.D.C. 2015). Other commenters asserted that budget neutrality is only used for setting prospective payment rates and is not revisited if agency estimates are incorrect. Some commenters supported a prospective rate reduction on OPPS non-drug items and services rather than attempting to recoup higher payments on a claim-by-claim basis from individual providers.

On beneficiary coinsurance, many commenters asserted that there is no law that requires hospitals to adjust beneficiaries' coinsurance for 340B-acquired drugs. Neither false claims nor the anti-kickback statutes would apply because beneficiaries did not receive any inducements to seek services. One commenter indicated that only 19 percent of patients would be directly affected with cost-sharing because the remainder either have supplemental insurance or Medicaid paying beneficiary coinsurance.

CMS responded that it plans on collecting cost information from 340B hospitals to devise a remedy for prior years if the district court's ruling is upheld on appeal. Relying on survey data could avoid the remedial complexities of an adverse court ruling. If 340B hospital survey data are not used to devise a remedy in the event of an adverse decision on appeal, CMS will consider the commenters' suggestions in determining the appropriate remedy in 2021 OPPS rulemaking.

7. High/Low Cost Threshold for Packaged Skin Substitutes

CMS has been packaging skin substitutes as drugs and biologicals that function as supplies when used in a surgical procedure since 2014. The packaging methodology also divides skin substitutes into high and low-cost groups in order to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures.

For 2020, CMS is continuing to determine the high cost/low cost status for each skin substitute product based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold. CMS is using 2018 data for this purpose.

The final 2020 MUC threshold is \$48 per cm² (rounded to the nearest \$1) and the final 2020 PDC threshold is \$790 (rounded to the nearest \$1). A skin substitute with a MUC or a PDC that exceeds either the MUC threshold or the PDC threshold will be assigned to the high cost group.

If the product is assigned to the high cost group in 2019, it will continue to be assigned to the high cost group in 2020. Otherwise, the skin substitute will be assigned to the low-cost group. Table 45 displays the 2020 cost category assignment for each skin substitute product. For 2020, CMS is continuing the following policies:

- Skin substitutes with pass-through payment status will be assigned to the high cost category.
- Skin substitutes with pricing information but without claims data will be assigned to either the high or low-cost categories based on the product's ASP+6 percent payment rate (WAC+3 percent if ASP is unavailable, 95 percent of AWP if neither ASP or WAC is available) as compared to the MUC threshold.
- New skin substitutes without pricing information would be assigned to the low-cost category until pricing information is available.

Most commenters supported continuing the above policies absent more comprehensive reform of CMS' skin substitute policy. There were comments opposing the assignment of a skin substitute to the high cost category in 2020 solely based on its 2019 assignment when the product no longer meets the high cost criteria. CMS disagreed with the latter comment suggesting that the policy for retaining a skin substitute in the high cost category even when it no longer meets the criteria is intended to improve payment stability and prevent a sudden large reduction in payment—a concern that has been raised in comments and is motivating CMS to consider more comprehensive reform of its skin substitute policy.

While CMS did not propose any additional changes to its skin substitute policies, it reviews comments in response to a comment solicitation in the 2019 OPPS rule and an additional solicitation in this year's proposed rule on two potential policy options. Under the first one, CMS would make a single episode payment that would cover all skin substitute application services for a given period of time (e.g. 4 weeks or 12 weeks). Under this option, CMS would assign the skin substitute codes to comprehensive APCs with the option for a complexity adjustment that would allow for an increase in the standard APC payment for more resource-intensive cases. CMS' research has found that most wound care episodes require one to three skin substitute applications. Those cases would likely receive the standard APC payment for the comprehensive procedure. Then the complexity adjustment could be applied for the relatively small number of cases that require more intensive treatments.

Under the second option that CMS explicitly states it had been considering for 2020, there would be only one payment category and set of procedure codes for the application of all skin substitute products. Commenters both supported and opposed this idea in last year's comment solicitation. CMS indicates that the responses show the potential of a single payment category to reduce the cost of wound care services for graft skin substitute procedures for both beneficiaries and Medicare. In addition, a single payment category may help lower administrative burden for providers. Conversely, CMS is cognizant of concerns that a single payment category may hinder innovation of new graft skin substitute products and cause some products that are currently well-utilized to leave the market.

Nonetheless, CMS is persuaded that a single payment category could potentially provide a more equitable payment for skin substitutes and their application procedures while recognizing that

substantially lower payment would be made for more expensive products. CMS believes some of the opposition to a single payment category might be mitigated if stakeholders have a period of time to adjust to the changes inherent in establishing a single payment category. Options may include:

- Delaying implementation of a single category payment for 1 or 2 years after the payment methodology is adopted; and
- Gradually lowering the MUC and PDC thresholds over 2 or more years to add more graft skin substitute procedures into the current high cost group until all graft skin substitute procedures are assigned to the high cost group and it becomes a single payment category.

Episode-Based Payment

Commenters both supported and opposed episode-based payment. There were concerns about the number of different payment groups, the length of the episode, adjusting for complexity, incentives to undertreat and whether the episode payment would be only for skin substitutes or would include other modalities like negative wound pressure therapy and hyperbaric oxygen therapy. Some commenters supported using the Center for Medicare and Medicaid Innovation to develop an episodic payment model before it is adopted under the OPPS. There were comments supporting a separate payment episode for each type of wound receiving treatment. Opponents of episode payment believe wound care is too complex and variable to be covered through episodic payment even with an option for a complexity adjustment. Others expressed administrative concerns and the potential burden on providers from moving to episode payment for treating wounds. CMS will consider all of these comments as it considers potential refinements to how to pay for skin substitute products and procedures under the OPPS.

Eliminating the High/Low Cost Categories

Under this option, CMS would eliminate the high and low-cost categories. It would eliminate the duplicate set of procedure codes needed for grafts using low-cost skin substitutes. For example, the geometric mean costs for HCPCS codes 15271 and C5271 were \$1,572.17 and \$728.28 in the proposed rule. HCPCS code C5271 would no longer be needed and the combined geometric mean cost would be \$1,465.18 for 2020. Commenters that supported this option believe it would lead to use of lower-cost, quality products and lower beneficiary copayments. It would reduce incentives to apply skin substitute products in excessive amounts, simplify coding and reducing administrative burden. Opponents raised concerns that a single payment category would not offer providers incentives to furnish high quality care and would group products with a mean unit cost ranging from less than \$1 to over \$750. Such a policy would limit innovation and discourage treatment of wounds that are difficult and costly to treat.

CMS will use this feedback to help inform development of its payment methodology for skin substitute application procedures in future rulemaking. It decided not to implement this policy in the final rule nor did it present any comments on the options for delaying implementation or gradually lowering the MUC or PDC cost thresholds.

VI. Estimate of OPPS Transitional Pass-Through Spending

CMS estimates total pass-through spending for drug and device pass-through payments during 2020 will be approximately \$698.4 million, or 0.88 percent of total OPPS projected payments for 2020 (approximately \$79 billion), which is less than the applicable pass-through payment percentage statutory limit of 2.0 percent.

A. Devices

CMS estimates pass-through spending of \$246.8 million in 2020 for devices—\$0.57 million for those recently eligible for pass-through payments that will continue for 2020 and \$246.2 million for those CMS knows or projects could be approved for pass-through status in 2020. CMS includes implantable biologicals newly eligible for pass-through payment in the estimate for this group.

B. Drugs and Biologicals

CMS estimates pass-through spending of \$451.6 million in 2020 for drugs and biologicals—\$399.6 million for those recently eligible for pass-through payments that will continue for 2020 and \$26 million for those CMS knows or projects could be approved for pass-through status in 2020. (Note: One of these figures or the total appear to be incorrect as the numbers add to \$425.6 million).

VII. Payment for Hospital Outpatient Visits and Critical Care Services

CMS solicited comments but did not propose any changes to the current clinic and emergency department hospital outpatient visits payment policies or to the payment policy for critical care services when these services are provided on the campus of a hospital. Two commenters asked CMS to develop a national set of guidelines for coding emergency department visits as has been recommended by MedPAC. CMS will consider that suggestion for future policy. For off-campus PBDs, CMS is continuing the 2-year transition to pay for clinic visits at 40 percent of the current OPPS rate. See section X. C. for details.

VIII. Payment for Partial Hospitalization Program (PHP) Services

A. PHP APC Update for 2020

CMS uses established policies to calculate the PHP APC per diem payment rates for Community Mental Health Centers (CMHCs) and hospital-based PHP providers based on geometric mean per diem costs using the most recent claims and cost data for each provider type. It finalizes a policy for 2020 only to use the 2019 final geometric mean per diem cost for CMHCs and hospital-based PHPs as a cost floor in developing the 2020 PHP APC per diem rates.

CMS continues 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)); it uses actual claims data from 2018 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 70455-70465) as modified in the 2017 OPPS/ASC final rule (81 FR 79687-79691), 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. The CMHC or hospital-based PHP APC per diem payment rates are the national, unadjusted payment rates calculated from the CMHC or hospital-based PHP APC geometric per diem costs, after applying the OPPS budget neutrality adjustments.

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 PHP providers which it excludes from the calculation of the PHP geometric mean per diem costs. For 2020, CMS continues its policy of excluding data from any CMHC when the CMHC's costs are more than ± 2 standard deviations from the geometric mean cost per day for all CMHCs and excluding hospital-based PHP service days when a CCR>5 is used to calculate costs for at least one of the component services. CMS also defaults any CMHC CCR that is greater than 1 to the statewide hospital ancillary CCR.

CMS did not adjust the CCR for any CMHCs nor did it exclude any CMHCs for other missing data or for failing the ± 2 standard deviation trim. It did exclude one CMHC for having no Medicare payment data. Thus, 43 CMHCs were included in the 2020 calculation. CMS removed 319 CMHC claims. The calculated geometric mean per diem cost for all CMHCs for providing 3 or more services per day is \$103.50 which represents a decrease of almost 15 percent from the 2019 geometric mean per diem cost for all CMHCs (\$121.62). CMS found that two large providers reported lower costs per day than those reported for 2019; this heavily influenced the calculation. CMS notes that the CMHC APC 5853 is heavily weighted to the costs of providing 4 or more services per day; 95 percent of CMHC days paid in 2018 were for 4 or more services per day.

The agency does not believe that the costs of furnishing these services have gone down over time and instead attributes the decrease to the impact of these two large providers. CMS is concerned generally by any significant fluctuation in the geometric mean per diem costs over time, and it worries about the impact of such a substantial decrease on beneficiary access to PHP services. Thus, as proposed, CMS uses the 2019 CMHC geometric mean per diem cost of \$121.62 as the cost floor for 2020. CMS notes this policy applies only for 2020.

Most commenters supported the cost floor policy. Some commenters repeated earlier requests to pay CMHCs at the same rate as applies for hospital-based programs; CMS declines to do so citing differing overhead costs and other considerations. Other commenters objected to the single tier payment system expressing concerns with quality and intensity of services. CMS says it does not yet have sufficient data on the impact of the single tier payment system but will continue to monitor the effect of its policy. A commenter suggested establishing a value-based purchasing program for CMHCs; CMS declines to do so citing the absence of statutory authority as well as the lack of quality measures.

For hospital-based PHP providers, CMS removed 62 providers as follows: 59 with zero daily costs and no PHP payment, one with all service days having a CCR greater than 5, and 2 with no allowable PHP HCPCS codes. For the final rule, no hospital-based PHPs were defaulted to using their overall hospital ancillary CCRs due to outlier cost center CCR values. The calculated geometric mean per diem cost for all hospital-based PHP providers for providing 3 or more services per day for the final rule is \$233.52 which represents an increase of 4.8 percent from the 2019 geometric mean per diem cost for these providers of \$222.76. Because the 2020 final rule geometric mean per diem cost for hospital-based PHPs exceeds the 2019 hospital-based PHP provider geometric mean per diem cost, CMS will not use the floor for hospital-based PHP services furnished in 2020.

CMS also considered using a 3-year rolling average calculated using the final PHP geometric mean per diem costs for CMHCs and hospital-based PHP providers in lieu of its floor policy. The policy still resulted in significantly lower geometric mean per diem costs for 2020, and it did not address the fluctuation in costs over time that concerns CMS.

Hospital-based PHPs complained that the agency's decision to implement section 603 of the Bipartisan Budget Act of 2015 (Section 603) for PHP programs in nonexcepted off-campus provider-based departments (PBDs) by setting the per diem equal to the CMHC rate is not viable for hospital-based PHPs and will limit the ability for them to create new PHP programs in a time of rising demand. CMS responds that Section 603 does not prohibit new PHP programs in off-campus PBDs and also notes that full hospital-based PHP payment would apply if the programs are operated on campus. CMS believes the CMHC rate is appropriate for off-campus PBDs because they have lower cost structures similar to CMHCs.

The 2020 geometric mean per diem costs and payment rates are as follows:

2020 APC	Group Title	PHP APC Geometric Mean Per Diem Costs*	Payment Rates**
5853	Partial Hospitalization (3 or more services per day) for CMHCs	\$121.62	\$ 124.29
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	\$233.52	\$ 238.64

* Table 45 of the final rule shows the PHP APC geometric mean per diem costs.

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

B. PHP Service Utilization

CMS has previously expressed concerns 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 2018 claims data shows that the provision of individual therapy has increased on days with 4 or more services provided by CMHCs and hospital-based PHPs. However, on days with 3 services, individual therapy provided by CMHCs and hospital-based PHPs has decreased. Table 46 of the final rule shows claims data from 2015 through 2018.

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 2018 claims, utilization of 3 service days is increasing as compared to the three preceding years. Compared to 2017, in 2018 hospital-based PHPs provided more days with 3 services only, more days with 4 services only, and fewer days with 5 or more services, and CMHCs provided more days with 3 services, fewer days with 4 services, and more days with 5 or more services. Commenters note that PHPs are voluntary and providers cannot force patients (with patient profiles that work against attendance and full daily participation) to attend every day.

CMS is concerned by this and hopes the data are an anomaly. It will continue to monitor the provision of days with only 3 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.

C. Outlier Policy for Community Mental Health Centers (CMHC)

For 2020, CMS finalizes its proposals 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 designates less than 0.01 percent of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs for PHP outliers. CMS sets the cutoff point for the outlier payments for CMHCs for 2020 at 3.4 times the highest CMHC PHP APC payment rate (CMHC PHP APC 5853), and it will pay 50 percent of CMHC geometric mean per diem costs over the threshold. Specifically, CMS will calculate a CMHC outlier payment equal to 50 percent of the difference between the CMHC's cost for the services and the product of 3.4 times the APC 5853 payment rate.

In the 2017 OPPS/ASC final rule, CMS implemented an outlier payment cap of 8 percent; thus, an individual CMHC may not receive more than 8 percent of its total per diem payments in outlier payments. CMS continues this policy for 2020 which only impacts CMHCs.

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

D. Update to PHP Allowable HCPCS Codes

CMS discussed in the 2019 OPPS/ASC final rule receiving new, revised and deleted Category I and III CPT codes from the AMA; this included the deletion and addition of CPT codes used for PHP services. In that final rule, CMS proposed to delete CPT codes 96101-96103 and 96118-96120 and replace them with CPT codes 96130-96133, 96136-96139, and 96146. CMS did not receive any comments and finalizes its proposal without modification.

Ey. Regulatory Impact

CMS estimates that payments to CMHCs will increase by 3.7 percent in 2020. The estimate includes the impact of the trimming methodology, wage index, and other adjustments.

IX. Changes to the Inpatient Only List

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

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

Not all of the established criteria need to be met for a procedure to be removed from the IPO list.

CMS proposed to remove CPT code 27130 (total hip arthroplasty, THA) from the IPO list. In the 2018 OPPS rule, CMS got both support and opposition to a comment request on removing THA from the IPO list. Supporters noted significant success involving same day discharge for patients who met the screening criteria and whose experienced medical teams were able to perform the procedure early enough in the day for the patients to achieve postoperative goals, allowing home discharge by the end of the day. The commenters believed that the benefits of providing the THA procedure on an outpatient basis would lead to significant enhancements in patient well-being, improved efficiency, and cost savings to the Medicare program. There would be shorter hospital stays resulting in fewer medical complications, improved results, and enhanced patient satisfaction.

Other commenters stated that it would not be clinically appropriate to remove partial hip arthroscopy (PHA) and THA from the IPO list, indicating that the patient safety profile of outpatient THA and PHA in the non-Medicare population is not well-established. These commenters stated that patients requiring PHA for fragility fractures are by nature higher risk, suffer from more extensive comorbidities and require closer monitoring and preoperative optimization; therefore, it would not be medically appropriate to remove the PHA procedure from the IPO list.

After reviewing the clinical considerations of THA and considering the public comments from past rules, additional feedback from stakeholders and further consultation with its clinical advisors, CMS proposed to remove THA from the IPO list on the basis that the simplest procedure described by the code may be performed in most outpatient departments) and the procedure is related to codes already removed from the IPO list. CMS proposed to assign CPT

code 27130 to C-APC 5115 with status indicator “J1,” meaning that a single bundled payment will be made for both the surgical procedure and all ancillary services during the outpatient encounter. CMS did not propose to remove PHA from the IPO list because CMS does not believe PHA meets the criteria for removal.

General Comments on Removing THA from the IPO List

CMS received many of the same type of comments on its proposal that it received on its 2010 comment solicitation. Supporters stated that good candidates for outpatient THA have relatively low anesthesia risk, do not have significant comorbidities, have in-home support, and are able to tolerate post-surgical outpatient rehabilitation in either an outpatient facility or in the home. Both supporters and opponents of the proposal requested that CMS provide detailed guidance on selection criteria for outpatient THA.

Opponents of the proposal requested a rigorous medical literature review demonstrating that THA can be performed safely in the outpatient or ASC setting especially for beneficiaries with multiple co-morbidities. Some commenters stated that THA does not meet criterion 2 (the simplest procedure described by the code may be performed in most outpatient departments) as all procedures described by CPT code 27130 have moderate risks for complications. These commenters argued that THA and TKA are not similar procedures so criterion 3 (the procedure is related to codes that we have already removed from the IPO list) is also not met.

CMS responded that appropriate site of service for THA should be based on the physician’s assessment of the patient and tailored to the individual patient’s needs. Patients with a relatively low anesthesia risk and without significant comorbidities who have family members at home who can assist them may likely be good candidates for an outpatient THA procedure. Patients that require a revision of a prior hip replacement, and/or have other complicating clinical conditions (including multiple co-morbidities such as obesity, diabetes, and heart disease), may not be strong candidates for outpatient THA. The decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician based on the beneficiary’s individual needs and preferences.

The final rule reiterates that removal of any procedure from the IPO list does not require the procedure to be performed only on an outpatient basis. The 2-midnight rule (discussed in section X.B. below) provides general guidance on when payment under Medicare Part A may be appropriate. However, the 2-midnight rule also recognizes the importance of the attending physician’s clinical judgment regarding the appropriate setting of care for a procedure to be performed. In response to creating selection criteria for when outpatient THA is appropriate, CMS believes that physicians with specialized clinical knowledge and experience are most suited to create such guidelines.

Impact on Comprehensive Care for Joint Replacement (CJR) Program and Bundled Payments for Care Initiative (BCPI Advanced)¹⁶

¹⁶ The first Bundled Payments for Care Initiative (BPCI) ended September 30, 2018, and is sometimes referred to as BPCI Original to distinguish it from the follow-on initiative named BPCI Advanced. The first BPCI Advanced participant cohort period began on October 1, 2018. <https://innovation.cms.gov/initiatives/bpci-advanced>

Several commenters opposed the removal of THA due to potential detrimental impacts on CJR and BPCI Advanced. Others supported the proposal but stated there will need to be adjustments made to the model to account for THA being allowed on an outpatient basis. CMS responded that CMMI may consider making future changes to the CJR and BPCI Advanced Models to address the removal of THA from the IPO list.

Public Comments Removing Other Procedures from the IPO List

In addition to removing CPT code 27130, CMS solicited comments on removing six codes from the IPO list. Public commenters requested CMS remove an additional 5 codes. All 12 codes are as provided in modified Table 49 from the final rule reprinted below.

CMS has received requests in the past to remove codes 22633 and 22634 from the IPO list on the basis that they are similar to CPT code 22551 which is currently performed in the outpatient hospital setting. Stakeholders indicated that codes 63265, 63266, 63267 and 63268 should be considered minimally invasive. Most outpatient departments are equipped to provide the services to the Medicare population and the simplest procedure described by the code may be performed in most outpatient departments.

Commenters agreed that these procedures were both related to codes that were previously removed from the IPO list and are performed safely in numerous hospitals on an outpatient basis. One commenter provided a March 2019 published retrospective cohort study of lumbar interbody fusion to treat spinal pathology using the American College of Surgeons National Surgical Quality Improvement Program database. The study showed the perioperative safety profile and operative efficiency and efficacy of performing transforaminal lumbar interbody fusions at an outpatient facility. ASCs commented that they often perform all listed procedures with few to no complications. ASCs asked CMS to add these codes to the ASC list. Opponents of removing the procedures from the IPO list expressed concern that all six procedures are complex procedures. Very few Medicare beneficiaries are likely to be good candidates to receive the procedures in the outpatient setting.

After reviewing clinical evidence and the public comments, including input from multiple spinal specialty societies and ASCs, CMS is removing all six codes from the IPO list. The APC and status indicator assignments are reflected in Table 49 below.

TABLE 49.—CHANGE TO THE IPO LIST FOR CY 2020

CY 2020 CPT Code	CY 2019 Long Descriptor	CY 2020 OPPS APC Assignment	CY 2020 OPPS Status Indicator
CHANGES PROPOSED and FINALIZED BY CMS			
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty) with or without autograft or allograft	5115	J1
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/ or discectomy sufficient to prepare		

CY 2020 CPT Code	CY 2019 Long Descriptor	CY 2020 OPPS APC Assignment	CY 2020 OPPS Status Indicator
	interspace (other than for decompression), single interspace and segment; lumbar;	5115	J1
22634	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/ or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar; each additional interspace and segment	N/A	N
63265	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; cervical	5114	J1
63266	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; thoracic	5114	J1
63267	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar	5114	J1
63268	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; sacral	5114	J1
CHANGES REQUESTED BY COMMENTERS and FINALIZED BY CMS			
00670	Anesthesia for extensive spine and spinal cord procedures (for example, spinal instrumentation or vascular procedures)	N/A	N
00802	Anesthesia for procedures on lower anterior abdominal wall; panniculectomy	N/A	N
00865	Anesthesia for extraperitoneal procedures in lower abdomen, including urinary tract; radical prostatectomy (suprapubic, retropubic)	N/A	N
00944	Anesthesia for vaginal procedures (including biopsy of labia, vagina, cervix or endometrium); vaginal hysterectomy	N/A	N
01214	Anesthesia for open procedures involving hip joint; total hip arthroplasty	N/A	N

Additional Requests for Changes to the IPO List:

Commenters requested that anesthesia codes 00670, 00802, 00854, 00944 and 01214 be removed from the IPO list on the basis that they are related to other codes that have been removed the IPO list. CMS agreed that these anesthesia procedures are performed with codes that may already be performed on outpatient basis. Anesthesia services are unconditionally packaged into the APC for the procedure in which anesthesia is being provided.

X. Nonrecurring Policy Changes

A. Supervision Level for Outpatient Therapeutic Services

With limited exceptions, Medicare requires direct supervision¹⁷ as a condition of payment for hospital outpatient therapeutic services covered and paid by Medicare that are furnished in

¹⁷ “Direct supervision” means that the physician or nonphysician practitioner must be immediately available to

hospitals and provider-based departments (PBDs) of hospitals. There has been either an administrative or statutory enforcement moratorium on the direct supervision rules for CAHs and rural hospitals under 100 beds for nearly all of the period since March 15, 2010 until now. Stakeholders stated that the enforcement moratorium is needed because small rural hospitals and CAHs have insufficient staff available to furnish direct supervision, particularly for critical specialty services.

The non-enforcement instructions have created a two-tiered system of physician supervision requirements. Direct supervision is required for most hospital outpatient therapeutic services in most hospital providers, but only general supervision¹⁸ is required for the same services in CAHs and small rural hospitals with fewer than 100 beds. CMS has not learned of any data or information from CAHs and small rural hospitals indicating that the quality of outpatient therapeutic services has been affected by requiring only general supervision.

In addition, CAHs and hospitals continue to be subject to conditions of participation (CoPs) that complement the supervision requirements that are a condition of payment to ensure that outpatient medical services Medicare patients receive are properly supervised. CMS has come to believe that the direct supervision requirement for hospital outpatient therapeutic services places an additional burden on providers that reduces their flexibility to provide medical care without improving the quality of care provided. Given that the direct supervision requirement has not been enforced for CAHs and small rural hospitals, CMS believes it is time to end what is effectively a two-tiered system of supervision levels for hospital outpatient therapeutic services. CMS proposed to change the generally applicable minimum required level of supervision for hospital outpatient therapeutic services from direct supervision to general supervision for services furnished by all hospitals and CAHs.

As it has done in the past, CMS will continue to have the Hospital Outpatient Payment Panel (HOP, a federal advisory committee that advises the Secretary on the OPPS) provide advice on the appropriate supervision levels for hospital outpatient services. It will also retain the ability to consider a change to the supervision level of an individual hospital outpatient therapeutic service through notice and comment rulemaking. CMS requested comments on its proposal and whether specific types of services, such as chemotherapy administration or radiation therapy, should be excepted from the policy.

The majority of commenters supported the proposal. Both CMS and the commenters agree that, although only general supervision is required for outpatient therapeutic services, providers and physicians have flexibility to require a higher level of supervision for any service they render if they believe a higher level is required to ensure the quality and safety of the procedure. CMS further explained the hospital CoPs require that a doctor of medicine (MD) or osteopathy (DO) be responsible for the care of every Medicare patient during a hospitalization. The CAH CoPs

furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed.

¹⁸ "General supervision" means the service is furnished under the physician's (or other practitioner's) overall direction and control, but the physician's (or other practitioner's) presence is not required during the performance of the service.

require an MD or DO to provide medical direction for the CAHs' health care activities, and consultation for, and medical supervision of, the health care staff.

MedPAC and other commenters strongly encouraged CMS to diligently monitor the impacts of the policy on the quality and safety of outpatient therapeutic services. There was also continued support by commenters for using the HOP Panel to make recommendations on supervision levels for individual therapeutic outpatient services. CMS agrees and will continue to have a system in place to change the default minimum level of physician supervision through notice and comment rulemaking based on recommendation from the HOP Panel.

Opponents of the policy change argued that qualified physicians need to directly supervise services, especially radiation therapy, hyperbaric oxygen treatment, and wound care.

Commenters were concerned that beneficiaries' health and safety could be at risk if hospitals perform these procedures in the absence of direct physician supervision. CMS believes its supervision requirements continue to provide the safeguards Medicare beneficiaries need to receive quality services and again noted that facilities can require a higher level of supervision for specific services if they believe more than general supervision is needed.

After reviewing all of the public comments, CMS is finalizing its proposal without modification.

B. Short Inpatient Stays

Since FY 2014, CMS has established that an inpatient admission is considered reasonable and necessary when the physician expects the patient to require a stay that crosses at least 2 midnights. Procedures on the IPO list would continue to be appropriate for inpatient hospital admission regardless of the expected length of stay.

Since 2016, CMS has allowed for case-by-case exceptions to the 2-midnight benchmark where the admitting physician does not expect the patient to require hospital care spanning 2 midnights but documentation in the medical record supports the physician's determination that the patient requires inpatient hospital care. The decision to formally admit a patient to the hospital is subject to the clinical judgment of a medical reviewer. The following criteria will be relevant to whether an inpatient admission with an expected length of stay of less than 2 midnights is appropriate for Medicare Part A payment:

- Complex medical factors such as history and comorbidities;
- The severity of signs and symptoms;
- Current medical needs; and
- The risk of an adverse event.

The 2-midnight benchmark is applicable once procedures have been removed from the IPO list. Procedures that are removed from the IPO list are also subject to initial medical reviews of claims for short-stay inpatient admissions conducted by Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs). BFCC-QIOs may also refer providers to the Recovery Audit Contractors (RACs) for further medical review due to exhibiting persistent noncompliance with Medicare payment policies, including, but not limited to:

- Having high denial rates;
- Consistently failing to adhere to the 2-midnight rule; or
- Failing to improve their performance after QIO educational intervention.

CMS proposed that procedures would not be eligible for referral to RACs for noncompliance with the 2-midnight rule within the first calendar year of their removal from the IPO list. During this 1-year period, BFCC-QIOs would have the opportunity to review such claims in order to provide education for practitioners and providers about compliance with the 2-midnight rule, but claims identified as noncompliant would not be denied under Medicare Part A.

Commenters supported the proposal but asked CMS to extend the period of time before a claim is referred to the RAC or denied for noncompliance with 2-midnight rule to two years. CMS agreed with the commenters that a 2-year exemption period will allow providers time to gather information on procedures newly removed from the IPO list. The 2-year exemption period will also allow education and guidance for the broader provider community and time to develop patient selection criteria to identify which patients are, and are not, appropriate candidates for outpatient procedures.

CMS further clarified that the exemption period applies only to reviews for site of service, not medical necessity. Section 1154(a)(1) of the Act authorizes BFCC-QIOs to review whether services are medically necessary including whether services that are provided on an inpatient basis could be appropriately and effectively provided on an outpatient basis. Accordingly, BFCC-QIOs will continue to conduct initial medical reviews for both the medical necessity of the services, and the medical necessity of the site-of-service. BFCC-QIOs will continue to be permitted and expected to deny claims if the service itself is determined not to be reasonable and medically necessary. The 2-year moratorium will apply only to a BFCC-QIO denial based on site-of-service or referral to a RAC. BFCC-QIOs will continue to review claims for education and compliance with the 2-midnight rule even though they may not deny the claim based on site-of-service.

CMS is finalizing its proposal but modifying the exemption period from 1 to 2 years.

C. Controlling Unnecessary Increases in the Volume of Outpatient Services

In 2019, CMS adopted a policy to pay a PFS equivalent amount for a clinical visit (G0463) when provided at an off-campus PBD excepted from section 603 of the Bipartisan Budget Act (BBA) of 2015 (referred to as excepted off-campus PBDs). Under this policy, CMS would pay the clinic visit at 40 percent of the full OPPS rate phased in over two years; 70 percent in 2019 and 40 percent in 2020 and future years. Consistent with the policy adopted in the 2019 OPPS rule, CMS proposed to pay 40 percent of the OPPS rate for clinic visits in 2020 provided in excepted off-campus PBDs. In addition, CMS is continuing to implement the policy as a savings not subject to budget neutrality.

Comments in Support of the Policy

Comments in support of the policy came from MedPAC, health insurance plans, physician associations, specialty medical associations and individual Medicare beneficiaries. The supporters indicated that this policy is “an important and necessary reform that can help reduce provider consolidation and thereby provide beneficiaries with more care options at a lower cost.” Commenters added that CMS cannot address the payment disparity between the outpatient hospital and physician office settings as long as it applies payment changes within the OPPS so they are budget neutral. MedPAC added that its 2012 and 2014 recommendations would apply site-neutral payment to additional services beyond the clinic visit and to both services provided on the campus and off the campus of a hospital.

CMS’ reiterated its response to comments in the 2019 OPPS final rule—outlining the growth in the OPPS spending over the years and its belief that implementing a volume control without increasing spending would simply shift services within the OPPS system rather than control for unnecessary spending. To the extent that similar services can be safely provided in more than one setting, CMS does not believe it is prudent for the Medicare program to pay more for these services in one setting than another. The final rule further asserts that budget neutrality only applies to “adjustments” to payment rates (such as the wage index and outliers) under section 1833(t)(2) of the Act and not the “method” established under section 1833(t)(2)(F) of the Act for controlling for the unnecessary increases in the volume of covered OPD services (i.e. the payment change to the clinic visit is not an “adjustment”).

One commenter generally supported site neutral payment but does not “believe that it is possible to sustain a high-quality health care system if site neutrality is defined as shrinking all payments to the lowest amount paid in any setting.” The commenter requested that savings from this policy be used to increase physician payments which have not been updated for medical inflation contributing to the differential in PFS and OPPS payments. CMS responded that the overall amount of Medicare payments to physicians and other entities made under the PFS is determined by the PFS statute implying it does not have the authority to do what this commenter requested.

Some commenters were concerned about the impact this payment change might have on rural providers and safety net health systems and requested that CMS exempt PBDs in Health Professional Shortage Areas or Medically Underserved Areas.” CMS responded that it believes the phase-in will help mitigate concerns about the impact of this policy on rural areas but it will continue to monitor access in these areas.

Comments Opposed to the Policy

Comments opposed to the policy indicated that the recent decision from the United States District Court for the District of Columbia, American Hospital Association, et al. v. Azar, No. 1:18-cv-02841-RMC (D.D.C. Sept. 17, 2019) requires CMS to revert back to the higher payment rates from 2018. Further, the Hospital Outpatient Panel (HOP) unanimously recommended that CMS freeze the payment policy for clinic visits furnished by excepted off-campus PBDs at 2019 rates and evaluate whether beneficiary access has been compromised. Commenters reiterated comments made on the 2019 OPPS rule that outpatient department spending has increased for a

variety of reasons that are outside of hospitals' control suggesting that the spending increases of concern to CMS are not unnecessary. Such reasons may include the hospital readmissions reduction program, hospital value-based purchasing, the 2-midnight rule as well demographic changes among Medicare beneficiaries.

CMS' response indicated the commenters provided some data illustrating that certain HOPDs serve unique patient populations and provide services to medically complex beneficiaries, but the data did not demonstrate the need for higher payment for clinic visits furnished in excepted off-campus PBDs. The fact that the commenters did not supply new or additional data supporting these assertions suggests to CMS that the payment differential is likely the main driver for unnecessary volume increases in outpatient department services, particularly clinic visits.

In response to the court decision, CMS acknowledges that the district court vacated its policy for 2019 and it is working to ensure affected 2019 claims for clinic visits are paid consistent with the court's order. However, the court's decision does not apply to 2020 and CMS is not changing its planned phase-in of the 2nd year reduction in payment while it appeals the district court decision. While CMS is not accepting the HOP's recommendation, it will continue to monitor and study the utilization of outpatient services as the HOP recommended.

Some commenters suggested remedies for refunding payments to hospitals for 2019 consistent with the court's order. CMS replied that it will consider these comments as it considers how to implement the court's order but also noted that it is appealing the court's decision.

CMS is finalizing its proposed policy without modification. For CY 2020, CMS will pay 40 percent of the full OPPS rate for G0463 with modifier "PO" on the claim. The "PO" modifier should be used for all services furnished in excepted off-campus PBDs (i.e. off-campus PBDs that furnished services before November 2, 2015). Considering the effects of estimated changes in enrollment, utilization, and case-mix, this policy results in an estimated 2020 savings of approximately \$800 million, with approximately \$640 million of the savings accruing to Medicare, and approximately \$160 million saved by Medicare beneficiaries in the form of reduced copayments.

The impact of this policy is shown in column 5 of Table 68 at the end of this summary.

XI. OPPS Payment Status and Comment Indicators

OPPS Payment Status Indicator Definitions

For 2020, CMS did not propose any changes to status indicators. Status indicators and their definitions can be found in Addendum D1 of the final rule. Each status indicator will identify whether a given code is payable under the OPPS or another payment system, and also whether particular OPPS policies apply to the code. The 2020 payment status indicator assignments for APCs and HCPCS codes are shown in Addenda A and B respectively.

Comment Indicator Definitions

For 2020, CMS is continuing to use the following comment indicators:

“CH”—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.

“NC”—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year for which CMS is requesting comments in the proposed rule, final APC assignment; comments will not be accepted on the final APC assignment for the new code.

“NI”—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.

“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 OPPS comment indicators for 2020 are listed in Addendum D2 of the final rule.

XII. MedPAC Recommendations

OPPS Update: MedPAC recommends that Congress update Medicare OPPS payment rates by 2 percent, with the difference between this and the update amount specified in current law to be used to increase payments in a new suggested Medicare quality program, the “Hospital Value Incentive Program (HVIP).” CMS indicates that MedPAC’s recommended update would require a change in law. The final rule update will be 2.6 percent or the hospital market basket of 3.0 percent less 0.4 percentage points for multifactor productivity.

ASC Update: MedPAC indicates that payments to ASCs are adequate and recommended no payment update. CMS is adopting an ASC update of 2.6 percent equal to the hospital market basket less 0.4 percentage points for multifactor productivity consistent with the law. CMS has the authority to select the market basket used in the update but once selected is required to use that market basket less multifactor productivity in the update.

MedPAC commented in opposition to using the hospital market basket to update ASC rates as it does not believe the hospital market basket is representative of ASC costs. CMS responded that using the same update mechanism for ASCs and hospitals could encourage migration of services to the lower cost ASC setting. The final rule update will be 2.6 percent or the hospital market basket of 3.0 percent less 0.4 percentage points for multifactor productivity.

ASC Cost Data: MedPAC recommended that Congress require ASCs to report cost data to enable the Commission to examine the growth of ASCs’ costs over time and analyze Medicare payments relative to the costs of efficient providers. CMS could use ASC cost data to examine whether an existing Medicare price index is an appropriate proxy for ASC costs or an ASC

specific market basket should be developed. Further, MedPAC suggested that CMS could limit the scope of the cost reporting system to minimize administrative burden on ASCs and the program. CMS recognizes that the submission of cost data places additional administrative burden on ASCs and is not proposing any cost reporting requirements for ASCs.

XIII. Updates to the ASC Payment System

Summary of Selected Key Elements of ASC Payment Rates for 2020		
	ASCs reporting quality data	ASCs not reporting quality data
2019 ASC Conversion Factor		\$46.532
Wage index budget neutrality adjustment		1.0001
2020 Update		
Hospital market basket update		3.0%
Multi-factor productivity adjustment (MFP)		-0.4%
Net MFP adjusted update		2.6%
Penalty for not reporting quality data	0.0%	-2.0%
Net MFP and quality adjusted update	2.6%	0.6%
2020 ASC Conversion Factor	\$47.747	\$46.816

CMS estimates that under the final rule, total ASC payments for 2020 will be \$4.96 billion, an increase of about \$230 million over 2019 levels inclusive of changes in enrollment, utilization and case mix changes.

As with the rest of the OPPS final rule and other CMS rules, addenda related to the ASC section (and referenced in this summary) are available only on the CMS website, at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1717-FC.html>. All ASC Addenda to the final rule are contained in the zipped folders entitled Addendum AA, BB, DD1, and DD2.

A. Background

Covered surgical procedures in an ASC are those that would not be expected to pose a significant risk to the beneficiary, require an overnight stay or active medical monitoring and care at midnight following the procedures. Payment for ancillary items and services (with some exceptions) are packaged into the ASC payment. The ASC payment is generally a percentage of the OPPS payment rate unless the service is “office-based.” Payment for office-based services is capped based on the PFS non-facility payment.

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.

Until 2019, CMS has defined a surgical procedure as any procedure in the surgery CPT code range (CPT codes 10000 through 69999) or Level II HCPCS codes or Category III CPT codes

that directly crosswalk or are clinically similar to procedures in the CPT surgical range that meet the criteria to be paid in an ASC. Beginning with 2019, CMS is including “surgery-like” procedures outside the CPT surgical range that meet the criteria for ASC payment on the ASC list.

B. Treatment of New and Revised Codes

CMS evaluates new codes for inclusion on the ASC list or as separately paid ancillary services and if ASC list services are office-based. 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 the proposed rule; and
- New codes for which it will be seeking comments in the forthcoming final rule with comment period.

Table 53 from the final rule provides the process and timeline for ASC list updates:

Comment and Finalization Timeframes for New or Revised HCPCS Codes (from CMS Table 53)				
ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 1, 2019	Level II HCPCS Codes	April 1, 2019	2020 OPPS/ASC proposed rule	2020 OPPS/ASC final rule with comment period
July 2019	Level II HCPCS codes Category I (certain vaccine codes) and III CPT codes	July 1, 2019		
October 2019	Level II HCPCS Codes	October 1, 2019	2020 OPPS/ASC final rule with comment period	2021 OPPS/ASC final rule with comment period
January 2020	Category I and III CPT codes	January 1, 2020	2020 OPPS/ASC proposed rule	2020 OPPS/ASC final rule with comment period
	Level II HCPCS Codes		2020 OPPS/ASC final rule with comment period	2021 OPPS/ASC final rule with comment period

Treatment of New and Revised Level II HCPCS Codes and Category III CPT Codes Implemented in April and July of 2019 for Which CMS Solicited Public Comments in the Proposed Rule

In April and July of 2019 change requests (CRs), CMS made 22 new Level II HCPCS codes and 1 new Category III CPT Code effective as covered ASC services. These codes that were not included in the 2018 OPPS final rule. Tables 50-52, copied below, set out the codes, descriptors, and the 2020 payment indicators.

New Level II HCPCS Codes for Ancillary Services Effective on April 1, 2019 (Table 50)			
2019 HCPCS Code	2020 HCPCS Code	Long Descriptor	Final CY 2020 Payment Indicator
C9040	J3031	Injection, fremanezumab-vfrm, 1mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)	K2
C9041	C9041	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	K2
C9042*	J9036	Injection, bendamustine hcl (belrapzo), 1 mg	D5
C9043	J0642	Injection, levoleucovorin, 1 mg	K2
C9044	J9119	Injection, cemiplimab-rwlc, 1 mg	K2
C9045	J9313	Injection, moxatumomab pasudotox-tdfk, 0.01 mg	K2
C9046	C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	K2
C9141**	J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl (jivi) 1 i.u.	K2

*HCPCS code C9042, which was effective April 1, 2019, was deleted June 30, 2019 and replaced with HCPCS code J9036 (Injection, bendamustine hydrochloride, (Belrapzo/bendamustine), 1 mg) effective July 1, 2019.

**HCPCS code C9141, which was effective April 1, 2019, was deleted June 30, 2019 and replaced with HCPCS code J7208 (Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl, (jivi), 1 i.u.), 1 mg) effective July 1, 2019.

New Level II HCPCS Codes for Covered Surgical Procedures and Ancillary Services Effective on July 1, 2019 (Table 51)			
2019 HCPCS Code	2020 HCPCS Code	CY 2019 Long Descriptor	Final 2020 PI
C9047	C9047	Injection, caplacizumab-yhdp, 1 mg	K2
C9048	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	K2
C9049	J9269	Injection, tagraxofusp-erzs, 10 mcg	K2
C9050	J9210	Injection, emapalumab-lzsg, 1 mg	K2
C9051	J0121	Injection, omadacycline, 1 mg	K2
C9052	J1303	Injection, ravulizumab-cwvz, 10 mg	K2
J7208	J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl, (jivi), 1 i.u.	K2
J9030	J9030	BCG live intravesical instillation, 1 mg	K2
J9036	J9036	Injection, bendamustine hydrochloride, (Belrapzo/bendamustine), 1 mg	K2
J9356	J9356	Injection, trastuzumab, 10 mg and Hyaluronidase-oysk	K2
0548T*	0548T*	Transperineal periurethral balloon continence device; bilateral placement, including cystoscopy and fluoroscopy	J8
0549T	0549T	Transperineal periurethral balloon continence device; unilateral placement, including cystoscopy and fluoroscopy	J8
0550T	0550T	Transperineal periurethral balloon continence device; removal, each balloon	G2

0551T	0551T	Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume	R2
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*The predecessor code for CPT code 0548T was HCPCS code C9746 (Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed and/or fluoroscopy, when performed), which was effective July 1, 2017 and deleted on June 30, 2019.

New Category III CPT Code for Covered Ancillary Service Effective on July 1, 2019 (Table 52)			
2019 HCPCS	CY 2019 Long Descriptor	2020 CI	Final 2020 PI
0558T	Computed tomography scan taken for the purpose of biomechanical computed tomography analysis	NP	Z2

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

New and Revised Level II HCPCS Codes That Will Be Effective October 1, 2019 and January 1, 2020 for Which CMS will be Soliciting Public Comments in the 2020 OPPS/ASC Final Rule with Comment Period.

CMS is continuing to assign comment indicator “NI” in Addendum BB to the 2020 OPPS/ASC final rule for those new and revised Level II HCPCS codes that are effective October 1, 2019. This indicates that CMS has assigned the codes an interim OPPS payment status for 2020.

CMS invites comments in the 2020 OPPS/ASC final rule with comment period on the interim payment indicators which will then be finalized in the 2021 OPPS/ASC final rule with comment period.

CPT Codes for which CMS Sought Public Comments in the Proposed Rule

CMS sought comment on the proposed new and revised CPT codes effective January 1, 2020 that were received in time to be included in the proposed rule. They will be finalized in the 2020 OPPS/ASC final rule with comment period.

For the 2020 ASC update, the new and revised codes can be found in Addendum AA and BB. The codes are assigned comment indicator “NP” indicating that it is new or has had substantial revision. In addition, long descriptors are available in Addendum O.

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. CMS’ medical advisors review these procedures for consistency

with other procedures performed routinely in physicians' offices. Based on its review of 2018 volume and utilization data, CMS proposed to permanently designate nine additional procedures as office-based (shown in Table 29 in the proposed rule). After consideration of comments received, CMS finalizes its proposal, with modification, to designate four ASC covered surgical procedures as permanently office-based for 2020 and subsequent years (as shown in Table 55 in the final rule, and reproduced below). CMS notes in response to comments that it inadvertently included the five codes as office-based in the proposed rule that it did not finalize (CPT codes 31634, 31647, 50727, 59414, and 61880) as volume and utilization data do not suggest that these procedures are performed more than 50 percent of the time in physicians' offices.

ASC Covered Surgical Procedures to be Newly Designated as Permanently Office-based for CY 2020 (Table 55)			
CY 2020 CPT Code	CY 2020 Long Descriptor	CY 2019 ASC Payment Indicator	CY 2020 ASC Payment Indicator*
31298	Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (e.g., balloon dilation)	G2	P2*
36465	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (eg, great saphenous vein, accessory saphenous vein)	G2	P2*
36466	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (eg, great saphenous vein, accessory saphenous vein), same leg	G2	P2*
36482	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated	G2	P3*

*Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the PFS final rates. For a discussion of the PFS rates, CMS refers readers to the CY 2020 PFS final rule.

CMS also reviewed 2018 volume and utilization data for 12 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 11 of these procedures and proposed to maintain the temporary office-based designations for these codes (CPT codes 10005, 10007, 10009, 10011, 11102, 11104, 11106, 65785, 67229, 0402T, and 0512T) for 2020. The volume and utilization data for the remaining procedure (CPT code 38222) was sufficient to indicate that this procedure is performed predominately in physicians' offices and thus CMS proposes to assign it an office-based indicator ("G2") for 2020. Table 56 (reproduced below) in the final rule lists the procedures and CMS' payment indicators for 2020. CMS did not receive any comments, and finalizes its proposal, without modification.

CY 2020 Payment Indicators for ASC Covered Surgical Procedures Designated as Temporarily Office-Based in the CY 2019 OPPS/ASC Final Rule with Comment Period (Table 56)			
2020 CPT/HCPCS Code	CY 2020 Long Descriptor	2019 ASC Payment Indicator	2020 ASC Payment Indicator*
10005	Fine needle aspiration biopsy, including ultrasound guidance; first lesion	P3	P3*
10007	Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion	P3	P3*
10009	Fine needle aspiration biopsy, including CT guidance; first lesion	P2	P2*
10011	Fine needle aspiration biopsy, including MR guidance; first lesion	R2	R2*
11102	Tangential biopsy of skin (eg, shave, scoop, saucerize, curette); single lesion	P3	P3*
11104	Punch biopsy of skin (including simple closure, when performed); single lesion	P2	P2*
11106	Incisional biopsy of skin (eg, wedge) (including simple closure, when performed); single lesion	P3	P3*
65785	Implantation of intrastromal corneal ring segments	P2	P2*
67229	Treatment of extensive or progressive retinopathy, 1 or more sessions, preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (eg, retinopathy of prematurity), photocoagulation or cryotherapy	R2	R2*
0402T	Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed)	R2	R2*
0512T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	R2	R2*

CMS finalizes its proposal, without modification, to designate seven new 2020 CPT codes as ASC covered surgical procedures as temporary office-based, using a 5-digit CMS placeholder code. Table 57 in the final rule (reproduced below) lists the procedures and payment indicators.

2020 Payment Indicators for New 2020 CPT Codes for ASC Covered Surgical Procedures Designated as Temporarily Office-based (Table 57)			
2020 CPT Code	2020 OPPS/ASC proposed rule 5-digit CMS placeholder code	CY 2020 Long Descriptor	2020 ASC Payment Indicator**
64454	64XX0	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed	P3**
64624	64XX1	Destruction by neurolytic agent, genicular nerve branches, including imaging guidance, when performed	P3**
93985	93X00	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study	P2**
93986	93X01	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study	P2**
0551T		Transperineal perirethral balloon continence device; adjustment of balloon(s) fluid volume	R2**
0566T	05X4T	Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; injection of cellular implant into knee joint including ultrasound guidance, unilateral	R2**
0588T	0X71T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve.	R2**

**Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the PFS final rates. For a discussion of the MPFS rates, CMS refers readers to the CY 2020 PFS final rule.

ASC Covered Surgical Procedures to Be Designated as Device-Intensive

Surgical procedures designated as device-intensive are subject to a special payment methodology. The device portion of the payment is determined by applying the device offset percentage to the standard OPPS payment. The service portion of the ASC payment for device-intensive procedures is determined by applying the uniform ASC conversion factor to the non-device portion of the OPPS relative payment weight. The ASC device portion and ASC non-device portion are summed to establish the full payment for the device-intensive procedure under the ASC payment system. This policy applies only when the device-intensive procedure is furnished with a surgically inserted or implanted device (including single use medical devices)—a policy CMS inadvertently omitted from the 2019 final rule.

In the 2019 OPPS/ASC final rule, CMS lowered the device offset percentage threshold from 40 percent to 30 percent, and aligned the device-intensive policy with the criteria used for device pass-through status. Based on CMS' modifications to its device-intensive criteria, CMS updates

the ASC list of covered surgical procedures that are eligible for payment according to the device-intensive payment methodology for 2020, reflecting the individual HCPCS code device offset percentages based on 2018 OPPS claims and cost report data.¹⁹

CMS designates the ASC covered surgical procedures displayed in Addendum AA as device-intensive with a “J8” indicator.

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

CMS is making no changes to its policy for devices furnished with full or partial credit in the ASC system:

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

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

Additions to the List of ASC Covered Surgical Procedures

CMS finalizes its proposal, without modification, to add four mosaicplasty procedures, three coronary intervention procedures and total knee arthroplasty (TKA) to the list of ASC covered surgical procedures. These procedures are displayed in Table 60 of the final rule (duplicated below). CMS also notes that it inadvertently omitted 12 new CPT and new HCPCS codes effective January 1, 2020 from the proposed rule table, though it had included them in Addendum AA of the proposed rule.

¹⁹ Note that the device offset for ASCs may be higher than under the OPPS for APCs subject to the C-APC methodology under the OPPS that does not apply under the ASC system. For APCs paid under the C-APC methodology, the source of the ASC relative weight is the 2020 NFRM OPPS Relative Weights without C-APC Methodology for ASC Ratesetting at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1717-FC.html>. The device offset percentage is the same one that is used for the recalled/partial credit device policy that can be found at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Policy-Files.html>.

Table 60.— Additions to the List of ASC Covered Surgical Procedures for 2020

2020 CPT/ HCPCS Code	2020 Long Descriptor	2020 ASC Payment Indicator
15769	Grafting of autologous soft tissue, other, harvested by direct excision (eg, fat, dermis, fascia)	G2
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate	G2
15773	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; 25 cc or less injectate	G2
27447	Arthroplasty, knee, condyle and plateau; medial and lateral compartments with or without patella resurfacing (total knee arthroplasty)	J8
29867	Arthroscopy, knee, surgical; osteochondral allograft (eg, mosaicplasty)	J8
33016	Pericardiocentesis, including imaging guidance, when performed	G2
46948	Hemorrhoidectomy, internal, by transanal hemorrhoidal dearterialization, 2 or more hemorrhoid columns/groups, including ultrasound guidance, with mucopexy, when performed	G2
62328	Spinal puncture, lumbar, diagnostic; with fluoroscopic or CT guidance	G2
62329	Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter); with fluoroscopic or CT guidance	G2
64451	Injection(s), anesthetic agent(s) and/or steroid; nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)	G2
64625	Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)	G2
66987	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with endoscopic cyclophotocoagulation	J8
66988	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with endoscopic cyclophotocoagulation	J8

92920	Percutaneous transluminal coronary angioplasty; single major coronary artery or branch	J8
92921	Percutaneous transluminal coronary angioplasty; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	N1
92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	J8
92929	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	N1
0587T	Percutaneous implantation or replacement of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve	J8
C9600	Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	J8
C9601	Percutaneous transcatheter placement of drug-eluting intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	N1

Many commenters were supportive of CMS' proposal to add three coronary intervention procedures as well as the additional three procedures that represented their associated add-on procedures to the ASC CPL. Others opposed their inclusion and believed that these procedures should be performed in a hospital setting. In response, CMS believes that it is appropriate to exclude certain cardiac procedures from the ASC list because they involve major blood vessels, yet continue to provide ASC payment for certain procedures involving major blood vessels that have a history of safe performance in ASCs. CMS believes that these three coronary intervention procedures are safe to perform in an ASC.

With respect to providing TKA in the ASC setting, commenters were generally supportive, but those opposed to TKA in the ASC setting noted that the majority of Medicare beneficiaries would not be suitable candidates to receive this procedure in the ASC setting based on factors such as age, comorbidity, and body mass index. CMS agrees, but believes that there are a small number of less medically complex beneficiaries that could appropriately receive the TKA procedure in an ASC setting. CMS also acknowledges that beneficiaries may incur greater cost sharing for TKA procedures in an ASC setting under its proposal, but notes that some beneficiaries, especially those with supplemental insurance, may still choose to have their procedure performed in an ASC setting. CMS finalizes the addition of the TKA to the ASC list. It is not finalizing any of the additional requirements that it sought comment on, such as adding a modifier or requiring an ASC to have a certain amount of experience in performing a procedure before being eligible for payment from Medicare.

Comment Solicitation on Coronary Intervention Procedures

In addition to those recommended additions to the ASC list for 2020 described above, CMS also reviewed several other coronary intervention procedures, CPT codes 92924, 92925, 92933, 92934, 92937, 92938, 92943, 92944, 92973, C9602, C9604, C9605, C9607, and C9608. CMS stated in the proposed rule that it was not recommending adding them to the ASC list but sought comment on whether such procedures can be safely performed in an ASC.

Some commenters supported adding all of these procedures to the ASC list citing claims data, clinical trials, and clinical guidelines support their addition. Others were opposed indicating that these procedures often carry the risk of serious possible complications, such as in-facility death, damage to or perforations of coronary arteries, and intramural hematoma, among others. Thus, they argue that such procedures should only be performed in hospital settings where rapid access to onsite cardiac surgery as well as intensive care units are available. CMS agrees with the commenters in opposition, and believes that adding any of the listed coronary intervention procedures would expose beneficiaries to significant risk.

D. Update to ASC Covered Surgical Procedures and Covered Ancillary Services

ASC Payment for Covered Surgical Procedures

CMS continues its policy to update payments for office-based procedures and device-intensive procedures using its established methodology and using its modified definition for device-intensive procedures for all but low volume device-intensive procedures. Payment for office-based procedures will be the lesser of the 2020 PFS non-facility practice expense payment amount, or the 2020 ASC payment amount. CMS continues its policy for device removal procedures – such procedures that are conditionally packaged in the OPPS would be assigned the current ASC payment indicators and continue to be paid separately under the ASC payment system.

Limit on ASC Payment for Low Volume Device-Intensive Procedures

Data anomalies for low-volume procedures can result in inappropriate payment rates using the standard ASC methodology for rate-setting. CMS finalizes its proposal, without modification, for 2020 and subsequent years to limit the ASC payment rate for low-volume device intensive procedures to a payment rate equal to the OPPS payment rate for the procedure. Level 5 Intraocular Procedures are the only affected APC.

Payment for Covered Ancillary Services

CMS continues to update payments and make changes necessary to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services. It is not making any changes to prior year policies for how it determines payment for covered ancillary services. Under a new policy adopted in 2019, opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting are

unpackaged and paid separately at ASP+6 percent. CMS notes that it will continue to review and revise ASC payments for non-opioid alternatives for pain management as appropriate.

E. New Technology Intraocular Lenses (NTIOL)

CMS did not receive any requests for review to establish a new NTIOL class for 2020 by the March 1, 2019 deadline. CMS is not making any change to its payment adjustment of \$50 per lens for a 5-year period from the implementation date of a new NTIOL class.

F. ASC Payment and Comment Indicators

CMS continues its use of the current comment indicators “NP” and “CH.” Category I and III CPT codes that are new and revised for 2020 and any new and existing Level II HCPCS codes with substantial revisions were labeled with the comment indicator ‘NP’ to indicate that these codes were open for comment as part of the 2020 proposed rule. CMS did not receive any public comments on the ASC payment and comment indicators, and thus it is finalizing their use as proposed without modification.

Addenda DD1 and DD2 to this final rule provide a complete list of the ASC payment and comment indicators for 2020.

G. Calculation of the ASC Payment Rates and Conversion Factor

CMS continues to update relative weights using the national OPPS relative weights and the PFS non-facility PE RVU-based amounts when applicable. CMS scales the relative weights as under prior policy. Holding ASC use and mix of services constant, CMS computes the ratio of:

- Total payments using the 2019 relative payment rates, to
- Total payments using the 2020 relative payment rates.

The resulting ratio, 0.8550, is the weight scaler for 2020. 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. The scaler would not apply to ASC payments for separately payable covered ancillary services that have a predetermined national payment amount and are not based on OPPS relative payment weights (e.g., drugs and biologicals that are separately paid and services that are contractor-priced or paid at reasonable cost in ASCs). The supporting data file is posted on the CMS Web site at:

<http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/ASCPaymentSystem.html>.

Updating the ASC Conversion Factor

CMS continues to compute the budget neutrality adjustment factor for provider level changes (notably for changes in wage index values) to the conversion factor in the same manner as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor. Holding constant ASC use and mix of services in 2018 and the 2020 national payment

rates after application of the weight scaler, CMS computes the ratio of:

- ASC payments using the 2019 ASC wage indices, to
- ASC payments using the 2020 ASC wage indices.

The resulting ratio, 1.0001, is the wage index budget neutrality adjustment to the conversion factor for 2020.

To update ASC rates, CMS will utilize the hospital market basket update of 3.0 percent minus the multifactor productivity adjustment (MFP) of 0.4 percent. This yields an update of 2.6 percent for ASCs meeting quality reporting requirements.

CMS would continue its policy of reducing the update by 2.0 percentage points for ASCs not meeting the quality reporting requirements, yielding an update of 0.6 percent for such ASCs. The resulting 2020 ASC conversion factor is \$47.747 for ASCs reporting quality data, and \$46.816 for those that do not, computed as follows:

	ASCs reporting quality data	ASCs not reporting quality data
2019 ASC conversion factor	\$46.532	
Wage adjustment for budget neutrality	x 1.0001	
Net MFP-adjusted update	x 1.026	x 1.006
2020 ASC conversion factor	\$47.747	\$46.816

H. Impact

CMS provides the 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 2018 claims data. (Table 69 of the final rule and reproduced below). The eye and ocular adnexa group remains the largest source of payments, with 4 percent increase in payments attributable to the changes for 2020. The second largest group, nervous system, is estimated to see a 3 percent increase.

Table 69 – Estimated Impact of the Final 2020 Update to the ASC Payment System on Aggregate 2020 Medicare Program Payments by Surgical Specialty or Ancillary Items and Services Group

Surgical Specialty Group	Estimated 2019 ASC Payments (in Millions)	Estimated 2020 Percent Change
Total	\$5,044	3%
Eye and ocular adnexa	\$1,743	4%
Nervous system	\$1,106	3%
Digestive system	\$893	1%
Musculoskeletal system	\$608	2%
Genitourinary system	\$194	2%

Table 69 – Estimated Impact of the Final 2020 Update to the ASC Payment System on Aggregate 2020 Medicare Program Payments by Surgical Specialty or Ancillary Items and Services Group

Surgical Specialty Group	Estimated 2019 ASC Payments (in Millions)	Estimated 2020 Percent Change
Cardiovascular system	\$184	5%
Ancillary items and services	\$99	-12%

CMS provides estimated increases for 30 selected procedures in Table 70 in the final rule; the top 10 procedures are replicated below. CPT code 66984 (Cataract surgery with intraocular lens, 1 stage) is the largest aggregate payment procedure by far and is estimated to have a 3 percent increase in payment. The second largest aggregate payment procedures, CPT code 63685, is expected to see a 4 percent increase.

Excerpt from Table 70: Estimated Impact of the 2020 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	\$1,210	3%
63685	Insert/redo spine n generator	\$259	4%
45385	Colonoscopy w/lesion removal	\$200	0%
45380	Colonoscopy and biopsy	\$184	0%
63650	Implant neuroelectrodes	\$183	1%
43239	Egd biopsy single/multiple	\$177	1%
64483	Inj foramen epidural l/s	\$114	4%
0191T	Insert ant segment drain int	\$96	1%
66982	Cataract surgery complex	\$91	3%
64635	Destroy lumb/sac facet jnt	\$79	2%

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-1717-FC.html>. They include:

- AA -- ASC Covered Surgical Procedures for 2020 (Including surgical procedures for which payment is packaged)
- BB –ASC Covered Ancillary Services Integral to Covered Surgical Procedures for 2020 (Including Ancillary Services for Which Payment is Packaged)
- DD1 –ASC Payment Indicators for 2020
- DD2 –ASC Comment Indicators for 2020
- EE -- Surgical Procedures to be Excluded from Payment in ASCs for 2020

XIV. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

In this section, CMS finalizes removal of one measure from the OQR Program beginning with the 2022 payment determination. No changes were proposed to other policies, including those regarding priorities for measure selection; retention of measures; considerations in removing measures; data submission deadlines; public display of measures; QualityNet account and security administrator requirements; data submission requirements; data validation; extraordinary circumstances exceptions; or reconsiderations and appeals. A table at the end of this section shows the OQR Program measures for 2018 through 2022.

A. Measure Removal

CMS finalizes removal of the measure OP-33: External Beam Radiotherapy for Bone Metastases (NQF #1822) from the OQR Program beginning with 2022 payment. The basis for this decision is removal factor 8: costs outweigh the benefit of continued use of the measure. CMS discusses issues with reporting the measure, noting that it receives more questions about how to report this measure than any other in the program. Specific concerns are discussed with respect to measure exclusion, sampling concerns, and administrative burden, in particular the need for detailed manual review of patient records to determine which cases are included in both the measure denominator and the numerator. The measure was also removed from the PPS-exempt Cancer Hospital Quality Reporting Program (84 FR 42513) because it is burdensome and because the measure steward is no longer maintaining the measure. Because the measure is no longer being maintained, CMS states that it cannot ensure the measure is in line with clinical guidelines and standards.

The final rule corrects the effective date of removal to be January 1, 2020. CMS had proposed that the measure would no longer be required beginning with October 2020 encounters. Data is submitted annually on this measure using a web-based tool. The final reporting on this measure will be required by May 31, 2020 for 2019 encounters, which will apply to the OQR Program for 2021.

Removal of this measure is estimated to reduce reporting burden by 551 hours and \$21,379 across 3,300 hospitals. CMS also believes that additional burden and cost reduction will result from hospitals no longer having to implement, review, track, and maintain program requirements associated with this measure.

B. OQR Program Measures and Topics for Future Consideration

CMS summarizes responses it received to its request for comments on the potential addition to the OQR Program of four patient safety measures that were previously adopted for the ASC quality reporting (ASCQR) Program. Data collection for these four ASC measures was suspended beginning in 2019 (for the 2021 payment determination) because of concerns about their reliance on data submission using quality data codes (QDCs)²⁰. As discussed elsewhere in

²⁰ During rulemaking for 2019, CMS originally proposed to remove these four measures from the ASCQR Program because they were topped out, but was convinced by public comments that the measures have more value to stakeholders than it previously understood. However, because of its concern that ASCs cannot correct the QDC

this rule (section XV.B below), CMS also sought comments on changing the data submission method for these measures in the future to an online tool, which is what it would also use for the OQR Program were it to propose the addition of these measures in the future.

CMS believes these measures provide important data on events that should never occur and would align the OQR and ASCQR programs. National Quality Forum (NQF) endorsement of these measures was allowed to lapse by the measure steward. CMS intends to coordinate with the measure steward and seek NQF endorsement for the measures.

- ASC-1: Patient Burn, which assesses the percentage of admissions experiencing a burn prior to discharge.
- ASC-2: Patient Fall, which assesses the percentage of admissions experiencing a fall.
- ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; which assesses the percentage of patients experiencing any of these events.
- ASC-4: All-Cause Hospital Transfer/Admission, which assesses the rate of ASC admissions requiring a hospital transfer or admission upon discharge from the ASC.

CMS was also interested in comments on outcome measures that might be added to the program and on current process measures that might be removed in keeping with its goal of focusing on informed decision-making and OPD quality improvement.

Comments included recommendations for seeking NQF endorsement and review by the Measures Application Partnership before proposing addition of these measures; suggestions for data submission methods; and consideration of overlap between the ASC-4 measure of hospital transfers and admissions and OP-36 regarding hospital visits after outpatient surgery.

C. Summary Table of OQR Program Measures

The table below shows the final OQR Program measure sets for payment years 2018 through 2022. Specifications for OQR Program measures are available on the QualityNet website: <https://www.qualitynet.org/outpatient/oqr>

SUMMARY TABLE OF HOSPITAL OQR PROGRAM MEASURES 2018-2023						
NQF		2018	2019	2020	2021	2022
0287 ⁺	OP-1: Median Time to Fibrinolysis	X	X	Removed		
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED arrival	X	X	X	X	X
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention	X	X	X	X	X
0286 ⁺	OP-4: Aspirin at Arrival	X	X	Removed		
0289 ⁺	OP-5: Median Time to ECG	X	X	X	Removed	
0514 ⁺	OP-8: MRI Lumbar Spine for Low Back Pain	X	X	X	X	X

codes used to calculate the measures from claims once they are submitted, CMS elected to suspend data collection on these measures until a new data submission method could be developed.

SUMMARY TABLE OF HOSPITAL OQR PROGRAM MEASURES 2018-2023						
NQF		2018	2019	2020	2021	2022
	OP-9: Mammography Follow-up Rates	X	X	X	Removed	
	OP-10: Abdomen CT – Use of Contrast Material	X	X	X	X	X
0513	OP-11: Thorax CT – Use of Contrast Material	X	X	X	Removed	
	OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC Certified EHR System as Discrete Searchable Data	X	X	X	Removed	
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery	X	X	X	X	X
	OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)	X	X	X	Removed	
0491 ⁺	OP-17: Tracking Clinical Results between Visits	X	X	X	Removed	
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients	X	X	X	X	X
	OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional	X	X	Removed		
0662	OP-21: ED- Median Time to Pain Management for Long Bone Fracture	X	X	Removed		
0499 ⁺	OP-22: ED- Left Without Being Seen	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
	OP-25: Safe Surgery Checklist Use	X	X	Removed		
	OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures	X	X	Removed		
0431	OP-27: Influenza Vaccination Coverage among Healthcare Personnel	X	X	Removed		
0658	OP-29: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients	X	X	X	X	X
0659	OP-30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use	X	X	X	Removed	
1536 ⁺	OP-31: Cataracts – Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery	Voluntary				
2539	Op-32: Facility Seven Day Risk Standardized Hospital Visit Rate After Outpatient Colonoscopy	X	X	X	X	X

SUMMARY TABLE OF HOSPITAL OQR PROGRAM MEASURES 2018-2023						
NQF		2018	2019	2020	2021	2022
1822	OP-33: External Beam Radiotherapy for Bone Metastases	X	X	X	X	Removed
	OP-35: Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy			X	X	X
2687	OP-36: Hospital Visits After Hospital Outpatient Surgery			X	X	X
	OP-37a: OAS CAHPS – About Facilities and Staff*					
	OP-37b: OAS CAHPS – Communication About Procedure*					
	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery*					
	OP-37d: OAS CAHPS – Overall Rating of Facility*					
	OP-37e: OAS CAHPS – Recommendation of Facility*					

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

* Mandatory reporting on these measures, once scheduled to begin in 2018 for the 2020 payment determination, was indefinitely delayed (82 FR 59432). CMS implemented a voluntary national reporting program for the OAS CAHPS Survey in January 2016. More information is available at <https://oascahps.org/General-Information/National-Implementation>.

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

Existing policies with respect to computing and applying the payment reduction for hospitals that fail to meet the Hospital OQR Program requirements are continued for the 2020 update factor. The final reduction ratio for hospitals that fail to meet OQR Program requirements, called the “reporting ratio”, is 0.981. It is calculated by dividing the final reduced conversion factor of \$79.250 by the full conversion factor of \$80.784. Continuing previous policies, when applicable, the reporting ratio will be applied to all services calculated using the OPPS conversion factor and applied to all HCPCS codes to which CMS has assigned status indicators J1, J2, P, Q1, Q2, Q3, R, S, T, V, or U, excluding services paid under the New Technology APCs to which CMS has assigned status indicators S and T.

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

CMS reports that for 2019 payment, 14 hospitals (out of about 3,300) failed to meet the OQR Program requirements for a full update factor.

XV. Ambulatory Surgical Center Quality Reporting Program (ASCQR)

CMS adds one new measure to the ASCQR Program beginning with the 2024 payment determination. No changes were proposed to other policies, including those regarding priorities for measure selection; retention and removal of measures; public display of measures; QualityNet account and security administrator requirements; data submission requirements; extraordinary circumstances exceptions; or reconsiderations and appeals. A table at the end of this section shows the previously adopted ASCQR Program measures for 2018 through 2022 along with the additional measure for 2024.

A. New Measure

CMS adds one new measure for the ASCQR Program beginning with the 2024 payment determination, ASC-19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357). This new measure is related to two other measures that were previously adopted for the program to begin with the 2022 payment determination: ASC-17: Hospital Visits After Orthopedic Ambulatory Surgical Center Procedures and ASC-18: Hospital Visits After Urology Ambulatory Surgical Center Procedures. All three measures assess the same patient outcome for care provided in the ASC setting and use the same risk-adjustment methodology, although the procedures, risk variables and reporting of the outcome differ among them. As background, CMS describes the literature on adverse events after ambulatory surgery and opportunities for improved quality of care.

ASC-19 is a risk-adjusted measure of acute unplanned hospital visits with 7 days of a general surgery performed at an ASC among Medicare patients age 65 and older. An unplanned hospital visit is defined as an emergency department visit, observation stay, or unplanned inpatient admission. It was endorsed by the NQF in June 2018. Details on the measure's calculations, patient cohort, target procedures, and risk adjustment are discussed in the final rule. The measure will be calculated by CMS using claims data; no additional data would need to be reported by ASCs. Measure specifications and an updated technical report can be found in the downloads section of the following webpage: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

Under the final rule, measure performance will be publicly reported for facilities with sufficient case numbers to meet moderate reliability standards. A dry run of the measure would be conducted before any public reporting. This would include confidential feedback reports provided through QualityNet accounts, including patient-level data on the type of hospital visit, the admitting facility and the discharge diagnosis. These reports would continue after the measure was implemented in order to help ASCs identify performance gaps and develop quality improvement strategies.

CMS responds to numerous comments on this measure. Among other issues, the responses note that the measure is intended to focus only on the subset of ASC-covered surgeries that pose a meaningful risk of post-procedure hospital visits and state that CMS will continue to evaluate which procedures are included in the measure cohort; discuss the measure's use of unplanned hospital admissions; describe the measure's reliability testing results as consistent with similar

outcome measures; and argue that the use of 2 years of data for the cohort of procedures will result in a sufficient number of ASCs meeting the minimum volume threshold.

B. ASCQR Program Measures and Topics for Future Consideration

CMS describes comments it received on updating the data submission method for the four patient safety measures for which data submission is currently suspended. The measures are:

- ASC-1: Patient Burn
- ASC-2: Patient Fall
- ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
- ASC-4: All-Cause Hospital Transfer/Admission

These measures are calculated via QDCs reported on Medicare claims. In the 2019 OPPS/ASC final rule CMS suspended data submission on these measures out of concern that an ASC that identifies an erroneous or missing QDC is unable to add or correct it once the claim has been submitted to Medicare and processed. At that time, CMS indicated its intention to update the data submission method for these measures in the future.

CMS specifically sought comment on updating the data submission method for these measures to use of a CMS online data submission tool, via the QualityNet.org website, which it believes would address its concern about the ability of ASCs to correct data submission errors. Under this approach, ASCs would submit claims for payment but would no longer be required to include QDCs. Data would be submitted between January 1 and May 15 of a calendar year that is one year prior to the payment determination year with respect to services furnished during the calendar year 2 years prior to the payment determination year. As noted in section XIV.B above, CMS is also considering proposing addition of these measures to the OQR Program also involving use of an online web tool for data submission.

Some commenters supported the inclusion of these measures using an online reporting tool, while others did not, citing the lack of NQF endorsement and concerns about the measures being topped out, possible data submission issues, and reporting burden. CMS will consider these comments for future rulemaking.

C. Summary Table of ASCQR Program Measures

The table below shows the ASCQR Program measures previously adopted for payment determinations beginning in 2018, and the new addition for 2024. (Once adopted, measures are retained in the program unless proposed and finalized for removal.) Specifications for ASCQR Program measures are available on the QualityNet website:

<https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772475754>.

Final ASCQR Program Measures by Payment Determination Year

	2018	2019	2020	2021	2022
ASC-1: Patient Burn (NQF #0263)+	X	X	X	Suspended*	

	2018	2019	2020	2021	2022
ASC-2: Patient Fall (NQF #0266) +	X	X	X	Suspended*	
ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267) +	X	X	X	Suspended*	
ASC-4: All-Cause Hospital Transfer/Admission (NQF #0265) +	X	X	X	Suspended*	
ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing (NQF #0264) +	X	Removed			
ASC-6: Safe Surgery Checklist Use	X	Removed			
ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures (see below)	X	Removed			
ASC-8: Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)	X	X	Removed		
ASC-9: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658)	X	X	X	X	X
ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use (NQF #0659)	X	X	X	Removed	
ASC-11: Cataracts – Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery (NQF #1536) +					Voluntary
ASC-12: Facility 7-Day Risk Standardized Hospital Visit Rate after Outpatient Colonoscopy	X	X	X	X	X
ASC-13: Normothermia Outcome			X	X	X
ASC-14: Unplanned Anterior Vitrectomy			X	X	X
ASC-15a: OAS CAHPS – About Facilities and Staff*					
ASC-15b: OAS CAHPS – Communication About Procedure*					
ASC-15c: OAS CAHPS – Preparation for Discharge and Recovery*					
ASC-15d: OAS CAHPS – Overall Rating of Facility*					
ASC-15e: OAS CAHPS – Recommendation of Facility*					
ASC-17: Hospital Visits After Orthopedic ASC Procedure					X
ASC-18: Hospitals Visits After Urology ASC Procedure					X
ASC-19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at an ASC (NQF #3357)					Added in 2024
+ CMS notes that NQF endorsement for the measure has been removed.					
* Data collection suspended until new method data collection developed.					
** Mandatory reporting on these measures, once scheduled to begin in 2018 for the 2020 payment determination, was indefinitely delayed (82 FR 59432). CMS implemented a voluntary national reporting program for the OAS CAHPS Survey in January 2016. More information is available at https://oascahps.org/General-Information/National-Implementation .					

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

No changes were 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-priced, brachytherapy sources that are paid based on OPPS payment rates, and others. When the update reduction is applied to a facility, beneficiary copayments are based on the reduced payment rate.

CMS reports that for the 2019 payment determination, 203 of the 6,393 ASCs that met eligibility requirements for the ASCQR Program did not meet the requirements to receive the full annual payment update.

XVI. Public a List of Hospital Standard Charges & Price Transparency Quality Measurement

In the 2020 OPPS proposed rule, CMS proposed requirements for hospitals to make public a list of their standard charges pursuant to 2718(e) of the Public Health Service Act. It received over 1,400 comments that it intends to summarize in a forthcoming final rule. In addition, CMS did a request for information on (1) improving access to quality information by entities developing price transparency and (2) improving incentives for providers to share charge information with patients. It received 63 comments in response to that request for information. CMS will take the comments into account in developing future policies.

XVII. Organ Procurement Organizations (OPO): “Expected Donation Rate”

A. Definition of “Expected Donation Rate” and Measure Data Collection Timeline

Organ procurement organizations (OPOs) partner with transplant centers to maintain safe and equitable processes for procuring, distributing, and transplanting the maximum number of organs. OPOs identify eligible donors and recover organs from deceased donors. Each OPO is assigned to cover a geographically-defined designated service area (DSA). To receive payment under the Medicare or Medicaid programs for organ procurement services, an OPO must be certified, and recertification is required every 4 years. Certification requirements include meeting all OPO Conditions for Coverage (CfCs) established by CMS.²¹ Certified OPOs also must be members of, participate in, and abide by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN). Further, OPOs must meet outcome and process performance standards established by the Secretary, including a measure that incorporates an “expected donation rate.” The observed-to-expected donation ratio measure is one of three specified OPO outcome measures (see §486.318).

CMS proposed to harmonize its definition of expected donation rate with that of the Scientific Registry for Transplant Recipient’s (SRTR), given that the SRTR is responsible for providing statistical and other analytic support to the OPTN. CMS states a belief that definition and measure alignment would facilitate ongoing outcome measure enforcement, eliminate provider

²¹ The OPO CfCs are found at 42 CFR part 486, subpart G.

confusion, and provide consistency between the CMS requirements and the SRTR's data. CMS received comments from a wide range of stakeholders, and the vast majority of whom were supportive. CMS finalizes the revised definition as proposed: the expected donation rate per 100 eligible deaths is the rate expected for an OPO based on the national experience for OPOs serving similar eligible donor populations and DSAs. The rate is adjusted for the distributions of age, sex, race, and cause of death among eligible deaths.

Due to the occurrence of this final rule's anticipated effective date in the middle of the current OPO recertification cycle, CMS proposed a modification of the observed-to-expected donation ratio measure's data collection timeline.²² The change would be limited to the 2022 recertification cycle, after which the established timeline would be resumed. CMS proposed this change to give OPOs adequate time to comply with the revised definition for expected donation rate. Many commenters disagreed with the modified timeline, concerned that the modified (and shorter) data collection period could produce unintended distortions of OPO performance data, particularly for OPOs with smaller transplant volumes. Commenters suggested that the new definition be adopted at the start of the next full recertification cycle and use the previously-established data collection periods. After reviewing the comments, CMS agrees that there is a risk of unintended consequences and does not finalize the proposed abbreviated data collection period. CMS does, however, finalize a policy for the 2022 recertification cycle only that 1) would not require all OPOs to satisfy the observed-to-expected donation ratio measure incorporating the revised expected donation rate, and 2) would require all OPOs to meet at least one of the other two OPO outcome measures specified at §486.318 (donation rate measure and aggregate donor yield measure).

B. Potential Changes to the OPO and Transplant Center Regulations

In the proposed rule, CMS solicited public input regarding what revisions may be appropriate for the current CfCs for OPOs, set forth at 42 CFR 486.301 through 486.360, and the current CoPs for transplant centers (TCs), set forth at 42 CFR 482.68 through 482.104. CMS also asked for comments on the utility, validity, and reliability of two new potential OPO outcome measures: 1) the actual deceased donors as a percentage of inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation, and 2) the actual organs transplanted as a percentage of inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation. CMS describes receiving a wide range of comments, most of which supported changing the OPO CfCs and TC CoPs. Commenters made multiple specific suggestions including development of combined OPO and TC metrics; regulations to require support for donation after cardiac death; and development of metrics that include donor hospitals and TCs. CMS concludes by expressing appreciation for the input offered and a plan to consider that input in future rulemaking and when revising regulations.

XVIII. Clinical Laboratory Fee Schedule: Revisions to Laboratory Date of Service Policy

The date of service (DOS) is a required data field on all Medicare claims for laboratory services. If the DOS occurs while the patient is an inpatient of a hospital, Medicare will bundle payment

²² Data would be collected for 12 months of a 24-months rather than the usual 36 months of a 48-month period.

for the test into hospital service. If the DOS is on the same date as a hospital outpatient encounter, payment for the laboratory test is either packaged into the OPPS service payment or, if separately payable, must be billed by the hospital.

Most clinical diagnostic laboratory tests (CDLT) are packaged as integral, ancillary, supportive, dependent, or adjunctive to the primary service or services provided in the hospital outpatient setting during the same outpatient encounter and billed on the same claim. Medicare only pays separately for a CDLT when it is: (1) the only service provided to a beneficiary during an outpatient encounter; or (2) considered a preventive service.

Except as provided below, these rules apply even when the results of the test do not guide treatment during the hospital stay. Laboratory tests may be furnished by a laboratory to a hospital's patients "under arrangement." In this circumstance, the hospital would bill Medicare for the test and pay the laboratory that performed the test.

Generally, CMS requires the DOS for a laboratory test to be the date the specimen was obtained. If a laboratory specimen is archived for more than 30 days, the DOS is the date the specimen is removed from storage. For cancer recurrence and therapeutic interventions, the DOS is the date the test was performed (instead of the date of collection) if the following conditions are met:

- The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;
- The specimen was collected while the patient was undergoing a hospital surgical procedure;
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- The results of the test do not guide treatment provided during the hospital stay; and
- The test was reasonable and medically necessary for the treatment of an illness.

The DOS for chemotherapy sensitivity tests performed on live tissue is the date the test was performed if the above conditions are met substituting the below criterion for the first one:

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

For hospital outpatients only, the DOS for molecular pathology tests or advanced diagnostic laboratory tests (ADLT)²³ is the date the test is performed if:

- The test was performed following a hospital outpatient's discharge from the hospital outpatient department;
- The specimen was collected from a hospital outpatient during an encounter;
- It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;
- The results of the test do not guide treatment provided during the hospital outpatient encounter; and

²³ ADLTs are tests that are performed by a single laboratory only and meet other criteria specified in statute.

- The test was reasonable and medically necessary for the treatment of an illness.

This latest policy exception to the DOS rules for molecular pathology tests and ADLTs was adopted in 2018. Because of administrative difficulties encountered by hospitals and laboratories, CMS exercised enforcement discretion which allowed these tests to be billed by either the hospital or the laboratory but not both. The enforcement discretion period is in effect until January 2, 2020. The latest enforcement discretion announcement can be found at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy.html>

Stakeholders have informed CMS that hospitals are having difficulty with developing the systems changes necessary to provide the performing laboratory with information needed to bill Medicare (e.g. the patient's hospital outpatient status, beneficiary demographic information, and insurance information, etc.). In addition, molecular tests are often performed by blood banks and blood centers that are not enrolled in Medicare and do not have an established mechanism to bill Medicare directly.

CMS considered three potential changes to the laboratory DOS for molecular pathology tests and ADLTs only:

1. Changing the Test Results Requirement

Under this option, the test would be considered a hospital service unless the ordering physician determines that the test is not intended to guide treatment during a hospital outpatient encounter (either the one in which the sample was collected or a future one). In this situation, the test would not be considered a hospital service and the performing laboratory would be required to bill for the test. Conversely, if the other four requirements are met, but the ordering physician determines that the results of the laboratory test are intended to guide treatment during a hospital outpatient encounter, the DOS would be the date the specimen is collected and the hospital would bill for the test.

CMS specifically requested public comments on the administrative aspects of requiring the ordering physician to determine when the test results are not intended to guide the treatment during a hospital outpatient encounter. Further, CMS solicited comments on the process for the ordering physician to document that decision and provide notification to the hospital that collected the specimen for billing purposes.

Commenters opposed this option saying that since the new policy was adopted in 2018, it has improved access to molecular pathology services. The total number of molecular pathology test claims following a hospital outpatient encounter increased 55 percent from 43,012 claims in 2017 to 66,637 claims in 2018 demonstrating that the prior rule was interfering with access to medically necessary tests. Other comments stated that the physician cannot predict future care at the time the test is ordered without having the results of the test. Further, more than one physician may be involved in the patient's care making the prediction of future care even more uncertain.

Many stakeholders also pointed out the administrative complexities associated with requiring the ordering physician to predict the future use of the test results. The policy would require documentation in the beneficiary's medical record and coordination with the hospital and performing laboratory to ensure that the correct entity bills for the test. Commenters said physicians may delay ordering tests by 14 days to qualify under a different exception to the DOS rule that allows an independent laboratory to bill for the test.

There were also comments concerned that this policy would be inconsistent with long-standing guidance of the Office of the Inspector General that “[a] freestanding entity, that is, one that is not provider-based, may bill for services furnished to beneficiaries who do not meet the definition of a hospital outpatient at the time the service is furnished.” (65 FR 18440 through 18441).

CMS agrees with these comments and is not making this change considered to the DOS rule.

2. Limiting the Laboratory DOS Exception to ADLTs

Medicare statute requires that to be an ADLT, the test can be furnished only by a single laboratory. Therefore, there may be beneficiary access concerns that apply to ADLTs that do not apply to molecular pathology tests. For example, a hospital may not have an arrangement with the single laboratory that furnishes a particular ADLT, which could lead the hospital to delay the order for the ADLT until 14 days after the patient's discharge to avoid financial risk and thus potentially delay medically necessary care for the beneficiary.

Molecular pathology tests may not present the same concerns of delayed access to medically necessary care as ADLTs as they are not required to be furnished by a single laboratory and there may be kits for molecular pathology tests that a hospital can purchase, allowing the hospital to perform the test.

In the 2018 OPPS final rule, CMS concluded that molecular pathology tests presented the same access concerns as ADLTs when adopting the revised date of service rule because relatively few laboratories furnish molecular pathology tests. In the proposed rule, CMS said it no longer believes the same beneficiary access concerns that apply to ADLTs also apply to molecular pathology tests. CMS indicated that a number of kits have recently been approved by FDA that would allow a hospital to more easily perform some of these molecular pathology tests or establish an arrangement with an independent laboratory to perform the test.

Under this option, molecular pathology test would remain separately payable when the specimen is drawn during a hospital outpatient encounter but the changes to the DOS rules adopted for 2018 would only apply to ADLTs and not molecular pathology tests.

Commenters objected to this potential change to the laboratory DOS exception stating that even though laboratories that furnish molecular pathology tests may not be the only laboratory furnishing a given test, the laboratory may be the only one that furnishes the test for a specific clinical indication. Further, these commenters assert that very few “kits” have been approved by the FDA, and the vast majority of molecular pathology tests are performed by the laboratories

that developed and validated them and therefore, hospitals rarely perform molecular pathology tests. Hospitals do not have the capability to perform such specialized testing and the cost of bringing this specialized testing capability in house may be prohibitive for many hospitals, particularly if the volume of testing is expected to be low, as would be the case for smaller and rural hospitals.

Many commenters interpreted this policy option to only apply to non-molecular pathology ADLTs. These commenters were under the impression that CMS' DOS policy would not apply to molecular pathology tests that are also approved as ADLTs raising additional policy and administrative concerns about differentiating between ADLT and non-ADLT molecular pathology tests in the DOS rules. While it is not clear whether this interpretation of CMS' proposed policy is correct, it is not relevant as CMS has decided not to finalize this policy option.

CMS agrees with the commenters and is not finalizing a policy to limit the change in the DOS to only those tests approved as ADLTs.

3. Excluding Blood Banks and Blood Centers from the Laboratory DOS Exception for ADLTs and Molecular Tests

Blood banks and centers perform molecular pathology testing primarily to identify the most compatible blood product for a patient. Other laboratories typically provide molecular pathology testing for diagnostic purposes. Given the different purpose of molecular pathology testing performed by the blood banks and centers, CMS believes molecular pathology testing is so connected to the treatment furnished to the patient in the hospital that it must be considered a hospital service.

For this reason, CMS considered a regulatory change that would exclude blood banks and centers from the laboratory DOS exception that applies to ADLTs and molecular pathology services. Under this revision, the DOS for laboratory testing performed by blood banks and centers on specimens collected during a hospital outpatient encounter would, depending on the underlying service, be the date of specimen collection. As a result, the blood bank or center is furnishing a service under arrangements to the hospital. The hospital would bill for the laboratory test and the blood bank or center performing the test would seek payment from the hospital. A blood bank would be defined as an entity whose primary function is the collection, storage and dissemination of blood products.

Commenters strongly supported the potential revision to exclude blood banks and centers from the laboratory DOS exception agreeing that blood banks and centers are typically not Medicare enrolled entities that bill Medicare for patient care services. A few commenters requested that "processing" and "testing" be added to an "an entity whose primary function is the collection, storage and dissemination of blood products" to better distinguish blood banks and centers from other types of laboratories.

CMS agreed with these comments and is finalizing a policy to exclude blood banks and blood centers from the exception to the DOS rule. It is further modifying the definition of blood bank and blood center consistent with the comment to add “processing” and “testing” to the definition.

4. Additional Comments

One comment requested that CMS allow either the hospital or the laboratory (but not both) to bill for the test by mutual agreement. Absent an agreement, the default policy would be DOS exception. Alternatively, the commenter suggested that a hospital acting as a referral or outreach laboratory be allowed to bill for a test when a sample obtained from a hospital outpatient does not guide the patient’s treatment. CMS declined to do either of these alternatives but will consider them for the future.

Another commenter was concerned about the administrative burden of changing systems to comply with CMS’ policy that has not been implemented. CMS clarified that it has implemented the policy but is using enforcement discretion for hospitals and laboratories that are unable to comply with the requirement. Hospitals and laboratories that are able to comply with the requirement may do so.

There were comments asking that the DOS exception be applied to tests ordered for hospital inpatients and the technical component of physician pathology services paid under the physician fee schedule. CMS responded that broadening the policy to hospital inpatients would have broader policy implications for the IPPS that need to be carefully considered. Both of these comments will be considered as CMS develops future policy.

XIX. Prior Authorization for Certain Hospital Outpatient Department Services

A. Background

Section 1833(t)(2)(F) of the Act directs the Secretary to establish a method to control “unnecessary increases in the volume of services” under the OPPS. CMS has determined that some services have experienced significant increases in volume. CMS targeted services that represented procedures likely to be cosmetic surgical procedures and/or are directly related to cosmetic surgical procedures not covered by Medicare but that may be combined with or masquerading as therapeutic services.

CMS reviewed more than 1.1 billion claims from 2007 through 2017, and the agency found higher than expected volume increases for several services, many of which fall into five general categories: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation. CMS believes that the increase in volume of these services is unnecessary because it says (i) the data show the volume of utilization far exceeds what would be expected in light of average rate-of-increase in the number of Medicare beneficiaries; (ii) the procedures are often considered cosmetic; and (iii) it is unaware of other factors that might contribute to clinically valid volume increases.

Thus, CMS proposed to require prior authorization for certain covered OPD services as a condition of payment.

B. Prior Authorization Process

CMS proposed to establish a process through which providers must request prior authorization for provisional affirmation of coverage before the service is furnished to the beneficiary and before the claim is submitted for processing. It received 96 comments on the proposal. CMS finalizes its proposal with two changes: it adds two additional botulinum toxin injection codes and clarifies the process for an exemption from prior authorization requirements.

CMS adds a new subpart I to part 419 to (i) establish the conditions of payment for covered OPD services that require prior authorization; (ii) establish requirements for the submission of prior authorization requests, including expedited review requests; and (iii) permit suspension of the prior authorization process generally or for particular services. The prior authorization process will be implemented for dates of service on or after July 1, 2020.

Commenters objected to the short implementation timeframe. CMS responds that the prior authorization process does not reflect a change in burden relating to documentation; rather, the process merely requires the same documentation earlier. The agency seems confident that, with its education and outreach efforts, hospitals and physicians will be ready in time.

Commenters also questioned why ASCs and other provider types were exempt from this policy and cautioned about a shift of these services to other settings by reason of the prior authorization process for OPD services. CMS notes that it does not have similar statutory authority for the other provider types; however, it will monitor data from ASCs and other provider settings to see if it discerns a shift of services.

1. Basis, Scope and Definitions (§§419.80 and 419.81)

Section 419.80 cites section 1833(t)(2)(F) of the Act as the authority for the prior authorization policy which applies to certain covered OPD services as a condition of payment.

Some commenters challenged CMS' use of section 1833(t)(2)(F) as authority for this policy; CMS responds that it has ample authority under that section to control unnecessary increases in the volume of covered OPD services. It disagrees with commenters who believe the District Court's Decision in *AHA et al. v. Azar* (invalidating the agency's policy of reduced payment for clinic visits in excepted off-campus PBDs) precludes it from adopting a method to control unnecessary volume increases without tying that method to another provision of the OPPS statute. It reasons that this prior authorization policy does not have an immediate impact on payment amounts or budget neutrality calculations for the OPPS and is thus distinguishable from the District Court's holding.

Section 419.81 defines the terms "prior authorization," "provisional affirmation," and "list of hospital outpatient department services requiring prior authorization." Prior authorization means the process for a provider to request provisional affirmation of coverage before the service is

provided and the claim is submitted, CMS or its contractors will review the request. Provisional affirmation means a preliminary finding that a future claim meets Medicare coverage, coding, and payment rules under statute and regulations. CMS says it patterned these two definitions after the DMEPOS prior authorization process.

The term “list of hospital outpatient department services requiring prior authorization” (hereafter in this section of the summary referred to as “OPD prior authorization list”) is defined as the list that CMS publishes pursuant to new §419.83.

2. Prior Authorization for Certain Covered Hospital Outpatient Department Services (§419.82)

As a condition of payment for services included on the OPD prior authorization list, a provider must submit a prior authorization request to CMS that includes all relevant documentation necessary to show that the service meets Medicare coverage, coding and payment rules. Again, the request must be submitted before the service is furnished and before a claim is submitted. In response to comment, CMS clarifies that either the physician or the hospital may submit the prior authorization request. The agency notes that when a prior authorization request is submitted, it will be assigned a unique tracking number (UTN); the UTN must be included on any claim submitted for the services listed.

A claim submitted for a service on the OPD prior authorization list that has not received a provisional affirmation of coverage will be denied, unless the provider is exempt under §419.83(c) (described below). This denial includes any claims associated with the service, including for example anesthesiology services, physician services, and/or facility services. Additionally, CMS indicates that a service for which provisional affirmation was received may still be denied, based on technical requirements or information not available at the time that affirmation was provided. Commenters asked CMS to change this policy so a claim for which a provisional affirmation is granted could not be denied for any reason. CMS declines to do so, noting that it anticipates that most, if not all, claims for which a provisional affirmation is obtained would not be denied on the basis of medical necessity.

A provider may seek expedited review of a prior authorization request when a delay may seriously jeopardize the beneficiary’s life, health, or ability to regain maximum function; documentation is required to demonstrate the need for expedited review.

When a prior authorization request meets applicable Medicare rules, the agency will issue a provisional affirmation; if the request fails to satisfy applicable rules, the agency issues a “non-affirmation decision.” Provisional affirmation or non-affirmation decisions are made within 10 business days (2 business days in the case of an expedited review request). Some commenters asked for shorter timeframes, but noting that the services tend to be cosmetic, CMS believes its timeframes represent a good balance among program integrity needs, provider burden, and beneficiary concerns.

If a provider receives a non-affirmation decision with respect to a prior authorization request or an expedited prior authorization request, the provider may resubmit the request with additional relevant documentation. However, a non-affirmation decision is not considered an initial

determination and thus is not appealable. Noting commenter concerns about the lack of appeal rights, CMS observes that there is no limit on the number of prior authorization requests a provider may submit. Further it notes that appeal rights are available once a claim is actually denied.

When a claim is submitted for a service on the OPD prior authorization list without a provisional affirmation, that claim will be denied. In this case, the claim denial is an initial determination and a redetermination request may be submitted. Additionally, any claims associated with or related to the service on the OPD prior authorization list that was denied will be denied as well, including anesthesiology services, physician services, and/or facility services. These associated claims will be denied whether a non-affirmation was received for the service on the OPD prior authorization list or whether the provider did not submit a prior authorization request. The contractor is not required to request medical documentation before making the denial.

3. List of Hospital Outpatient Department Services Requiring Prior Authorization (§419.83)

CMS identifies the services included on the OPD prior authorization list by CPT codes listed in Table 65 of the final rule.²⁴ CMS only includes in the regulation text at §419.83(a)(1) the categories of services within which the identified services fall (viz., blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation). While updates to the service categories will be done through notice and comment rulemaking, any technical updates to the services themselves will be published on the CMS website.

CMS reserves the right to exempt a provider from the prior authorization process. CMS will conduct semiannual assessments of providers submitting prior authorization requests, and providers who maintain a 90 percent or higher provisional affirmation rate are exempt from the process. CMS may revoke that exemption if it determines that the provider has begun to submit claims that are not payable under Medicare rules. CMS indicates it might revoke the exemption if the rate of non-payable claims (determined at a semianual assessment) is higher than 10 percent.

Commenters expressed concern that the proposed regulation text did not specify the 90 percent threshold nor detail the notice of exemption and or withdrawal of exemption. CMS believes that its statement in the preamble to the final rule specifying a 90-percent threshold is sufficient. However, it does clarify that the notice for an exemption (or its withdrawal) will be delivered at least 60 calendar days before the implementation date. CMS also says it cannot exempt providers prior to July 1, 2020 which is the beginning of the prior authorization process due to lack of data. It also declines to adopt a policy whereby providers would be exempt if they only submitted certain data.

Additionally, CMS indicates that it could suspend the prior authorization process entirely, or for particular services, at any time. Notice of the suspension would be provided on CMS' webpage.

²⁴The preamble to the final rule appears to have inadvertently included two nearly identical versions of the portion of this section XIX that describes the comments received, responses made and final decisions. Each version contains its own table (Table 64 and Table 65, respectively, each with the same heading that refers to a proposed list). This summary refers to Table 65 as it includes the 2 new Botox injection codes added in the final rule.

CMS does not anticipate suspending the process, but it seeks to specify that it could do so under certain circumstances, such as when the costs of the prior authorization process exceed its savings.

C. List of Outpatient Department Services Requiring Prior Authorization

As noted above, CMS identifies the services that it includes on the list using certain criteria: (i) the services are most often considered cosmetic and thus are only rarely covered by Medicare; (ii) the current volume of utilization far exceeds what would be expected in light of the average rate-of-increase in the number of Medicare beneficiaries; and (iii) it is unaware of other factors that may contribute to the volume increases to indicate the services are increasingly medically necessary, such as clinical advancements or expanded coverage criteria.

CMS accepts a suggestion to add DYSPORT® (J0586) and XEOMIN® (J0588) in addition to BOTOX® and MYOBLOC® so all four FDA-approved botulinum toxin therapeutic products are on the list. This would prevent distortion that could otherwise occur in the marketplace whereby providers would be incentivized to administer botulinum toxin therapeutic products that are not subject to prior authorization. It adds these codes to the list in the final rule. In response to a question, CMS indicates that it will allow prior authorization for a specific course of treatment for botulinum toxin injection procedures, such as a number of treatments over a specific period of time.

CMS analyzed the utilization of these services by the 5 service categories and lists the CPT codes of those services within each service category in Table 65 of the final rule.

D. Regulatory Impact

CMS estimates the overall economic impact of the prior authorization process is approximately \$5.7 million in the first year based on 6 months. The 5-year and 10-year impacts are estimated at roughly \$46.5 million and \$98.7 million, respectively. CMS notes that the 5- and 10-year impacts account for year one including only 6 months. CMS believes this impact will also result in some savings; however, it is unable to quantify them.

XX. Cost Reporting, Hospital Chargemasters and Related Medicare Payment Issues

Medicare-certified institutional providers are required to submit an annual cost report to CMS which is used to set prospective payment rates for institutions. The cost report contains provider information such as facility characteristics, utilization data, cost and charges by cost center (in total and for Medicare), Medicare settlement data, and financial statement data. The reported charges are generally those derived from the hospital chargemaster. In the proposed rule, CMS sought comments on the cost reporting process and chargemaster. CMS received 46 comments on this request for comments. No further summary or action was indicated.

XXI. Grandfathered Children's Hospitals-within-Hospitals (HwHs)

A hospital-within-a-hospital (HwH) is a hospital that occupies space in the same building as another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital. On October 1, 1995, CMS created separateness and control rules governing HwHs to ensure that the HwH was a separate and distinct hospital from the one that it is within. The concern motivating the creation of these rules was that a separate IPPS exempt hospital in name only could locate within a parent IPPS hospital solely to be paid under a different payment system leading to two Medicare payments for what was essentially one episode of care.

HwHs that were in existence on or before September 30, 1995 are grandfathered from the separateness and control regulations established on October 1, 1995 so long as the HwH continues to operate under the same terms and conditions, including not increasing the number of beds. The HwH rules initially only applied to long-term care hospitals but were later expanded to all hospitals excluded from the IPPS (including children's hospitals).

CMS believes that there is no Medicare payment policy rationale for prohibiting grandfathered children's HwHs from increasing their number of beds. Because these hospitals receive a minimal level of Medicare reimbursement relative to other payers, CMS proposed a regulatory change to allow a grandfathered children's hospital HwH to increase its number of beds without losing grandfathered status. This proposal would allow the children's hospital to address changing community needs for services without any increased incentive for inappropriate patient shifting to maximize Medicare payments. Additionally, CMS does not believe that allowing a grandfathered children's HwH to increase its number of beds would impart an economic advantage relative to other hospitals.

Public commenters supported this proposal. CMS is finalizing the proposal without modification.

XXII. Opportunity to Apply for Resident Slots from Two Closed Teaching Hospitals

Medicare provides indirect medical education (IME) and direct graduate medical education (DGME) payments to hospitals based on the number of residents the hospitals trains. The hospital's payment is based on a cap at the number of residents trained in 1996. Section 5506 of the Affordable Care Act instructed the Secretary to establish a process to redistribute residency slots after a hospital closes. The final rule notifies the public about the closure of Hahnemann University Hospital, located in Philadelphia, PA (CCN 390290) and Ohio Valley Medical Center in Wheeling, West Virginia. Combined Table 66/67 below contains the identifying information and IME and DGME FTE resident caps for the closed teaching hospitals to be redistributed. CMS describes the redistribution process for each hospital as round 16 and 17 respectively.

Available Resident Cap FTEs

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME Resident Cap	DGME Resident Cap
390290	Hahnemann University Hospital	Philadelphia, PA	37964	9/6/2019	556.81	574.82
510039	Ohio Valley Medical Center	Wheeling, WV	48540	9/20/2019	22.93	22.93

Application Process for Available Resident Slots

The application period for hospitals to apply for slots under section 5506 is 90 days following notification to the public of a hospital closure. Therefore, hospitals must submit an application form to the CMS Central Office by January 30, 2020 to be eligible to receive slots from these closed hospitals. The mailing address for the CMS Central Office is included on the application form. Applications must be received by the CMS Central Office by the deadline date. **It is not sufficient for applications to be postmarked by this date.** The application is available at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/DGME.html>.

Hospitals should also access this same website for a list of the policies and procedures for applying for slots, and the redistribution of the slots, under sections 1886(h)(4)(H)(vi) and 1886(d)(5)(B)(v) of the Act.

After applying, the hospital must send a hard copy of the section 5506 slot application to the mailing address in the application. The hospital is strongly encouraged to notify the CMS Central Office of the mailed application by sending an email to: ACA5506application@cms.hhs.gov. In the email, the hospital should state:

On behalf of [insert hospital name and Medicare CCN#], I, [insert your name], am sending this email to notify CMS that I have mailed to CMS a hard copy of a section 5506 application under [Round 16 or Round 17 due to the closure of Hahnemann University Hospital in Philadelphia, PA or Ohio Valley Medical Center in Wheeling, WV]. If you have any questions, please contact me at [insert phone number] or [insert your email address].”

An applying hospital should not attach an electronic copy of the application to the email. The email will only serve to notify the CMS Central Office to expect a hard copy application that is being mailed to the CMS Central Office.

CMS has not established a deadline by when CMS will issue the final determinations to hospitals that receive slots under section 5506. However, CMS reviews all applications received by the deadline and will notify applicants of its determinations as soon as possible.

XXIII. Files Available to the Public via the Internet

Addenda for the 2020 OPPS final rule are available on the following CMS website:

<https://www.cms.gov/Medicare/Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1717-FC.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending>

Note that CMS has added a column to Addenda A and B entitled “Copayment Capped at the Inpatient Deductible of \$1,364.” An asterisk will appear in this column signifying that outpatient coinsurance is capped at the inpatient deductible for that year.

For addenda related to 2020 ASC payments, please see:

<https://www.cms.gov/Medicare/Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1717-FC.html>

TABLE 68—ESTIMATED 2020 IMPACT: CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

		(1)	(2)	(3)	(4)	(5)	(6)
		Number of Hospitals	APC Recalibration (all changes)	New Wage Index and Provider Adjustments	All Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update	Existing Off-Campus Provider-Based Department Visits Policy	All Changes
ALL FACILITIES *		3,732	0.0	0.1	2.7	-0.6	1.3
ALL HOSPITALS		3,625	0.0	0.1	2.7	-0.6	1.3
(excludes hospitals permanently held harmless and CMHCs)							
URBAN HOSPITALS		2,849	0.1	0.0	2.7	-0.5	1.3
LARGE URBAN		1,471	0.0	-0.2	2.4	-0.4	1.2
(GT 1 MILL.)							
OTHER URBAN		1,378	0.1	0.2	3.0	-0.6	1.4
(LE 1 MILL.)							
RURAL HOSPITALS		776	-0.5	0.7	2.8	-0.6	1.1
SOLE COMMUNITY		365	-0.5	0.7	2.8	-0.7	0.9
OTHER RURAL		411	-0.6	0.7	2.7	-0.5	1.3
BEDS (URBAN)							
0 - 99 BEDS		973	0.4	0.1	3.2	-0.4	1.9
100-199 BEDS		822	-0.1	0.0	2.5	-0.5	1.1
200-299 BEDS		444	0.0	0.0	2.6	-0.5	1.3
300-499 BEDS		390	0.1	0.3	3.0	-0.5	1.5
500 + BEDS		220	0.1	-0.1	2.6	-0.7	1.1
BEDS (RURAL)							
0 - 49 BEDS		342	-0.9	1.2	2.9	-0.3	1.5
50- 100 BEDS		267	-0.6	0.9	2.9	-0.7	0.9
101- 149 BEDS		87	-0.6	0.9	2.9	-0.6	1.2
150- 199 BEDS		43	-0.2	0.8	3.2	-0.9	1.3
200 + BEDS		37	-0.1	-0.5	1.9	-0.6	0.6

		(1)	(2)	(3)	(4)	(5)	(6)
		Number of Hospitals	APC Recalibration (all changes)	New Wage Index and Provider Adjustments	All Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update	Existing Off-Campus Provider-Based Department Visits Policy	All Changes
REGION (URBAN)							
	NEW ENGLAND	134	-0.3	-2.0	0.3	-1.0	-1.4
	MIDDLE ATLANTIC	335	0.0	0.1	2.7	-0.4	1.5
	SOUTH ATLANTIC	461	0.1	-0.1	2.5	-0.5	1.2
	EAST NORTH CENT.	456	-0.1	-0.2	2.3	-0.7	0.8
	EAST SOUTH CENT.	165	0.2	0.8	3.6	-0.2	2.6
	WEST NORTH CENT.	179	0.3	1.2	4.1	-0.6	1.7
	WEST SOUTH CENT.						
	MOUNTAIN	208	0.0	-0.2	2.4	-0.5	0.7
	PACIFIC	373	0.3	0.5	3.4	-0.5	2.1
	PUERTO RICO	47	1.0	17.8	22.0	0.0	20.9
REGION							
	NEW ENGLAND	21	-0.5	-1.4	0.7	-1.9	-1.8
	MIDDLE ATLANTIC	53	-0.6	-0.1	1.9	-1.0	0.2
	SOUTH ATLANTIC	119	-0.8	0.9	2.7	-0.2	1.7
	EAST NORTH CENT.	120	-0.5	-0.2	1.9	-0.7	0.4
	EAST SOUTH CENT.	150	-0.5	1.2	3.3	-0.2	2.3
	WEST NORTH CENT.	96	-0.3	1.5	3.8	-0.8	1.1
	WEST SOUTH CENT.	145	-0.6	1.0	3.0	-0.3	2.0
	MOUNTAIN	49	-0.3	2.4	4.8	-0.3	1.1
	PACIFIC	23	-0.6	0.7	2.7	-1.0	1.0
TEACHIN							
	NON-TEACHING	2,469	-0.1	0.3	2.8	-0.4	1.5
	MINOR	781	0.1	0.2	2.9	-0.6	1.3
	MAJOR	375	0.0	-0.2	2.4	-0.8	0.9
DSH PATIENT PERCENT							

		(1)	(2)	(3)	(4)	(5)	(6)
		Number of Hospitals	APC Recalibration (all changes)	New Wage Index and Provider Adjustments	All Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update	Existing Off-Campus Provider-Based Department Visits Policy	All Changes
	0	13	2.5	0.4	5.6	0.0	4.4
	GT 0 - 0.10	274	1.0	0.0	3.6	-0.3	2.3
	0.10 - 0.16	256	0.0	0.0	2.6	-0.5	1.2
	0.16 - 0.23	558	0.1	0.0	2.7	-0.4	1.4
	0.23 - 0.35	1,117	-0.1	0.2	2.8	-0.6	1.1
	GE 0.35	931	-0.1	0.1	2.6	-0.6	1.2
	DSH NOT AVAILABLE **	476	2.0	0.9	5.6	-0.4	4.7
URBAN TEACHING/DSH							
	TEACHING & DSH	1,038	0.1	0.0	2.7	-0.7	1.1
	NO TEACHING/DSH	1,344	0.1	0.1	2.8	-0.3	1.6
	NO TEACHING/NO DSH	12	2.5	0.5	5.7	0.0	4.8
	DSH NOT AVAILABLE**	455	1.8	0.8	5.3	-0.3	4.5
TYPE OF OWNERSHIP							
	VOLUNTARY	1,981	0.0	0.1	2.6	-0.6	1.1
	PROPRIETARY	1,182	0.4	0.2	3.2	-0.2	2.1
	GOVERNMENT	462	-0.1	0.3	2.8	-0.7	1.3
CMHCs		41	1.4	0.5	4.5	0.0	3.7
Column (1) shows total hospitals and/or CMHCs.							
Column (2) includes all final CY 2020 OPPS policies and compares those to the CY 2019 OPPS.							
Column (3) shows the budget neutral impact of updating the wage index by applying the FY 2020 hospital inpatient wage index and the non-budget neutral frontier adjustment. The rural SCH adjustment continues our policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the cancer hospital adjustment is 0.9999 because in CY 2020 the target payment-to-cost ratio is higher than CY 2019 PCR target (0.89).							

		(1)	(2)	(3)	(4)	(5)	(6)
		Number of Hospitals	APC Recalibration (all changes)	New Wage Index and Provider Adjustments	All Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update	Existing Off-Campus Provider-Based Department Visits Policy	
Column (4) shows the impact of all budget neutrality adjustments and the addition of the 2.6 percent OPD fee schedule update factor (3.0 percent reduced by 0.4 percentage point for the productivity adjustment).							
Column (5) shows the additional impact of the policy to pay clinic visits for nonexcepted providers under the otherwise applicable payment system. We note that we are completing the 2-year phase-in so the amount of the reduction will be the full difference in CY 2020 (or payment at 40 percent of the OPPS rate).							
Column (6) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate, and adding estimated outlier payments. Note that previous years included the frontier adjustment in this column, but we have moved the frontier adjustment to Column 3 in this table.							
* These 3,732 providers include children's and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.							