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

The Centers for Medicare & Medicaid Services (CMS) released the calendar year 2020[1] proposed rule for Medicare's hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system on July 29, 2019, If finalized, policies in the proposed rule will generally go into effect on January 1, 2020 unless otherwise specified. The proposed rule will be published in the August 9th issue of the *Federal Register*. **The public comment period closes on September 27, 2019.**

The proposed rule updates OPPS payment policies that apply to outpatient services provided to Medicare beneficiaries by general acute care hospitals, inpatient rehabilitation facilities, inpatient psychiatric facilities, long-term acute care hospitals, children's hospitals, and cancer hospitals, as well as for partial hospitalization services in community mental health centers (CMHCs). Also included is the proposed annual update to the ASC payment system and proposed 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-P.html Unless otherwise noted, this weblink can be used to access any information specified as being available on the CMS website.

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

I. Overview

A. Estimated Impact on Hospitals

The total 2020 increase in OPPS spending due only to changes in the 2020 OPPS proposed rule is estimated to be approximately $940 million. Including estimated changes in enrollment, utilization, beneficiary cost-sharing and case-mix, the 2020 increase in OPPS spending will be approximately $6.2 billion. Total OPPS spending is estimated to be $79.2 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 2021, CMS plans to adopt the remainder of the phase-in and pay 40 percent of the OPPS rate for a clinic visit furnished at excepted off campus PBD. Medicare makes payments under the OPPS to approximately 3,734 facilities (3,627 hospitals excluding CMHCs and cancer and children's hospitals held harmless to their pre-OPPS payment to cost ratios).

CMS estimates that the update to the conversion factor and other adjustments (not including the effects of outlier payments, pass-through payment estimates, the application of the frontier state wage adjustment, and controlling for unnecessary increases in the volume of covered HOPD services) will increase total OPPS payments by 2.0 percent in 2020. Considering all other factors, CMS estimates a 2.8 percent increase in payments between 2019 and 2020.

The update equals the market basket of 3.2 percent reduced by a multifactor productivity adjustment of 0.5 percentage points. The net update is 2.7 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 41 in the proposed rule (reproduced in the Appendix to this summary) includes the estimated impact of the proposed rule by provider type. It shows an estimated increase in expenditures of 2.0 percent for all facilities and 2.0 percent for all hospitals (all facilities except cancer and children's hospitals, and CMHCs). The following table shows components of the 2.0 percent total:

	% Change All Facilities
All changes	2.0
Fee schedule increase factor	2.7
Site Neutral Payment for Clinic Visits	-0.6
Difference in pass through estimates for 2019 and 2020	-0.2
Frontier Wage Index	0.1
Difference from 2018 outlier payments (1.01% vs. 1.0%)	-0.03

The fee schedule increase factor is 2.7 percent (3.2 percent for the hospital market basket less 0.5 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 $268.8 million, or 0.34 percent of OPPS spending. For 2019, CMS estimates pass-through spending would be 0.14 percent of OPPS spending. The -0.20 percent adjustment is designed to ensure that pass-through spending remains budget neutral from one year to the next. Frontier wage index is a non-budget neutral change that increases payments 0.1 percent. In addition, CMS estimates that actual outlier payments in 2019 will represent 1.03 percent of total OPPS payments compared to the 1.0 percent set aside, for an estimated decrease in 2020 payments of 0.03 percentage points.

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

Although CMS projects an estimated increase of 2.0 percent for all facilities, the proposed rule impacts vary depending on the type of facility. Impacts will differ for each hospital category based on the mix of services provided, location and other factors. Impacts for selected categories of hospitals are shown in the table below:

Facility Type	2020 Impact
All Hospitals	2.0
All Facilities (includes CMHCs and cancer and children's hospitals)	2.0
Urban	2.0
Large Urban	1.9
Other Urban	2.1
Rural	1.9
Beds	
0-99 (Urban)	2.6
0-49 (Rural)	2.6
500+ (Urban)	1.6
200+ (Rural)	1.7
Major Teaching	1.3
Type of ownership:	
Voluntary	1.8
Proprietary	3.0
Government	1.9
Puerto Rico	22.1

The larger increase for small urban hospitals (0-99 beds) is accounted for by APC recalibration (+0.5 percent) and a modestly lower reduction (-0.4 percent) from the site neutral policy than all hospitals (-0.6 percent). While small rural hospitals (0-49 beds) have a reduction (-0.8 percent) from APC recalibration, it is offset by the wage index changes (+1.5 percent) and a lower reduction (-0.2 percent) from the site neutral policy. 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 proposed 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 is proposing to narrow the difference between the top quartile and bottom quartile wage indexes, no longer include urban to rural reclassifications in the calculation of the rural floor wage index and cap reductions to the wage index at 5 percent. 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 18.2 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 proposed 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 March 31, 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 proposed 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-P.html (click on 2020 NPRM 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 proposed 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 proposes to delete 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 the outpatient claims to estimated costs, CMS multiplies the charges by a hospital-specific cost-to-charge ratio (CCR) associated with each revenue code and cost center. To calculate CCRs for 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 base at its most detailed level. Generally, the most detailed level will be the hospital-specific departmental level.

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

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

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

APC	APC Descriptor	Percentage Change
5521	Level 1 Imaging without Contrast	-2.0%
5522	Level 2 Imaging without Contrast	5.8%
5523	Level 3 Imaging without Contrast	4.6%
5524	Level 4 Imaging without Contrast	6.8%
5571	Level 1 Imaging with Contrast	8.4%
5572	Level 2 Imaging with Contrast	8.3%
5573	Level 3 Imaging with Contrast	2.2%
8005	CT and CTA without Contrast Composite	14.2%
8006	CT and CTA with Contrast Composite	11.5%
8007	MRI and MRA without Contrast Composite	6.7%
8008	MRI and MRA with Contrast Composite	7.4%

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

Cost Allocation Method	CT		MRI	
	Median CCR	Mean CCR	Median CCR	Mean CCR
All Providers	0.0359	0.0505	0.0763	0.1027
Square Feet Only	0.0290	0.0443	0.0665	0.0927
Direct Assign	0.0511	0.0609	0.0990	0.1197
Dollar Value	0.0432	0.0583	0.0879	0.1156
Direct Assign and Dollar Value	0.0433	0.0583	0.0886	0.1155

The proposed rule indicates that the number of valid MRI CCRs has increased by 17.5 percent to 2,184 providers and the number of valid CT CCRs has increased by 15.1 percent to 2,274 providers since CMS adopted its policy in 2014 of excluding providers that use the square foot cost allocation method. As shown in Table 2, eliminating these hospitals from the OPPS rate setting methodology increases the payment for all but one of the imaging APCs because hospitals that use the square foot allocation have lower CCRs for 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 is proposing to include those providers that use a "square feet" cost allocation method to estimate costs for CT and MRI beginning with 2020. In addition, recognizing the potential impact 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.

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 claim's 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 proposes to price code P9073 under its normal methodology rather than through a crosswalk to code P9037.

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 proposes 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 mm^2. For 2020, CMS proposes to set the proposed payment rate for C2645 at 1.02 per mm^2 based on 2018 claims data.

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 provided during the delivery of the comprehensive service and 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 is higher than the highest cost C-APC in a clinical family just to accommodate potential complexity adjustments.

Additional C-APCs for 2020

CMS is proposing 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.

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 does not believe the policy needs to be extended because the criteria for billing to the "Comprehensive Observations Services" C-APC make it highly unlikely that a new technology service will be billed in conjunction with it.

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 indicates that this conclusion is supported by MedPAC in its March 2019 Report to Congress.

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 1.4401. The unscaled 2020 relative payments are multiplied by 1.4401 to determine the 2020 scaled relative weights that are shown in Addendum A and B.

B. Conversion Factor Update

CMS is proposing a conversion factor for 2020 of $81.398 for hospitals receiving the full update for outpatient quality reporting and $79.770 for hospitals subject to a 2.0 percentage point

reduction in the update for not reporting outpatient quality data. The calculation is as shown in the below table:

2019 Conversion Factor		$79.490
Update		1.027
Wage Index Budget Neutrality		
Standard Adj.	1.0005	
5% Cap	0.9988	
Subtotal		0.9993
Cancer Hospital Adjustment		0.9998
Pass-Through Budget Neutrality		0.9980
2020 Conversion Factor		$81.398[2]

The update of 1.027 (2.7 percent) equals the market basket of 3.2 percent less 0.5 percentage points for multifactor productivity. Wage index budget neutrality of 0.9993 (-0.07 percent) is the product of the standard wage index budget neutrality of 1.0005 (0.05 percent) for changes to the wage data and 0.9988 (-0.12 percent) for CMS' proposal to cap any reductions in the wage index from 2019 to 2020 at 5 percent. The cancer hospital adjustment is 0.9998 (-0.02 percent).

Pass-through spending for drugs, biologicals and devices for 2019 are estimated to be 0.14 percent of OPPS spending. CMS estimates that pass-through spending for drugs, biologicals and devices for 2020 will be $268.8 million or 0.34 percent of OPPS spending. CMS proposes to apply an adjustment of 0.9980 (-0.2 percent) for the increase in pass-through spending.

CMS reports that the reduced conversion factor for hospitals not meeting the OQR requirements will be $79.770 which equals 98 percent of the full conversion factor. However, substituting an update of 1.007 (0.7 percent of 2.7 percent less 2.0 percentage points) into the above formula produces a higher conversion factor ($79.814).

C. Wage Index Changes

CMS proposes to continue 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 proposed rule wage index is based on the FY 2020 IPPS proposed post-reclassified wage index; any adjustments for the FY 2020 IPPS proposed post-reclassified wage index are reflected in the proposed 2020 OPPS wage index including the following FY 2020 IPPS rule proposals:

1. Calculate the rural floor without including the wage data of urban hospitals that have reclassified as rural;
2. Remove the wage data of urban hospitals that have reclassified as rural from the calculation of "the wage index for rural areas in the state";[3]

[2] HPA calculates a slightly different CF of $81.400.

[3] This 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.

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 reduce the wage index values above the 75th percentile wage index value by 4.3 percent; and
4. Apply a 5-percent cap on the reduction in any FY 2020 wage index.

For the 5 percent cap, CMS proposed to apply a budget neutrality adjustment to the standardized amount. CMS is proposing an analogous budget neutrality adjustment for the OPPS that is reflected in the update to the OPPS conversion factor.

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 proposes to use the latest OMB statistical area delineations and continue 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 proposes to continue 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 proposes a target PCR of 0.90. Consistent with section 1833(t)(18)(C) of the Act, CMS is reducing the proposed target PCR from 0.90 to 0.89.

Table 6 in the proposed 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 51.9 percent. As indicated in the conversion factor update section, the revised cancer hospital adjustment requires a -0.02 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 proposing to continue to set aside 1.0 percent of the estimated aggregate total payments under the OPPS for outlier payments. It proposes to calculate 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 proposes a $4,950 fixed-dollar threshold (compared to $4,825 in 2019).

CMS is again proposing to set 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 April, 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 1.11189 to approximate 2020 charges from 2018 claims.

H. Calculation of an Adjusted Medicare Payment

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

I. Beneficiary 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 proposed rule include a new column with a "#" to designated those APC and HCPCS codes where the deductible limit applies.

III. OPPS Ambulatory Payment Classification (APC) Group Policies

A. Treatment of New CPT and Level II HCPCS Codes

Table 9 (copied below from the proposed rule) summarizes the process CMS uses for updating codes through the OPPS quarterly update Change Requests (CRs), seeking public comment, and finalizing the status and payment of these codes under the OPPS.

TABLE 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

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
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
January 20120	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 Solicits Public Comments in this Proposed Rule

In the April 2019 OPPS quarterly update, CMS made effective eight new Level II HCPCS codes and assigned them to interim OPPS status indicators and APCs (Table 7). The proposed payment rates, where applicable, can be found in Addendum B to this proposed rule.

For the April 2019 update, there were no new CPT codes.

2. July 2019 HCPCS Codes - CMS Solicits Public Comments in this Proposed Rule

In the July 2019 OPPS quarterly update, CMS made effective 58 new codes and assigned them to interim OPPS status indicators and APCs (Table 8). The proposed payment rates, where applicable, can be found in Addendum B to this proposed rule.

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

CMS proposes to continue the practice of providing interim payment status indicators, APC assignments and payment rates, if applicable, for HCPCS codes that will be effective October 1, 2019 in Addendum B to the 2020 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 proposes that these status indicators and APC assignments would be applicable in 2020. **CMS will invite public comment in the 2020 OPPS/ASC final rule** about the status indicators, APC assignments, and payment rates for these codes and this information would be finalized in the 2021 OPPS/ASC final rule.

4. January 2020 HCPCS Codes

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

CMS will solicit comments on the new Level II HCPCS codes that will be effective in the January 1, 2020 in the 2020 OPPS/ASC final rule. Unlike the CPT codes that are effective January 1 and included in the OPPS/ASC proposed rules, and except for G-codes listed in

Addendum O of this proposed rule, most Level II HCPCS codes are not released until November to be effective January 1 and CMS is not able to include them in the proposed 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 proposes that these status indicators and APC assignments would be applicable in 2020. **CMS will invite public comment in the 2020 OPPS/ASC final rule** about the status indicators, APC assignments, and payment rates for these codes and this information would be finalized in the 2021 OPPS/ASC final rule.

b. CPT Codes - CMS Will Be Soliciting Public Comments in This Proposed Rule

For the 2020 OPPS update, CMS received the CPT codes that will be effective January 1, 2020 in time to be included in this proposed rule. CMS will continue to assign a new comment indicator "NP" and is requesting comments on the proposed APC assignment, payment rates and status indicators. (NP indicates that the code is new for the next CY or the code is an existing code with substantial revision to its code descriptor in the next CY as compared to the current CY, with a proposed APC assignment and that comments will be accepted on the proposed APC assignment and status indicator.) CMS proposes to finalize the status indicators and APC assignments for these codes in the 2020 OPPS/ASC final rule.

Because the CPT code descriptors in Addendum B are short descriptors, CMS included the long descriptors for the new and revised CPT codes in Addendum O. CMS notes that these new and revised CPT procedure codes have a placeholder for the fifth character and the final CPT code numbers will be included in the final rule.

B. Variations within APCs

1. Application of the 2 Times Rule

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

The Secretary is also required to consult with an expert outside advisory panel composed of appropriate representatives of providers to review the clinical integrity of the APC groups and the relative payment weights and advise the Secretary about any issues. The Panel recommendations for specific services for the 2019 OPPS and CMS' responses will be discussed in the 2020 OPPS final rule.

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

2. Proposed APC Exceptions to the 2 Times Rule

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

- resource homogeneity;
- clinical homogeneity;
- hospital outpatient setting utilization; frequency of service (volume); and
- opportunity for upcoding and code fragments.

CMS notes that in cases in which a recommendation by the Panel appears to result in or a violation of the 2 times rule, CMS generally accepts the Panel's recommendations because the Panel's recommendations are based on explicit consideration of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates.

Table 10 (reproduced below), lists the 18 APCs that CMS is proposing to exempt from the 2 times rule for 2020 based on \ claims data from January 1, 2018, through December 31, 2018 and processed on or before December 31, 2018. For the final rule, CMS plans to use claims data for dates of service from January 1, 2018 and December 31, 2018 that were processed on or before June 30, 2019 and updated CCRs, if available.

Table 10: Proposed APC Exceptions to the 2 Times Rule for 2020

2020 APC	APC Title
5112	Level 2 Musculoskeletal Procedures
5161	Level 1 ENT Procedures
5181	Level 1 Vascular Procedures
5311	Level 1 Lower GI Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5571	Level 1 Imaging with Contrast
5612	Level 2 Therapeutic Radiation Treatment Preparation
5672	Level 2 Pathology
5691	Level 1 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5733	Level 3 Minor Procedures
5734	Level 4 Minor Procedures

Table 10: Proposed APC Exceptions to the 2 Times Rule for 2020	
2020 APC	**APC Title**
5822	Level 2 Health and Behavior Services
5823	Level 3 Health and Behavior Services

C. New Technology APCs

1. New Technology APC Groups

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

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

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

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

CMS has used its equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how it determines the costs for low-volume services assigned to New Technology APCs (82 FR 59281). Instead of using this authority on a case-by-case basis, in the 2019 OPPS final rule (83 FR 58892 – 58893), CMS finalized a different payment methodology for these low-volume services using its equitable adjustment authority. For 2020, CMS proposes to continue this policy:

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

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

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

CMS proposes to continue their current policy to retain services within New Technology APC groups until they obtain sufficient claims data to justify reassignment of the service to a clinically appropriate APC. CMS notes, that in cases where it determines, based on additional information, the initial New Technology APC assignment is no longer appropriate it will reassign the procedure or service to a different New Technology APC that more appropriately reflects its costs. This policy allows CMS to reassign a service in less than 2 years if sufficient claims data are available and also retain a service in a New Technology APC for more than 2 years if there is not sufficient claims data to base a reassignment.

a. Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (APCs 1537, 5114 and 5414)
Table 11 lists the 4 CPT/HCPCS codes that describe MRgFUS procedures. For 2020, CMS proposes to assign 3 of the codes to standard APCs and proposes to maintain procedures described by CPT code 0398T to 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.

Using the proposed methodology for low-volume services, based on the 37 claims, CMS calculated a geometric mean cost of approximately $8,829, an arithmetic mean of $10,021, and a median of $11,985. CMS believes that the arithmetic mean is the most appropriate representative cost of the procedures described by CPT code 0398T and proposes maintaining the procedure described by CPT code 0398T to APC 1575 (New Technology – Level 38 ($10,0001-$15,000)), with a proposed payment rate of $12,500.50.

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

For 2020, CMS has only identified 35 paid claims for the 4-year period of 2015 through 2018. CMS calculated a geometric mean of $146,059, an arithmetic mean of $152,123, and a median of $151,267. All three estimates of the cost of the Argus II procedure fall within the cost band for New Technology APC 1908, with an estimated cost between $145,001 and $160,000. CMS

proposes to maintain the assignment to APC 1908 (New Technology – Level 52 ($145,0001-$152,000)), with a proposed payment rate of $152.500.50. CMS notes that the proposed payment rate includes both the surgical procedure (CPT code 0100T) and the use of the Argus II device (HCPCS code C1841).

In 2019, CMS implemented a policy to exclude payment for all procedures assigned to New Technology APCs from being bundled into the payment for procedures assigned to a C-APC. This policy was based on the finding that payment for the Argus® II procedure was sometimes bundled into the payment for another procedure.

For 2020, CMS proposes to continue to exclude payment for any procedure that is assigned to a New Technology APC from being packaged when included on a claim with a service assigned to status indicator "J1". CMS notes this does not exclude payment for a procedure assigned to a New Technology APC from being packaged when included on a claim with a service assigned to status indicator "J2".

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 proposes to continue to assign the procedures described by C9751 to New Technology APC 1571 ((Level 34) ($8,001 - $8,500)), with a proposed rate of $8,250.50 (Table 12).

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.

For 2020, based on 2018 claims data, CMS has identified 1,100 claims with a geometric mean cost of approximately $32. CMS proposes to reassign the service described by P9100 to New Technology APC 1494 (Level 1D ($31 - $40)), with a proposed payment of $35.50.

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 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.

For 2020, based on 2018 claims data, CMS identified 840 claims with a estimated geometric mean cost of approximately $788.19. CMS proposes to reassign the service described by CPT code 0503T to adjust the payment rate to better reflect the cost for this service. Specifically, CMS proposes to reassign CPT code 0503T to New Technology APC 1509 (Level 9) ($701 - $800), with a proposed payment of $750.50.

D. APC-Specific Policies

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

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

1.Intraocular Procedures (APC s 5491 through 5494)
In 2019, based on a single claim available for ratesetting, CMS reassigned procedure code CPT 0308T (Insertion of ocular telescope prosthesis including removal of lens) from APC 54965 (Level 5 Intraocular Procedure).to APC 5494 (Level 4 Intraocular Procedure). This created a discrepancy in payments between the OPPS setting and the ASC setting with the ASC payments were higher; this discrepancy was due because of the impact of the comprehensive payment methodology within the OPPS and the device-intensive service payment methodology within the ASC payment system.

For 2020, based on several claims reporting this procedure, CMS calculated a geometric mean cost of $28,122.51 and a median cost of $19,864.38. Because these costs are significantly higher than the geometric mean cost of the other procedures assigned to APC 5494 and the 2019 discrepancy between payments within the OPPS and ASC payment system with the assignment of this procedure to APC 5494, CMS proposes to reestablish APC 5495 (Level 5 Intraocular Procedures) and reassign the procedure described by CPT code 0308T to APC 5495. CMS proposes to establish the 2020 payment rate based on its median cost. (As discussed below in the *Proposed Payment for ASC* section, CMS proposes that the ASC payment would not be higher than the OPPS payment rate for this procedure performed in the hospital outpatient setting).

2. Musculoskeletal Procedures (APCs 5111 through 5116)
In 2016, CMS consolidated the APCs for musculoskeletal procedures to a six-level structure. CMS continues to review this APC six-level structure and for 2020, it does not propose any changes to the Musculoskeletal APCs (Table 13).

For 2020, based on approximately 60,000 hospital outpatient claims reporting total knee arthroplasty (TKA) procedure (CPT code 27447), CMS calculated a geometric mean cost of approximately $12,472.05. CMS proposes to continue to assign CPT code 27447 to APC 5115 (Level 5 Musculoskeletal Procedures).

For 2020, CMS proposes to remove total hip arthroplasty (THA) (CPT code 27130) form the inpatient only list (discussed below in *Proposed Procedures that Would be Paid Only as Inpatient Procedures* section). Using the estimated costs derived from the available claims data and the IPPS payment of $11,900 for TKA/THA procedures without major complications or comorbidities (MS-DRG 470), CMS proposes to assign THA (CPR code 27130) to the Level 5 Musculoskeletal Procedures APC which has a geometric mean cost of $11,879.66.

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, 2022 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:

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

2. The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury to improve the functioning of a malformed body part; and

3. The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion.

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

1. Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or
2. A material or supply furnished incident to a service (e.g. a suture, customized surgical kit, or a clip, other than a radiological site marker).

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

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

As discussed below in section IV.A.4, CMS proposes an alternative pathway to grant fast-track device pass-through payment under the OPPS for devices approved under the FDA Breakthrough Device Program for OPPS device pass-through payment applications received on or after January 1, 2020.

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 (June1, 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.

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

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.

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)). CMS states that C1887 may be applicable because the device is used in intravascular interventional procedures to deliver diagnostic and therapeutic agents in peripheral vasculatures. HCPCS code C1751 may be applicable because the applicant describes the device as being inserted through a small incision in the groin or the wrist.

Substantial clinical improvement. The applicant claims 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 summarizes 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 is 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.

Cost. CMS believes the Surefire® Spark™ Infusion System meets all the cost criteria.

2. TracPatch

TracPatch is described as a 24/7 remote monitoring wearable device which utilizes an accelerometer, temperature sensor and a step counter. Using 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.

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 Velco strips. The applicant also claims the device meets the requirements of §419.66(b)(4). CMS is 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.

Criteria established at §419.66(c).
Existing payment category. The applicant suggested a category descriptor of "Real time patient monitoring surface sensor technology for pre- and post-op Total Knee Arthroplasty." CMS has not identified an existing pass-through payment category describing the TracPatch.

Substantial clinical improvement. The applicant claims that using TracPatch significantly improves clinical outcomes but did not provide any clinical research evidence to support this claim. The applicant only provided testimonials from physicians and large hospital systems. CMS is concerned that it does not have sufficient information to determine if TracPatch is a substantial clinical improvement over current methods to monitor recovery from total knee arthroplasty.

Cost. CMS believes that TracPatch meets all the cost criteria.

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

LivaNova USA Inc. submitted an application for the VNS Therapy® System, a 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 states 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 states 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 notes that the payment application would have needed to have been submitted to CMS by September 2008.

CMS is also concerned that the neurostimulator device for the VNS Therapy® is the same device that has been used since 1997 to treat epilepsy.[4] Although the applicant discusses the differences between the two devices, CMS is still 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.

Eligibility. According to the applicant, the VNS Therapy® meets all the eligibility requirements.

Criteria established at §419.66(c).

Existing payment category. The applicant suggested a category descriptor of "Generator, neurostimulator (implantable), TRD, non-rechargeable. CMS notes 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 asserts that this device category descriptor for C1767 is too broad and the VNS Therapy® should have a separate code. The applicant cites the separate new device category created for a non-rechargeable neurostimulation system to treat central sleep apnea (C1823). CMS notes that C1823 was established because of specific device features which distinguish the device to treat

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

sleep apnea from devices in C1767. In response to the applicants request for a new device category based on a beneficiary's diagnosis, CMS states the OPPS does not differentiate payment by diagnosis.

Substantial clinical improvement. According to the applicant, the VNS Therapy® is a substantial clinical improvement because it is a treatment option for beneficiaries who have failed four or more antidepressant treatments. CMS discusses eight studies reviewed in detail in the "Decision Memo for VNS for TRD" (CAG-00313R2)[5] and an additional study submitted by the applicant. CMS is concerned that the clinical utility of the VNS Therapy® for TRD has not been well demonstrated and the majority of studies were case series, open labeled, or not randomized. In addition, the CAG decision memo identified some positive findings regarding clinical improvement with the use of VNS therapy but also identified significant issues with strength of the evidence and clinical significance of the outcomes.

Cost. CMS believes the VNS Therapy® meets all the cost criteria.

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.

Criteria established at §419.66(c).
Existing payment category. CMS has not identified an existing pass-through payment category that describes the Optimizer® System.

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 discusses the studies submitted to support these claims. CMS has 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.

[5]The decision memo is available at https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=292.

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

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.

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

CMS reiterates 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.

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.

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."

[6] In 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).

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 acknowledges there may be some evidence of the improved safety of the AquaBeam System over TURP but there are no studies comparing other treatment modalities that are likely to have a similar safety profile as the AquaBeam System. CMS believes it has insufficient evidence that the AquaBeam System provides substantial clinical improvement over other similar products.

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

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 endoprothesis 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 pacilitaxel, which helps prevent the artery from restenosis, and the drug delivery system is designed to sustain the release of pacilitaxel 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 is concerned the

IMPERIAL study, which showed significant differences in primary patency at 12 months, was designed for non-inferiority and not superiority.

CMS also notes 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 invites comments on the implications of the meta-analysis results to a finding of substantial clinical improvement for the Eluvia™ stent**.

CMS notes that the applicant also applied for the IPPS new technology add-on payment for the Eluvia™ System (86 FR 19314).[8] CMS reiterates several of the concerns discussed in the IPPS proposed rule and also summarizes a written public comment it received in response to the New Technology Town Hall meeting. The commenter raised several concerns about the information presented by the applicant at the meeting. The commenter does not believe the data demonstrated the use of the Eluvia™ stent results in a sustained clinical improvement compared to the Zilver® Drug-Eluting Peripheral Stent.

Based on the evidence, CMS is concerned that there is a lack of sufficient evidence that the Eluvia™ System provides a substantial clinical improvement over other similar products.

Cost. Section 419.66(d) establishes three cost significance criteria that must be met. CMS believes the Eluvia™ System meets the first cost significance requirement but does not meet the second and third cost significance requirements.

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 (ß-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 FDA PMA 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.

[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," J*AHA*, vol. 7(24).

[8] In the 2020 IPPS final rule, after consideration of public comments and the latest information from the FDA advisory panel, CMS does not approve the Eluvia stent for a new technology add-on payment (CMS-1716-F).

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 ß-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 discusses the data examining the use of autograft arthrodesis of the ankle and/or hindfoot and arthrodesis with the use of AUGMENT® Bone Graft. CMS is concerned that it is unable to sufficiently determine substantial clinical improvement using the provided data. It notes that a long-term study of at least 60 months is currently underway to assess long-term safety and efficacy.

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

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

CMS acknowledges that applicants and commenters have indicated it would be helpful for CMS to provide greater guidance on what constitutes "substantial clinical improvement." 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. CMS notes 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 notes that any comments it received on potential revisions to the OPPS substantial clinical improvement in response to the FY 2020 IPPS/LTCH PPS proposed rule will be included in the 2020 OPPS/ASC final rule. **CMS also invites comment on this topic in this proposed rule.**

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

The discussion and proposal discussed below aligns with the proposal in the FY 2020 IPPS/LTCH PPS proposed rule for an alternative pathway for the new technology add-on payment under the IPPS.[10]

[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).
[7]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).

CMS discusses 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.[11] 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 proposes 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 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).

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.

[11] 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.

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 finalizes 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, 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

[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.

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 is not proposing any changes to the device-intensive policy. The full listing of proposed 2020 device-intensive procedures 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.

For 2020, CMS is not proposing any changed 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 is not proposing 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 finalizes its proposal to continue this policy.

For 2020, CMS proposes 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). CMS proposed to assign this CPT code to APC 5495 (Level 5 Intraocular Procedures). The 2020 proposed rule geometric mean

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

cost for the procedure (based on 7 claims) is approximately $28,237 and the median cost is $19,270. The proposed 2020 payment rate (using the median cost) is approximately $19,740 (addendum B).

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

A. Transitional Pass-Through Payments

Section 1833(t)(6) of the Act provides for temporary additional payments or "transitional pass-through payments" for certain drugs and biologicals. For pass-through payment purposes, radiopharmaceuticals are "drugs." As required by statute, transitional pass-through payments for a drug or biological can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made under the OPPS. CMS makes transitional pass-through payment for drugs and biologicals using the ASP+6 percent methodology with quarterly updates to ASP. Pass-through drugs and biologicals for 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.

Table 14 of the proposed 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 15 of the proposed rule lists 65 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 (CAA) of 2018. Pass-through payment for these products will expire on September 30, 2020. Table 16 lists the codes that qualify for these additional 2 years of pass-through payments.

For 2020, CMS is continuing to propose 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 drugs[14], 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 17 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 is 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 its 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 establishing any appropriate APC offset amounts: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files.html. However, in response to an inquiry, CMS has indicated that the file will not be posted until after the final rule.

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 the CMS' Office of the Actuary to trend the $50 threshold forward from the third quarter of 2005 to the third quarter of 2020. CMS

[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.

rounds the resulting dollar amount ($131.19) to the nearest $5 increment. Based on this calculation, CMS proposes to adopt 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, CMS uses an estimated payment rate of ASP+6 percent for each HCPCS code. CMS used the manufacturer-submitted ASP data from the fourth quarter of 2018 (data that were used for payment purposes in the physician's office setting effective April 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 proposes to package products with a per day cost of less than or equal to $130 and pay 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: Proposed rule 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: Payment rates for HCPCS codes for separately payable drugs and non-implantable biologicals included in Addenda A and B to 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.

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 18 of the proposed 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 proposes to 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 #6 below for more detail about CMS' proposal in the context of ongoing litigation regarding this policy). Medicare's payment represents the combined acquisition and pharmacy overhead payment for drugs and biologicals.

Consistent with policy in the PFS, CMS is proposing to pay 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.

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

The payment rates shown for drugs and biologicals in Addenda A and B of the proposed 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 4th 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. For drugs and biologicals that have ASP information available for the proposed rule or final rule that do not have ASP information available for the quarter beginning January 2020, payment will be paid based on mean unit cost data derived from 2018 hospital claims.

Biosimilar Biological Products

CMS pays for biosimilar biological products using parallel policies that it uses for other drugs and biologicals with one important distinction. The 6 percent add-on to ASP 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 minus 22.5 percent of 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.

3. Payment Policy for Therapeutic Radiopharmaceuticals

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

4. Payment for Blood Clotting Factors

For 2020, CMS proposes to continue paying for blood clotting factors at ASP+6 percent and updating the furnishing fee by the Consumer Price Index (CPI) for medical care. The CPI won't be available until after publication of the 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 proposing to continue 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 proposed 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 is proposing to continue to pay ASP-22.5 percent for 340B-acquired drugs under the OPPS and when furnished in off-campus PBDs that are not paid under the OPPS and paid under a special PFS rate equal to 40 percent of the OPPS payment amount.

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 intends to pursue its appeal rights.

CMS is taking the steps necessary to craft an appropriate remedy in the event of an unfavorable decision on appeal. The proposed 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 $1.7 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.

The agency intends to obtain public input to further 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 next available rulemaking vehicle, which is the 2021 OPPS/ASC proposed rule in the event the agency loses on appeal.

CMS also seeks public comment on the appropriate 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] CMS welcomes public comments on payment rates other than ASP+3 percent that commenters believe would be appropriate for purposes of addressing 2020 payment.

[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)).

This request for public comment includes whether the remedy should be made:

- On a claim-by-claim basis?
- Through an upward adjustment to 340B claims in the future to account for any past underpayments?
- 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 budget neutralized in a future year (e.g. 2021)?

CMS is soliciting public comments on the best, most appropriate way to maintain budget neutrality, either under a retrospective claim-by-claim approach, with a prospective approach, or any other proposed remedy including whether to make the relevant budget neutrality adjustment across multiple years. Public comments should also address the best, most appropriate treatment of Medicare beneficiary cost-sharing responsibilities under any proposed remedy. CMS continues to review the viability of alternative remedies in the event of an adverse decision from the Court of Appeals.

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 proposes to continue 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 will use 2018 data for this purpose.

The proposed 2020 MUC threshold is \$49 per cm^2 (rounded to the nearest \$1) and the proposed 2020 PDC threshold is \$789 (rounded to the nearest \$1). Table 19 displays the proposed 2020 cost category assignment for each skin substitute product. For 2020, CMS proposes to continue the following proposals:

- 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.

While CMS is not proposing any additional changes to its skin substitute policies, it reviews comments on its comment solicitation in the 2019 OPPS rule. CMS further raises 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 that it is considering for adopting in the 2020 final rule, there would be only one payment category and set of procedure codes for the application of all graft 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.

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 $268.8 million, or 0.34 percent of total OPPS projected payments for 2020 (approximately $80 billion), which is less than the applicable pass-through payment percentage statutory limit of 2.0 percent.

A. Devices

CMS estimates spending of $10.6 million for device categories CMS knows or projects may be approved for pass-through status in 2020 and includes contingent projections for new device categories 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 $258.2 million in 2020 for drugs and biologicals ($241.1 million those recently eligible for pass-through payments that will continue for 2020 and $17.1 million for those CMS knows or projects could be approved for pass-through status in 2020).

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. For off-campus PBDs, CMS is proposing to continue 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

For 2020, CMS proposes to continue its established policies to calculate the PHP APC per diem payment rates for Community Mental Health Centers (CMHCs) and hospital-based PHP providers based on geometric mean per diem costs using the most recent claims and cost data for each provider type, with one exception. As described further below, for 2020 only CMS proposes to use the 2019 final geometric mean per diem cost for CMHCs and hospital-based PHPs as a floor in developing the 2020 PHP APC per diem rates.

CMS would continue to use CMHC APC 5853 (Partial Hospitalization (3 or more services per day)) and hospital-based PHP APC 5863 (Partial Hospitalization (3 or more services per day)) using actual claims data from 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 70462-70466) as modified in the 2017 OPPS/ASC final rule, including the application of a ±2 standard deviation trim on costs per day for all CMHCs and a CCR greater than 5 (CCR>5) trim for hospital-based PHP providers.

CMS analyzes PHP claims and cost data, including provider service usage, coding practices and rate setting methodology, and the agency identifies aberrant data (defined as data so abnormal that they skew the resulting geometric mean per diem costs) from CMHCs and hospital-based PHP providers which it excludes from the calculation of the proposed PHP geometric mean per diem costs. CMS proposes to continue its policy to exclude data from any CMHC when the CMHC's costs are more than ±2 standard deviations from the geometric mean cost per day for all CMHCs and to exclude hospital-based PHP service days when a CCR>5 is used to calculate costs for at least one of the component services. CMS also proposes to default any CMHC CCR that is greater than 1 to the statewide hospital ancillary CCR.

CMS did not exclude any CMHCs nor adjust the CCR for any CMHCs; all 41 CMHCs were included in the 2020 calculation. CMS removed 188 CMHC claims. The calculated geometric

mean per diem cost for all CMHCs for providing 3 or more services per day is $103.42 which represents a decrease of almost 15 percent from the 2019 geometric mean per diem cost for all CMHCs ($121.62). CMS determined that a single large provider that reported low costs per day 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 the one large provider. 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, it proposes to use the 2019 CMHC geometric mean per diem cost as a floor for 2020; if the most recent data used in the final rule results in a CMHC geometric mean per diem cost below the 2019 cost, CMS will finalize the 2019 CMHC geometric mean per diem cost for PHP services furnished in 2020. CMS notes it only proposes to apply this policy for 2020.

For hospital-based PHP providers, CMS excluded 63 providers as follows: one with all service days having a CCR greater than 5, 60 with zero daily costs and no PHP payment, and 2 with no allowable PHP HCPCS codes. Three 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 is $198.53 which represents a decrease of almost 11 percent from the 2019 geometric mean per diem cost for these providers ($222.76). Similar to its finding for CMHCs, CMS determined that a single hospital-based PHP provider with a large number of paid PHP service days had a significant decrease in its cost per day which heavily influenced the calculation. Thus, it proposes to use the 2019 hospital-based PHP provider geometric mean per diem cost as a floor for 2020; if the most recent data used in the final rule result in a geometric mean per diem cost for hospital-based PHP providers below the 2019 cost, CMS will finalize the 2019 geometric mean per diem cost for PHP services furnished in 2020. CMS notes it only proposes to apply this policy for 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 would not have addressed the fluctuation in costs over time that concerns CMS. CMS estimates the difference in the (prescaled) PHP provider geometric mean per diem costs for 2020 from its floor policy rather than the calculated costs without the floor policy is $10.7 million ($1.4 million to CMCHs and $9.3 million to hospital-based PHP providers).

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

2018 APC	Group Title	Proposed PHP APC Geometric Mean Per Diem Costs*	Proposed Payment Rates**
5853	Partial Hospitalization (3 or more services per day) for CMHCs	$121.62	$ 124.59
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	$222.76	$ 228.20

* Table 20 of the proposed rule shows the proposed PHP APC geometric mean per diem costs.
** The proposed payment rates are from Addendum A to the proposed rule.

B. PHP Service Utilization

CMS has previously expressed concern about the low frequency of individual therapy in PHP services. CMS believes that appropriate treatment for PHP patients includes individual therapy, and its analysis of 2018 claims data shows that the provision of individual therapy on days with 4 or more services by CMHCs and hospital-based PHPs have increased. However, on days with 3 services, individual therapy provided by CMHCs decreased and hospital-based PHPs maintained the same rate of individual therapy. Table 21 of the proposed 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, CMS believes that PHPs maintained an appropriately low utilization of 3 service days as compared to the three preceding years, but the agency will continue to monitor utilization of days with only 3 PHP services. CMS reiterates its expectation that days with only 3 services should be the exception and not the typical PHP day; it believes that the typical PHP day should generally consist of 5 or 6 units of service.

C. Outlier Policy for CMHCs

For 2020, CMS proposes to continue to calculate the CMHC outlier percentage, cutoff point and percentage payment amount, outlier reconciliation, outlier payment cap, and fixed-dollar threshold pursuant to established policies. In the preamble to the rule, CMS provides a more detailed explanation of the steps involved in calculating the CMHC outlier percentage.

CMS proposes to designate less than 0.01 percent of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs for PHP outliers. CMS proposes to set 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 to pay 50 percent of CMHC geometric mean per diem costs over the threshold. Specifically, CMS will calculate a CMHC outlier payment equal to 50 percent of the difference between the CMHC's cost for the services and the product of 3.4 times the APC 5853 payment rate.

In the 2017 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 proposes to continue this policy for 2020. This payment cap only impacts CMHCs.

CMS does not propose to set a fixed-dollar threshold for CMHC outlier payments that it proposes to apply 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. The agency will consider the comments it received on the proposed deletions and additions and seeks to finalize its proposals in the 2020 OPPS/ASC final rule.

E. Regulatory Impact

CMS estimates that payments to CMHCs will increase by 3.9 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 includes 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.
- A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.
- A determination is made that the procedure can be appropriately and safely performed in an ASC and is on the list of approved ASC procedures or has been proposed for addition to the ASC list.

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

CMS proposes 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, including 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 believes that THA meets criterion 2 (the simplest procedure described by the code may be performed in most outpatient departments) and criterion 3 (the procedure is related to codes already removed from the IPO list). For appropriately selected patients, CMS believes outpatient THA is appropriate. CMS proposes to remove THA from the IPO list and 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 furnished in conjunction with it during the outpatient encounter. At this time, CMS is not proposing to remove PHA from the IPO list because it does not believe it meets the criteria for removal.

CMS is further soliciting comments on removing the codes listed in Table 23 reproduced below from the IPO list.

TABLE 23.—IPO List CPT Codes to be Potentially Removed from the IPO List

CPT Code	Long Descriptor
22633	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;
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
63265	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; cervical
63266	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; thoracic
63267	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar
63268	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; sacral

Upon review of the clinical characteristics of CPT code 22633 and CPT code 22634, CMS believes these services are related to CPT code 22551(Arthrodesis, anterior interbody, cervical) which is currently performed in the outpatient hospital setting. However, CMS is concerned the available data do not provide a large enough sampling of outpatient procedures and do not directly address the criteria for removal from the IPO list.

Over the years, stakeholders have argued CPT codes 63265, 63266, 63267, and 63268 should be considered minimally invasive meeting criteria one and two for removal from the IPO list: 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. CMS does not believe there is sufficient information to demonstrate that these codes meet the IPO list removal criteria.

X. Nonrecurring Policy Changes

A. Supervision Level for Outpatient Therapeutic Services

With limited exceptions, Medicare requires direct supervision[16] for hospital outpatient therapeutic services covered and paid by Medicare that are furnished in 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 supervision[17] 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 that complement the general supervision requirements 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

[16] "Direct supervision" means that the physician or nonphysician practitioner must be immediately available to 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.
[17] "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.

of supervision levels for hospital outpatient therapeutic services. CMS is proposing 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 (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 requests comments on its proposal and whether specific types of services, such as chemotherapy administration or radiation therapy, should be excepted from this proposal.

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 proposes 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. CMS believes that 1-year period is an adequate amount of time for providers to gain experience with application of the 2-midnight rule. A 1-year period allows providers sufficient time to update their billing systems and gain experience with newly removed procedures eligible to be paid under either the IPPS or the OPPS, while avoiding potential adverse site-of-service determinations.

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 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 proposes to pay 40 percent of the OPPS rate for clinic visits in 2020 provided in excepted off-campus PBD. In addition, CMS is continuing to implement policy as a savings not subject to budget neutrality. The impact of this policy is shown in column 5 of Table 41 at the end of this summary.

XI. OPPS Payment Status and Comment Indicators

OPPS Payment Status Indicator Definitions

For 2020, CMS is not proposing any changes to status indicators. Status indicators and their definitions can be found in Addendum D1 of the proposed rule. Each status indicator will identify whether a given code is payable under the 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 proposes to continue using the following comment indicators:

‘‘CH’’—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.
‘‘NC’’— New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year for which CMS is requesting comments in the proposed rule, final APC assignment; comments will not be accepted on the final APC assignment for the new code.
‘‘NI’’—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.

‘‘NP’’—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.

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

XII. Medicare Payment Advisor Commission (MedPAC) Recommendations

CMS is advising stakeholders of the following 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.

ASC Update: MedPAC indicates that payments to ASCs are adequate and recommended no payment update. CMS is proposing an ASC update of 2.7 percent equal to the hospital market basket less 0.5 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.

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 Ambulatory Surgical Center (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	1.0008	
2020 Update		
Hospital market basket update	3.2%	
Multi-factor productivity adjustment (MFP)	-0.5%	
Net MFP adjusted update	2.7%	
Penalty for not reporting quality data	0.0%	-2.0%
Net MFP and quality adjusted update	2.7%	0.7%
2019 ASC Conversion Factor	$47.827	$46.895

CMS estimates that under the proposed rule, total ASC payments for 2020 will increase by $200 million over 2019 levels inclusive of changes in enrollment, utilization and case mix changes.

As with the rest of the OPPS proposed rule and other CMS rules, addenda related to the ASC section (and referenced in this summary) are available only on the CMS website, at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1717-P.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 this proposed rule; and
- New codes for which it will be seeking comments in the forthcoming final rule with comment period.

Table 28 provides the process and timeline for ASC list updates:

Comment and Finalization Timeframes for New or Revised HCPCS Codes (from CMS Table 28)				
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 is Soliciting Public Comments in this Proposed Rule

CMS, in April and July of 2019 change requests (CRs), made effective 22 new Level II HCPCS codes and 1 new Category III CPT Code describing covered ASC services that were not included in the 2018 OPPS final rule. Tables 25-27, 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 25)			
2019 HCPCS Code	**Long Descriptor**	**Proposed CY 2020 Comment Indicator**	**Proposed CY 2020 Payment Indicator**
C9040	Injection, fremanezumab-vfrm, 1mg	NP	K2
C9041	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	NP	K2
C9042*	Injection, bendamustine hcl (belrapzo), 1 mg	CH	D5
C9043	Injection, levoleucovorin, 1 mg	NP	K2
C9044	Injection, cemiplimab-rwlc, 1 mg	NP	K2
C9045	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	NP	K2
C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	NP	K2
C9141**	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl (jivi) 1 i.u.	CH	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 26)			
2019 HCPCS Code	**CY 2019 Long Descriptor**	**Proposed 2020 CI**	**Proposed 2020 PI**
C9047	Injection, caplacizumab-yhdp, 1 mg	NP	K2
C9048	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	NP	K2
C9049	Injection, tagraxofusp-erzs, 10 mcg	NP	K2
C9050	Injection, emapalumab-lzsg, 1 mg	NP	K2
C9051	Injection, omadacycline, 1 mg	NP	K2
C9052	Injection, ravulizumab-cwvz, 10 mg	NP	K2
J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl, (jivi), 1 i.u.	NP	K2
J9030	BCG live intravesical instillation, 1 mg	NP	K2
J9036	Injection, bendamustine hydrochloride, (Belrapzo/bendamustine), 1 mg	NP	K2
J9356	Injection, trastuzumab, 10 mg and Hyaluronidase-oysk	NP	K2
0548T*	Transperineal periurethral balloon continence device; bilateral placement, including cystoscopy and fluoroscopy	NP	J8
0549T	Transperineal periurethral balloon continence device; unilateral placement, including cystoscopy and fluoroscopy	NP	J8

2019 HCPCS Code	CY 2019 Long Descriptor	Proposed 2020 CI	Proposed 2020 PI
0550T	Transperineal periurethral balloon continence device; removal, each balloon	NP	G2
0551T	Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume	NP	R2
*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 27)			
2019 HCPCS Code	**CY 2019 Long Descriptor**	**Proposed 2020 CI**	**Proposed 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 proposes to continue 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 Public Comments are Solicited in the Proposed Rule

CMS seeks comment on the following proposed new and revised CPT codes effective January 1, 2020 that were received in time to be include in this 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.

ASC Covered Surgical Procedures Proposed to be Newly Designated as Permanently Office-based for CY 2020 (Table 29)			
CY 2020 CPT Code	**CY 2020 Long Descriptor**	**CY 2019 ASC Payment Indicator**	**Proposed CY 2020 ASC Payment Indicator***
31298	Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (eg, balloon dilation)	G2	P2*
31634	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, with assessment of air leak, with administration of occlusive substance (eg, fibrin glue), if performed	G2	P3*
31647	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe	G2	R2*
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*
50727	Revision of urinary-cutaneous anastomosis (any type urostomy)	G2	R2*
59414	Delivery of placenta (separate procedure)	G2	R2*
61880	Revision or removal of intracranial neurostimulator electrodes	G2	R2*

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

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

Covered Surgical Procedures Designated as Office-Based

CMS annually reviews volume and utilization data to identify "office-based" procedures that are added to the ASC list of covered surgical procedures and are performed more than 50 percent of the time in physicians' offices and that CMS' medical advisors believe are of a level of complexity consistent with other procedures performed routinely in physicians' offices. Based on its review of 2018 volume and utilization data, CMS proposed to permanently designate nine additional procedures as office-based (shown in Table 29 in the proposed rule and re-produced below).

CMS re-evaluated data for CPT codes 36902 and 36905 and concludes that the data do not support assigning an office-based designation for those procedures for 2020. They will, therefore, retain their current payment indicator, "G2".

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 30 (reproduced below) in the proposed rule lists the procedures and CMS' proposed payment indicators for 2020.

Proposed 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 30)			
2020 CPT/HCPCS Code	**CY 2020 Long Descriptor**	**2019 ASC Payment Indicator**	**Proposed 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*

2020 CPT/HCPCS Code	CY 2020 Long Descriptor	2019 ASC Payment Indicator	Proposed 2020 ASC Payment Indicator*
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*
38222	Diagnostic bone marrow; biopsy(ies) and aspiration(s)	P3	G2
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 proposes to designate seven new 2020 CPT codes as ASC covered surgical procedures as temporary office-based, using a 5-digit CMS placeholder code. Table 31 in the proposed rule (reproduced below) lists the procedures and proposed payment indicators.

Proposed 2020 Payment Indicators for New 2020 CPT Codes for ASC Covered Surgical Procedures Designated as Temporarily Office-based (Table 31)		
2020 OPPS/ASC proposed rule 5-digit CMS placeholder code	**CY 2020 Long Descriptor**	**Proposed 2020 ASC Payment Indicator****
64XX0	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed	P3**
64XX1	Destruction by neurolytic agent, genicular nerve branches, including imaging guidance, when performed	P3**
93X00	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study	R2**
93X01	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study	R2**
0551T	Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume	R2**
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**
0X71T	Health and well-being coaching face-to-face; group (2 or more individuals), at least 30 minutes	R2**
**Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the PFS proposed rates. For a discussion of the MPFS rates, we refer readers to the CY 2020 PFS proposed 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 proposes to update the ASC list of covered surgical procedures that are eligible for payment according to the device-intensive payment methodology for 2020, reflecting the proposed individual HCPCS

code device offset percentages based on 2018 OPPS claims and cost report data.

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 proposes to add four mosaicplasty procedures, three coronary intervention procedures and total knee arthroplasty (TKA) to the ASC list. Prior comments on the addition of TKA were both in support of an opposed to making it an ASC list procedure. CMS notes, however, that after examining Medicare Advantage data where over 800 TKS procedures were performed on Medicare Advantage enrollees in ASCs in 2016, it believes that some beneficiaries are clinically suitable for TKA in ASC settings. CMS solicits feedback on selection criteria for patients appropriate for TKA in ASC settings.

CMS seeks comment on the impact of state regulations and market forces on the ASC list and whether any changes to how CMS makes modifications should take those factors into account. CMS is also interested in how proposed additions to the list of ASC covered surgical procedures might affect rural hospitals.

The procedures that CMS proposes to add to the ASC list of covered surgical procedures, as well as their respective add-on procedures which are packaged under the ASC payment system are

displayed in Table 32 (duplicated below.)

TABLE 32.—PROPOSED ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR 2020		
2020 CPT Code	**CY 2020 Long Descriptor**	**Proposed 2020 ASC Payment Indicator**
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
92920	Percutaneous transluminal coronary angioplasty; single major coronary artery or branch	G2
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
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

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. At this time, CMS is not recommending adding them to the ASC list but is seeking comment on whether such procedures can be safely performed in an ASC and requests commenters provide supporting materials or data.

Potential Procedures for Addition to the 2020 ASC List of Covered Surgical Procedures (Table 33)	
2020 CPT Code	**2020 Long Descriptor**
92924	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; single major coronary artery or branch
92925	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)
92933	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch
92934	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)
92937	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel
92938	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure)
92943	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single vessel
92944	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)
92973	Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch
C9602	Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch
C9604	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel

2020 CPT Code	2020 Long Descriptor
C9605	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure)
C9607	PCI of chronic total occlusion, any method(s), with drug-eluting stent
C9608	Percutaneous transluminal revascularization o f chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; each additional corona

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

Proposed ASC Payment for Covered Surgical Procedures

CMS proposes to continue it 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.

Proposed 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 proposes 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.

Proposed Payment for Covered Ancillary Services

CMS proposes to update payments and make changes necessary to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services. 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. 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 proposes to continue using the current comment indicators "NP" and "CH." Category I and III CPT codes that are new and revised for 2018 and any new and existing Level II HCPCS codes with substantial revisions were labeled with the proposed new comment indicator 'NP" to indicate that these codes are open for comment as part of the 2020 proposed rule.

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

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

CMS proposes to continue 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, 0.8452, 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, 1.0008, 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 3.2 percent minus the multifactor productivity adjustment (MFP) of 0.5 percent. This yields an update of 2.7 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 0.7 percent for such ASCs. The resulting 2020 ASC conversion factor is $47.827 for ASCs reporting quality data, and $46.532 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 1.0008	
Net MFP-adjusted update	x 1.027	x 1.007
2019 ASC conversion factor	$47.827	$46.532

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 42 of the proposed rule and reproduced below). The eye and ocular adnexa group remains the largest source of payments, with 3 percent increase in payments attributable to the changes proposed for 2020. The second largest group, nervous system, is estimated to see a 3 percent increase.

Table 42 – Estimated Impact of the Proposed 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	**$5,043**	**3%**
Eye and ocular adnexa	$1,743	3%
Nervous system	$1,106	3%
Digestive system	$893	1%
Musculoskeletal system	$608	2%
Genitourinary system	$194	2%
Cardiovascular system	$184	5%
Ancillary items and services	$99	5%

CMS provides estimated increases for 30 selected procedures in Table 43 in the final rule; the top 10 procedures are replicated below. CPT code 66984 (Cataract surgery with intraocular lens, 1

stage) is the largest aggregate payment procedure by far and is estimated to have a 2 percent decline in payment. The second largest aggregate payment procedures, CPT code 63685, is expected to see a 4 percent increase.

Excerpt from Table 43: 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	1%
63650	Implant neuroelectrodes	$183	4%
43239	Egd biopsy single/multiple	$177	1%
64483	Inj foramen epidural l/s	$114	2%
0191T	Insert ant segment drain int	$96	1%
66982	Cataract surgery complex	$91	3%
64635	Destroy lumb/sac facet jnt	$79	1%

As noted at the beginning of this ASC section, Addenda tables available only on the website provide additional details; they are at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1717-P.html. They include:

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

XIV. Requirements for the Hospital OQR Program

In this section, CMS proposes to remove one measure from the OQR Program beginning with the 2022 payment determination. No changes are 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 previously adopted OQR Program measures for 2018 through the proposed measure set for 2022.

A. Measure Removal

CMS proposes to remove the measure OP-33: External Beam Radiotherapy for Bone Metastases (NQF #1822) from the OQR Program beginning with 2022 payment. The basis for this proposal

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 has also been proposed for removal from the PPS-exempt Cancer Hospital Quality Reporting Program (84 FR 19502-3) 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.

Under the proposal, reporting on the measure would no longer be required beginning with October 2020 encounters. (It is unclear why the proposed date is not January 1, 2020, given that the reporting period for measures submitted via a web-based tool for 2021 payment is calendar year 2019.) CMS considered proposing removal of the measure beginning with 2021 payment but decided not to do this out of concern about facilities' planning and operational procedures given that the reporting period for 2021 payment has already begun. (Data submission for 2021 payment using a web-based tool will occur between January 1, 2020 and May 15, 2020.)

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 would 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

Comments are sought 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)[18]. In section XV.B below CMS is seeking 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. That is, comments are sought on the possible addition of these measures with data submission through an online tool. In addition, the measures would need to be specified for the hospital OPD.

CMS believes these measures provide important data on events that should never occur, and would align the OQR and ASCQR programs. 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.

[18] 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 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.

- 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 is 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.

C. Summary Table of OQR Program Measures

The table below shows the final OQR Program measure sets for payment years 2018 through 2021 and the proposed measure set for 2022. (Once adopted, measures are retained in the program unless proposed and finalized for removal.) Specifications for OQR Program measures are available on the QualityNet website: https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1196289981244.

SUMMARY TABLE OF HOSPITAL OQR PROGRAM MEASURES 2018-2022 *Proposals in Italics*						
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
	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

SUMMARY TABLE OF HOSPITAL OQR PROGRAM MEASURES 2018-2022 *Proposals in Italics*						
NQF		**2018**	**2019**	**2020**	**2021**	**2022**
	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
1822	OP-33: External Beam Radiotherapy for Bone Metastases	X	X	X	X	***Remove***
	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*					

SUMMARY TABLE OF HOSPITAL OQR PROGRAM MEASURES 2018-2022 *Proposals in Italics*						
NQF		**2018**	**2019**	**2020**	**2021**	**2022**
	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. Voluntary reporting is not discussed in this proposed rule. 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 would be continued for the 2020 update factor. The reduction ratio for hospitals that fail to meet OQR Program requirements, called the "reporting ratio", is 0.98. It is calculated by dividing the proposed reduced conversion factor of $79.770 by the proposed full conversion factor of $81.398. Continuing previous policies, when applicable, the reporting ratio would 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 would 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. Requirements for the ASCQR Program

CMS proposes the addition of one new measure to the ASCQR Program beginning with the 2024 payment determination. No changes are 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 beginning with the 2018 payment determination along with the proposed additional measure for 2024.

A. New Measure

CMS proposes 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 proposed 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. It notes that ASCs may be unaware of patients' subsequent unplanned hospital visits, and that beneficiaries may benefit from transparent data on the frequency of such visits in choosing where to have ambulatory surgery.

Proposed 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. Input from a Technical Expert Panel (TEP) and results of a public comment period are discussed. In particular, CMS modified the cohort list of procedures in consultation with general surgeons. The Measure Applications Partnership (MAP) provided conditional support for this measure, pending NQF review and endorsement, and noted concerns about the attribution model used in the measure. Subsequently, CMS completed field testing for the measure and reviewed reliability results with the TEP. The measure was endorsed by the NQF in June 2018, described at http://www.qualityforum.org/QPS/3357. CMS provides the following link to information on the TEP and public comments: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Development-of-Facility-Level-Quality-Measure-of-Unplanned-Hospital-Visits-after-General-Surgery-Ambulatory-Surgical-Center-Procedures.zip.

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.

Details on the measure's calculations, patient cohort, target procedures, and risk adjustment are provided in the proposed rule or through links referenced there, and in the technical reports at the link provided immediately above. The measure would be calculated by CMS using claims data; no additional data would need to be reported by ASCs.

CMS proposes that if the measure is adopted, measure performance would 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.

B. ASCQR Program Measures and Topics for Future Consideration

CMS seeks comments 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. CMS indicated its intention to update the data submission method for these measures in the future.

CMS seeks comment on updating the data submission method for these measures to use of a CMS online data submission tool, via the QualityNet.org website. To implement this, ASCs or any agents submitting the data on behalf of an ASC would have to maintain a QualityNet account, set up by a QualityNet security administrator. CMS believes this method 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. Under previously codified policies (42 CFR 416.310(c)(1)), the data collection time period for quality measures for which data are submitted via a CMS online data submission tool is for services furnished during the calendar year 2 years prior to the payment determination year. Data collected must be submitted during the time period of January 1 to May 15 in the year 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.)

In addition to comments on whether an online data submission tool would be appropriate for these measures, CMS seeks comments on the burden associated with this reporting method. It recognizes that using an online data submission tool would add some burden to the ASCQR Program.

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 proposed change 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

Proposals in Italics

	2018	2019	2020	2021	2022
ASC-1: Patient Burn (NQF #0263)+	X	X	X	Suspended*	
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)					***Proposed for addition 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; it is not discussed in this proposed rule. 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 are proposed to the policies for determining the payment reduction for ASCs that fail to meet the ASCQR Program requirements. Medicare law requires that a 2.0 percentage point reduction to the ASC annual update is applied to ASCs that fail to meet the requirements. The reduction applies to services calculated using the ASC conversion factor with the payment indicators of A2, G2, P2, R2, Z2, and the service portion of device-intensive procedures identified by J8. The reduction does not apply to services that are assigned other status indicators for which payments are not calculated using the conversion factor, including separately payable drugs and biologicals, pass through devices that are contractor-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. Requirements for Hospitals to Make Public a List of Their Standard Charges

A. Introduction and Overview

Section 2718(e) of the Public Health Service (PHS) Act requires each hospital operating within the United States for each year to establish (and update) and make public a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1886(d)(4) of the Social Security Act (the Act). In the FY 2015 IPPS/LTCH PPS rule, CMS required hospitals to either make public a list of their standard charges or their policies for allowing the public to view a list of those charges in response to an inquiry. In the FY 2019 IPPS/LTCH PPS rule, CMS required hospitals to make available a list of their current standard charges via the Internet in a machine-readable format and to update this information at least annually, or more often as appropriate.

Traditional economic analysis suggests that if consumers have better pricing information for health care services, providers would face pressure to lower prices and provide better quality care. The Government Accountability Office (GAO) report (2011), "Health Care Price Transparency: Meaningful Price Information is Difficult for Consumers to Obtain Prior to Receiving Care," found transparency initiatives were best able to provide reasonable estimates of consumers' complete costs when they had access and integrated pricing data from both providers and insurers.

CMS says there continues to be a gap in easily accessible pricing information for consumers to use for health care shopping purposes. Yet it believes that ensuring public access to hospital

standard charge data will promote and support current and future price transparency efforts enabling health care consumers to make more informed decisions, increase market competition, and ultimately drive down the cost of health care services.

In response to stakeholder engagement CMS indicates that most commenters supported furthering price transparency efforts, although a few stakeholders opposed efforts to make hospital pricing information available to the public for a variety of reasons including the complexity of the information, concerns about whether it would be understood and commercial sensitivity. Some stakeholders noted that the most useful pricing information for consumers is information that displays a patient's expected out-of-pocket costs for nonurgent health care services that can be scheduled in advance, also referred to as "shoppable" services.

In response to stakeholders and in accordance with President's Executive Order on "Improving Price and Quality Transparency in American Healthcare to Put Patients First" (June 24, 2019), CMS is proposing an expansion of hospital charge display requirements to include charges and information based on negotiated rates and for common shoppable items and services, in a manner that is consumer-friendly. CMS is also proposing to establish a mechanism for monitoring and the application of penalties for noncompliance.

B. Definition of "Hospital" and Special Requirements for Certain Types of Hospitals

1. Definition of a Hospital

CMS proposes to define a "hospital" as an institution in any of the 50 United States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands that is: (1) licensed as a hospital pursuant to state law or (2) approved, by the agency of such state or locality responsible for licensing hospitals, as meeting the standards to be a licensed hospital. This definition would apply to all Medicare-enrolled hospitals and any institutions that are operating as hospitals under state or local law but might not be considered hospitals for purposes of Medicare participation.

The proposed definition would include critical access hospitals (CAHs), inpatient psychiatric facilities (IPFs), sole community hospitals (SCHs), and inpatient rehabilitation facilities (IRFs) as well as any other type of institution, so long as such institutions are licensed as a hospital (or otherwise approved) as meeting hospital licensing standards. CMS considered whether to exempt CAHs, children's hospitals, and state psychiatric hospitals from these requirements but did not do so because such hospitals are open to the general public, and their charges are generally not made available to the public but is requesting comments on whether exceptions to the proposed requirements might be warranted for some of these hospitals.

Some hospitals are going above and beyond CMS' proposed requirements, for example, by offering patient-friendly price transparency tools that calculate individualized out-of-pocket cost estimates. CMS seeks comment on whether offering such tools could qualify a hospital to be excepted from some of the proposed requirements.

The proposed definition of "hospital" would exclude ambulatory surgical centers (ASCs) or other non-hospital sites-of-care that may offer ambulatory surgical services, laboratory or imaging services, or other services that are similar or identical to the services offered by hospital outpatient departments. Despite being excluded from the definition of a hospital, CMS encourages these non-hospital sites to make public their lists of standard charges in alignment with these proposed requirements so that consumers can make effective pricing comparisons.

2. Special Requirements for Federally-Owned Hospitals

CMS is proposing to deem federally-owned or operated hospitals as meeting the requirements of section 2718(e) of the PHS Act when their charges for hospital provided services are publicized to their patients in advance (for example, through the *Federal Register*). These hospitals do not treat the general public (except for emergency services) and do not have rates that are subject to negotiation. Hospitals subject to these special requirements would include federally-owned or operated hospitals, including Indian Health Service (IHS) facilities (including Tribally-owned and operated facilities), Veterans Affairs (VA) facilities, and Department of Defense Military Treatment Facilities (MTFs).

C. Definition of "Items and Services" Provided by Hospitals

CMS is proposing that, for purposes of section 2718(e) of the PHS Act, "items and services" provided by the hospital are all items and services, including individual items and services and service packages, that could be provided by a hospital to a patient in connection with an inpatient admission or an outpatient department visit for which the hospital has established a standard charge. For purposes of section 2718(e) of the PHS Act, CMS proposes "chargemaster" to mean the list of all individual items and services maintained by a hospital for which the hospital has established a standard charge.

Each individual item or service found on the hospital chargemaster has a corresponding "gross" charge and may also have a corresponding negotiated discount because some hospitals negotiate with third-party payers to establish a flat percent discounted rate off the gross charge for each individual item and service listed on the chargemaster. In contrast to the chargemaster or so-called "fee-for-service" price list, hospitals also routinely negotiate rates with third-party payers for bundles of services or "service packages" in lieu of charging for each item. For purposes of section 2718(e) of the PHS Act, CMS is proposing to define a "service package" as an aggregation of individual items and services into a single service with a single charge. CMS' proposed definition of "items and services" includes both individual items and services and service packages.

The proposed definition of "items and services" would include services furnished by physicians and non-physician practitioners employed by the hospital. CMS considered but decided against proposing to include services provided by physicians and non-physician practitioners who are not employed by the hospitals, but who provide services at a hospital location. CMS does not believe that the services of non-employed physicians and non-physician practitioners fall within the scope of services "provided by the hospital."

D. Definitions of Types of "Standard Charges"

CMS proposes to define standard charges as gross charges and payer-specific negotiated charges. A "gross charge" would be defined as the charge for an individual item or service that is reflected on a hospital's chargemaster, absent any discounts. The gross charges often apply to a specific group of individuals who are self-pay, but do not reflect charges negotiated by third-party payers. CMS proposes requiring the posting of gross charges because higher gross charges have been found to be associated with both higher negotiated rates and, in turn, higher premiums and out-of-pocket costs for insured individuals.

A "payer-specific negotiated charge" would be defined as the charge that the hospital has negotiated with a third-party payer for an item or service. "Third-party payer" for purposes of section 2718(e) of the PHS Act would be defined as an entity that is, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service. This definition excludes an individual who pays for a health care item or service that he or she receives (such as self-pay patients).

CMS is focusing on negotiated rates by third-party payers because many third-party payers do not reveal their negotiated rates, even to individuals on behalf of whom they pay. Having insight into the charges that have been negotiated on one's behalf, however, is necessary for insured health care consumers to determine their potential out-of-pocket obligations prior to receipt of a health care service. Knowing a negotiated charge is also important because a growing number of insured health care consumers are finding that some services are more affordable if the consumer chooses to forego insurance and pay out of pocket.

CMS acknowledges that the impact resulting from the release of negotiated rates is largely unknown. Some stakeholders have expressed concern with the public display of de-identified negotiated rates which may have the unintended consequence of increasing health care costs of hospital services in highly concentrated markets or as a result of anticompetitive behaviors without additional legislative or regulatory efforts.

Moreover, CMS recognizes that it may be requiring release of a large amount of data. However, CMS indicates that most (if not all) hospitals maintain such data electronically because these data are used routinely for billing, and therefore believes it presents little burden for a hospital to electronically pull and display these data online in a machine-readable format.

Hospitals would display all negotiated charges, including, for example, charges negotiated with Medicare Advantage (MA) plans. Hospitals would not include payment rates that are not negotiated, such as those set by Medicare fee-for-service. However, display of a non-negotiated rate would not be precluded.

Some alternatives to the above definitions of standard charges CMS is seeking comment on include:

Alternatives for Private Payer Negotiated Rates:

- *Volume driven negotiated charge*. The most frequently charged rate across all rates the hospital has negotiated with third-party payers for an item or service would be displayed.
- *Minimum, median and maximum negotiated charge*. Under this definition, the hospital would be required to make public the lowest, median, and highest charges of the distribution of all negotiated charges across all third-party payer plans and products.
- *All Allowed Charges.* This definition would include charges for all items and services for all third-party payer plans and products, including those that are non-negotiated (such as FFS Medicare rates).

Alternatives for Self-Pay Patients:

- *Discounted Cash Price*. The price the hospital would charge individuals who pay cash (or cash equivalent) for an individual item or service or service package. However, the rule acknowledges that many hospitals do not determine or maintain a standard cash discount that would apply uniformly to all self-pay consumers.
- *Median Cash Price*. The median cash price would be the midpoint of all cash discounts offered to consumers, including prices for self-pay patients and those qualifying for financial assistance.

E. Public Disclosure of All Hospital Standard Charges for All Items and Services

CMS is proposing that standard charges be made public through (1) a comprehensive machine-readable file that makes public all standard charge information for all hospital items and services and (2) a consumer-friendly display of common "shoppable" services derived from the machine-readable file.

1. Information that Must be made Available

The rule would require that hospitals make public a list of each item or service the hospital provides and that the list include the following:

- Description of each item or service (including both individual items and services and service packages).
- The gross charge that applies in, as applicable, the hospital inpatient setting and outpatient department setting.
- The payer-specific negotiated charge that applies when provided in, as applicable, the hospital inpatient setting and outpatient department setting. Each list of payer-specific charges must be clearly associated with the name of the third-party payer.
- Any code used by the hospital for purposes of accounting or billing for the item or service, including, but not limited to, the HCPCS code, DRG, National Drug Code (NDC), or other common payer identifier.
- Revenue code, as applicable.

CMS is proposing that hospitals associate each standard charge with a CPT or HCPCS code, DRG, NDC, or other common payer identifier, as applicable. Hospitals use revenue codes to

associate items and services to various hospital departments. When a hospital charges differently for the same item or service in a different department, CMS proposes that the hospital associate the charge with the department represented by the revenue code, providing the public with the charges they may expect for hospital services provided in different hospital departments.

2. File Format Requirements

Machine-readable format is defined as a digital representation of data or information in a file that can be imported or read into a computer system for further processing. Examples of machine-readable formats include, but are not limited to, .XML, JSON and .CSV formats. CMS believes that making public such data in a machine-readable format poses little burden on hospitals because many (if not all) hospitals already keep these data in electronic format in their accounting systems for purposes of, for example, ensuring accurate billing.

CMS requests comments on only allowing the data to be posted in a XML format and other alternatives that could allow public access to hospital standard charge data in real time. Such technology may require or involve a type of portal or standard(s) in which entities have access to certain non-sensitive data elements or files within the hospital IT system environment, such as the chargemaster, but that otherwise restricts access to (i) sensitive, personal identifying information (PII), (ii) commercial, protected health information, and/or (iii) confidential information. For example, application programming interface (API) standards could be used to facilitate public access to real-time hospital charge information.

More information on API certification criteria and how APIs can be used by patients and health care providers and other entities to exchange electronic information can be found on the website at: https://www.healthit.gov/api-education-module/story_content/external_files/hhs_transcript_module.pdf

CMS is specifically seeking public comment on adopting a requirement that hospitals make public their standard charges through an "openly published" (or simply "open") API through which they would disclose the standard charges and associated data elements. An "open API" would simply be one for which the technical and other information required for a third-party application to connect to it is openly published. Open API does not imply that any and all applications or application developers would have unfettered access to sensitive information.

3. Location and Accessibility Requirements

CMS is proposing that a hospital would have discretion to choose the Internet location it uses to post its file containing the list of standard charges so long as the file is displayed on a publicly-available webpage; it is displayed prominently and clearly identifies the hospital location with which the standard charges information is associated; and the standard charge data are easily accessible, without barriers, and the data can be digitally searched.

"Displayed prominently" would mean that the value and purpose of the webpage and its content is clearly communicated, there is no reliance on breadcrumbs[19] to help with navigation, and the link to the standard charge file is visually distinguished on the webpage. "Easily accessible" would mean that standard charge data are presented in a single machine-readable file that is searchable and that the standard charges file posted on a website can be accessed with the fewest number of clicks. "Without barriers" would mean the data can be accessed free of charge, and users would not have to input information (such as their name, email address, or other PII) or register to access or use the standard charge data file.

Hospitals are encouraged to review the HHS Web Standards and Usability Guidelines (available at: https://webstandards.hhs.gov/) which are intended to provide best practices over a broad range of web design and digital communications issues. CMS also requests comments on requiring hospitals to submit a link to a CMS-specified central website that would make the hospital's charge data public on a CMS webpage. CMS further seeks public comments on potential additional requirements, including easily-searchable file naming conventions and whether to specify the website location for posting rather than permitting hospitals some flexibility in choosing an appropriate website.

4. Frequency of Updates

CMS is proposing to require hospitals to update all standard charges at least once annually. The proposal further would require hospitals to clearly indicate the date of the last update with some discretion as long as that date is clearly indicated and associated with the file or location containing the standard charge information.

5. Requirements for Making Public Separate Files for Different Hospital Locations

The proposed requirements would separately apply to each hospital location such that each hospital location would be required to make public a separate identifiable list of standard charges.

F. Consumer-Friendly Display of the Payer-Specific Negotiated Charges for Selected Shoppable Services

CMS proposes to define "shoppable service" as a service package that can be scheduled by a health care consumer in advance. Shoppable services are typically those that are routinely provided in non-urgent situations that do not require immediate action or attention to the patient, thus allowing patients to price shop and schedule a service at a time that is convenient for them. Additionally, CMS is proposing that the charges for such services be displayed as a grouping of related services, meaning that the charge for the shoppable service is displayed along with charges for ancillary items and services the hospital customarily provides as part of or in addition to the primary shoppable service.

19 Breadcrumb **Navigation** is a form of site **navigation** that shows visitors where they are on a site's hierarchy of pages without having to examine a URL structure.

"Ancillary service" is defined as an item or service a hospital customarily provides as part of or in conjunction with a shoppable primary service. To the extent that a hospital customarily provides (and bills for) such services as a part of or in conjunction with the primary service, the hospital should group the service charge along with the other payer-specific negotiated charges that are displayed for the shoppable service.

Selected Shoppable Services

CMS proposes that hospitals make public a list of their payer-specific negotiated charges for as many of the 70 shoppable services that are identified in Table 37 of the proposed rule (reproduced below) and as many additional shoppable services selected by the hospital as is necessary for a combined total of at least 300 shoppable services (hospitals could selected the additional services to the ones listed below based on the utilization or billing rate of the services in the past year). CMS plans to increase the required number of shoppable services over time.

TABLE 37.—PROPOSED LIST
70 CMS-SPECIFIED SHOPPABLE SERVICES

Category/Service	2020 CPT/HCPCS Primary Code
Evaluation & Management Services	
Psychotherapy, 30 min	90832
Psychotherapy, 45 min	90834
Psychotherapy, 60 min	90837
Family psychotherapy, not including patient 50 min	90846
Family psychotherapy, including patient, 50 min	90847
Group psychotherapy	90853
New patient office or other outpatient visit, typically 30 min	99203
New patient office or other outpatient visit, typically 45 min	99204
New patient office or other outpatient visit, typically 60 min	99205
Patient office consultation, typically 40 min	99243
Patient office consultation, typically 60 min	99244
Initial new patient preventive medicine evaluation (18-39 years)	99385
Initial new patient preventive medicine evaluation (40-64 years)	99386
Laboratory & Pathology Services	
Basic metabolic panel	80048
Blood test, comprehensive group of blood chemicals	80053
Obstetric blood test panel	80055
Blood test, lipids (cholesterol and triglycerides)	80061
Kidney function panel test	80069
Liver function blood test panel	80076
Manual urinalysis test with examination using microscope	81000 or 81001
Automated urinalysis test	81002 or 81003
PSA (prostate specific antigen)	84153-84154
Blood test, thyroid stimulating hormone (TSH)	84443
Complete blood cell count, with differential white blood cells, automated	85025

Category/Service	2020 CPT/HCPCS Primary Code
Complete blood count, automated	85027
Blood test, clotting time	85610
Coagulation assessment blood test	85730
Radiology Services	
CT scan, head or brain, without contrast	70450
MRI scan of brain before and after contrast	70553
X-Ray, lower back, minimum four views	72110
MRI scan of lower spinal canal	72148
CT scan, pelvis, with contrast	72193
MRI scan of leg joint	73721
CT scan of abdomen and pelvis with contrast	74177
Ultrasound of abdomen	76700
Abdominal ultrasound of pregnant uterus (greater or equal to 14 weeks 0 days) single or first fetus	76805
Ultrasound pelvis through vagina	76830
Mammography of one breast	77065
Mammography of both breasts	77066
Mammography, screening, bilateral	77067
Medicine and Surgery Services	
Cardiac valve and other major cardiothoracic procedures with cardiac catheterization with major complications or comorbidities	216
Spinal fusion except cervical without major comorbid conditions or complications (MCC)	460
Major joint replacement or reattachment of lower extremity without major comorbid conditions or complications (MCC).	470
Cervical spinal fusion without comorbid conditions (CC) or major comorbid conditions or complications (MCC).	473
Uterine and adnexa procedures for non-malignancy without comorbid conditions (CC) or major comorbid conditions or complications (MCC)	743
Removal of 1 or more breast growth, open procedure	19120
Shaving of shoulder bone using an endoscope	29826
Removal of one knee cartilage using an endoscope	29881
Removal of tonsils and adenoid glands patient younger than age 12	42820
Diagnostic examination of esophagus, stomach, and/or upper small bowel using an endoscope	43235
Biopsy of the esophagus, stomach, and/or upper small bowel using an endoscope	43239
Diagnostic examination of large bowel using an endoscope	45378
Biopsy of large bowel using an endoscope	45380
Removal of polyps or growths of large bowel using an endoscope	45385
Ultrasound examination of lower large bowel using an endoscope	45391
Removal of gallbladder using an endoscope	47562
Repair of groin hernia patient age 5 years or older	49505
Biopsy of prostate gland	55700
Surgical removal of prostate and surrounding lymph nodes using an endoscope	55866

Category/Service	2020 CPT/HCPCS Primary Code
Routine obstetric care for vaginal delivery, including pre-and post-delivery care	59400
Routine obstetric care for cesarean delivery including pre-and post-delivery care	59510
Routine obstetric care for vaginal delivery after prior cesarean delivery including pre-and post-delivery care	59610
Injection of substance into spinal canal of lower back or sacrum using imaging guidance	62322-62323
Injections of anesthetic and/or steroid drug into lower or sacralspine nerve root using imaging guidance	64483
Removal of recurring cataract in lens capsule using laser	66821
Removal of cataract with insertion of lens	66984
Electrocardiogram, routine, with interpretation and report	93000
Insertion of catheter into left heart for diagnosis	93452
Sleep study	95810
Physical therapy, therapeutic exercise	97110

*The five codes listed with 3 digits are reproduced as presented in the proposed rule.

Required Corresponding Data Elements

CMS is proposing a consumer-friendly display of payer-specific negotiated charge information as follows:

- A plain-language description of each shoppable service. (Hospitals are invited to review and use the Federal plain language guidelines (https://plainlanguage.gov/guidelines).)
- The payer-specific negotiated charge that applies to each shoppable service ("N/A" if it is not a service the hospital provides).
- A list of all the associated ancillary items and services that the hospital provides with the shoppable service, including the payer-specific negotiated charge for each ancillary item or service.
- The location at which each shoppable service is provided including whether the payer-specific negotiated charge for the shoppable service applies at that location to the provision of that shoppable service in the inpatient setting or the outpatient department setting or both.
- Any primary code used by the hospital for purposes of accounting or billing for the shoppable service, including, but not limited to, the CPT or HCPCS code, DRG, or other commonly used service billing code.

CMS recognizes that not all hospitals will customarily provide exactly the same ancillary items or services with a primary shoppable service and therefore believes it is important for hospitals to display a list of ancillary services provided in conjunction with the shoppable service.

Format of Display of Consumer-Friendly Information

CMS is not proposing a specific format for making such data public online in a consumer-friendly manner. Hospitals retain flexibility on how best to display the payer-specific negotiated

charge data and proposed associated data elements, so long as the website is easily accessible to the public. CMS is further proposing to require hospitals make the data elements available in a consumer-friendly manner offline (for example, in a brochure or booklet) upon request within 72 hours.

G. Monitoring and Enforcement of Requirements for Making Standard Charges Public

Monitoring

CMS proposes to rely predominantly on complaints by individuals or entities regarding a hospital's potential noncompliance and its review of individuals' or entities' analysis of noncompliance. As it gains experience with compliance review of complaints, CMS may consider self-initiating audits of hospitals' websites as a monitoring method.

Enforcement

Under the authority of section 2718(b)(3) of the PHS Act, CMS may take any of the following actions when a hospital is non-compliant with section 2718(e) of the PHS Act:

- Written warning notice to the hospital of the specific violation(s).
- Request a corrective action plan (CAP) from the hospital if its noncompliance constitutes a material violation of one or more requirements.
- Imposition of civil monetary penalties (CMP) and publicizing the penalty on a CMS website.

CMS proposes that a material violation may include, but is not limited to, the following:

- A hospital's failure to make public its standard charges.
- A hospital's failure to make public its standard charges in the form and manner required.

A hospital submitting a CAP must do so, in the form and manner, and by the deadline, specified in the notice of violation issued by CMS to the hospital and must comply with the requirements of the CAP. A hospital's CAP must specify elements including, but not limited to, the deficiency or deficiencies that caused noncompliance to occur and the corrective actions or processes the hospital will take to come into compliance. The CAP would be subject to CMS review and approval. CMS may monitor and evaluate the hospital's compliance with the corrective actions.

Civil Monetary Penalties

CMS is proposing that the maximum daily dollar amount for a CMP to which a hospital may be subject would be $300. The CMP amount would be adjusted annually by applying the cost-of-living adjustment multiplier determined by the Office of Management and Budget for adjusting applicable CMP amounts pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

If CMS imposes a penalty, it is proposing to provide a written notice to the hospital via certified mail or another form of traceable carrier. This notice may include, but would not be limited to, the following:

- The basis for the hospital's noncompliance, including, but not limited to: 1) CMS' determination as to which requirement(s) the hospital violated; and 2) the hospital's failure to respond to CMS' request to submit a CAP or comply with the requirements of a CAP.
- CMS' determination as to the effective date for the violation(s). This date would be the latest date of the following:
    - The first day the hospital is required to meet the disclosure requirements.
    - 12 months after the date of the last annual update.
    - A date determined by CMS, such as one resulting from monitoring activities or the date of a CAP.
- The amount of the penalty as of the date of the notice.
- A statement that a CMP may continue to be imposed for continuing violation(s).
- Payment instructions.
- Intent to publicize the hospital's noncompliance and a CMP on the hospital on a CMS website.
- A statement of the hospital's right to a hearing.
- A statement that the hospital's failure to request a hearing within 30 calendar days of the issuance of the notice permits the imposition of the penalty, and any subsequent penalties pursuant to continuing violations, without right of appeal.

A hospital must pay a CMP in full within 60 calendar days after the date of the notice of imposition of a CMP or 60 calendar days after the date of a final and binding decision to uphold, in whole or in part, the CMP (moved to the next business day if the 60th day is a weekend or federal holiday). In the event that a hospital requests a hearing, CMS would indicate in its public posting that the CMP is under review. CMS would modify or remove the posting accordingly based on the outcome of the hearing.

H. Appeals Process

CMS is proposing to align the procedures for the appeals process with the procedures established under section 2718(b)(3) of the PHS Act for an issuer to appeal a CMP imposed for failure to report information and pay rebates related to medical loss ratios. Generally, under this proposed approach, a hospital upon which CMS has imposed a penalty may request a hearing before an Administrative Law Judge (ALJ). The Administrator of CMS, at his or her discretion, may review in whole or in part the ALJ's decision. A hospital against which a final order imposing a CMP is entered may obtain judicial review.

For purposes of appeals of CMPs, CMS proposes the following:

- Civil money penalty means a civil monetary penalty according to proposed new 45 CFR 180.90.
- Respondent means a hospital that received a notice of imposition of a CMP according to proposed new 45 CFR 180.90(b).

- References to a notice of assessment or proposed assessment, or notice of proposed determination of CMPs, are considered to be references to the notice of imposition of a CMP specified in proposed new 45 CFR 180.90(b).
- Under 45 CFR 150.417(b), in deciding whether the amount of a civil money penalty is reasonable, the ALJ may only consider evidence of record relating to:
    - The hospital's posting(s) of its standard charges, if available.
    - Material the hospital timely previously submitted to CMS (including with respect to corrective actions and CAPs).
    - Material CMS used to monitor and assess the hospital's compliance according to proposed new 45 CFR 180.70(a)(2).
- The ALJ's consideration of evidence of acts other than those at issue does not apply.

If a hospital does not request a hearing within 30 calendar days (moved to the next business day if the 30th day is a weekend or federal holiday) of the issuance of the notice of imposition of a CMP, CMS may impose additional penalties pursuant to continuing violations without right of appeal. The hospital will have no right to appeal a penalty with respect to which it has not requested a hearing unless the hospital can show good cause for failing to timely exercise its right to a hearing.

Alternatively, CMS considered and is seeking public comment on allowing either party dissatisfied with a hearing decision by the ALJ to request Departmental Appeals Board review of the ALJ's decision.

XVII. Request for Information: Price Transparency Quality Measurement

Among the comments CMS received from stakeholders in response to RFIs on price transparency included in Medicare payment rules last year were suggestions that quality of care and outcome data be paired with price information in a user-friendly format to help patients make informed decisions about where to receive care. **CMS now seeks stakeholder views on related issues in two broad categories: (1) improving access to quality information by entities developing price transparency and (2) improving incentives for providers to share charge information with patients.** The specific questions CMS asks are reproduced here.

1. Improving availability and access to existing quality of health care information for third parties and health care entities to use when developing price transparency tools and when communicating charges for health care services. Stakeholders are invited to submit specific suggestions and comments on the following:

    - What type of existing quality of health care information would be most beneficial to patients, and how can health care providers and suppliers best enable patients to use quality of health care information in conjunction with information on charges in their decision making before or at the time a service is sought? For example, would it be feasible to use health care quality information from the Medicare Quality Payment Program (QPP) or the Quality Measures Inventory (QMI)? Could quality of health care information from state-mandated quality reporting initiatives or quality reporting initiatives by nationally recognized accrediting entities, such as the National

Committee for Quality Assurance, URAC, the Joint Commission, and the National Quality Forum, be engaged to help patients meaningfully assess quality information at the time care is sought?

- How can CMS help providers, suppliers, and third parties create patient-friendly interfaces with this information? What steps should be taken to ensure that quality outcome and experience of care measure data can be used by providers, suppliers, third party pricing tool developers, and consumers when and where health care decisions are being made? Are there potential strategies CMS should consider to create standardized quality data? We are also interested in comments on the timing of information delivery relative to the referral or event, the form of delivery of the information, and the channels (for instance, verbally by the referring doctor, via a mobile application, and on a website, among others) through which the information could best be delivered.
- Is there value in displaying volume and complications of procedures side by side with charge information for patients? If so, should this information be best displayed at the individual physician level, the group practice level, or the facility level and why?
- Should health care providers and suppliers integrate quality information when informing patients of how much their out-of-pocket costs for services will be before patients are furnished services? How would providers that are not included in certain hospital-based quality initiatives, such as critical access hospitals, integrate quality information? What can be done better to inform patients of quality outcomes and patient experience with various providers and suppliers?

2. Improving incentives and assessing the ability of health care providers and suppliers to communicate and share charge information with patients. Stakeholders are invited to submit specific suggestions and comments on the following:

    - Should CMS develop Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) questions to assess how well hospitals and other providers and suppliers communicate and discuss the cost of care with their patients? Example questions could be: “How well did your doctor communicate the expected out-of-pocket cost for your health care services in advance?” “Were you surprised by the amount of out-of-pocket costs you had for a given procedure or hospital stay?”
    - Are there existing measures or measure concepts to develop that can help patients when assessing the accuracy of charges that providers and suppliers communicate in advance of a service, including the accuracy of expected out-of-pocket cost information? What indices should be used to assess how well a provider or supplier aggregates charge and quality information for public display?
    - Are there Medicare value-based purchasing initiatives that could be improved by developing or implementing additional assessments of how well Medicare providers and suppliers engage and respond to patient inquiries related to cost of care, or how Medicare providers and suppliers engage in shared decision making for future care, including discussions of both charges and quality of referral services?

XVIII. Organ Procurement Organization Conditions for Coverage: Revision to "Expected Donation Rate"

A. Background

Seriously ill patients awaiting organ transplants each year far outnumber clinically usable donated organs. OPOs partner with transplant centers (TCs) to maintain safe and equitable processes for procuring, distributing, and transplanting the maximum number of organs; specifically, OPOs identify eligible donors and recover organs from deceased donors. OPOs are subject to provisions of the Act and of the Public Health Service Act (PHS Act).

To receive payment under the Medicare or Medicaid programs for organ procurement services, an OPO first must be certified, and recertification is required every 4 years. Certification requirements include meeting all OPO Conditions for Coverage (CfCs) established by CMS, including process and outcome measures.[20] An OPO also must execute an agreement with CMS, after which the OPO may be "designated", that is, assigned a geographically-defined Donation Service Area (DSA). Further, a designated OPO must become a member of, participate in, and abide by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN). The OPTN's members are those professionals active in the United States organ donation and transplantation system, and the OPTN's board establishes and maintains national transplant policies (e.g., policies guiding allocation of available organs).[21] Once designated, an OPO may start to receive procurement payments from CMS.

B. OPO Metrics and Expected Donation Rate (§486.318)

Section 371(b) of the PHS Act directs the Secretary to establish performance measures for OPOs. Each OPO collects data from TCs in its DSA for submission to the OPTN, and data from all OPOs are transmitted monthly from the OPTN to the Scientific Registry of Transplant Recipients (SRTR) for analysis.[22] Three outcome metrics are described in the CfCs at §486.318, specifying standards to be met by each OPO during each 4-year certification cycle. One standard requires that an OPO's observed donation rate (actual organ donors/eligible donor deaths), as calculated by SRTR, not be significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for recertification.

The current CfCs direct that the expected donation rate be based on the national experience for OPOs serving similar hospitals and DSAs; adjustments are made for hospital characteristics including: primary service; hospital control/ownership; Metropolitan Statistical Area size and case-mix index; trauma center status; and total bed size, ICU bed numbers; and neurosurgery unit availability. SRTR modified the expected donation rate definition in 2009 to reflect DSA variations in eligible donors. While the rate remains based on the national experience for OPOs

[20] The OPO CfCs are found at 42 CFR part 486, subpart G.
[21] The OPTN functions under a federal contract administered by HRSA; the current contractor is the United Network for Organ Sharing (UNOS). For more about OPTN, see https://optn.transplant.hrsa.gov/.
[22] SRTR functions under a federal contract administered by HRSA; the current contractor is the Hennepin Healthcare Research Institute. For more about SRTR, see https://www.srtr.org/about-srtr/mission-vision-and-values/.

serving similar hospitals and DSAs, adjustments now are made for patient characteristics: age, sex, race, and causes of death among eligible donor deaths. SRTR determined that this approach better isolates the effects of OPO practices on donation in their DSAs.

CMS states that, due to an oversight, a corresponding change in the OPO CfC's expected donation rate definition was not made at the time of the SRTR change. CMS proposes to correct the oversight by revising the CfC definition to 1) be based on the national experience for OPOs serving similar eligible donor populations and DSAs; and 2) be adjusted for the distributions of age, sex, race, and cause of death among eligible deaths. The changes if finalized would become effective with the final rule, thereby occurring during the ongoing 2022 OPO certification cycle. Therefore, CMS further proposes to reduce the data collection for the expected donation rate measure, using 12 of the 24 months of data following the effective date (in place of the usual 36 months of data during a full 48-month certification cycle).[23] Since the definition change would not be retroactive, revising the measurement time period would compensate for the effect of a mid-cycle definition change. The revised time period would apply only to the 2022 cycle; the time period would return to 36 months for subsequent cycles.

C. Request for Information: Organ Procurement and Transplant Center Regulations

In 2012, the Secretary's Advisory Committee on Organ Transplantation (ACOT) recommended that CMS and HRSA lead a comprehensive, broad-based stakeholder review of transplantation regulations and requirements intended to identify revisions for increasing donation, improving outcomes, reducing donor organ wastage, and decreasing administrative burden for TCs and OPOs. Specific recommended goals included improved risk adjustment methodologies for TCs and a statistically sound method for yield measures for OPOs. While the proposed redefinition of expected donation rate would address OPO yield measures, CMS states it is considering a comprehensive proposal to update the CfCs for OPOs (§486.301 through 486.360) and possibly the CoPs for TCs, (§482.68 through 482.104).

To support a broad review of OPO CfCs, CMS seeks input on the following key areas:

- Do the current OPO outcome measures that are set forth at 42 CFR 486.318 accurately and reliably reflect an OPO's performance?
- What are the impacts or consequences of the current outcome measures on: (1) an OPO's performance; and (2) the availability of transplantable organs?
- What impact, if any, do the certification and decertification processes for OPOs have on organ procurement and transplantation?
- Are there any potential, empirically based outcome measures, other than those currently at §486.318, that could be used either in addition to, or instead of, the current outcome measures for OPOs? If recommending another outcome measure, what is the empirical evidence for that recommended measure?
- In addition to the outcome measures, are there other indicators of quality that could be used for OPOs in the CfCs? If recommending another quality indicator, why should that indicator be used and what is the supporting evidence for this indicator?

[23] Data collected from January 1, 2020 through December 31, 2020 would be used for the 2022 cycle.

- Are there any transplant center CoPs that conflict with or should be harmonized with the OPOs CfCs? If yes, identify the specific requirements and address how to harmonize or otherwise modify the requirements.

CMS also invites public comment on the validity and reliability of two potential OPO outcome measures and their consistency with statutory requirements:

- 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
- 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 states a belief that the first measure would represent an increase in consistency and quality over current measures by relying on independent data to measure true organ donation potential.[24] The measure would also account for geographic variations in the causes, age distribution, and percentages of in-hospital deaths across the United States. CMS notes that the second measure would incent maximum total organ procurement and placements of all procured organs.

Finally, CMS seeks public comments about parameters for the potential measures:[25]

- How should CMS determine what percentage indicates that an OPO's performance is acceptable or successful?
    - If commenters cannot recommend a specific percentage, how should CMS determine what the parameters for the outcome measures should be?
- What would be the benefit or consequences, or perhaps unintended consequences, of using these measures?
- What would be the potential impact on OPOs, transplant centers, organ donation, and transplant recipients, including potential additional compliance burdens?
- How would revising the OPO outcome measures would benefit or negatively impact patient outcomes, access, and quality of life?

XIX. Clinical Laboratory Fee Schedule: Potential 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 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.

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[24] Data would be derived from the CDC Detailed Mortality File and the National Center for Health Statistic's National Vital Statistics Report rather than self-reported by OPOs.

[25] CMS refers readers to descriptions of these measures in Changing Metrics of Organ Procurement Organization Performance in order to Increase Organ Donation Rates in the United States, Am J Transplant, 2017 Dec; 17(12): 3183-3192. doi: 10.1111/ajt.14391. Epub 2017 Jul20.

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 CDLTs 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 obtained 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)[26] 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
- The test was reasonable and medically necessary for the treatment of an illness.

This latest policy for molecular pathology tests and ADLTs was adopted in 2018. Because of administrative difficulties encountered by hospitals and laboratories, CMS exercised

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

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 is considering 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 is specifically interested in 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 solicits 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. While CMS does not explicitly propose this policy, it would consider finalizing this potential revision to the laboratory DOS policy as a result of its review of the comments

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. CMS no longer believes the same beneficiary access concerns that apply to ADLTs also apply to molecular pathology tests. CMS indicates 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 service 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. Again, CMS does not explicitly propose this policy but indicates that it would consider finalizing this approach as a result of the public comments received.

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 is considering 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 potential 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 an under arrangements service 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 entity whose primary function is the collection, storage and dissemination of blood products.

CMS would consider finalizing this revision to the laboratory DOS policy in the final rule as well.

XX. 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 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 proposes to require prior authorization for certain covered OPD services as a condition of payment.

B. Prior Authorization Process

CMS proposes to establish a process through which providers would request prior authorization for provisional affirmation of coverage before the service is furnished to the beneficiary and before the claim is submitted for processing. CMS would add 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 request), and (iii) permit suspension of the prior authorization process generally or for particular services. CMS proposes to implement the process for dates of service on or after July 1, 2020.

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

Proposed §419.80 would cite section 1833(t)(2)(F) as the authority for the prior authorization policy which would apply to certain covered OPD services as a condition of payment.

Proposed §419.81 would define the terms prior authorization, provision affirmation, and list of hospital outpatient department services requiring prior authorization. Prior authorization would be defined as 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 would review the request.

Provisional affirmation would be defined as 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") would be defined as the list that CMS publishes pursuant to new §419.83 (described below).

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 would have to 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. A claim submitted for a service on the OPD prior authorization list that has not received a provisional affirmation of coverage would be denied, unless the provider is exempt under proposed §419.83(c) (described below). This denial would include any claims associated with the service, including 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.

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

Where the prior authorization request meets applicable Medicare rules, the agency would issue a provisional affirmation; if the request fails to satisfy applicable rules, the agency would issue a "non-affirmation decision." Provisional affirmation or non-affirmation decisions would be made within 10 business days (2 business days in the case of an expedited review request).

Where a provider received a non-affirmation decision with respect to a prior authorization request or an expedited prior authorization request, the provider could resubmit the request with additional relevant documentation. However, a non-affirmation decision would not be considered an initial determination and would not be appealable.

When a claim is submitted for a service on the OPD prior authorization list without a provisional affirmation, that claim would 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 would be denied as well; these would include anesthesiology services, physician services, and/or facility services. These associated claims would 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 would not be required to request medical documentation before making the denial.

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

CMS proposes to identify the services included on the OPD prior authorization list by CPT codes listed in Table 38 of the proposed rule. CMS would only include in the regulation at proposed §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, or geographic restrictions, would be done through notice

and comment rulemaking, any technical updates to the services themselves would be published on the CMS website.

CMS proposes to reserve the right to exempt a provider from the prior authorization process. CMS would conduct semiannual assessments of providers submitting prior authorization requests, and for those providers who maintain a 90 percent or higher provisional affirmation rate, the agency would exempt the providers from the process. CMS could 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 nonpayable claims (determined at a semiannual assessment) is higher than 10 percent.

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. 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 identified the services that it proposes to include on the list shown in Table 38 of the proposed rule using certain criteria: the services are most often considered cosmetic and thus are only rarely covered by Medicare; 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 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 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 38.

D. Regulatory Impact

CMS estimates the overall economic impact of the prior authorization proposal is approximately $8.4 million in the first year based on 6 months. The 5-year and 10-year impacts are estimated at roughly $71.8 million and $152 million, respectively. CMS notes that the 5- and 10-year impacts account for year one including only 6 months.

XXI. 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. CMS is seeking public comments on:

- Whether it would be possible to modernize or streamline the Medicare cost reporting process, for example, by replacing it with other processes or if it could be modified in content, methodology, or approach.
- Whether and how the replacement or modification of the chargemaster might affect the submission of data used by CMS to calculate relative weights, outlier payments, critical access hospital payments, new technology add-on payments, pretransplant cost reimbursement as well as alternative sources that could be used to calculate these payments.
- Whether the chargemaster might be updated more frequently than on an annual basis and how this more frequent updating could affect costs for patients.

XXII. 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 believes that such a regulatory change would allow these hospitals 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.

XXIII. Files Available to the Public via the Internet

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

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

Note that CMS has added a column 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/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1717-P.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending

TABLE 41—ESTIMATED IMPACT OF THE PROPOSED 2020 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

		(1)	(2)	(3)	(4)	(5)	(6)
		Number of Hospitals	**Proposed APC Recalibration (all proposed changes)**	**Proposed New Wage Index and Provider Adjustments**	**All Proposed Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update**	**Existing Off-Provider-Based Departmen Visits**	**All Proposed Changes**
ALL FACILITIES *		3,734	0.0	0.1	2.8	-0.6	2.0
ALL HOSPITALS		3,627	0.0	0.1	2.9	-0.6	2.0
(excludes hospitals permanently held harmless and CMHCs)							
URBAN HOSPITALS		2,845	0.1	0.0	2.8	-0.6	2.0
	LARGE URBAN	1,481	0.0	-0.3	2.5	-0.4	1.9
	(GT 1 MILL.)						
	OTHER URBAN	1,364	0.2	0.2	3.1	-0.6	2.1
	(LE 1 MILL.)						
RURAL HOSPITALS		782	-0.4	0.8	3.0	-0.6	1.9
	SOLE COMMUNITY	367	-0.4	0.8	3.1	-0.7	1.8
	OTHER RURAL	415	-0.5	0.8	3.0	-0.5	2.2
BEDS (URBAN)							
	0 - 99 BEDS	950	0.5	0.1	3.3	-0.4	2.6
	100-199 BEDS	834	0.0	0.0	2.8	-0.5	2.0
	200-299 BEDS	451	0.1	-0.1	2.8	-0.4	2.0
	300-499 BEDS	395	0.2	0.3	3.1	-0.5	2.2
	500 + BEDS	215	0.0	-0.2	2.5	-0.7	1.6
BEDS (RURAL)							
	0 - 49 BEDS	329	-0.8	1.5	3.4	-0.2	2.6

		(1)	(2)	(3)	(4)	(5)	(6)
		Number of Hospitals	**Proposed APC Recalibration (all proposed changes)**	**Proposed New Wage Index and Provider Adjustments**	**All Proposed Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update**	**Existing Off-Provider-Based Departmen Visits**	**All Proposed Changes**
	50- 100 BEDS	283	-0.5	0.9	3.1	-0.7	1.8
	101- 149 BEDS	90	-0.5	0.9	3.0	-0.6	2.0
	150- 199 BEDS	42	-0.2	0.8	3.4	-1.0	1.9
	200 + BEDS	38	-0.1	-0.3	2.3	-0.5	1.7
REGION (URBAN)							
	NEW ENGLAND	135	-0.3	-1.9	0.5	-1.0	-0.5
	MIDDLE ATLANTIC	330	0.0	-0.3	2.4	-0.4	1.8
	SOUTH ATLANTIC	460	0.1	0.0	2.8	-0.5	2.1
	EAST NORTH CENT.	457	-0.1	0.0	2.6	-0.8	1.6
	EAST SOUTH CENT.	167	0.2	0.9	3.8	-0.2	3.4
	WEST NORTH CENT.	177	0.2	1.4	4.4	-0.6	2.5
	WEST SOUTH CENT.	489	0.4	0.3	3.5	-0.5	2.8
	MOUNTAIN	206	0.0	-0.1	2.7	-0.5	1.5
8	PACIFIC	375	0.3	0.0	3.1	-0.5	2.4

		(1)	(2)	(3)	(4)	(5)	(6)
		Number of Hospitals	**Proposed APC Recalibration (all proposed changes)**	**Proposed New Wage Index and Provider Adjustments**	**All Proposed Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update**	**Existing Off-Provider-Based Departmen Visits**	**All Proposed Changes**
	PUERTO RICO	49	1.2	17.9	22.5	0.0	22.1
REGION (RURAL)							
	NEW ENGLAND	21	-0.6	-1.3	0.8	-1.9	-1.1
	MIDDLE ATLANTIC	53	-0.5	0.0	2.2	-1.0	1.0
	SOUTH ATLANTIC	119	-0.7	0.7	2.7	-0.2	2.3
	EAST NORTH CENT.	120	-0.3	0.0	2.4	-0.7	1.5
	EAST SOUTH CENT.	151	-0.4	1.4	3.7	-0.2	3.3
	WEST NORTH CENT.	96	-0.2	1.7	4.2	-0.8	2.1
	WEST SOUTH CENT.	150	-0.5	1.2	3.5	-0.3	3.0
	MOUNTAIN	49	-0.3	2.6	5.1	-0.3	2.0
	PACIFIC	23	-0.6	0.1	2.2	-1.0	1.1

		(1)	(2)	(3)	(4)	(5)	(6)
		Number of Hospitals	**Proposed APC Recalibration (all proposed changes)**	**Proposed New Wage Index and Provider Adjustments**	**All Proposed Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update**	**Existing Off-Provider-Based Departmen Visits**	**All Proposed Changes**
TEACHING STATUS							
	NON-TEACHING	2,491	0.1	0.3	3.0	-0.4	2.3
	MINOR	777	0.1	0.3	3.1	-0.6	2.1
	MAJOR	359	-0.1	-0.3	2.3	-0.8	1.3
DSH PATIENT PERCENT							
	0	13	3.1	1.4	7.4	0.0	6.6
	GT 0 - 0.10	269	1.1	0.0	3.9	-0.4	3.0
	0.10 - 0.16	260	0.2	0.0	2.9	-0.4	2.1
	0.16 - 0.23	558	0.2	0.1	3.0	-0.4	2.3
	0.23 - 0.35	1,115	0.0	0.2	2.9	-0.7	1.9
	GE 0.35	933	-0.2	0.0	2.6	-0.6	1.8
	DSH NOT AVAILABLE **	479	0.1	0.5	3.4	-0.4	2.8
URBAN TEACHING/DSH							

		(1)	(2)	(3)	(4)	(5)	(6)
		Number of Hospitals	**Proposed APC Recalibration (all proposed changes)**	**Proposed New Wage Index and Provider Adjustments**	**All Proposed Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update**	**Existing Off-Provider-Based Departmen Visits**	**All Proposed Changes**
	TEACHING & DSH	1,019	0.0	0.0	2.7	-0.7	1.8
	NO TEACHING/DSH	1,359	0.2	0.1	3.0	-0.3	2.4
	NO TEACHING/NO DSH	11	3.2	1.4	7.5	0.0	7.1
	DSH NOT AVAILABLE**	456	0.1	0.2	3.0	-0.3	2.5
TYPE OF OWNERSHIP							
	VOLUNTARY	1,972	0.0	0.1	2.7	-0.6	1.8
	PROPRIETARY	1,194	0.6	0.2	3.6	-0.2	3.0
	GOVERNMENT	461	-0.2	0.2	2.8	-0.7	1.9
CMHCs		41	0.9	0.4	4.1	0.0	3.9

Column (1) shows total hospitals and/or CMHCs.
Column (2) includes all proposed 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 proposed 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 proposed budget neutrality adjustment for the cancer hospital adjustment is 0.9997 because in CY 2020 the target payment-to-cost ratio is higher than CY 2019 PCR target (0.89).
Column (4) shows the impact of all budget neutrality adjustments and the addition of the proposed 2.7 percent OPD fee

schedule update factor (3.2 percent reduced by 0.5 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 proposed 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 3,734 providers include children's and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.
**Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric and long-term care hospitals.