

Medicare Program: 2021 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs Interim Final Rule Summary

The Centers for Medicare & Medicaid Services (CMS) released the calendar year 2021¹ final rule with comment for Medicare’s hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system on December 2, 2020. Policies in the final rule will generally go into effect on January 1, 2021 unless otherwise specified. The final rule will be published in the December 29, 2020 issue of the *Federal Register*.

Comments are limited to:

- Payment classifications assigned to the interim APC assignments and/or status indicators of new or replacement Level II healthcare common procedure (HCPCS) codes. **The public comment period for these issues will end on January 4, 2021.**
- Reporting COVID-19 therapeutic inventory, usage and acute respiratory illness data. **The public comment period for this issue will end on February 2, 2021.**

The final rule would normally be published by November 2, 2020 to allow for a 60-day delay for the rule to be effective on January 1, 2021 in accord with the Congressional Review Act. In the proposed rule, CMS waived the 60-day delay because of the COVID-19 public health emergency (PHE). In the final rule, CMS is also waiving the 30-day delay in the effective date required under the Administrative Procedures Act.

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

Addenda containing relative weights, payment rates, wage indices and other payment information are available only on the CMS website at: [CMS-1736-FC | CMS](https://www.cms.gov/1736-FC). Unless otherwise noted, this weblink can be used to access any information specified as being available on the CMS website.

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

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I. Overview

A. Estimated Impact on Hospitals

The total 2021 increase in OPSS spending due only to changes in the 2021 OPSS final rule is estimated to be approximately \$1.49 billion (compared to \$1.61 billion in the proposed rule). Taking into account estimated changes in enrollment, utilization, and case-mix for 2021, CMS estimates that OPSS expenditures, including beneficiary cost-sharing will be approximately \$83.9 billion, which is approximately \$7.5 billion higher than estimated OPSS expenditures in 2020 (these figures are the same as in the proposed rule and may not have been updated).

CMS estimates that the update to the conversion factor and the multifactor productivity adjustment (not including the effects of outlier payments, pass-through payment estimates, the application of the frontier state wage adjustment, and controlling for unnecessary increases in the volume of covered outpatient services) will increase total OPSS payments by 2.4 percent in 2021 (2.8 percent in the proposed rule). Considering all other factors, CMS estimates the same 2.4 percent increase in payments between 2020 and 2021 (2.5 percent in proposed rule).

The update equals the market basket of 2.4 percent. While the market basket is usually reduced for multifactor productivity, multifactor productivity for 2021 is estimated to be negative. As the market basket is reduced and not increased for multifactor productivity, the net update will be 2.4 percent. (The net proposed rule update was a market basket of 3.0 percent less multifactor productivity of 0.4 percentage points or 2.6 percent). Hospitals that satisfactorily report quality data will qualify for the full update of 2.4 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 3,141 hospitals that met eligibility requirements to report quality data, CMS determined that 78 hospitals will not receive the full OPSS increase factor.

Medicare makes payments under the OPSS to approximately 3,665 facilities (3,558 hospitals excluding CMHCs and cancer and children’s hospitals held harmless to their pre-OPSS payment to cost ratios). Table 79 in the final rule (reproduced in the Appendix to this summary) includes the estimated impact of the final rule by provider type. It shows an estimated increase in expenditures of 2.4 percent for all facilities and 2.4 percent for all hospitals (all facilities except cancer and children’s hospitals, and CMHCs). The following table shows components of the 2.4 percent total:

	% Change All Facilities
Fee schedule increase factor	2.4
Difference in pass through estimates for 2020 and 2021	-0.04
Difference from 2020 outlier payments (1.01% vs. 1.0%)	+0.03
All changes	2.4

CMS estimates that pass-through spending for drugs, biologicals and devices for 2021 will be \$769.3 million, or 0.920 percent of OPSS spending. For 2020, CMS estimates pass-through spending would be 0.880 percent of OPSS spending. The -0.04 percent adjustment is designed to ensure that pass-through spending remains budget neutral from one year to the next. In addition, CMS estimates that actual outlier payments in 2020 will represent 0.97 percent of total OPSS payments compared to the 1.0 percent set aside, a +0.03 percentage points change in 2021 payments.

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

Although CMS projects an estimated increase of 2.4 percent for all facilities, the 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	2021 Impact
All Hospitals	2.4%
All Facilities (includes CMHCs and cancer and children’s hospitals)	2.4%
Urban	2.4%
Large Urban	2.4%
Other Urban	2.4%
Rural	2.5%
Beds	
0-99 (Urban)	2.6%
0-49 (Rural)	2.5%

Facility Type	2021 Impact
500+ (Urban)	2.0%
200+ (Rural)	2.5%
Major Teaching	1.9%
Type of ownership:	
Voluntary	2.3%
Proprietary	3.2%
Government	2.2%

The smaller and larger than average increase in total payments for teaching and proprietary hospitals appears to be accounted for by changes to the APC relative weights.

B. Estimated Impact on Beneficiaries

CMS estimates that the aggregate beneficiary coinsurance percentage will be 18.3 percent for all services paid under the OPSS in 2021. 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 (\$1,484 in 2021) which accounts for the aggregate coinsurance percentage being less than 20 percent.

II. Updates Affecting OPSS Payments

A. Recalibration of Ambulatory Payment Reclassification (APC) Relative Payment Weights

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

1. Database Construction

a. Database Source and Methodology

For the 2021 rule, CMS is using hospital final action claims for services furnished from January 1, 2019 through December 31, 2019 processed through the Common Working File as of June 30, 2020. Cost data are from the most recently filed cost reports which, in most cases, are from 2018. In a separate document available on the CMS website, CMS provides a detailed description of the claims preparation process and an accounting of claims used in the development of the final rule payment rates, including the number of claims available at each stage of the process: [\(Medicare CY 2021 Outpatient Prospective Payment System \(OPSS\) Final Rule Claims Accounting \(cms.gov\)\).](#)

Continuing past years’ methodology, CMS calculated the cost of each procedure only from single procedure claims. CMS created “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 2021 rule, CMS is bypassing the 173 HCPCS codes identified in Addendum N. CMS indicates the list of bypass codes may include codes that were reported on claims in 2019 but were deleted for 2020.

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

To convert billed charges on outpatient claims to estimated costs, CMS is multiplying the charges by a hospital-specific CCR associated with each revenue code and cost center. To calculate CCRs for 2021, 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 2019, the year of claims data used for deriving the 2021 payment rates. CCRs are calculated for the standard and nonstandard cost centers accepted by the electronic cost report data at its most detailed level. Generally, the most detailed level will be the hospital-specific departmental level.

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

Table 1 of the final rule shows the relative effect on imaging APC payments after removing cost data for providers that report CT and MRI standard cost centers using square feet as the cost allocation method. Table 2 of the final rule provides statistical values based on the CT and MRI standard cost center CCRs using the different cost allocation methods. Tables 1 and 2 are shown below.

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

APC	APC Descriptor	% Change Excluding Sq. Ft. CCRs
5521	Level 1 Imaging without Contrast	-2.8%
5522	Level 2 Imaging without Contrast	5.5%
5523	Level 3 Imaging without Contrast	4.3%
5524	Level 4 Imaging without Contrast	5.3%
5571	Level 1 Imaging with Contrast	6.8%
5572	Level 2 Imaging with Contrast	8.2%
5573	Level 3 Imaging with Contrast	2.3%

APC	APC Descriptor	% Change Excluding Sq. Ft. CCRs
8005	CT and CTA without Contrast Composite	13.9%
8006	CT and CTA with Contrast Composite	10.8%
8007	MRI and MRA without Contrast Composite	7.6%
8008	MRI and MRA with Contrast Composite	7.2%

Table 2—CCR Statistical Values Based on Use of Different Cost Allocation Methods

Cost Allocation Method	CT		MRI	
	Median CCR	Mean CCR	Median CCR	Mean CCR
All Providers	0.0342	0.0483	0.0752	0.1008
Square Feet Only	0.0285	0.0435	0.0660	0.0919
Direct Assign	0.0459	0.0557	0.0910	0.1151
Dollar Value	0.0405	0.0546	0.0858	0.1126
Direct Assign and Dollar Value	0.0406	0.0548	0.0862	0.1128

The final rule indicates that the number of valid MRI CCRs has increased by 18.7 percent to 2,199 providers and the number of valid CT CCRs has increased by 16.5 percent to 2,280 providers since CMS adopted its policy in 2014 of excluding providers that use the square foot cost allocation method. As shown in Table 1, eliminating these hospitals from the OPSS rate setting methodology increases the payment for all but one of the imaging APCs because hospitals that use the square foot allocation have lower CCRs for their imaging cost centers. CMS believes that because many providers continue to use the “square feet” cost allocation methodology, it is valid for attributing costs.

In the 2020 OPSS final rule, CMS adopted a policy to apply 50 percent of the payment impact from ending the transition in 2020 and 100 percent of the payment impact from ending the transition in 2021. For 2020, CMS calculated the imaging payment rates based on 50 percent of the transition methodology (excluding square foot CCRs) and 50 percent of the standard methodology (including square foot CCRs). For 2021, CMS proposed to set the imaging APC payment rates at 100 percent of the payment rate using the standard payment methodology under the policy it adopted in the 2020 OPSS final rule.

CMS acknowledges that rates set under the OPSS are used as a cap on payment for these imaging services paid under the physician fee schedule (PFS). Recognizing the potential impact that the CT and MRI CCRs may have on other payment systems, CMS will continue to monitor OPSS imaging payments and consider the potential impacts of payment changes on the PFS and ASC payment systems.

Several commenters requested that CMS not use the CT and MRI-specific cost centers and instead estimate cost using the single diagnostic radiology cost center to mitigate the impact of inaccurate reporting of costs on CT and MRI services. As CMS did not propose any change to the transition policy it adopted in the 2020 final rule, it is moving to the policy previously

announced of using all hospital cost reports regardless of the cost allocation methodology used for the MRI and CT cost centers.

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

In past years, 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 2021. The 2019 claims data that CMS is using for 2021 includes data from off-campus provider-based departments 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

CMS is continuing to determine the relative weights for blood and blood product APCs 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. 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.

In 2020, CMS established a new HCPCS code, P9099 (Blood component or product not otherwise classified) which allows providers to report unclassified blood products. This code is not payable by Medicare. While blood products are typically paid separately and not packaged, CMS proposed to unconditionally package HCPCS code P9099 because it is not possible to accurately determine an appropriate rate for multiple products with varying costs. CMS believed packaging the costs of unclassified blood products would be an improvement over the current non-payable status for HCPCS code P9099 as it would allow for tracking of the costs and utilization of unclassified blood products. Another option CMS considered was assigning HCPCS code P9099 to the lowest cost blood products APC with a 2021 payment rate of \$7.79 per unit (\$8.02 per unit in the proposed rule). CMS rejected this option as the cross-walked payment rate could be significantly lower than the cost of the product.

There were public comments objecting to paying HCPCS code P9099 at the same rate of the lowest cost blood product and also to making it unconditionally packaged. Public comments suggested paying HCPCS code P9099 at the weighted average of the rate paid for all blood

products. CMS rejected this comment saying that it could result in overpayment of relatively inexpensive blood products that use a not otherwise classified code. Further, CMS believes that paying at a weighted average of charges reduced to cost would provide disincentives to seek a more specific HCPCS code. Instead, CMS is finalizing a policy of paying for unlisted blood products at \$7.79 per unit in 2021 or at the rate of the lowest cost blood product.

Brachytherapy sources

The statute requires the Secretary to create APCs for brachytherapy consisting of a seed or seeds (or radioactive source) – i.e., “brachytherapy sources” – separately from other services or groups of services, in order to reflect the number, isotope, and radioactive intensity of the brachytherapy sources furnished. Since 2010, CMS has used the standard OPPS payment methodology for brachytherapy sources, with payment rates based on source-specific costs as required by statute. CMS proposed no changes to its brachytherapy policy for 2021.

If CMS does not have billing data to set the payment rates, it may use external data to set prices for brachytherapy sources. For 2018 and 2019, CMS used external data to set a payment rate for HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) at \$4.69 per mm². For 2020, CMS proposed to set the payment rate for HCPCS code C2645 at \$1.02 per mm² based on 2018 claims data. However, in response to public comments, CMS used its equitable adjustment authority to continue using a rate of \$4.69 per mm² for 2020. As CMS has only one claim in the 2019 data to set a rate for HCPCS code C2645, it proposed to continue the rate of \$4.69 per mm² for 2021. While CMS received comments asking that it remove outlier claims for brachytherapy sources or take other action to stabilize payment, it did not receive any comments on using its equitable adjustment authority to set the payment rate for HCPCS code C2645. CMS is finalizing its proposal without change. No other actions are being taken in response to public comments.

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

b. Comprehensive APCs (C-APCs) for 2020

A C-APC is defined as a classification for a primary service and all adjunctive services provided to support the delivery of the primary service. When such a primary service is reported on a hospital outpatient claim, Medicare makes a single payment for that service and all other items and services reported on the hospital outpatient claim that are integral, ancillary, supportive, dependent, and adjunctive to the primary service. A single prospective payment is made for the comprehensive service based on the costs of all reported services on the claim.

Certain combinations of comprehensive services are recognized for higher payment through complexity adjustments. Qualifying services are reassigned from the originating C-APC to a higher paying C-APC in the same clinical family of comprehensive APCs. Currently, code

combinations satisfying the complexity criteria are moved to the next higher cost C-APC within the clinical family, unless (1) the APC reassignment is not clinically appropriate, or (2) the primary service is already assigned to the highest cost APC within the C-APC clinical family. CMS does not create new APCs with a geometric mean cost that are higher than the highest cost C-APC in a clinical family just to accommodate potential complexity adjustments.

One commenter asked CMS not to include the cost of a complexity adjusted cases in calculating the geometric mean cost of the higher weighted APC to which the case is assigned as this causes a decline in the relative weight. Other commenters asked CMS to change the minimum number of claims required to assign a particular code combination to a higher weighted APC. One commenter asked that blue light cystoscopy with Cysview be assigned to a higher weighted APC through a complexity adjustment. There were also general comments opposed to the C-APC methodology or the claims used for rate setting or requests to exempt specific categories of services from the C-APC methodology. CMS declined to make any changes to the C-APC policy in response to these comments.

For 2019, 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. This policy includes new technology services that are assigned to the “Comprehensive Observation Services” C-APC.

As a result of its annual review of the services and the APC assignments under the OPSS, CMS did not propose to convert any conventional APCs to C-APCs in 2021. However, CMS did create an additional level in the C-APCs for “Urology and Related Services” and “Neurostimulator and Related Procedures.” Further, CMS did adopt an exception to the C-APC policy in the November 6, 2020 IFC titled “Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency” for drugs and biologicals approved by the Food and Drug Administration (FDA) to treat COVID-19 for use in the outpatient department or not limited for use in inpatient settings. Such drugs and biologicals will be paid separately outside of the C-APC for the duration of the COVID-19 public health emergency.

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 did not propose any changes to composite policies for mental health services and multiple imaging services for 2021.

3. Changes to Packaged Items and Services

a. Packaging Policies and Non-Opioid Treatment Alternatives

Except as described below for protein-based Multianalyte Assays with Algorithmic Analyses (MAAAs) laboratory tests, CMS did not propose any changes to its packaging policies. Section 6082 of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act requires the Secretary to review payments under the OPSS to ensure that there are not financial incentives to use opioids instead of non-opioid alternatives. CMS reviewed prior analysis done under the SUPPORT Act and did not propose any changes to its packaging policies for 2021 for non-opioid treatment alternatives.

CMS received a variety of comments asking that it not package particular items and services; evaluate whether to package items that were previously paid under the pass-through provisions; or no longer package drugs and biologicals that function as supplies. Other comments asked CMS to pay separately for non-opioid treatment alternatives where the drug functions as a supply in the hospital outpatient department. CMS' response indicates that utilization continues to increase for Exparel, a non-opioid drug that functions as a supply to treat post-surgical pain suggesting that its packaging policies are not discouraging utilization of these products. There were also comments asking CMS to pay separately for particular procedures or devices that can serve as alternatives to opioid treatments (pain blocks and spinal cord stimulators). The rule indicates that CMS did not find compelling evidence to provide separate payment for other procedures or devices mentioned in the comments as alternatives to treatment with opioids.

Of particular note were comments asking CMS to pay separately for two ophthalmological products (Dexycu and Omidria) as drugs and biologicals that function as supplies under the non-opioid treatment alternatives policy. With respect to Dexycu, CMS indicated the drug is currently paid separately under pass-through but that it would revisit whether to pay for the drug separately as a non-opioid treatment alternative once pass-through expires. With respect to Omidria, CMS was unconvinced that the clinical evidence demonstrates that Omidria reduces opioid use. CMS' review of cataract procedures performed between January and July 2019 did not demonstrate a decrease in fentanyl utilization in the outpatient department and ASCs where Omidria is used. Nevertheless, CMS will pay separately for Omidria as drug or biological that functions as a supply under the non-opioid treatment policy in ASCs only despite the lack of convincing evidence that use of the product is resulting in a decline in opioid usage.

b. Protein-Based MAAAs

Stakeholders have suggested that some protein-based MAAAs to diagnose cancer should not be packaged into OPSS payment. These commenters state that these MAAAs are similar to DNA and RNA-based MAAA tests that are separately paid under the OPSS. CMS agrees that cancer-related protein-based MAAAs may be relatively unconnected to the primary hospital outpatient service during which the specimen was collected from the patient and are instead used to guide future treatment through surgical procedures or chemotherapeutic interventions. Treatments that are based on the results of cancer-related protein-based MAAAs are typically furnished after the patient is no longer in the hospital, in which case they are not tied to the same hospital outpatient

encounter during which the specimen was collected.

CMS proposed to exclude cancer-related protein-based MAAAs from the OPSS packaging policy and pay for them separately under the clinical laboratory fee schedule (CLFS). Using the AMA CPT 2020 manual criteria to identify a MAAA that is cancer-related, CMS proposed to make CPT codes 81500, 81503, 81535, 81536, 81538 and 81539 separately payable. As CPT code 81538 is designated as an advanced diagnostic laboratory test that is already separately paid, this code was not included in the proposal. CMS' policy would apply to protein-based cancer-related MAAAs that do not currently exist, but that are developed in the future. CMS proposed to exclude CPT code 81490 from this policy because it is used to determine disease activity in rheumatoid arthritis patients, guide current therapy to reduce further joint damage, and may be tied to the primary hospital outpatient service, that is, the hospital outpatient encounter during which the specimen was collected.

Public commenters supported CMS' proposed policy that it is finalizing with a change to add CPT code 81490 to the list of codes excluded from the packaging policy. With regard to CPT code 81490, CMS indicated the test is typically used to determine potential interventions outside of the hospital outpatient encounter and is generally used by rheumatologists to make longer-term changes in rheumatoid arthritis treatment.

Commenters also asked that CMS expand the policy to pathology tests and non-cancer related MAAAs, other tests that have similar characteristics to MAAAs but are not assigned to the MAAA section of the CPT, several specific CPT codes and all proprietary laboratory analysis (PLA) codes. CMS disagreed with these comments indicating that the pattern of clinical usage of these tests does not demonstrate they are less tied to the primary service in the hospital outpatient department like other tests excluded from the packaging policy.

4. Calculation of OPSS Scaled Payment Weights.

As in past years, CMS proposed to standardize the relative weights based on APC 5012 and HCPCS code G0463 (a hospital outpatient clinic visit) which is the most commonly billed OPSS service. CMS proposed 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 provider-based department at a PFS equivalent rate under a site neutral policy, CMS proposed to continue 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 2020 and 2021 do not increase or decrease expenditures. However, SCODs are not affected by the budget neutrality adjustment.

CMS proposed to follow its past practice to determine budget neutrality for changes in the OPSS relative weights. Holding all other variables constant, CMS multiplies the 2020 and 2021 relative weights respectively for each APC by its associated volume from 2019. It sums the 2020 and

2021 relative weights respectively, and then divides the 2020 aggregate relative weights by the 2021 aggregate relative weights to determine the weight scaler. Using this process, CMS proposed adopting a weight scaler of 1.4443. Using updated data for the final rule, CMS determined a weight scaler of 1.4341. The unscaled 2021 relative payments are multiplied by 1.4443 to determine the 2021 scaled relative weights that are shown in Addendum A and B.

B. Conversion Factor Update

CMS proposed a conversion factor for 2021 of \$83.6970 for hospitals receiving the full update for outpatient quality reporting and \$82.0650 for hospitals subject to a 2.0 percentage point reduction in the update for not reporting outpatient quality data. For the final rule, the components of the update are shown in the below table:

2020 Conversion Factor	\$80.7930	Resulting CF
Remove pass-through and outliers from prior year CF	1.0192	82.341
Wage Index Budget Neutrality	1.0020	82.506
Budget Neutrality Wage Index Cap	0.9992	82.440
Cancer Hospital Adjustment	1.0000	82.440
Rural Hospital Adjustment	1.0000	82.440
340B Budget Neutrality	1.0000	82.440
Update	1.0240	84.418
Pass-Through and Outlier Adjustment	0.9808	82.797
2021 Conversion Factor		82.797

CMS removes the prior year’s pass-through and outlier adjustment from the 2020 conversion factor which increases it by 1.92 percent. Wage index budget neutrality is 1.0020 (0.20 percent) for changes to the wage data. The budget neutrality adjustment for CMS’ policy of capping any reductions in the wage index at 5 percent is 0.9992 (-0.08 percent). The cancer and rural hospital adjustments are 1.0000 (0.0 percent). As CMS is not changing its 340B policy, the budget neutrality adjustment remains at 1.00 (although public commenters disagree with this adjustment and believe it needs to be updated for changes in the mix of drugs). The update of 1.024 (2.4 percent) equals the market basket of 2.4 percent with no adjustment for multifactor productivity as multifactor productivity is negative. CMS estimates that pass-through spending for drugs, biologicals and devices for 2021 will be \$769.3 million or 0.92 percent of OPPI spending. The outlier adjustment is 0.99 (-1.0 percent). The combined adjustment for pass-through and outliers is 0.9808 (-1.92 percent).

CMS reports that the reduced conversion factor for hospitals not meeting the OQR requirements will be \$81.183. However, if 1.004 is substituted for 1.0240 in the above table, the resulting conversion factor for hospitals that do not meet the OQR requirements would be \$81.9030. CMS calculates the conversion factor for hospitals that do not meet the OQR requirements by multiplying the full conversion factor (\$82.979) by a “reporting ratio” of 0.9805. The rule does not explain the calculation of the reporting ratio. Ostensibly, it is the ratio of the reduced update to the full update considering all of the adjustment factors above. However, that ratio would be 0.9892 rather than 0.9805.

C. Wage Index Changes

CMS proposed to continue using a labor share of 60 percent and the fiscal year IPPS post-reclassified wage index for the OPSS in 2021. It also proposed using the latest OMB statistical area delineations and continuing past adjustments required by the ACA (the “frontier state” adjustment that requires a wage index floor of 1.0). The latest OMB statistical area delineations are from OMB Bulletin No. 18-04 that includes some material changes that affect hospital wage indexes. Consistent with the policy adopted in the FY 2021 IPPS rule, CMS proposed to apply a 5 percent cap on any decrease in a hospital’s final wage index to help mitigate any significant negative impacts of adopting the revised OMB delineations.

There were a number of comments opposed to using the latest OMB statistical area delineations. Public comments indicated that CMS is not obligated by statute to use these delineations for the wage index and there was insufficient advance notice and significant negative payment impacts from adopting them. There were other comments requesting that CMS pursue more comprehensive reform of the wage index.

CMS is not making any changes in its final rule policies in response to these comments indicating that it is important to use the updated labor market area delineations in order to maintain a more accurate and up-to-date payment system that reflects the reality of current labor market conditions. The rule further states that hospitals have been on notice of the OMB changes to the labor market delineations for nearly 2 years. The rule reiterates the 5 percent cap on reductions to the wage index will mitigate the final impact of this policy. CMS noted that the President’s FY 2021 Budget included a proposal to conduct and report on a demonstration to improve the Medicare inpatient hospital wage index.

There were a number of comments on wage index policies adopted in prior years such as raising low wage indexes and not allowing the wage data from an urban to rural reclassified hospital to raise the rural wage index. As these comments were unrelated to any proposals in this year’s OPSS proposed rule, CMS referred readers to prior rules for their responses to these comments.

For non-IPPS hospitals paid under the OPSS for 2021, CMS proposed to continue its 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. This policy is being adopted for 2021 without modification.

For CMHCs, CMS proposed to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. CMS notes that consistent with its current policy, the wage index that applies to CMHCs includes the rural floor adjustment but it does not include the out-migration adjustment, which only applies to hospitals. This policy is being adopted for 2021 without modification.

D. Statewide Average Default Cost-to-Charge Ratios (CCRs)

In cases where there is no data to calculate a hospital’s CCR, CMS proposed to continue using 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 proposed to use 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 updated the default statewide average CCRs for 2021 using the most recent cost report data. The table of statewide average CCRs is no longer being included in the OPSS rule. CMS says it is available at the link provided at the beginning of this summary but it is actually at: [2021 | CMS](#).

E. Sole Community Hospital (SCH) Adjustment

For 2021, CMS proposed to continue applying a 7.1 percent payment adjustment under section 1833(t)(13)(B) of Social Security Act (the Act) for rural SCHs, including essential access community hospitals, for all services and procedures paid under the OPSS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs. The adjustment is budget neutral and is applied before calculating outliers and copayments.

Public comments asked that CMS make the adjustment permanent and expand the adjustment to additional hospitals such as urban SCHs and Medicare Dependent Hospitals. CMS is finalizing its policy as proposed indicating that its prior analysis only supported an adjustment for rural SCHs, not any type of urban provider. Further, section 1833(t)(13)(B) of the Act only authorizes the adjustment for rural hospitals.

F. Cancer Hospital Adjustment

Eleven cancer hospitals meeting specific statutory classification criteria are exempt from the IPPS. Medicare pays these hospitals under the OPSS for covered outpatient hospital services. The Affordable Care Act 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 OPSS budget neutrality.

The cancer hospital adjustment is applied at cost report settlement rather than on a claim by claim basis. For 2021, CMS updated its calculations using the latest available cost data and is using a target PCR of 0.90. Consistent with section 1833(t)(18)(C) of the Act, CMS is reducing the target PCR from 0.90 to 0.89.

Table 5 in the final rule shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals, with increases in OPSS payments for 2021 ranging from 9.9 percent to 43.2 percent. No additional budget neutrality adjustment is required for the cancer hospital adjustment in 2021 compared to 2020.

G. Outpatient Outlier Payments

CMS makes OPSS outlier payments on a service-by-service basis when the cost of a service exceeds the outlier threshold. For 2021, CMS proposed to continue setting aside 1.0 percent of the estimated aggregate total payments under the OPSS for outlier payments. It proposed calculating the fixed-dollar threshold using the same methodology that was used to set the threshold for 2020 and previous years. CMS proposed to continue setting 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 payment threshold and the fixed-dollar threshold are met. For 2021, CMS calculated a proposed rule fixed-dollar threshold of \$5,300 (compared to \$5,075 in 2020). The \$5,300 threshold is unchanged in the final rule.

CMS again proposed 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 proposed to continue its policy that if a CMHC's cost for partial hospitalization services paid under APC 5853 (Partial Hospitalization for CMHCs) exceeds 3.40 times the payment rate for APC 5853, the outlier payment will be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 5853 payment rate.

Hospitals that fail to report data required for the quality measures selected by the Secretary incur a 2.0 percentage point reduction to their OPSS annual payment update factor, resulting in reduced OPSS payments for most services. For hospitals failing to satisfy the quality reporting requirements, CMS proposed to continue its policy that a hospital's costs for the service are compared to the reduced payment level for purposes of determining outlier eligibility and payment amount. CMS finalized all of these methodological proposals without change.

To model hospital outlier payments and set the outlier threshold for the final rule, CMS applied the hospital-specific overall ancillary CCRs available in the October, 2020 update to the Outpatient Provider-Specific File after adjustment using a CCR inflation adjustment factor of 0.974495 to approximate 2021 CCRs and a charge inflation factor of 1.13218 to approximate 2021 charges from 2019 claims. The CCR adjustment and charge-inflation factors are the same that were used to set the FY 2021 IPPS rule fixed loss threshold.

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. The steps show how to determine the APC payments that would be made under the OPSS 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), 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 will be \$1,484 in 2021. The inpatient hospital deductible limit is applied to the *actual* co-payment amount after adjusting for the wage index. Addenda A and B include a column with a "*" to designate those APC and HCPCS codes where the deductible limit applies.

III. APC Group Policies

A. Treatment of New and Revised HCPCS Codes

CPT and Level II HCPCS code changes that affect the OPSS are published through the annual rulemaking cycle and through the OPSS quarterly Change Requests. Generally, code changes are effective January 1, April 1, July 1, or October 1. CMS assigns the new codes to interim status indicators (SIs) and APCs; the interim assignments are finalized in the OPSS final rule. The proposed status indicators, APC assignments, and payment rates can be found in Addendum B of this proposed rule.²

1. April 2020 Codes - CMS Solicited Public Comments in the Proposed Rule

CMS finalizes its proposals for the APC and SI assignments the 13 Level II HCPCS codes (Table 6). For the April 2019 update, there were no new CPT codes.

2. July 2020 HCPCS Codes - CMS Solicited Public Comments in the Proposed Rule

CMS finalizes its proposals for APC and SI assignments for over 100 new codes (Table 7). Several of the HCPCS-C codes have been replaced with HCPCS J codes, effective January 1, 2021.³

3. October 2020 HCPCS Codes - CMS Solicits Public Comments in the 2021 Final Rule

CMS provides interim payment status indicators, APC assignments and payment rates, if applicable, for HCPCS codes that are effective October 1, 2020 in Addendum B to the 2021 final rule. These codes are flagged with comment indicator "NI" in Addendum B, indicating that CMS has assigned the codes an interim OPSS payment status for 2021. **CMS solicits public comments** about the status indicators, APC assignments, and payment rates for these codes and this information will be finalized in the 2022 OPSS final rule.⁴

² Addendum D1 includes the complete list of status indicators and corresponding definitions. Addendum D2 includes the complete list of comment indicators and definitions.

³ Comments and CMS' responses about specific codes are addressed in their respective sections of this final rule, including sections III.C (New Technology APCs) and III.D. (OPSS APC-Specific Policies).

⁴ CMS received comments about two codes. CMS' responses are addressed in their respective sections of this final

4. January 2021 HCPCS Codes

a. New Level II HCPCS Codes – CMS Solicits Public Comments in the 2021 Final Rule

Unlike the CPT codes that are effective January 1 and included in the OPPS proposed rules, and except for G-codes listed in Addendum O of this 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.

New Level II HCPCS codes that are effective January 1, 2021 are flagged with comment indicator “NI” in Addendum B, indicating that CMS has assigned the codes an interim OPPS payment status for 2021. **CMS solicits public comment in the 2021 OPPS final rule** about the status indicators, APC assignments, and payment rates for these codes and this information will be finalized in the 2022 OPPS/ASC final rule.

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

For the 2021 OPPS update, CMS received the CPT codes that will be effective January 1, 2021 in time to be included in the proposed rule (available in Addendum B). 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 finalizes the SIs, APC assignments and payment rates for the new CPT codes that are effective January 1, 2021 (available in Addendum B).⁵

Table 8 (reproduced below) summarizes the process used by CMS for updating codes.

TABLE 8: Comment Timeframe for New or Revised HCPCS codes				
OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2020	HCPCS (CPT and Level II Codes)	April 1, 2020	2021 OPPS/ASC proposed rule	2021 OPPS/ASC final rule with comment period
July 2020	HCPCS (CPT and Level II Codes)	July 1, 2020	2021 OPPS/ASC proposed rule	2021 OPPS/ASC final rule with comment period
October 2020	HCPCS (CPT and Level II Codes)	October 1, 2020	2021 OPPS/ASC final rule with comment period	2022 OPPS/ASC final rule with comment period
January 2021	CPT Codes	January 1, 2021	2021 OPPS/ASC proposed rule	2021 OPPS/ASC final rule with comment period

rule, II.A.(2)(a)(1) (Blood Products) and III.D. (OPPS APC-Specific Policies).

⁵ Comments and CMS’ responses about specific codes are addressed in sections III.C (New Technology APCs) and III.D. (OPPS APC-Specific Policies) and IV. (Payment for Devices) of this final rule.

TABLE 8: Comment Timeframe for New or Revised HCPCS codes				
OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
	Level II HCPCS Codes	January 1, 2021	2021 OPPS/ASC final rule with comment period	2022 OPPS/ASC final rule with comment period

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 significant 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.

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’s recommendations for specific services for the 2021 OPPS and CMS’ responses are discussed in this rule.

In the proposed rule, CMS identified APCs with violations of the 2 times rules and proposed changes to the procedure codes assigned to these APCs in Addendum B (identified with comment indicator “CH”). CMS noted that in many cases, the proposed procedure code reassignments and associated APC configurations for 2021 are related to changes in costs of services that were observed in the 2019 claims data.

2. APC Exceptions to the 2 Times Rule

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

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

CMS notes that in cases in which a recommendation by the Panel appears to result in 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.

Based on the updated final rule 2019 claims data (claims data for dates of service from January 1, 2019 and December 31, 2019 that were processed on or before June 30, 2020 and updated CCRs, if available), CMS identified 23 APCs with violations of the 2 times rule. Of these 23 total APCs, 18 were identified in the proposed rule and five are newly identified APCs.

TABLE 9: CY 2021 APC EXCEPTIONS TO THE 2 TIMES RULE	
CY 2021 APC	CY 2021 APC Title
5051	Level 1 Skin Procedures
5055	Level 5 Skin Procedures
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5101*	Level 1 Level 1 Strapping and Cast Application*
5112	Level 2 Musculoskeletal Procedures
5161*	Level 1 ENT Procedures*
5301	Level 1 Upper GI 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
5593*	Level 3 Nuclear Medicine and Related Services*
5612	Level 2 Therapeutic Radiation Treatment Preparation
5627	Level 7 Radiation Therapy
5673*	Level 3 Pathology*
5691	Level 1 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5734*	Level 4 Minor Procedures*
5821	Level 1 Health and Behavior Services
5823	Level 3 Health and Behavior Services
*Indicates newly identified APC with violation of the 2 times rule.	

C. New Technology APCs

1. New Technology APC Groups

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

The final payment rates for these New Technology APCs are included in Addendum A to this 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 2021, CMS finalizes its proposal 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;
- The results of each statistical methodology will be included in annual rulemaking and it will solicit public comment on which methodology should be used to establish the payment rate; and
- Assign the service to the New Technology APC with the cost band that includes its finalized payment rate.

3. Procedures Assigned to New Technology APC Groups for 2021

CMS finalizes its proposal to continue the current policy to retain services within New Technology APC groups until they obtain sufficient claims data is obtained 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)

There are four CPT/HCPCS codes that describe magnetic resonance image-guided, high-intensity focused ultrasound (MRgFUS) procedures. For 2020, CMS assigned 3 of the codes (CPT codes 0071T and 0072T and HCPCS codes C9734) to clinical APCs and maintained procedures described by CPT code 0398T to a New Technology APC. CPT code 0398T was first assigned to a New Technology APC in 2016.

Using available 2019 claims data, CMS identified 149 paid claims for CPT code 0398T (MRgFUS for treatment of essential tremors) with a geometric mean of \$12,798.38. Because this service no longer met the definition for a low-volume new technology service, CMS proposed to assign the service to a clinical APC and determined that the most appropriate APC was the Neurostimulator and Related Procedures APC series (APC 5461- 5464). Based on the geometric mean cost of CPT code 0398T (\$12,798.38), CMS was concerned that the payment rate for APC 5462 (\$6,169.27) was too low and the payment rate for APC 5463 would be too high (\$19,737.37) for this procedure. CMS proposed to restructure this APC family and create an additional payment level. CMS created a proposed Level 3, “Proposed APC 5463”, with a payment rate of approximately \$12,286. CMS proposed to reassign CPT code 0398 to “Proposed APC 5463.”

Final Decision: After reviewing public comments, CMS finalizes its proposal to assign CPT code 0398 to APC 5463. (Table 10).

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 OPPI 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 OPPI payment of \$95,000.

For 2021, CMS only identified 35 paid claims for the 4-year period of 2016 through 2019. CMS calculated a geometric mean of \$148,807, an arithmetic mean of \$154,504 and a median cost of \$151,974. All three estimates of the cost of the Argus II procedure fell within the cost band for New Technology APC 1908, with an estimated cost between \$145,001 and \$160,000. CMS proposed to maintain the assignment of CPT code 0100T to APC 1908 (New Technology – Level 52 (\$145,0001-\$152,000)).

Final Decision: CMS finalizes its proposal to assign CPT code 0100T to APC 1908 (New Technology – Level 52). CMS notes this payment rate includes both the surgical procedure (CPT code 0100T) and the use of the Argus II device (HCPCS code C1841).

c. Administration of Subretinal Therapies Requiring Vitrectomy

Voretigen neparvovec-rzyl (Luxturna®) was approved by the FDA in December 2017 as an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. HCPCS code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes) was granted drug-pass through status July 1, 2018 and assigned status indicator “G” (paid under OPPS; separate APC payment). A typical patient receives a standard dose of 150 billion vector genomes, with an approximate payment rate of \$436,575.

The drug pass-through status for J3398 expires June 30, 2021. Based on available information, CMS believes that J3398 would be commonly billed with HCPCS code 67036 (Vitrectomy, mechanical, pars plana approach) which is assigned to a comprehensive APC (APC 5492- Level 2 Intraocular Procedures). CMS agrees with the manufacturer that HCPCS code 67036 would not account for the drug administration since J3398 would be packaged into the comprehensive APC. CMS proposed to establish a new HCPCS code C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) to describe this procedure. For 2021, CMS proposed to assign C9770 to APC 1561 (New Technology Level 24 (\$3001- \$3500)) (Table 11).

Comments/Responses: Commenters were largely supportive of CMS’ proposal to create a “C” code to describe the administration of the drug and assign this code to New Technology 1561. A few commenters recommended assignment to APC 1562 or 1563. Based on its clinical review, CMS continues to believe that HCPCS code 67036 (assigned to APC 1561) represents a similar procedure and utilizes the same resources associated with the new code, C9770.

Final Decision: CMS finalizes its proposal to assign HCPCS code C9770 to APC 1561 (New Technology – Level 24) (Table 12).

d. 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. For 2021, based on 2019 claims data, CMS identified 4 claims. CMS calculated a geometric mean of \$4,051, an arithmetic mean of \$4,067, and a median cost of \$4,001. CMS proposed to change the assignment of C9751 to APC 1563 (New Technology Level 26 (\$4,001-\$4,500)) with a proposed payment rate of \$4250.50.

Comments/Responses: Two commenters did not support CMS’ proposal. They stated the claims data volume was insufficient to change the APC assignment and recommended that HCPCS code C9751 continue to be assigned to APC 1571. Using the most recent available data, CMS calculated the geometric mean cost for the service to be approximately \$2,693; the arithmetic mean cost to be approximately \$3,086; and the median cost to be approximately \$3,708. CMS concludes, the median cost estimated the highest cost for the service and provides a reasonable estimate of the midpoint cost of the three claims paid for this service. This payment rate falls within the band for APC 1562 (New Technology - Level 25 (\$3501-\$4000)).

Final Decision: CMS finalizes, with modification, its proposal and assigns HCPCS code C9751 to APC 1562 (New Technology – Level 25) (Table 13).

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.

For 2021, based on 2019 claims data, CMS identified 2,820 claims with a geometric mean cost of approximately \$851. CMS considered reassigning CPT code 0503T to APC 5724 (Level 4 - Diagnostic Tests and Related Services) which has a payment rate of \$903 based on clinical and resource similarity to other services within the APC. Because of the payment rate, CMS did not propose this reassignment and instead proposed to reassign CPT code 0503T to New Technology APC 1510 (New Technology Level 10 (\$801- \$900)).

Comments/Responses: The developer of HeartFlow and multiple other commenters stated that the code should not be assigned to New Technology APC 1510 and instead should be assigned to APC 5593 (Level 3 Nuclear Medicine and Related Services) with a payment rate of around \$1,270. Commenters asserted that the HeartFlow procedure has enough clinical similarity to other procedures currently assigned to the nuclear medicine and related services APC. CMS disagrees because the nuclear medicine and related procedures APC family describes diagnostic and therapeutic procedures and many involve imaging with radiopharmaceuticals and other nuclear materials as critical supplies. CMS states that in comparison, HeartFlow is a computer algorithm that does not directly take images nor is it used on its own to generate a diagnosis for a patient; HeartFlow analyzed diagnostic images through other medical procedures and assists with interpretation of diagnostic images. CMS concludes there is little clinical similarity between HeartFlow and the procedures assigned to APC 5593.

Other commenters disagreed with the assignment because hospital costs are higher. CMS discusses its updated analysis which found the geometric mean for CPT code 0503T is \$804.35 and falls within the cost band for New Technology APC 1510 (New Technology – Level 10). CMS notes that HeartFlow is one of the first procedures utilizing artificial intelligence to be separately paid under the OPPI and providers are still learning how to accurately report the charges, including allocating the staff resources between the HeartFlow procedure and the coronary CT imaging services.

Final Decision: CMS finalizes its proposal, with modification by using its equitable adjustment authority, and continues the 2020 APC assignment and assigns CPT code 053T to APC 1511 (New Technology – Level 11).

f. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT)

Effective January 1, 2020, CMS assigned three CPT codes (78431- 78433) describing services associated with cardiac PET/CT studies to New Technology APCs (APCs 1522, 1523, and 1523, respectively). CMS has not received any claims with these CPT codes and proposed to continue to maintain the 2020 assignment for 2021

Final Decision: CMS finalizes its proposal to assign three CPT codes (78431- 78433) describing services associated with cardiac PET/CT studies to New Technology APCs (APCs 1522, 1523, and 1523, respectively) (Table 14).

g. Pathogen Test for Platelets/Rapid Bacterial Testing

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, CMS reassigned the service described by P9100 to New Technology APC 1494 (Level 1D (\$31 - \$40)).

CMS noted that P9100 has been assigned to a new technology APC since July 2107 and it had sufficient claims data to reassign P9100 to a clinical APC. For 2021, based on 2019 claims data, CMS identified 70 single claims (out of 1,835 total claims) with a geometric mean cost of approximately \$30. Based on resource cost and clinical homogeneity, CMS proposed to reassign P9100 to APC 5732 with a geometric mean of approximately \$33.

Final Decision: CMS finalizes its proposal to reassign HCPCS code P9100 from New Technology APC 1494 to clinical APC 5732.

h. V-Wave Interatrial Shunt Procedure

CMS discussed a randomized, double-blinded control IDE study in progress for the V-Wave interatrial shunt. The developer of the V-Wave was concerned that the current coding of services would reveal to the study participants whether they received the interatrial shunt because an additional procedure code, CPT 93799, would be included on the claims for participants receiving the interatrial shunt. As a result, CMS created a temporary HCPCS code, C9758, to describe the V-wave interatrial shunt procedure for both the experimental and control group in the study. CMS has not received any claims for the code and proposes to continue to assign the code to New Technology APC 1589 (New Technology (Level 38 (\$10,001- \$15,000))).

Comments/Responses: Three commenters, including the developers, requested deletion of the code because V-Wave has decided not to seek Medicare payment for its clinical trial. Commenters also provided additional information about the procedures and provided information about procedures that had comparable non-device service costs. Based on these recommendations, CMS estimated the non-device costs of the V-Wave interatrial shunt and the Corvia Medical interatrial shunt procedures of \$6,500.

Final Decision: CMS finalizes its proposal with modifications, and reassigns HCPCS code C9758 to New Technology APC 1590 (Table 15). CMS notes this reflects the cost of having surgery every time and receiving the interatrial shunt one-half of the time when the procedure is performed.

i. Corvial Medical Interatrial Shunt Procedure

Corvia Medical is currently conducting a pivotal trial for their interatrial shunt procedure. On July 1, 2020, CMS established HCPCS code C9760 to facilitate the implantation of the shunt. In the proposed rule, CMS assigned HCPCS code C9760 to New Technology ACP 1589.

Comments/Responses: CMS agrees with comments recommending a revision for the code descriptor and revises the descriptor to remove the reference that the code includes placebo control subjects who would not receive a shunt implant. Commenters also provided additional information about the procedure and the associated costs and suggested similar procedures that use comparable non-device service costs. Based on these recommendations, CMS estimated the non-device costs of the V-Wave interatrial shunt and the Corvia Medical interatrial shunt procedures of \$6,500.

Final Decision: CMS finalizes its proposal with modifications, and reassigns HCPCS code C9760 to New Technology APC 1592 (Table 16). CMS notes this reflects the cost of having surgery every time and receiving the interatrial shunt every time the procedure is performed.

j. Supervised Visits for Esketamine Self-Administration

Spravato™ (esketamine) nasal spray, was approved by the FDA on March 5, 2019 for treatment of depression in adults with treatment-resistant depression (TRD). Because of the risk of serious outcomes resulting from sedation and dissociated from Spravato administration and the potential for abuse and misuse of the product, Spravato is only available through a restricted distribution system under a REMS; patients must be monitored by a health care provider for at least 2 hours and can be administered only in a certified medical office.

Effective January 1, 2020, CMS created two HCPCS codes (G2082 and G2083) for an outpatient visit for the evaluation and management of an established patient that requires supervision of a physician or other qualified health care professional, provision of esketamine nasal self-administration and 2 hours post-administration observation (G2082 includes 56 mg of esketamine and G2083 is for administration of more than 56 mg esketamine).

For 2021, CMS has not received any OPPS claims for either HCPCS code G2082 or G2083 and proposed to continue to assign HCPCS code G2082 to New Technology APC 1508 and assign HCPCS code G2083 to New Technology APC 1511.

Final Decision: CMS finalizes its proposal to assign HCPCS code G2082 to New Technology APC 1508 and assign HCPCS code G2083 to New Technology APC 1511.

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 rule identifies with a comment indicator “CH” those HCPCS codes for which CMS makes a change to the APC assignment or status indicator.

In the final rule, CMS responds to comments about specific APC and status indicator assignments. Highlights of CMS’ discussions are summarized; the numbering is consistent with the preamble format. The reader is referred to the final rule for more specific details.

1. Administration of Lacrimal Ophthalmic Inserts Into Lacrimal Canaliculus (APC 5692)

CMS made no specific proposal related to this procedure. Several commenters had concerns with continuing the assignment for CPT code 0356T in APC 5692 (Level 2 Drug Administration). CPT code 0356T describes insertion of drug-eluting implant into the lacrimal punctum and is used for the insertion of HCPCS J1096 (Dexamethasone, lacrimal ophthalmic insert). Commenters stated that the administration of dexamethasone after ophthalmic surgery is a distinct surgical procedure.

After consideration of comments, CMS continues to believe the assignment of CPT code 0356T to APC 5692 is appropriate based on its clinical and resource use similarity to other services in the APC. It does not consider this an independent procedure when performed during ophthalmic surgeries and believes that conditionally packaging the payment for this procedure into the payment for the primary procedure is appropriate.⁶

Final Decision: CMS finalizes its proposed policy to assign CPT code 0356T to APC 5692 (Level 2 Drug Administration).

2. Chimeric Antigen Receptor T Cell (CAR T-Cell Therapy) (APCs 5694, 9035, 9194, and 9391)

CMS made no specific proposals related to the CAR T-Cell preparation codes, described by CPT codes 0537T, 0538T, and 0539T. These codes are described by status indicator “B” (Codes that are not recognized by OPSS when submitted on an outpatient hospital Part B bill type (12x and 13x)) and are not paid under the OPSS. Commenters believe that these procedures do not represent steps required to manufacture the CAR T-cell and should be paid separately.

After consideration of comments, CMS continues to believe these codes represent the various steps required to collect and prepare the CAR-T cells; Medicare does not generally pay

⁶ In the 2018 OPSS/ASC final rule, CMS finalized to conditionally package low-cost drug administration services assigned to APC 5691 and APC 5692 (82 FR 52391 through 52393)

separately for each step used to manufacture a drug or biological product. In addition, the current HCPCS codes include leukapheresis and dose preparation procedures and payment for these services is incorporated into the drug codes (Table 18). CMS notes these codes can be reported for tracking purposes.

Final Decision: CMS finalizes its proposed policy to assign status indicator “B” to CPT codes 0537T, 0538T, and 0539T (Table 19).

3. Eustachian Tube Balloon Dilatation Procedure (APC 5165)

Effective January 1, 2021, the CPT Editorial Panel established two CPT codes to describe the eustachian tube balloon dilatation procedure: CPT codes 69705 for unilateral procedure and CPT code 69706 for the bilateral procedure. The surgical procedure was previously described by HCPCS code C9745. For 2021, CMS proposed to delete HCPCS code C9745 and assign CPT code 69705 to APC 5164 and CPT code 699705 to APC 6165. CMS also proposed to assign both codes to the ASC payment indicator “J8” device-intensive.

Commenters were concerned with the proposed APC assignment for the unilateral procedure (CPT code 69705) because the major portion of the procedure cost is the device (approximately \$2,180) used in the procedure and the device cost is the same whether it is a unilateral or bilateral procedure. Commenters noted that in the PFS, both codes included the full cost of the device kit. CMS’ medical advisors agree and believe it is appropriate to assign the unilateral and bilateral procedures to the same APC.

Final Decision: CMS finalizes its proposed policy with modification and assigns both CPT codes 69705 and 69706 to APC 6165 (Table 20).

4. Eye-Movement Analysis Without Spatial Calibration (APC 5734)

Effective July 1, 2020, the CPT Editorial Panel established a new CPT code 0615T to describe eye-movement analysis without spatial calibration that involves the use of the EyeBOX system as an aid in the diagnosis of concussion. In the July quarterly OPPS update, CMS assigned CPT code to APC 5734 (Level 4 Minor Procedures” with status indicator “Q1” (conditionally packaged).

A commenter requested CMS assign CPT code 0615T to APC 5722 (Level 2 Diagnostic Tests and Related Services) because the reimbursement was too low and the clinical characteristics and resources are more similar to services in APC 5722. CMS notes that because the code was established July 1, 2020 it does not have any claims for OPPS ratesetting. CMS notes that other eye-related diagnostic tests in APC 5722 involves injections and it continues to believe that the resources for CPT code 0615T are similar to other codes in APC 5734.

Final Decision: CMS finalizes its proposal to assign CPT code 0615T to APC 5734 with status indicator “Q”.

5. Gynecologic Procedures and Services (APC 5416)

CMS made no specific proposal for CPT code 0404T (transcervical uterine fibroid ablation) and maintained its assignment to APC 5416 (Level 6 Gynecologic Procedures). Several commenters stated the ASC payment rate is insufficient and a commenter suggested reassignment to APC 5362 (Laparoscopy and Related Services) or APC 5376 (Level 6 Urology and Related Services). A commenter explained that CMS has no claims data for this code because the code is rarely performed in Medicare patients and due to the device's commercial availability. CMS disagrees with commenters' assessment that CPT code 0404T is similar to the referenced procedures in APC 5362.

Final Decision: CMS finalizes its proposal to assign CPT code 0404T to APC 5416.

6. Hemodialysis Arteriovenous Fistula (AVF) Procedures (APC 5194)

For 2019, CMS established two new HCPCS codes for surgical procedures associated with new technology for AVF procedures: HCPCS code C9754 for the Ellipsys System and C9755 for the WavelinQ system. For 2020, both codes were assigned to APC 5194 (Level 4 Endovascular Procedures). To enable physicians to report these procedures when performed in the non-facility setting, effective July 1, 2020 the C-codes were deleted and replaced with G2170 and G2171, respectively. The G codes were assigned to APC 5194.

For 2021, based on 57 available claims, CMS proposed to reassign G2170 from APC 5194 to APC 5193 (Level 3 Endovascular Procedures). CMS proposed to maintain the assignment of G2171 in APC 5194. At the August 2020 HOP Panel Meeting, the HOP panel agreed with a presenter's request to maintain the assignment of G2170 to APC 5194. Most commenters to the proposed reassignment argued that the number of single claims was too low to base a reassignment of the code. After consideration of the HOP panel recommendation and comments, CMS believes that to ensure beneficiaries access to these dialysis-related procedures, it should maintain both codes in APC 5194.

Final Decision: CMS finalizes its proposed policy with modifications and assigns HCPCS codes G2170 and G2171 to APC 5194.

7. Health and Behavior Services (APC 5822)

For 2021, based on the latest OPPS claims data, CMS proposed to revise the payment rate associated with APC 5822 (Level 2 Health and Behavior Services) from \$78.54 to \$75.26. Some commenters were concerned with the proposed payment decrease and urged CMS to reexamine the data. CMS evaluation of the claims data for this final rule resulted in a geometric mean cost of APC 5822 of approximately \$72.94, based on approximately one million single claims.

Final Decision: CMS finalizes its proposed policy to decrease the payment rate for APC 5822.

8. High-density Lipoprotein (HCL) Therapy (APC 5243)

For 2021, CMS proposed to continue to assign CPT code 0342T (Therapeutic apheresis with selective hdl delipidation and plasma reinfusion) to APC 5243 (Level 3 Blood Product Exchange and Related Services). A commenter reported that their company expects FDA HDE for their system and they intend to apply for a NTAP. CMS acknowledges this information and when it receives the NTAP application will review and make an appropriate determination about the code assignment.

Final Decision: CMS finalizes its proposed policy to assign CPT code 0342T to APC 5243.

9. Imaging With and Without Contrast (APCs 5523, 5524, 5571, 5572, and 5573)

a. Cardiac Computed Tomography (CT) (APC 5571). For FY 2021, CMS proposed to maintain the assignment of three cardiac CT exams (CPT codes 75572, 75573, and 5574) to APC 5571 (Level 1 Imaging with Contrast). Many commenters opposed the assignment of these codes because the proposed payment rate of \$181.41 is inadequate. They noted that the proposed payment will result in decrease reimbursement for cardiac CT exams for the fourth consecutive year. Commenters discussed these procedures and requested reassigning CPT codes 75572 and 75573 to APC 5572 and CPT code 75574 to APC 5573.

CMS discusses the analysis it performed for these codes. CMS' analysis of claims data for the final rule, indicates the geometric mean costs for the cardiac CT scan codes ranges from \$157 and \$196 (Table 21). Table 21 also shows that the resources associated with CT exams are not similar to those of single photon emission CT (SPECT) nuclear scans (CPT code 78452) or nuclear stress tests (CPT codes 93350 and 93351). CMS also summarizes the claims volume for these codes and concludes it has sufficient single claims frequency to determine the OPSS payment rate (Table 22). Reassigning the CPT codes to the requested APCs results in significant overpayment of these procedures (Table 23).

Commenters also stated the current methodology disadvantages cardiac CT exams disproportionately and requested CMS exercise its authority to create an exception to the current methodology and suggested using the general cardiology revenue code to set the payment rates. CMS responds that it relies on hospital cost and charge information as reported through the claims and cost report data. CMS references section 20.5 in Chapter 4 (Part B Hospital) of the Medicare Claims Processing Manual which includes CMS "does not instruct hospitals on the assignment of HCPCS codes to revenue codes for services provided under OPSS."

Final Decision: CMS finalizes its proposal to assign the cardiac CT exam codes (CPT codes 75572, 75573, and 75574) to APC 5571.

b. Cardiac Magnetic Resonance (CMR) Imaging (APC 5523, 5524, 5572, and 5573). For 2021, CMS proposed to maintain the assignment of four CMR imaging CPT codes (CPT codes 75557, 75559, 75561, and 75663) to APCs 5523, 5524, 5572, and 5573, respectively. Commenters were concerned with the lack of payment stability for these services and suggested reassignment to other APCs. Some commenters were also concerned about the clinical

homogeneity in the Imaging APCs and questioned the reconfiguration from the Imaging APCs from 17 to 7 APCs.

CMS discusses the analysis it performed for these codes. CMS' analysis of claims data for the final rule, indicates the geometric mean costs for these exams is within the range of each assigned APC (Table 24). CMS discusses the policies associated with the Imaging APC reconfiguration and states that the change in 2017 were based on stakeholder recommendations.⁷

Final Decision: CMS finalizes its proposed assignment of the CMR imaging CPT codes.

10. IDx-DR: Artificial Intelligence System to Detect Diabetic Retinopathy (APC 5732)

The IDx-DR is a medical device that uses an artificial intelligence algorithm to detect greater than mild diabetic retinopathy in adults. A provider uploads digital images of the patient's retinas to a cloud server on which the IDx-DR software is installed, analyzes the pictures, and provides a report to the provider. The test was approved for marketing by the FDA in April 2018; effective January 1, 2021 CPT code 92229 is for the test associated with the IDx-DR technology.

CMS believes that IDx-DR is a diagnostic test that is payable under the hospital OPps. CMS considered the test similar to existing CPT codes for remote imaging of retinal disease (CPT codes 92227 and 92228), which are assigned to APC 5732 (Level 2 Minor Procedures and status indicator "Q1" (conditionally packaged when performed with another service on the same day). For 2021, CMS proposed to assign CPT code 92229 to APC 5732 and status indicator "Q1".

Some commenters disagreed with the proposed assignment; some requested assignment to APC 5733 (Level 3 Minor Procedures) and others requested assignment to APC 5734 (Level 4 Minor Procedures). The commenters requesting assignment to APC 5734 stated that procedure is similar to the technical components described by CPT code 99250 (Fundus photography). Several commenters also requested a change in the proposed status indicator assignment from "Q1" and indicated that HOPDs would likely schedule patients to receive the test during an outpatient visit separate from the clinic visit or not to even perform the test.

CMS discusses the coding decisions by the CPT Editorial Panel and concludes that if the code was similar to CPT code 99250 its final code number would not be 99229. After consideration of the comments, CMS believes that CPT code 92229 should be assigned to APC 5733. CMS has concerns about HOPDs potentially scheduling the IDx-DR test on a separate clinic day to receive separate payment but after reviewing the issues, it revises the status indicator to "S" to ensure patient access to the test.

Final Decision: CMS finalizes its proposal with modifications and assigns CPT code 92229 to APC 5733 with status indicator "S".

⁷ Discussed in 80 FR 70392 through 70397 and 81 FR 79628 through 7963.1

11. Implantable Interstitial Glucose Sensor System (APC 5051 and 5054).

For 2021, for codes related to an implantable interstitial glucose sensor, CMS proposed assigning CPT code 0447T to APC 5051 (Level 1 Skin Procedures) and CPT codes 0446T and 0448T to APC 5053 (Level 3 Skin Procedures) (see Table 25 for long CPT descriptors). A commenter agreed with the assignment of CPT code 0447T but thought that CPT codes 0446T and 0448T should be reassigned to APC 5054 (Level 4 Skin Procedures) or New Technology APC 1523. The commenter stated that APC 5053 does not account for the Eversense Implantable Continuous Glucose Sensor which provides real-time glucose monitoring and noted that these costs were included in the codes in the PFS proposed rule (84 FR 62627). Based on its review of the comments and input from its medical advisors, CMS believes the codes should be reassigned to APC 5054.

Final Decision: CMS finalizes its proposal with modifications. CPT code 0447T is assigned to APC 5051 and reassigns CPT codes 0446T and 0448T to APC 5052 (table 25).

12. Intervertebral Disc Allogeneic Cellular and/or Tissue-based Product Percutaneous Injection APC 5115)

For 2021, CMS assigned four CPT codes for intervertebral disc allogeneic cellular and/or tissue-based product percutaneous injection to the following: CPT code 0627T and 0629T were assigned to APC 5443 (Level 3 Nerve Injections) and CPT codes 0628T and 0630T were assigned to status indicator “N” to indicate they are packaged under OPPS since they are add-on codes. Commenters, including a medical device company who submitted a New Technology APC application, disagreed with the assignments of codes 0627T and 0629T because they did not think the procedures are comparable to a simple nerve injection. Based on its review of the information submitted and input from its clinical advisors, CMS reassigns CPT codes 0627T and 0629T to comprehensive APC 5115 (Level 5 Musculoskeletal Procedures) with status indicator “J”.

Final Decision: CMS finalizes its proposal with modifications and assigns CPT codes 0627T and 0627 to comprehensive APC 5115 (Table26).

13. Intraocular Procedures (APCs 5491 through 5485)

For 2020, based on several claims reporting CPT code 0308T (Insertion of ocular telescope prosthesis including removal of lens), CMS calculated a geometric mean cost of \$28,122.51 and a median cost of \$19,864.38. Because these costs were significantly higher than the geometric mean cost of the other procedures assigned to APC 5494 (Level 4 Intraocular Procedure) CMS reestablished APC 5495 (Level 5 Intraocular Procedures) and reassigned the procedure described by CPT code 0308T to APC 5495. CMS also finalized that the ASC payment would not be higher than the OPPS payment rate for this procedure performed in the hospital outpatient setting.

For 2021, there was a single claim containing the code 0308T but the claim was not able to be used for rate setting. CMS proposed to assign 0308T a payment weight based on the most

recently available data from the 2020 OPPTS final rule, and maintain the assignment to APC 5495.

Final Decision: CMS finalizes its proposal to maintain the assignment of CPT cod 0308T to APC 5495.

14. Irreversible Electroporation Ablation of Tumors (NanoKnife System) (APC 5362)

Effective July 1, 2020, the CPT Editorial Panel established two new CPT codes (CPT codes 0600T and 0601T) that describe the procedures used with NanoKnife System. CMS proposed to assign the codes to APC 5361 (Level 1 Laparoscopy and Related Procedures). One commenter stated that the codes would be more appropriately placed in New Technology APC 1576, consistent with the commenter's application for a New Technology APC. Based on its review of the information submitted, CMS assigns CPT codes 0600T and 0601T to APC 5362 (Level 2 Laparoscopy and Related Procedures).

Final Decision: CMS finalizes its proposal with modifications and assigns CPT codes 0600T and 0601T to APC 5362 (Table 27).

15. Medical Physics Dose Evaluation (APC 5611)

For 2021, CMS proposed to assign new CPT code 76145 (Medical physics dose evaluation) to APC 5611 (Level 1 Therapeutic Radiation Treatment Preparation). Several commenters disagreed with this assignment and requested a reassignment to APC 5724 (Level 4 Diagnostic Tests and Related Services). Commenters stated that the code is not a radiation oncology code and will be performed in the interventional radiology or interventional cardiology setting and provided details about the work associated with this code. Based on its review of the service and input from its medical advisors, CMS believes APC 5611 is appropriate.

Final Decision: CMS finalizes its proposal to assign CPT code 76145 to APC 5611.

16. Musculoskeletal Procedures (APCs 5111 through 5116)

Prior to the 2016 OPPTS, payment for musculoskeletal procedures was based on APCs structured according to anatomy and the type of musculoskeletal procedure. As part of the 2016 APC reorganization, CMS consolidated these individual APCs into a Musculoskeletal APC series (80 FR 70397 through 70398). Annually, commenters have expressed concerns about the current APC levels and CMS has requested comments on the creation of a new APC level between Level 5 and Level 6.

For 2021, based on the available 2019 claims data, CMS proposed to maintain the APC structure. CMS noted that as a result of its proposal to remove codes that were previously on the Inpatient Only List and assign them to clinical APCs, many of these codes were proposed assignment to the Musculoskeletal Procedure APC series and may impact the geometric means for these APCs.

CMS also discussed the assignment of CPT code 22869 (insertion of interlaminar/interspinous process stabilization/distraction device) to APC 5115. CMS continued to believe it was appropriate to assign CPT code 22869 to APC 5115.

One commenter requested CMS create a seventh Musculoskeletal APC level above APC 5116 to account for the procedures from the IPO list. Another commenter requested CMS consider an additional APC level between the current APCs 5114 and 5115. CMS appreciates these recommendations and will consider these in future rulemaking.

Final Decision: CMS finalizes its proposal to maintain the six-level Musculoskeletal Procedures APC structure. CMS also finalized the proposed assignment of CPT codes 28297 and 28740 to APC 5114 and CPT codes 22869 and 22473 to APC 5115. Table 28 (reproduced below) displays the final 2021 Musculoskeletal Procedures APC series' structure and APC geometric mean costs.

APC	Group Title	Number of Codes Assigned to the APC in the 2021 OP/AS final rule	2020 Final APC Geometric Mean Cost	Final 2021 APC Geometric Mean Cost
5111	Level 1 Musculoskeletal Procedures	103	\$210.99	\$200.86
5112	Level 2 Musculoskeletal Procedures	136	\$1,326.17	\$1,356.36
5113	Level 3 Musculoskeletal Procedures	411	\$2,678.42	\$2,757.24
5114	Level 4 Musculoskeletal Procedures	445	\$5,852.95	\$6,103.01
5115	Level 5 Musculoskeletal Procedures	120	\$11,644.09	\$11,996.45
5116	Level 6 Musculoskeletal Procedures	50	\$15,602.23	\$15,457.97

17. Neurostimulator and Related Procedures (APCs 5461 through 5465)

Based on the available 2019 claims data, CMS proposed creating an additional Neurostimulator and Related Procedures level, between the Level 2 and 3 APCs. CMS stated this will allow for a smoother distribution of the costs between the different levels based on their resource costs and clinical characteristics.

Most commenters supported the proposal. Multiple commenters requested an additional Level 6 APC. Commenters were concerned that the payment rate for the current Level 4 APC and the proposed Level 5 APC was dominated by CPT code 63685 (Insertion or replacement of spinal neurostimulator pulse generator or receiver) with a geometric mean of \$29, 123.02. Commenters stated that higher cost neurostimulator services with relatively low utilization are substantially underpaid. CMS appreciates these concerns but does not believe this would mitigate other services being underpaid which is inherent in the OP/AS payment structure. CMS maintains the 5-level structure.

In response to a commenters' concerns about CPT codes (O587T- 0590T) describing the surgical procedure associated with the PROTECT PNS Neurostimulation System, CMS reviews the clinical characteristics of the procedure and obtains input from its medical advisor. CMS reassigns 0588T to APC 5461.

Final Decision: CMS finalizes its proposal to establish a five-level APC structure for the Neurostimulator and Related Procedure series. Table 30, reproduced below, provides information about the Neurostimulator and Related Procedures APCs.

TABLE 30: FINAL GEOMETRIC MEAN COST FOR THE NEUROSTIMULATOR AND RELATED PROCEDURES APCs FOR CY 2021				
APC	APC Descriptor	SI	CY 2021 Proposed Geometric Mean Cost	CY 2021 Final Geometric Mean Cost
5461	Level 1 Neurostimulator and Related Procedures	J1	\$3,370.70	\$3,190.64
5462	Level 2 Neurostimulator and Related Procedures	J1	\$6,105.05	\$6,001.45
5463	Level 3 Neurostimulator and Related Procedures	J1	\$12,286.43	\$10,945.77
5464	Level 4 Neurostimulator and Related Procedures	J1	\$20,032.49	\$19,950.42
5465	Level 5 Neurostimulator and Related Procedures	J1	\$28,876.14	\$28,683.43

CMS finalizes its proposal with modifications for assigning the CPT codes for the PROTECT PNS System (Table 29).

18. Noncontact Real-Time Fluorescence Wound Imaging/MolecuLight (APC 5722)

Beginning July 1, 2020, two new CPT codes (CPT codes 0598T and 599T, defined in Table 31) are effective for reporting noncontact real-time fluorescence wound imaging for bacterial presence in chronic and acute wounds. CMS reviewed a new technology application for the procedure described by CPT codes 0598T and 0599T. Based on its review of the new technology application and input from its physicians, CMS assigned CPT code 0598T to APC 5722 (Level 2 Diagnostic Tests and Related Services with a payment rate of \$253.10. Because CPT code 0599T is an add-on code, CMS assigned this code to status indicator “N” to indicate the payment is included in the primary procedure.

Some commenters agreed with the APC assignment for CPT code 0598T but thought the code 0599T should not have status indicator “N” (packaged) and others stated the payment would be inadequate based on hospital outpatient charges for CPT code 0598T. CMS states that based on its review on the new technology application and input from its clinical advisors, it believes APC 5722 is appropriate.

Final Decision: CMS finalizes its proposal to assign CPT code 0598T to APC 5722 with status indicator “T” and to assign CPT code 0599T status indicator “N” (Table 31).

19. Nuclear Medicine Services: Single-Photon Emission Computed Tomography (SPECT) Studies (APC 5593)

For 2021, CMS proposed to reassign CPT code 78803 for SPECT Studies from APC 5593 (Level 3 Nuclear Medicine and Related Services) to APC 5592 (Level 2 Nuclear Medicine and Related Services). Several commenters objected to this reassignment and raised concerns that the payment decrease would limit patient access and restrict hospitals from offering the test. CMS discusses the issue related to this single code replacing seven deleted codes and reviewed the claims data to determine the appropriate placement for CPT code 77803 (Table 32). Based on this review, CMS believes that the code should be assigned to APC 5593.

Final Decision: CMS finalizes its proposal with modification and assigns CPR code 78803 to APC 5593.

20. Pathogen Test for Platelets/Rapid Bacterial Testing (APC 5732)

For 2021, CMS proposed to revise the APC assignment for HCPCS code P9100 from New Technology APC 1494 to clinical APC 5732 (Level 2 Minor Procedures).

Final Decision: CMS finalizes its proposal to assign GCPCS code P9100 to APC 5732.

21. Payment for Radioisotopes Derived From Non-Highly Enriched Uranium (non-HEU) Services (APC 1442)

Beginning in 2013, CMS finalized a policy to provide an additional payment of \$10 for the marginal cost for radioisotopes produced by non-HEU sources (77 FR 68323). Hospitals report HCPCS code Q9969. Commenter requested an increase in the payment rate for HCPCS add-on code Q996 from \$10. CMS believes the payment is appropriate.

Final Decision: CMS finalizes its proposal to maintain payment for HCPCS code Q9969 at \$10.

22. Percutaneous Transcatheter Ultrasound Nerve Ablation

CMS discusses the Therapeutics Intra-Vascular Ultrasound System and the request it received for Medicare coverage for the Category B IDE study for the system. In anticipation of coverage, the manufacturer requested assignment of a payable status indicator. CMS has not approved the

coverage for this Category B IDE clinical study and it does not believe the code should have payment until coverage is approved.

Final Decision: CMS finalizes the proposed assignment of status indicator “E1” to CPT code 0632T.

23. Peripheral Intravascular Lithotripsy (IVL) Procedure (APCs 5192, 5193, and 5194)

The final rule provides an overview of this procedure, the proposed APC assignments for the HCPCS C-codes, discussion of these procedures at the HOP Panel meeting, and CMS’ responses to comments.

Final Decision: CMS finalized its proposal with modifications, including adding four additional HCPCS C-codes to describe these procedures. Table 33 provides the Final APC assignments and SI indicators for HCPCS codes C9764 through C9767 and HCPCS C9772 through C9975.

24. Remote Physiologic Monitoring (APC 5741)

a. Initial Remote Monitoring of Physiologic Parameters (APC 5741). For 2021, CMS proposed to assign CPT code 99454 (Initial remote physiologic monitoring) to APC 5741 (Level 1 Electronic Analysis of Devices) with status indicator “Q1” to indicate the payment for the code is packaged when the code is billed on the same claim as a HCPCS code assigned to OPPS status indicator “S”, “T”, or “V” but is paid separately when it is the only major service on the claims. A commenter requested a change in the status indicator to allow payment even when used in conjunction with other services and reassignment to APC 5742. Based on claims analysis, CMS believes the APC assignment is appropriately and also that the service is a packaged service.

Final Decision: CMS finalizes its proposal to assign CPT code 99454 to APC 5741 with status indicator “Q1”.

b. Remote Physiological Monitoring (RPM) Services, Virtual Check-In, E-Visits, Telephone/M and Medication Management Services. For 2021, CMS proposed APC assignments and status indicators for 29 codes (Table 34) associated with RPM, virtual check-in, E-visits, Telephone E/M, and medication management services. At the HOP Panel Meeting, a presenter requested that CMS revise the status indicator for these codes. The HOP Panel also recommended some changes to the status indicators. The final rule provides an overview of the discussion at the HOP Panel meeting, HOP Panel recommendations, and CMS’ response. CMS concludes that it needs further evaluation of the codes to determine which services should be paid separately under the OPPS.

Final Decision: CMS finalizes its proposals for these 29 codes listed in Table 34.

25. Review of Electrocardiograms from an Implanted Brain Neurostimulator (APC 5741)

For 2021, CMS proposed to assign CPT code 95836 (Electrocardiogram from an implanted brain neurostimulator) to APC 5741 (Level 1 Electronic Analysis of Devices). A commenter

urged CMS to reassign the code to APC 5742. Based on analysis of claims data for this final rule, CMS believes its proposed assignment is correct.

Final Decision: CMS finalizes its proposal to assign CPT code 95836 to APC 5741.

26. Therapeutic Apheresis

The manufacturer of the LIXELLE device, requested that CMS provide payment for the apheresis procedure used with the device under the OPSS. In March 2015, FDA approved the device with an approved HDE. FDA regulations require the manufacturer to conduct a post-approval study. The manufacturer requested payment for the procedure through three potential pathways. The manufacturer stated the post-approval study cannot be completed without CMS payment. CMS appreciates these comments and will consider these in future rulemaking.

27. Tympanostomy Using an Automated Tube Delivery System (APC 5163)

For 2021, CMS proposed to assign CPT code 0583T (Tympanostomy, requiring insertion of ventilating tube) to status indicator “E1” to indicate that the code is not payable by Medicare when submitted on outpatient claims because they are not covered by any Medicare outpatient benefit category, are statutorily excluded from Medicare payment, or are not reasonable and necessary. Some commenters requested assignment of the code to APC 5164 (Level 4 ENT Procedures) with either status indicator “S” or “T”, which would allow payment. The manufacturer of the device indicated the surgical procedure is primarily performed on children and is important to the Medicaid population. Based on review of the procedure and input from its medical advisors, CMS believes the surgical procedure is most similar to procedures in APC 5163 (Level 3 ENT Procedures) and the status indicator should be “J1” (comprehensive APC).

Final Decision: CMS finalizes its proposal with modifications and assigns CPT code 0583T to APC 5163 with status indicator “J1”.

28. Unlisted Dental Procedures (5161)

For 2021, CMS proposed to continue to assign CPT code 41899 (unlisted procedure, dentoalveolar structures) to APC 5161 (Level 1 ENT Procedures). Two dental specialty societies stated this reimbursement was insufficient to cover the facility costs. CMS discusses the limitations of unlisted codes; because of the lack of any specificity, unlisted codes are assigned to the lowest level APC in the appropriate clinical category.

Final Decision: CMS finalizes its proposal to assign CPT code 41899 to APC 5161.

29. Urology and Related Services (APC 5371 through 53878)

In the 2020 OPSS final rule, in response to a commenter’s suggestion that CMS revise the assignments for services assigned to the Urology and Related Services APC, CMS stated it would consider revisions to these APCs in future rulemaking.

For 2021, CMS evaluated the available 2019 claims data and observed that the large geometric mean cost differential between APC 5376 (level 6) and APC 5377 (level 7) had continued to increase. Based on this analysis, CMS proposed to create an additional urology and related services APC level (APC 5378- level 8) and re-organize the current APCs 5376 and 5377. Table 19 of the proposed rule and included in the final rule (reproduced below) displays the proposed 2021 Urology and Related Services APC series' structure and APC geometric mean costs.

APC	Group Title	SI	2020 OPPS Geometric Mean Cost	Proposed 2021 OPPS Geometric Mean Cost
5371	Level 1 Urology and Related Services	T	\$229.83	\$262.04
5372	Level 2 Urology and Related Services	T	\$544.53	\$565.10
5373	Level 3 Urology and Related Services	J1	\$1,733.35	\$1,758.24
5374	Level 4 Urology and Related Services	J1	\$2,953.45	\$3,010.01
5375	Level 5 Urology and Related Services	J1	\$4,140.38	\$4,324.38
5376	Level 6 Urology and Related Services	J1	\$7,893.96	\$8,089.78
5377	Level 7 Urology and Related Services	J1	\$17,195.00	\$11,275.15
5378	Level 8 Urology and Related Services	J1	N/A	\$18,015.54

CMS proposed re-organization reassignments for the following services:

- CPT code 53440 and CPT code 0548T from the current APC 5376 to APC 5377; and
- CPT codes 55416, 53444, 54410, 54411, 54401, 54405, 53447, and 53445 from the current APC 5377 to APC 5378.

Several commenters supported the CMS proposal. Many commenters had recommendations about specific code reassignments; these comments and CMS' responses are discussed in the final rule. Based on evaluation of available claims data for the final rule, CMS does not modify any code reassignments.

Final Decision: CMS finalizes its proposal to reorganize the Urology and Related Services APCs.

a. **High Intensity Focused Ultrasound of the Prostate (HIFU) Procedure (APC 5373).** For 2021, CMS proposed to assign HCPCS code C9747 to APC 5375. Several commenters recommended reassigning this code to APC 5376. Based on evaluation of available claims data for the final rule, CMS believes this is the appropriate assignment for this code.

Final Decision: CMS finalizes its proposal to assign HCPCS code C9747 to APC 5375. CMS notes that effective January 1, 2021, the CPT Editorial Panel established CPT code 58880 for this procedure, for 2021, CMS is deleting the HCPCS code and is assigning CPT code 58880 to APC 5375.

b. Optilume Procedure – Ptilume Drug Coated Balloon Catheter System (APC 5375). For the July 202 update, the CPT Editorial Panel established a new CPT code, 0619T, to describe the surgical procedure associated with the Optilume Drug Coated Balloon Catheter System. CMS assigned CPT code 0619T to APC 5375 with a status indicator of “J1” (comprehensive APC). A commenter described the procedure and the associated resources and recommended assignment to APC 5376. Based on its evaluation, CMS believes that the code is appropriately assigned. CMS also states that until it has additional cost data, the device-offset of 31 percent is appropriate.

Final Decision: CMS finalizes its proposal to assign CPT code 0619T to APC 5375.

30. *Venous Mechanical Thrombectomy (APC 5193)*

A commenter supported CMS proposal to reassign CPT code 37187 from APC 5192 to APC 5193 (Level 3 Endovascular Procedures).

Final Decision: CMS finalizes its proposal to assign CPT code 37187 to APC 5193.

IV. 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 OPSS final rule (81 FR 79655), CMS finalized a policy change allowing quarterly expiration of pass-through payments status for devices. Except for brachytherapy sources, for devices that are no longer eligible for pass-through payments, CMS packages the costs of the devices into the procedures with which the devices are reported in the claims data used to set the payment rates.

Currently, there are seven device categories eligible for pass-through payment. Table 35 (reproduced below) lists the devices and their pass-through expiration.

Table 35: Expiration of Transitional Pass-Through Payments for Certain Devices			
HCPCS Codes	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads	1/1/2019	12/31/2021
C1824	Generator, cardiac contractility modulation (implantable)	1/1/2020	12/31/2022
C1982	Catheter, pressure-generating, one-way valve, intermittently occlusive	1/1/2020	12/31/2022

Table 35: Expiration of Transitional Pass-Through Payments for Certain Devices			
HCPCS Codes	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1839	Iris prosthesis	1/1/2020	12/31/2022
C1734	Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)	1/1/2020	12/31/2022
C2596	Probe, image-guided, robotic, waterjet ablation	1/1/2020	12/31/2022
C1748	Endoscope, single-use (that is, disposable), Upper GI, imaging/illumination device (insertable)	7/1/2020	6/30/2023

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

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

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

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

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

In 2020, CMS finalized an alternative pathway for devices that receive FDA marketing authorization and are granted a Breakthrough Device designation (84 FR 61295). Under this alternative pathway, devices granted an FDA Breakthrough Device designation are not evaluated for the substantial clinical improvement criterion, but need to meet the other requirements for pass-through payment status.

Comments/Responses: Some commenters requested for devices granted a FDA Breakthrough Designation, CMS waive the criterion that for a device to be included in the new device category is must not be 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 (§419.66(c)(1)). Commenters noted that under the IPPS New Technology Add-on Payment (NTAP), devices granted an FDA Breakthrough Designation and have received FDA marketing authorization are considered new and not substantially similar to an existing technology. CMS reminds stakeholders that the criterion for establishing a new device category are unique to the OPSS device pass-through policy and it continues to believe this is a necessary criterion for all devices, including devices granted an FDA Breakthrough Designation.

b. Applications Received for Device Pass-Through Payments for 2021

CMS received five applications by the March 1, 2021 quarterly deadline, the last quarterly deadline in time for this proposed rule; three of the applications were for devices eligible under the alternative pathway. Two of the applications were approved under the alternative pathway:

CUSTOMFLEX[®] ARTIFICIALIRIS (effective January 1, 2020) and EXALT[™] Model D Single-Use Duodenoscope (effective July 1, 2020).

Applications received for the remaining 2020 quarters (June 1, September 1, and December 1) will be discussed in the 2022 OPPS proposed rule. Detailed instructions on 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 is also available to meet with applicants or potential applicants to discuss research trial design in advance of submitting any application.

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

i. Alternative Pathway Device Pass-Through Applications

CMS approves device pass-through applications for three devices with FDA Breakthrough Designation:

- CUSTOMFLEX[®] ARTIFICIALIRIS;
- EXALT[™] Model D Single-Use Duodenoscope; and
- BAROSTIM NEO[®] System.

(1) CUSTOMFLEX[®] ARTIFICIALIRIS

VEO Ophthalmics submitted an application for the CUSTOMFLEX[®] ARTIFICIALIRIS a foldable iris prosthesis that is customized for each patient and intended to serve as an artificial iris prosthesis. The prosthesis is inserted at the time of cataract surgery or during a subsequent stand-alone procedure. It is indicated for use in children and adults for the treatment of full or partial aniridia resulting from congenital aniridia, acquired defects, or other conditions. According to the applicant, currently available treatment for symptomatic glare, photophobia and cosmesis are limited. The only other artificial iris device in the U.S. was available under FDA compassionate use exemption and is no longer available.

CMS received the application for the CUSTOMFLEX[®] ARTIFICIALIRIS application by the June 1, 2019 quarterly deadline and preliminarily approved it for transitional pass through payment, effective January 1, 2020.

Newness. The FDA granted the CUSTOMFLEX[®] ARTIFICIALIRIS premarket approval on May 30, 2018 and was designated a Breakthrough Device on December 21, 2017. The applicant notes that commercial availability of the device began on September 12, 2018 after it received FDA approval for the final labeling. CMS received the application on May 31, 2019, which is within 3 years of the date of the initial FDA marketing authorization.

Eligibility. According to the applicant, the CUSTOMFLEX[®] ARTIFICIALIRIS meets all the eligibility requirements. The device is implanted via injection through a corneal incision.

Criteria established at §419.66(c).

Existing payment category. CMS did not identify any existing pass-through payment category that may be applicable to the CUSTOMFLEX® ARTIFICIALIRIS.

Substantial clinical improvement. Devices that apply under the alternative pathway for devices are not subject to evaluation for substantial clinical improvement.

Cost. CMS believes the CUSTOMFLEX® ARTIFICIALIRIS meets all the cost criteria. Commenters stated the CUSTOMFLEX® ARTIFICIALIRIS should continue to receive transitional pass-through payment under the alternative pathway.

Final Decision: CMS received the application for the CUSTOMFLEX® ARTIFICIALIRIS application by the June 1, 2019 quarterly deadline and preliminarily approved it for transitional pass through payment, effective January 1, 2020. CMS determines that the CUSTOMFLEX® ARTIFICIALIRIS will continue to receive transitional pass-through payment under the alternative pathway for 2021.

(2) EXALT™ Model D Single-Use Duodenoscope

Boston Scientific Corporation submitted an application for the EXALT™ Model D Single-Use Duodenoscope, a sterile, single-use, flexible duodenoscope used to examine the duodenum and perform endoscopic retrograde cholangiopancreatography (ERCP). The applicant stated the duodenoscope is used during ERCP performed to examine bile and pancreatic ducts and eliminates the risk of nosocomial infections. After the conclusion of the procedure, the scope has no further medical use and is fully disposable.

CMS received the application for the EXALT™ Model D Single-Use Duodenoscope application by the June 1, 2019 quarterly deadline and preliminarily approved it for transitional pass through payment, effective January 1, 2020.

Newness. The applicant was designated a Breakthrough Device on November 19, 2019 and 510(k) premarket clearance on December 13, 2019. CMS received the application on January 17, 2020, which is within 3 years of the date of the initial FDA marketing authorization.

Eligibility. According to the applicant, the EXALT™ Model D Single-Use Duodenoscope meets all the eligibility requirements. The device is a single use duodenoscope.

Criteria established at §419.66(c).

Existing payment category. CMS agreed with the applicant that there is no other existing pass-through payment category applicable to the EXALT™ Model D Single-Use Duodenoscope. The applicant stated that HCPCS C1749 does not appropriately describe the device because it is different from other endoscopic imaging devices described by C1749.

Substantial clinical improvement. Devices that apply under the alternative pathway for devices are not subject to evaluation for substantial clinical improvement.

Cost. CMS believes the EXALT™ Model D Single-Use Duodenoscope meets all the cost criteria. Commenters stated the EXALT™ Model D Single-Use Duodenoscope should continue to receive transitional pass-through payment under the alternative pathway.

Final Decision: CMS received the application for the EXALT™ Model D Single-Use Duodenoscope application by the June 1, 2019 quarterly deadline and preliminarily approved it for transitional pass through payment, effective January 1, 2020. CMS determines that the EXALT™ Model D Single-Use Duodenoscope will continue to receive transitional pass-through payment under the alternative pathway for 2021.

(3) BAROSTIM NEO™ System⁸

CVRx submitted as application for the BAROSTIM NEO® System, a neuromodulation therapy that triggers the body's main cardiovascular reflex to regulate blood pressure and address the underlying causes progressive heart failure. Barostim functions by stimulating the carotid baroreceptor which results in centrally mediated reduction of sympathetic activity and increase in parasympathetic activity.

Newness. The BAROSTIM NEO® System was designated a Breakthrough Device and received FDA approval on August 16, 2019. The device was available on the market immediately upon FDA approval. CMS received the application on November 27, 2019 which is within 3 years of the date of the initial FDA marketing authorization.

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

Criteria established at §419.66(c).

Existing payment category. The applicant suggested a category descriptor of “Generator, neurostimulator (implantable), non-rechargeable with carotid sinus stimulation lead”. The applicant also discussed why existing device categories are not applicable to the BAROSTIM NEO™ System. Device category C1767 (Generator, neurostimulator(implantable), non-rechargeable), is not appropriate because the system is the only system that delivers baroreflex activation therapy (BAT) which is proprietary to CVRx. According to the applicant this is a unique therapy that works to stimulate the baroreceptors in the carotid artery and rebalance the autonomic input to the heart to improve heart failure symptoms. Device category C1823 (Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads), is not appropriate because the BAROSTIM NEO™ System uses only a single stimulation lead positioned on the carotid artery instead of a stimulation lead to the phrenic nerve and a sensing lead to the diaphragm for the treatment of central sleep apnea. Device category C1778 (Lead, neurostimulator (Implantable)) involves implanting leads on nerves and the BAROSTIM NEO™ System lead is sutured onto the carotid artery. The applicant reiterated that the BAROSTIM NEO™ generator is uniquely designed to send electric current via the

⁸In the FY 2021 IPPS proposed rule, CMS proposed to approve the BAROSTIM NEO® System for new technology add-on payments for FY 2021.

BAROSTIM NEO™ carotid sinus lead and the system is the only device currently approved by the FDA that utilizes this mechanism of action for treating patients with advanced heart failure. CMS was concerned that the BAROSTIM NEO™ System may be appropriately described by existing pass-through payment category, C1767.

In comments, the manufacturer of the device stated that the existing categories do not appropriately describe systems that activate special receptors in the carotid artery (baroreceptors) where are in a different anatomical location than nerves. The manufacturer provided additional information about baroreceptors, including the distinction between baroreceptors and nerves. BAROSTIM NEO™ System uses electricity to activate the baroreceptors and stimulate the baroreflex and does not directly stimulate neurons. CMS agrees with the commenter and concludes there is no existing pass-through payment category that appropriately describes the BAROSTIM NEO™ System.

Substantial clinical improvement. Devices that apply under the alternative pathway for devices are not subject to evaluation for substantial clinical improvement.

Cost. CMS agrees with the applicant that the device meets the cost criterion.

Final Decision: After consideration of comments, CMS approves the BAROSTIM NEO™ System for device-pass through payment status beginning January 1, 2021.

ii. Traditional Device Pass-Through Applications

CMS approves device pass-through applications for two devices:

- Hemospray® Endoscopic Hemostat and
- SpineJack® Expansion Kit

(1) Hemospray® Endoscopic Hemostat⁹

Cook Medical submitted an application for the Hemospray® Endoscopic Hemostat, a carbon dioxide powdered delivery system inserted through an endoscope to deliver the inert powder, bentonite, which forms an adhesive barrier to tissue. Hemospray® is indicated for hemostasis of nonvariceal gastrointestinal (GI) bleeding.

Newness. Hemospray® received FDA de novo approval on May 7, 2018 and was classified as a Class II device for intraluminal GI use. According to the applicant, FDA required revisions to the instructions for use of the system delayed the commercial availability of the system until July 1, 2018. CMS received the application on December 2, 2019, which is within 3 years of the date of the initial FDA marketing authorization.

Eligibility. According to the applicant, the Hemospray® Endoscopic Hemostat meets all the eligibility requirements.

⁹ The Hemospray® Endoscopic Hemostat was also approved for the hospital inpatient new technology add-on payment for FY 2021.

Criteria established at §419.66(c).

Existing payment category. CMS did not identify any existing pass-through payment category that may be applicable to the Hemospray® Endoscopic Hemostat.

Substantial clinical improvement. The applicant stated that Hemospray® is a topically applied mineral powder that offers a novel primary treatment option for the management of endoscopic bleeding. It would provide a substantial clinical improvement as a primary treatment or as rescue treatment after the failure of a conventional treatment method and in treating malignant lesions. The applicant provided six articles and one abstract; CMS summarized this information and discussed specific concerns with the submitted information. CMS noted that the majority of studies lacked a comparator and may suffer from selection bias. It noted several issues with one randomized study including the small sample size of 20 patients. CMS was concerned that the samples in the studies might not represent the Medicare population as most of the samples are predominantly male and many of the studies were not done in the U.S. CMS was also concerned about the potential for adverse events from Hemospray® and noted that the evaluation of adverse events in the studies was limited.

The manufacturer responded to CMS' concerns. The manufacturer stated that the selection bias is toward patients with the highest risk of morbidity or mortality and the high rate of successful treatment for these patients with Hemospray® represents substantial clinical improvement. The manufacturer explains that the research and studies are largely international because the device was commercially available outside the U.S. for 5 to 7 years before FDA approval. They believe the data is representative of the U.S. population and provided data indicating that 60 percent of patients undergoing endoscopic control of bleeding are male. As for adverse events, the manufacturer stated that the product is clearly labeled, they conduct physician training and diligently report complaints or complications.

After reviewing the additional information, CMS determines that Hemospray® meets the substantial clinical improvement criterion. CMS will continue to monitor available data for Hemospray® for adverse events.

Cost. CMS believes the Hemospray® Endoscopic Hemostat meets all the cost criteria.

Final Decision: After consideration of comments, CMS approves the Hemospray® Endoscopic Hemostat for device-pass through payment status beginning January 1, 2021.

(2) The SpineJack® Expansion Kit¹⁰

Stryker, Inc. submitted an application for SpineJack® System, an implantable fracture reduction system for use in reduction of painful osteoporotic vertebral compression fractures (VCFs). The SpineJack® System is used in combination with Stryker VertaPlex and VertaPlex High Viscosity (HV) bone cement. The SpineJack® system is designed to be implanted into a collapsed vertebral

¹⁰The SpineJack® Expansion Kit was also approved for the hospital inpatient new technology add-on payment for FY 2021.

body (VB) via a percutaneous transpedicular approach under fluoroscopic guidance. Once in place, the implants are expanded to mechanically restore vertebral body height and maintain the restoration. The implants remain within the vertebral body and, together with the delivered polymethylmethacrylate (PMMA) bone cement, stabilize the restoration, provide pain relief, and improve patient mobility. The SpineJack[®] system further reduces the risk of future adjacent fractures (ALFs).

The applicant stated that treatment of osteoporotic VCF in older adults begins with conservative care; vertebral augmentation (VA) may be indicated in patients that continue to have significant pain. Vertebroplasty (VP) and balloon kyphoplasty procedures (BKF) are two common minimally invasive percutaneous VA procedures; BKP is the most commonly performed procedure and considered the gold standard for VA treatment. Other treatment options include the use of a spiral coiled implant made from polyetheretherketone (PEEK), which is part of the Kiva[®] system.

Newness. The applicant states the device received FDA 510(k) clearance on August 30, 2018 and was available on the U.S. market October 11, 2018. CMS received the application on February 4, 2020 which is within 3 years of the date of the initial FDA marketing authorization.

Eligibility. According to the applicant, the SpineJack[®] system meets all the eligibility requirements.

Criteria established at §419.66(c).

Existing payment category. The applicant does not believe the SpineJack[®] Expansion Kit is described by an existing category and requested category descriptor “Vertebral body height restoration device, scissor jack (implantable)”. CMS identified one existing pass-through payment category that may be applicable to the device, HCPCS code C1821 (interspinous process, distraction device (implantable)).

In response to CMS’ comment about a potential existing pass-through payment category (C1821), the applicant described how the SpineJack[®] system and implantable interspinous process distraction are vastly different medical devices. After consideration of this information, CMS concludes there is no existing pass-through device category that appropriately describes the SpineJack[®] system.

Substantial clinical improvement. The applicant stated the SpineJack[®] system represents a substantial clinical improvement over existing therapies because clinical research supports that it reduces future interventions, hospitalizations, and hospitalizations through a decrease in ALFs. The applicant also asserted the treatment greatly reduces pain scores and the use of pain medications as compared to BKP. The applicant submitted eight studies to support these statements.

The applicant noted that the system has been available for treatment of osteoporotic VCFs for over 10 years in Europe and as a result the SpineJack[®] system has been extensively studied. The applicant highlighted the results from a recent, large, prospective, randomized study that compared SpineJack[®] to kyphoplasty in osteoporotic patients (SAKOS) study. The SAKOS

study was the pivotal trial supporting the FDA 510(k) clearance and although the SAKOS study was performed in Europe, the FDA determined the study demographics were very similar to what has been reported for U.S. based studies of BKP. In addition, over 82 percent of the patients in the study were 65 years of age or older.

CMS acknowledges the results of the SAKOS trial and notes the results do not appear to have been corroborated in any other randomized controlled study. In addition, since the PEEK coiled system was considered the predicate device for the SpineJack 510, CMS is interested in information comparing the SpineJack[®] system to the PEEK coiled implant. CMS is also interested in information comparing the SpineJack[®] system to conservative medical therapy and notes an active study on clinicaltrials.gov comparing the system to conservative therapy. CMS notes that two recent systematic reviews of vertebral compression fractures¹¹ for the American Society for Bone and Mineral Research (ASBMR) do not support vertebral augmentation procedures due to lack of evidence comparing the treatment to conservative medical management. The ASBMR recommends more rigorous studies of treatment options that include placebo controls and more data on serious adverse events.

Many commenters shared their academic knowledge and first-hand clinical experience with vertebral augmentation procedures, including expertise with a wide range of devices. The manufacturer and commenters disagreed with CMS' concern about the ASBMR report stating that recent systematic reviews of the management of vertebral compression fracture do not support vertebral procedures; a commenter disagreed with CMS' interpretation of the ASBMR report. The applicant stated that the latest clinical evidence and a policy statement from the Advancement of Spine Surgery (ISASS) provided robust support for the use of vertebral augmentation (VA) over non-surgical management (NSM) in the treatment of osteoporotic vertebral compression fractures. The applicant and commenters also responded to CMS' concerns about the SAKOS trial and explained the limitations of a comparative study with the PEEK coiled implant. Commenters and the applicant discussed why comparison trials would be inappropriate for a variety of reasons, including research showing improvement for patients treated with VA as opposed to NSM and evidence showing an increased risk of morbidity and mortality in elderly patients with osteoporotic VCF.

One commenter, a manufacturer of BKP implants, criticized the evidence presented to support that the SpineJack[®] system demonstrates substantial clinical improvement. The commenter raised several criticisms of the SAKOS study, including the fact that the SpineJack[®] system was compared to older BKP technology instead of the most current BKP technology available at the time of the study. The commenter also disputed the applicant's assertions related to clinical improvement.

11 Buchbinder R., Johnston R.V., Rischin K.J., Homik J., Jones C.A., Golmohammadi K., Kallmes D.F., "Percutaneous vertebroplasty for osteoporotic vertebral compression fracture," Cochrane Database Syst Rev. 2018 Apr 4 and Nov 6. PMID: 29618171; Ebeling P.R., Akesson K., Bauer D.C., Buchbinder R., Eastell R., Fink H.A., Giangregorio L., Guanabens N., Kado D., Kallmes D., Katzman W., Rodriguez A., Wermers R., Wilson H.A., Boussein M.L., "The Efficacy and Safety of Vertebral Augmentation: A Second ASBMR Task Force Report." J Bone Miner Res., 2019, vol. 34(1), pp. 3-21

After reviewing the additional information, CMS determines that the SpineJack[®] system meets the substantial clinical improvement criterion.

Cost. CMS believes the SpineJack[®] Expansion Kit meets all the cost criteria.

Final Decision: After consideration of comments, CMS approves the SpineJack[®] Expansion Kit for device-pass through payment status beginning January 1, 2021.

3. Technical Clarification to the Alternative Pathway to the OPPS Device Pass-Through

To be eligible for approval under the alternative pathway, the device must be part of the FDA's Breakthrough Devices Program and received FDA marketing authorization. In response to question about the requirement for marketing authorization, CMS clarified in the FY 2021 IPPS PPS proposed rule that when a product has more than one indication, an applicant cannot combine a marketing authorization for an indication that differs from the technology's indication under the Breakthrough Device Program and the device the applicant is seeking to qualify for payment under the alternative pathway (85 FR 32692).

In the proposed rule, CMS clarified that the same policy applies for purposes of the OPPS alternative pathway policy. Specifically, CMS clarified that under the OPPS, in order to be eligible for the alternative pathway, the device must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation.

CMS finalizes its proposal to amend the regulations at §419.66(c)(2) to state that "A new medical device is part of the FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Devices designation." CMS notes that the transitional pass-through payment application for the device must be received within 2 to 3 years of the initial FDA marketing authorization (or a verifiable market delay) for the device for the indication covered by the Breakthrough Devices Program designation.

4. Comment Solicitation on Continuing to Provide Separate Payment in CYs 2022 and Future Years for Devices with OPPS Device Pass-Through Payment Status During the COVID-19 Public Health Emergency (PHE)

Due to the COVID-19 PHE, CMS received multiple inquiries from stakeholders concerning potential adjustments to the pass-through payments for devices with OPPS transitional pass-through payment status that may be impacted by the PHE. Stakeholders were concerned that devices on pass-through status are frequently used during elective procedures and that CMS' ability to calculate appropriate payment for these devices when they transition off of pass-through status could be impacted by reduced use of these devices during the PHE.

In response to these concerns, in the proposed rule CMS requested comments on whether it should use its equitable adjustment authority under section 1833(t)(2)(E) of the Act to provide separate payment for some period of time after pass-through status ends for these devices in order to account for the time that utilization for the devices was reduced due to the PHE. Several commenters supported CMS' consideration of continuing to provide separate payment after pass-through status ends for devices to account for the reduced utilization during the PHE; two commenters supported CMS' use of its equitable adjustment authority. Commenters

provided a variety of time durations for the pass-through extension. Some commenters thought the extension should not be limited to devices but should also include pass-through payment for drugs.

CMS acknowledges these comments and will consider them when determining whether a change is warranted in response to the PHE as it develops the 2022 OPPS/ASC proposed rule.

B. Device-Intensive Procedures

1. 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, 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

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.

for a new procedure requiring the implantation of a medical device, device-intensive status is applied to the code if the HCPCS code-level device offset is greater than 30 percent.

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

For 2021 CMS does not finalize any changes to the device-intensive policy. In response to stakeholders requests for additional detail on its device-intensive methodology, CMS updated its narrative with a description of our device offset percentage calculation which can be found under supporting documentation for this final rule on the CMS website at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospital/OutpatientPPS/index.html>. The full listing of 2021 device-intensive procedures provided in Addendum P.¹³

Comments/Responses: A number of commenters and the Advisory Panel on Hospital Outpatient Payment (HOP Panel) recommended that CMS consider lowering the device-intensive threshold from 30 to 25 percent to avoid excessive payment gaps when the device costs do not reach the device intensive threshold. CMS acknowledges that payment rates under the ASC payment system for a particular procedure may be subject to fluctuation if device-intensive status varies for the procedure on a year-to-year basis, but this potential payment gap will exist for any threshold value. CMS discusses how lowering the device-intensive thresholds puts downward pressure on the ASC weight scalar and reduces the non-device portion of ASC payment rates for most surgical procedures. Because of this concern, CMS does not accept the recommendations to lower the device-intensive threshold.

In response to commenters suggesting alternative criteria for device intensive procedures, CMS believes the existing criteria are adequate to differentiate implantable and insertable device costs from non-invasive equipment costs and other procedure-related costs. CMS acknowledges that the reliance on OPPS scaled relative weights to develop the ASC payment rates may not capture the geometric mean cost of procedures with significant capital equipment costs in the ASC setting.

For discussion about specific codes, the reader is advised to review the final rule.

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

2. Device Edit Policy

In the 2017 OPSS 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 and subsequent years, the description of HCPCS code C1889 is: “Implantable/insertable device, not otherwise classified.

For 2021, CMS does not make any changes to the device edit policy.

Comments/Responses: Some commenters requested CMS restore the device-to-procedure and procedure-to device edits. CMS continues to believe these edits are not necessary because hospitals have experience in coding and reporting these claims fully. CMS notes it expects hospitals to code and report their codes appropriately whether or not there are claims processing edits in place.

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

CMS reduces OPSS 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.

In the 2014 OPSS final rule (78 FR 75005 through 75007), CMS adopted a policy of reducing OPSS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit by the lesser of the device offset amount for the APC or the amount of the credit. CMS discussed this policy in subregulatory guidance but did not make conforming changes to the regulation text at §419.45(b)(1) and (2). Accordingly, CMS is revising its regulations to incorporate this policy.

4. Payment Policy for Low Volume Device-Intensive Procedures

In the 2017 OPSS final rule, CMS finalized that the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC be calculated using the median cost instead of the geometric mean cost. For 2020, CMS finalized continuation of this policy for 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. In 2020, this policy applied to

CPT code 0308T (Insertion of ocular telescope prosthesis including removal or crystalline lens or intraocular lens prosthesis which was assigned to APC 5495 (Level 5 Intraocular Procedures). For 2021, CMS continues this policy but, this policy will not apply to any procedure in 2021.

V. Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

A. Transitional Pass-Through Payment: Drugs, Biologicals and Radiopharmaceuticals

Section 1833(t)(6) of the Act provides for temporary additional payments or “transitional pass-through payments” for certain drugs and biologicals. For pass-through payment purposes, radiopharmaceuticals are “drugs.” As required by statute, transitional pass-through payments for a drug or biological can be made for at least 2 years, but not more than 3 years, after the payment was first made under the OPDS. Pass-through drugs and biologicals for 2021 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 periods 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 36 of the final rule lists 29 drugs and biologicals for which CMS is ending pass-through payment after 2020. Each of the products will have received at least the full 3 years of pass-through payments once the additional payments expire. There are five codes on this list (A9586, J1097, Q4195, Q4196 and Q9950) that have already had 3 years of pass-through payment. Pass-through payment for these products was extended by an additional two years effective October 1, 2018 by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018. There are also two diagnostic radiopharmaceuticals (Q9982 and Q9983) that received nine months of extended pass-through from January 1, 2020 to September 30, 2020 under Division N, Title I, Subtitle A, Section 107(a) of the Further Consolidated Appropriations Act of 2020. Pass-through payment for the products that received statutory extensions expired on September 30, 2020.

CMS will end pass-through payment in 2021 for 25 drugs and biologicals listed in Table 37 of the final rule. Each of the products will have received at least the full 3 years of pass-through payments once the additional payments expire.

Table 38 of the final rule lists 68 drugs and biologicals where CMS will be continuing pass-through payment in 2021 (22 of these drugs and biologicals were approved for pass-through payment since the proposed rule). For 2021, CMS will continue average sales price (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.

As indicated in more detail below CMS published an IFC on November 27, 2020 establishing a Most Favored Nation (MFN) Model that will more closely align payment for 50 Medicare Part B drugs and biologicals with international prices. The Medicare Part B drugs will be the 50 with the highest expenditures. CMS does not reference the MFN model in the OPSS final rule. While it seems unlikely that a new drug eligible for pass-through will be among the highest 50 in expenditures for Part B drugs, if it were, CMS' policy in this context is unstated as to whether Medicare would pay ASP+6 percent or the MFN price.

Except when paid on pass-through, payment for policy packaged drugs and biologicals 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.

For policy packaged drugs, CMS proposed that the pass-through payment amount would equal ASP+6 percent for 2021 minus a payment offset for any predecessor drug products included in the APC. CMS also proposed to pay for diagnostic and therapeutic radiopharmaceuticals receiving pass-through payment at ASP+6 percent. As diagnostic radiopharmaceuticals are also policy packaged, CMS proposed a payment offset from the associated APC. If ASP data are not available, CMS proposed to provide pass-through payment at wholesale acquisition cost (WAC)+3 percent. If WAC information also is not available, CMS proposed to provide payment for pass-through drugs and biologicals at 95 percent of their most recent average wholesale price (AWP). All of these proposals are finalized without modification.

Table 39 of the final rule lists the APCs where CMS will apply an offset for policy packaged drugs paid on pass-through. 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: [2021 | CMS](#).

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 OPSS payment rate for the associated procedure or service.

Cost Threshold for Packaging of “Threshold-Packaged Drugs”

“Threshold-packaged drugs” under the OPSS are drugs, non-implantable biologicals and therapeutic radiopharmaceuticals whose packaging status is determined by the packaging threshold. If a drug's average cost per day exceeds the annually determined packaging threshold, it is separately payable and, if not, it is packaged. For 2020, the packaging threshold for drugs,

biologicals, and radiopharmaceuticals that are not new and do not have pass-through status is \$130.

To calculate the 2021 threshold, CMS proposed to use the most recently available four quarter moving average Producer Price Index forecast levels for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from CMS' Office of the Actuary to trend the \$50 threshold forward from the third quarter of 2005 to the third quarter of 2021. CMS rounds the resulting dollar amount (\$130.95) to the nearest \$5 increment. Based on this calculation, CMS proposed adopting a packaging threshold for 2021 of \$130. CMS is finalizing the \$130 packaging threshold for 2021.

CMS will continue using the following process to determine the 2021 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 2019 claims data processed before January 1, 2020, 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 2019 and were paid (either as packaged or separate payment) under the OPPS.

To calculate the per day cost for the final rule, CMS uses ASP+6 percent for each HCPCS code with manufacturer-submitted ASP data from the 2nd quarter of 2020 (data that were used for drugs and biologicals payment in physicians' offices effective October 1, 2020). For products that do not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, CMS will use their mean unit cost derived from 2019 hospital claims data. CMS will 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 2021.

CMS uses quarterly ASP updates as follows:

- 4th quarter of 2019: Per day cost, budget neutrality estimates, packaging determinations, impact analyses, and Addenda A and B for the 2021 OPPS proposed rule;
- 2nd quarter of 2020: Per day cost, budget neutrality estimates, packaging determinations, impact analyses, and Addenda A and B for the 2021 OPPS final rule; and
- 3rd quarter of 2020: Payment rates effective January 1, 2021 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, 2021 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 2021 final rule are subject to quarterly updates.

As in past years, CMS is applying the following policies to determine the 2021 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 are separately payable in 2020 and were proposed for separate payment in 2021 are separately payable in 2021 even if the updated data used for the 2021 final rule indicate per day costs equal to or less than the \$130 threshold.
- HCPCS codes that are packaged in 2020, proposed for separate payment in 2021, and have per day costs equal to or less than \$130 based on the updated data used for the 2021 final rule are packaged in 2021.
- HCPCS codes for which CMS proposed packaged payment in 2021 and have per day costs greater than \$130 based on the updated data used for the 2021 final rule are separately payable in 2021.

Interaction of the MFN Model with ASP Pricing for Outpatient Drugs

On November 27, 2020, CMS published an IFC establishing an MFN Model that will more closely align payment for Medicare Part B drugs and biologicals with international prices. The MFN Model will begin on January 1, 2021. Under the MFN Model, CMS will make payment for Part B drugs (including in hospital outpatient departments) for 50 drugs accounting for the highest Medicare Part B drug expenditures on the basis of prices paid in 22 Organization for Economic Cooperation and Development countries with a gross domestic product that is at least 60 percent of the US'.

CMS makes no mention of the MFN Model in the 2021 OPSS final rule. However, in the MFN IFC, CMS states that it:

will calculate the MFN Drug Payment Amount for a calendar quarter for the MFN Model drug based on a phased-in blend of the applicable ASP and the MFN Price, which we will determine by selecting the lowest GDP-adjusted country-level price from the included countries for the applicable ASP calendar quarter. (85 FR 76200)

Further, the MFN IFC states:

for the initial calculations to calculate payment amounts for the start of the MFN Model on January 1, 2021, the beginning of the first calendar quarter in 2021, we will use the January 2021 ASP Pricing File (which will be based on manufacturers' ASP for the third quarter of 2020, from July 1, 2020, to September 30, 2020) and international drug pricing information for the third quarter of 2020, from July 1, 2020, to September 30, 2020. For each subsequent calendar quarter for a performance year, the MFN Drug Payment Amount will be established by calculating the MFN Price based on more recent international drug pricing information, using data for the applicable ASP calendar quarter, if available. (85 FR 76213)

While the 2021 OPSS final rule indicates that all separately payable drugs will be paid based on ASP in 2021, the MFN IFC indicates that the top 50 Part B drugs based on expenditures will be

priced beginning in 2021 based on a blend of ASP and international prices. These regulations are clearly inconsistent in how Part B drugs will be priced beginning January 1, but it seems likely that CMS intends to use a blend of international prices and ASP for drugs included in the MFN and ASP for all other drugs. Following established practice detailed above, CMS would not change its 2021 packaging determinations based on MFN prices. However, it seems that packaging decisions in 2022 could be affected by MFN prices if the blended MFN and ASP price result in a Part B drug's per day cost being below the packaging threshold.

Policy Packaged Drugs, Biologicals, and Radiopharmaceuticals

CMS did not propose any changes for policy packaged drugs, biologicals and radiopharmaceuticals. Nevertheless, CMS received one comment requesting that it pay separately for ophthalmic drugs administered during surgery that treat or prevent post-operative indications. Another commenter asked CMS to apply edits for radiolabeled products to ensure their costs are included in the APCs for nuclear medicine procedures. The HOP Panel and other commenters requested CMS always pay separately for radiopharmaceuticals including when they function as a supply for a diagnostic procedure. CMS declined to make any policy changes in response to these comments.

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

For 2021, 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 40 of the final rule.

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

Except for separately payable, non-pass-through drugs acquired with a 340B discount, CMS proposed to continue paying for separately payable drugs and biologicals at ASP+6 percent in 2021. For drugs acquired under the 340B drug discount program, CMS proposed to pay ASP-28.7 percent beginning in 2021 (see section V.B.6 below for more detail about this policy and CMS' decision to continue payment for 340B acquired drugs at ASP-22.5 percent rather than finalize its proposal to increase the reduction to 28.7 percent). Medicare's payment represents the combined acquisition and pharmacy overhead payment for drugs and biologicals.

Consistent with policy in the PFS, CMS again proposed to pay for drugs under the OPPS 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 PFS policy, CMS proposed to limit this WAC+3 percent policy under the OPPS 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. CMS proposed that drugs paid using WAC and that are acquired under the 340B program would be paid at WAC-28.7 percent. If ASP and WAC are unavailable, CMS proposed that Medicare will pay 95 percent of average wholesale price (AWP) or 63.9 percent of AWP if the drug is acquired under the 340B program. However, this latter subtraction from WAC or paying based

on 63.9 percent of AWP for drugs acquired under the 340B program was not finalized. Under the final rule policy, new drugs paid based on WAC will be paid WAC-22.5 percent when acquired under the 340B program and 69.46 percent of AWP when paid based on AWP.

CMS also proposed to continue to include payments for separately payable drugs and biologicals in determining budget neutrality adjustments (i.e., the budget neutral weight scaler). However, the weight scaler is not applied to separately payable drugs due to the statutory requirement that drug and biological payments be based on acquisition costs or the amount required by statute in physician's offices when hospital acquisition costs are unavailable.

The payment rates shown for drugs and biologicals in Addenda A and B of the final rule are not the payment rates that Medicare will pay on January 1, 2021. Payment rates effective January 2021 will be released near the end of December 2020 and will be based on ASP data submitted by manufacturers for the third quarter of 2020 (July 1, 2020 through September 30, 2020). However, as described above but not discussed in the 2021 OPPS final rule, the 50 Part B drugs that account for the most expenditures will be paid in 2021 based on a blend of ASP prices and international prices. Payment rates will be updated quarterly throughout 2021.

Payment rates for drugs and biologicals in Addenda A and B of the final rule for which there was no ASP information available for the 2nd quarter of 2020 are based on mean unit cost in the available 2019 claims data. If ASP information becomes available for the quarter beginning in January 2021, CMS will pay for these drugs and biologicals based on the newly available ASP information. In the MFN IFC, CMS states if international sources do not contain drug pricing information, it "will establish the MFN Drug Payment Amount at the applicable ASP for the applicable calendar quarter...that applies, until international drug pricing information is available." (85 FR 76205)

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 proposed to pay for the biosimilar at ASP-28.7 percent of its own ASP rather than doing the subtraction from the reference product ASP. Consistent with past year policies, if WAC is used for pricing, CMS proposed that the add-on will be +3 percent or +6 percent of the reference product WAC depending on whether the biosimilar is in an initial sales period or -28.7 percent of its own WAC if acquired under the 340B drug discount program. In the final rule, the subtraction from ASP will be -22.5 percent rather than -28.7 percent for drugs acquired under the 340B program.

Biosimilars are eligible for pass-through payment like any other drug or biological. Pass-through would apply to each new biosimilar irrespective of whether a second product is biosimilar to the same reference product as another biosimilar that already received pass-through payment. Under

pass-through, a biosimilar would be paid ASP+6 percent of the reference product's ASP even when acquired under the 340B drug discount program.

One commenter objected to biosimilars receiving pass-through payment indicating that biosimilars are not new or innovative like the reference product was at one time. The higher payment for the biosimilar at ASP+6 percent even when acquired under the 340B program will advantage the biosimilar over the reference product and result in higher expenditures for Medicare and its beneficiaries. CMS disagreed with the comment stating that competition among multiple products will result in drug prices declining over time even if there is a short-term increase in spending.

Other commenters ask CMS to provide additional support for biosimilars in the form of more beneficial payment policies. CMS disagreed with these comments as well saying that its policies are not intended to advantage or disadvantage a particular product. Proposed policies are being finalized without modification.

3. Payment Policy for Therapeutic Radiopharmaceuticals

For 2021, CMS proposed to continue paying for therapeutic radiopharmaceuticals at ASP+6 percent. For therapeutic radiopharmaceuticals for which ASP data are unavailable, CMS also proposed to determine 2021 payment rates based on 2019 geometric mean unit cost. Both of these policies are being finalized as proposed.

4. Payment for Blood Clotting Factors

For 2021, CMS will continue paying for blood clotting factors at ASP+6 percent and updating the 2020 \$0.226 per unit furnishing fee by the Consumer Price Index (CPI) for medical care. The CPI won't be available until after publication of the 2021 OPPS final rule, so CMS will announce the updated fee through program instructions and will post the updated rate on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html>.

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

CMS is continuing the same payment policy in 2021 for non-pass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data as in earlier years. In priority order, CMS will pay for these products using ASP+6 percent if ASP is reported, WAC+6 percent if WAC is available and at 95 percent of AWP if ASP and WAC are unavailable. The 2021 payment status of each of the non-pass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data is listed in Addendum B of the final rule.

6. OPPS Payment Methodology for 340B Purchased Drugs

a. Overview and Background.

CMS provides the regulatory and litigation history regarding its policy to pay for drugs acquired under the 340B program at ASP-22.5 percent. In summary:

- Beginning in 2018, CMS adopted a policy to pay for drugs acquired under the 340B program at ASP-22.5 percent to approximate a minimum average discount for 340B drugs, which was based on findings of the General Accountability Office (GAO) and MedPAC that hospitals acquire drugs at a significant discount under the 340B program.
 - For policy reasons explained in prior rulemaking, CMS exempts CAHs, rural SCHs and cancer hospitals from the 340B payment adjustment.
 - Pass-through drugs and vaccines acquired under the 340B program are also exempted from the adjustment.
- In 2019, CMS applied the policy to off-campus provider-based departments that are subject to section 603 of the Bipartisan Budget Act (BBA) of 2015 and not paid under the OPSS.
- On December 27, 2018, the United States District Court for the District of Columbia (the district court) concluded that the Secretary lacked authority to bring the default rate in line with average acquisition cost unless, according to CMS, the Secretary obtains survey data from hospitals on their acquisition costs.¹⁴ While the initial decision applied only to CMS' 2018 policy, the district court later made the same finding for CMS' 2019 policy.
- Pending an appeal of the district court decision, CMS began gathering the survey data from 340B hospitals in late 2019 and earlier this year as part of an effort to adopt a policy it believes would be consistent with the district court decision. In the 2020 OPSS rule, CMS indicated that this survey “may be used in setting the Medicare payment amount for drugs acquired by 340B hospitals for cost years going forward, and also may be used to devise a remedy for prior years if the district court’s ruling is upheld on appeal.”
- On July 31, 2020—just two business days before the 2021 OPSS proposed rule was released—the United States Circuit Court for the District of Columbia (the appeals court) entered an opinion reversing the district court’s judgment.

b. Hospital Acquisition Cost Survey for 340B-Acquired Drugs and Biologicals.

CMS conducted a 340B hospital survey to collect drug acquisition cost data for the fourth quarter of 2018 and the first quarter of 2019. The rule indicates that CMS conducted this survey under the authority of section 1833(t)(14)(D)(ii)(II) of the Act which states that “the Secretary, taking into account [GAO] recommendations, shall conduct periodic subsequent surveys to determine the hospital acquisition cost” for drugs and biologicals. GAO’s 2006 report recommended that CMS conduct a streamlined hospital survey only once or twice per decade because of the significant operational difficulties and burden that such a survey would place on hospitals.¹⁵ CMS indicates it considered GAO’s conclusion that the 2005 survey created

¹⁴ While CMS indicates that it was the lack of survey data that resulted in the District Court finding that its policy was inconsistent with the law and this defect could be rectified with survey data on average acquisition cost, support for this statement was not provided in the final rule and could not be found in the District Court decision.

¹⁵ GAO Report to Congress: Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient

“considerable burden” for hospitals and only surveyed 340B hospitals given its belief that the current payment rate for non-340B hospitals continues to be an appropriate rate.

The survey was provided to 1,422 hospitals between April 24 and May 15, 2020 including rural SCHs, children’s hospitals and cancer hospitals that are exempt from the 340B policy. CMS requested that hospitals provide either the 340B ceiling price, a 340B sub-ceiling price, or another amount, depending on the discounts the hospital received when it acquired a particular drug. The ceiling price is the maximum amount covered entities may permissibly be required to pay for a drug under section 340B(a)(1) of the Public Health Service Act. CMS notes that the survey instrument itself reflected two rounds of public comment through the Paperwork Reduction Act submission process.

The survey sample was 100 percent of the potential respondent universe. Respondents could either answer the “detailed survey” where they provided acquisition costs for each individual drug or biological or the “quick survey” where the hospital indicated that it preferred that CMS utilize the 340B ceiling prices obtained from the Health Resources and Services Administration—the federal agency that administers the 340B drug discount program. Where the acquisition price for a particular drug was not available, not submitted in response to the survey or the hospital did not respond to the survey at all, CMS used the 340B ceiling price for that drug as a proxy for the hospitals’ acquisition cost.

c. Survey Results:

Seven percent (100 surveys) responded using the detailed survey; 55 percent (780) responded using the quick survey option; and the remaining 38 percent (542) did not respond. CMS found that the survey respondent hospitals were generally similar to the general 340B survey population (e.g. there was no non-response bias).

d. Payment Policy for 2021 and Subsequent Years:

Grouping of Hospitals by 340B Covered Entity Status: CMS states that it may vary its payment for drugs and biologicals by hospital group under section 1833(t)(14)(A)(iii)(I) of the Act “based on volume of covered OPD services or other relevant characteristics.” CMS proposed to use 340B covered entity status as a relevant characteristic to group hospitals for purposes of payment based on average acquisition cost under section 1833(t)(14)(A)(iii)(I) of the Act.

Applying a Single Reduction Amount to ASP for 340B-Acquired Drugs: Under the authority of section 1833(t)(14)(A)(iii)(I) of the Act that provides that the payment amount for a drug or biological “is equal to the average acquisition cost...determined by the Secretary taking into account the hospital acquisition cost survey data collected...”, CMS proposed to apply a single uniform reduction to all drugs acquired under the 340B program. CMS further indicated that a single uniform reduction will protect the confidentiality of ceiling prices for individual drugs under section 1927(b)(3)(D) of the Act.

Rate-Setting Challenges for CMS, 4 (April 2006).

Methodological Issues: Based on its analysis of the available information, CMS estimated that the typical acquisition cost for 340B drugs for hospitals paid under the OPSS is ASP-34.7 percent. This average discount was determined using a geometric mean measure of central tendency; volume weighting; mapping of multi-source national drug codes (NDC) to a single HCPCS code; the effect of including penny priced drugs; and applying trimming methodologies to remove anomalous or outlier data.

- Selecting an averaging methodology. CMS considered multiple measures of central tendency (arithmetic mean, median, geometric mean) and proposed to apply a geometric mean as the averaging methodology. Among the averaging methodologies evaluated (before making the additional methodological determinations described below), using the geometric mean would produce the lowest reduction to ASP (-58.3 percent).
- Volume Weighting. CMS proposed to volume weight the survey results using 2018 and 2019 utilization data under the OPSS. Volume weighting reduced the adjustment to 58.0 percent.
- HCPCS Codes with NDCs. For a small portion of the drugs and biologicals subject to the 340B drug acquisition cost survey, multiple NDCs map to a single HCPCS code. Detailed survey respondents provided acquisition costs at the HCPCS level so nothing further was required by CMS. For quick survey respondents and non-respondents, CMS did not know how the combination of NDCs mapped to the HCPCS codes these entities would have used during the given quarters. To address this issue, CMS proposed to select the one most beneficial to hospitals: using the highest cost NDC for each HCPCS (as opposed to using the average cost NDC for each HCPCS). This option reduced the adjustment to -47.0 percent.
- Penny Pricing. Provisions of the 340B program can result in ceiling price of \$0. In these cases, manufacturers are required to charge \$0.01. As penny prices represent the maximum (ceiling) price the 340B hospital would pay for a drug, CMS believed it would be appropriate to include penny pricing in the determination of the average ASP adjustment. However, consistent with selecting a methodology most advantageous to hospitals. CMS proposed to exclude penny pricing. Excluding penny pricing reduced the adjustment to -40.9 percent.
- Outliers. CMS considered that hospitals may have erroneously reported an acquisition cost higher than the ceiling price or, inconsistent with the law, that a hospital may have been charged more than the ceiling price. To address the latter possibility, CMS did not uniformly eliminate higher than ceiling acquisition prices and instead only excluded data that were more than three standard deviations from the geometric mean. This proposal reduced the adjustment to -34.7 percent.

Table 41 of the final rule shows various combinations of the above methodological proposals together. While the combination of several methodological decisions may be more favorable to hospitals (specifically use of an arithmetic mean either with or without penny pricing or use of a median without penny pricing), CMS believes that a geometric mean is a superior measure of central tendency as it mitigates the effects of outliers relative to the arithmetic mean and median and is consistent with other OPSS averaging methodologies.

Determining an Add-on Payment for 340B Drugs Under the OPPTS. While CMS believes that its decision to determine an average acquisition cost most beneficial to hospitals obviates the need for an add-on to ASP -34.7 percent, it nonetheless proposed an add-on of 6 percent for services associated with drug acquisition that are not separately paid for, such as handling, storage, and other overhead. The proposed rule said that utilizing a drug add-on will ensure a level of payment parity with the add-on that applies to Part B drugs outside of the 340B program.

Drugs Priced Using WAC or AWP. For WAC-priced drugs acquired under the 340B program, CMS proposed to pay WAC-28.7 percent. For AWP priced drugs, CMS proposed to pay 63.90 percent of AWP (95 percent of AWP divided by 1.06 times (1-28.7 percent)).

340B Payment Policy Exemptions. CMS proposed to continue exempting CAHs, children's hospitals, cancer hospitals, rural SCHs, vaccines and drugs paid on pass-through from the 340B policy for reasons explained in prior rules.

e. Alternative Proposal to Continue Policy to Pay ASP-22.5 Percent.

CMS continues to believe that ASP-22.5 percent is an appropriate payment rate for 340B-acquired drugs under the authority of 1833(t)(14)(A)(iii)(II) for the reasons provided in earlier rules. As this policy has been upheld by the appeals court, CMS proposed in the alternative that the agency could continue the current Medicare payment policy of paying for 340B acquired drugs at ASP-22.5 percent for 2021. **CMS adopted this alternative in the final rule and will continue to pay for 340B acquired drugs as ASP-22.5 percent rather than ASP-28.7 percent.**

Comments Regarding 340B Survey Methodology and Implementation

Legal Issues

Several commenters contended that the law does not permit CMS to use one methodology to price Part B drugs for one group of hospitals and a different methodology for the remainder of hospitals. Further, commenters objected to the low survey response rate being used to support CMS' proposal as section 1833(t)(14)(D)(iii) requires that surveys "shall have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost." There were also concerns that the limited period of the data collection was unrepresentative of yearly fluctuations in drug pricing.

CMS disagreed stating that the statute does not require the Secretary to survey all hospitals. Rather, it requires Medicare to have a large enough sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each separately payable drug. The final rule reiterates that it would be burdensome and unnecessary to survey non-340B hospitals because ASP data is an adequate proxy of the average drug acquisition costs of such providers. CMS believes the sampling timeframe is appropriate for providing a conservative estimate for the proposed ASP reduction.

Response Rate

Even though the overall response rate was 62 percent, 55 percent used the quick response option (340B ceiling prices) which commenters said was not necessarily reflective of their acquisition costs. CMS responded that 340B ceiling price used for both non-respondents and the quick survey option respondents was a reasonable proxy for acquisition costs as it represents the maximum price a hospital could be charged for a 340B acquired drug.

6 Percent Add-on

Commenters supported the 6 percent add-on. CMS responded that it still does not believe that the add-on is necessary as its conservative estimate of average acquisition costs may already account for the costs of overhead and handling. However, the point is moot as CMS did not finalize its proposal to price Part B drugs acquired through the 340B program at ASP-28.7 percent.

340B Compliance Costs

Commenters stated that CMS should also take into consideration the costs that 340B entities incur to maintain their status and comply with 340B program requirements. CMS responded that the statute does not mention covering 340B program compliance cost.

Administrative Issues

Hospitals cannot always identify when a drug is purchased under the 340B program or at full market rates but assigns the “JG” modifier to the claim applying the discount to all of their purchased drugs, even if the drug was not purchased under the 340B program. CMS reiterated its use of the 340B ceiling price represents a price that will be higher than the hospital actually paid and it did not receive any comments demonstrating that 340B hospitals pay more than the ceiling price for a particular drug. The final rule advises hospitals not to use the “JG” modifier where the drug was not acquired under the 340B program.

Methodological Issues

Commenters expressed support for CMS’ exclusion of penny pricing in the calculation of the proposed 340B payment rate and eliminating any drugs with inflationary penalties from the calculation, as the commenters believed these penalties are unevenly distributed among drugs and among hospitals. Commenters were not supportive of CMS’ volume weighting methodology as 340B utilization may differ from overall hospital utilization. CMS does not believe it would be appropriate to eliminate all drugs with inflationary penalties at this time and noted that the 340B hospitals drug utilization pattern did not vary significantly from the overall OPPS utilization.

Several commenters asked for the release of the survey data that CMS used in order to calculate the 340B payment reduction. CMS responded that it is required by law to maintain the confidentiality of the individual survey responses as well as ceiling prices for individual drugs. However, the agency is exploring the possibility of providing microdata to qualified researchers

through their restricted access infrastructure in accordance with best practices for transparency.

General Opposition to 340B Drug Payment Changes

Many commenters continue to oppose any reduction in payment for 340B drugs detailing the many types of charity care and uncompensated care programs hospitals undertake using 340B drug discounts. CMS responded that it has not seen evidence that the current OPPS 340B drug payment policy has limited patient access to 340B drugs. Further, Medicare payments for drugs are not intended to cross-subsidize other programs. CMS also noted that its 340B policy results in lower beneficiary coinsurance for Part B drugs.

Biosimilars

Commenters mirrored earlier suggestions for special treatment for biosimilars or that biosimilars should be treated the same as their reference product. As CMS is not finalizing its proposal to increase the reduction from ASP to -28.7 percent, no changes are being made to biosimilar payments.

Justifying Continuation of the Policy and Budget Neutrality Adjustment

Several commenters stated that CMS has not considered changes in utilization and volume for hospitals that are actively participating in the 340B program since the policy was initially proposed in 2017. Further, the budget neutrality adjustment has not been recalculated annually to ensure that the OPPS conversion factor is properly adjusted.

CMS responded stating that commenters have not provided any evidence that ASP-22.5 percent is no longer a conservative estimate of their drug acquisition costs. With respect to OPPS budget neutrality and the conversion factor, CMS indicates that the adjusted percentage payment has remained at ASP-22.5 percent and any change would be included as part of the broader budget neutrality adjustments, but collectively there would not be a separate budget neutrality adjustment specifically for the 340B drug payment policy.

Final Policy: CMS will continue paying ASP-22.5 percent for 340B-acquired drugs and biologicals, including when furnished in nonexcepted off-campus PBDs. For WAC priced drugs, the 340B payment adjustment will continue to be WAC-22.5 percent. For drugs without an ASP or WAC, 340B drugs will continue to be paid at 69.46 percent of AWP. CMS is continuing to exempt rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals from the 340B payment adjustment. These hospitals must continue to report informational modifier "TB" for 340B-acquired drugs, and will continue to be paid ASP+6 percent. CMS may revisit its policy to exempt rural SCHs, as well as other hospital types, from the 340B drug payment reduction in future rulemaking.

7. High/Low Cost Threshold for Packaged Skin Substitutes

CMS has been packaging skin substitutes as drugs and biologicals that function as supplies when used in a surgical procedure since 2014. The packaging methodology also divides skin

substitutes into high and low-cost groups in order to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures. Skin substitutes assigned to the high cost group are billed with HCPCS codes 15271, 15273, 15275 and 15277. Skin substitutes assigned to the low-cost group are billed with HCPCS codes C5271, C5273, C5275 and C5277. Based on the geometric mean costs, these HCPCS codes will be assigned to APCs as follows:

APC	HCPCS	Geometric Mean Cost
5053 (Level 3 Skin Procedures)	C5271, C5275, C5277	\$497.02
5054 (Level 4 Skin Procedures)	C5273, 15271, 15275, 15277	\$1,622.74
5055 (Level 5 Skin Procedures)	15273	\$2,766.13

For 2021, CMS proposed continuing to determine the high cost/low cost status for each skin substitute product based on either a product’s geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product’s per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold. CMS proposed using 2019 data for this purpose.

The final 2021 MUC threshold is \$48 per cm² rounded to the nearest \$1 (\$47 in the proposed rule) and the final 2021 PDC threshold is \$949 rounded to the nearest \$1 (\$936 in the proposed rule). A skin substitute with a MUC or a PDC that exceeds either the MUC threshold or the PDC threshold will be assigned to the high cost group. If the product is assigned to the high cost group in 2020, CMS proposed to continue assigning it to the high cost group in 2021. Otherwise, CMS proposed assigning the skin substitute to the low-cost group. CMS is finalizing these proposals.

Table 42 displays the 2021 cost category assignment for each skin substitute product. For 2021, CMS is continuing the following policies:

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

Comments both supported and opposed continuing the current policies of having a high and low-cost skin substitute group. Other comments requested specific products be reassigned from the low cost to the high cost category—some of which have already been reassigned as requested while others did not qualify based on CMS’ analysis or any information provided by the commenters. CMS noted that two products commenters requested be assigned to the high cost groups are not graft skin substitutes priced using the skin substitute methodology.

While CMS did not propose any additional changes to its skin substitute policies, it reviews comments in response to comment solicitations in the 2019 and 2020 OPPS rules. CMS has considered whether to: 1) 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) or 2) eliminate the high

and low-cost skin substitute categories. Both of these options had support and opposition in the public comments.

For 2021, CMS proposed to include synthetic products in addition to biological products in its low-cost description of skin substitutes. The new description would define skin substitutes as a category of biological and synthetic products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers.

The most significant comments regarding this issue asked CMS to create product specific codes for synthetic skin substitute products as occurs for other skin substitute products derived from human tissue. Each of these products would then be assigned to a high or low-cost group based on MUC or PDC like other skin substitutes. Other comments asked CMS to assign synthetic skin substitute products only to the low-cost group.

CMS declined to commit to product specific codes in the future for synthetic skin substitutes because there is only one synthetic skin substitute in existence and there have been no claims for that product. Absent any claims, CMS indicated that the product is appropriately assigned to the high cost group based on pricing data provided by the product's manufacturer.

VI. Estimate of Transitional Pass-Through Spending

CMS estimates total pass-through spending for drug and device pass-through payments during 2021 will be approximately \$769.3 million, or 0.920 percent of total OPSS projected payments for 2021 (approximately \$83.9 billion), which is less than the applicable pass-through payment percentage statutory limit of 2.0 percent.

A. Devices

CMS estimates pass-through spending of \$309.8 million in 2021 for devices—\$210.8 million for those recently eligible for pass-through payments that will continue for 2021 and \$99.0 million for those CMS knows or projects could be approved for pass-through status in 2021. 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 \$459.5 million in 2021 for drugs and biologicals—\$449.5 million for those recently eligible for pass-through payments that will continue for 2021 and \$10 million for those CMS knows or projects could be approved for pass-through status in 2021. This estimate is slightly less than the proposed rule estimate and can be accounted for by CMS not finalizing its proposal to pay for drugs acquired with a 340B discount at ASP-28.7 percent and instead retaining the current policy of paying for these drugs as ASP-22.5 percent.

VII. Hospital Outpatient Visits and Critical Care Services

CMS solicited comments but did not propose any changes to the current clinic and emergency department hospital outpatient visits payment policies or to the payment policy for critical care services when these services are provided on the campus of a hospital.

CMS proposed to continue paying 40 percent of the full OPSS rate for a clinic visit in an off-campus provider-based department that is exempted from section 603 of BBA 2015. The rule notes that this policy was vacated by a United States District Court in 2019, but that decision was reversed on appeal on July 17, 2020. As Appeals Court reversed the District Court decision, CMS' rule has been upheld. Public commenters both supported and opposed this policy reiterating comments made in past years as well as arguments that have been made in litigation. Some commenters asked that the policy be held in abeyance until there is a final resolution of ongoing litigation. CMS is not making any changes to its policy for clinic visits provided in off-campus provider-based departments for 2021.

VIII. Partial Hospitalization Program (PHP) Services

A. Background

CMS provides background on the development of its payment methodology for PPP services. It also describes policies established for the COVID-19 PHE where hospital and Community Mental Health Center (CMHC) staff may furnish certain outpatient therapy, counseling, and educational services (including certain PHP services), incident to a physician's services, to beneficiaries in temporary expansion locations, including the beneficiary's home, so long as the location meets all conditions of participation to the extent not waived. A hospital or CMHC may furnish those services using telecommunications technology to a beneficiary in a temporary expansion location if that beneficiary is registered as an outpatient.

B. PHP APC Update for 2021

For 2021, CMS continues its established policies to calculate the PHP APC per diem payment rates for CMHCs and hospital-based PHP providers based on geometric mean per diem costs using the most recent claims and cost data for each provider type.

CMS had proposed to use the 2020 final geometric mean per diem cost for CMHCs and hospital-based PHPs as a floor in developing the PHP APC per diem rates for each provider type for 2021 and subsequent years; however, the 2021 final geometric mean per diem cost for CMHCs and hospital-based PHPs calculated using the most recent updated data are significantly higher than those rates for 2020. Thus, CMS does not need to finalize the floor methodology.

CMS continues to use CMHC APC 5853 (Partial Hospitalization (3 or more services per day)) and hospital-based PHP APC 5863 (Partial Hospitalization (3 or more services per day)) using actual claims data from 2019 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 OPSS/ASC final rule (80 FR 70462-70466) as modified in the 2017 OPSS/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 2019 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 final 2021 PHP geometric mean per diem costs. CMS continues 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 defaults any CMHC CCR that is greater than 1 to the statewide hospital ancillary CCR.

1. CMHCs

37 CMHCs were included in the 2021 calculation. CMS excluded two CMHCs because of the ± 2 standard deviation trim, and one CMHC was excluded from rate setting because it had no days with 3 or more units of allowable PHP services. No CMHC was removed for missing wage index data for all its service days, and CMS did not adjust the CCR for any CMHCs with a CCR greater than 1. CMS removed 439 CMHC claims which left 10,495 CMHC claims for the 2021 ratesetting. The calculated geometric mean per diem cost for all CMHCs for providing 3 or more services per day is \$136.14 which is significantly higher than the \$104 calculated for the proposed rule and which represents an increase of roughly 11.9 percent from the 2020 geometric mean per diem cost (\$121.62) for all CMHCs.

In the proposed rule, CMS was about the impact of such a substantial decrease on beneficiary access to PHP services from CMHCs, and it proposed to use the 2020 CMHC geometric mean per diem cost of \$121.62 as a floor for 2021 and each subsequent year. CMS concludes in the final rule that its proposed floor policy is not necessary for 2021 because the final calculated CMHC geometric mean per diem cost for this final rule with comment period is substantially higher than the proposed cost floor.

In the proposed rule, CMS determined that six providers (representing almost 40 percent of all CMHC days) reported lower costs per day than those reported for the 2020 ratesetting. CMS notes that the CMHC APC 5853 is heavily weighted to the costs of providing 4 or more services per day. The agency did not believe that the costs of furnishing these services have gone down over time and instead attributed the decrease to the impact of the six providers. For the final rule, the geometric mean costs for three of those six providers (collectively representing 15.7 percent of all CMHC days) increased substantially along with the geometric mean costs of a fourth provider, resulting in the significantly higher geometric mean per diem cost of \$136.14. Thus, CMS does not finalize its floor policy at this time.

Commenters supported use of the floor and expressed concerns that declining per diem payment rates result in a decline in the number of PHPs, especially at CMHCs. CMS does not believe that lower payment rates alone are responsible for the decline in the number of PHPs and instead notes that other factors, such as business management or marketing decisions, competition,

oversaturation of certain geographic areas, and federal and state fraud and abuse efforts, impact closure of PHPs. CMS adamantly rejects suggestions that its data are skewed and its calculations are incorrect; it notes that due to the small number of CMHCs (e.g., the 37 used for the final rule) the calculations can be influenced by a few large providers.

2. Hospital-based PHP Providers

For hospital-based PHP providers, CMS excluded 72 providers as follows: one with all service days having a CCR greater than five, 68 with no PHP payment, 2 with no allowable PHP HCPCS codes, and one with geometric mean costs per day outside the ± 3 standard deviation limit. Six hospital-based PHP providers were defaulted to their overall hospital ancillary CCRs due to outlier cost center CCR values. The calculated geometric mean per diem cost for 2021 for all hospital-based PHP providers for providing 3 or more services per day is \$253.76 which represents an increase of 8.7 percent from the 2020 geometric mean per diem cost for these providers (\$233.52). As noted above, CMS does not finalize its proposal to establish a cost floor for hospital-based PHPs at this time because the data do not support the need for one.

Commenters expressed similar concerns about low reimbursement rates and their impact on access to PHP services, and CMS responds that, while it is concerned about access to PHP services, declining payment rates alone have not caused the reduction in the number of PHPs. Its goal is to establish accurate and reasonable payment rates based on cost data, and it believes the geometric mean per diem cost methodology results in accurate rates that will support access to PHP services.

3. 2021 Costs and Payment Rates

The final 2021 geometric mean per diem costs and payment rates are as follows:

2020 APC	Group Title	2021 PHP APC Geometric Mean Per Diem Costs*	2021 Payment Rates**
5853	Partial Hospitalization (3 or more services per day) for CMHCs	\$136.14	\$ 139.75
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	\$253.76	\$ 260.49

* Table 43 in the final rule shows the proposed PHP APC geometric mean per diem costs.

** The 2021 payment rates are from Addendum A to the final rule.

C. **PHP Service Utilization**

CMS has previously expressed concern about the low frequency of individual therapy in PHP services. CMS believes that appropriate treatment for PHP patients includes individual therapy, and its analysis of 2019 claims data shows that the provision of individual therapy by CMHCs on days with 4 or more services has slightly increased, but on days with 3 services, individual therapy provided by CMHCs has sharply decreased. For hospital-based providers, the provision of individual therapy has slightly decreased on days with only 3 services and remained the same on days with four or more services. These very small decreases correspond with a modest

increase of less than one tenth of one percent in the provision of individual therapy on all days with three or more services. Table 44 in the final rule shows claims data from 2015 through 2019.

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 2019 claims, CMS notes that CMHC utilization of 3 service days is increasing while the utilization of 3 service days by hospital-based providers is decreasing. 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.

D. Outlier Policy for CMHCs

For 2021, CMS continues to calculate the CMHC outlier percentage, cutoff point and percentage payment amount, outlier reconciliation, outlier payment cap, and fixed-dollar threshold pursuant to established policies. In the preamble to the rule, CMS provides a more detailed explanation of the steps involved in calculating the CMHC outlier percentage.

CMS designates less than 0.01 percent of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs for PHP outliers. CMS sets the cutoff point for the outlier payments for CMHCs for 2021 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 continues this policy for 2021. This payment cap only impacts CMHCs.

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

E. Regulatory Impact

CMS estimates that payments to CMHCs will increase by 11.9 percent in 2021; this represents a substantial increase from the proposed rule estimate of 1.3 percent. The estimate includes the impact of the trimming methodology, wage index, and other adjustments.

IX. Inpatient Only (IPO) List

Services on the IPO list are not paid under the OPPS. Currently, the IPO list includes approximately 1,740 services. Services on the IPO list require inpatient care because of the invasive nature of the procedure, the need for at least 24 hours of postoperative recovery time, or the underlying physical condition of the patient requiring surgery. CMS annually reviews the

IPO list to identify any services that should be removed from or added to the list based on the most recent data and medical evidence available using criteria specified annually in the OPSS rule.

In previous years, CMS received comments from stakeholders who believe the IPO list should be eliminated and deference given to the clinical judgment of physicians for selecting where to perform a service. Stakeholders have also commented that exclusion of services from payment under the OPSS is unnecessary and could have an adverse effect on advances in surgical care. Some stakeholders have suggested that when a service is removed from the IPO list, it creates an expectation among hospitals that the service must be furnished in the outpatient setting, regardless of the clinical judgment of the physician or needs of the patient.

Other stakeholders have supported maintaining the IPO list and consider it an important tool to ensure that Medicare beneficiaries receive quality care. Stakeholders have also supported use of the IPO list because services included on the IPO list are an exception to the 2-midnight rule and are considered appropriate for inpatient hospital admission and payment under Medicare Part A regardless of the expected length of stay.

In the 2020 OPSS final rule, CMS finalized a policy to exempt procedures that have been removed from the IPO list from certain medical review activities for 2 calendar years following their removal from the IPO list. For 2021 and subsequent years, CMS proposed to continue this 2-year exemption from site-of-service claim denials for procedures that are removed from the IPO list. CMS also requested comment on whether a 2-year exemption continues to be appropriate, or if a longer or shorter period may be warranted. (See section X. B for more information).

While CMS previously saw a need for the IPO list, it now believes physicians should use clinical judgment, together with consideration of the beneficiary's specific needs, to select an inpatient or outpatient setting for care. As medical practice continues to develop, CMS believes the difference between the need for inpatient care and the appropriateness of outpatient care has become less distinct for many services. CMS further believes that the evolving nature of the practice of medicine, state and local licensure requirements, accreditation requirements, hospital conditions of participation (CoPs), medical malpractice laws, and CMS quality and monitoring initiatives and programs will continue to ensure the safety of beneficiaries in both the inpatient and outpatient settings, even in the absence of the IPO list. Nevertheless, CMS recognizes that some commenters may not share this view and requested that commenters submit evidence on what effect, if any, they believe eliminating the IPO list may have on the quality of care.

Stakeholders commenting on this issue previously raised concerns that removing procedures from the IPO list will result in higher beneficiary coinsurance. While beneficiary coinsurance is capped at the inpatient deductible for any individual outpatient procedure, total coinsurance may be more than the inpatient deductible if the beneficiary receives multiple outpatient services. However, CMS believes multiple coinsurance payments exceeding the inpatient deductible are less likely for surgical services being removed from the IPO list because surgical services are likely to be assigned to a C-APC that will have a single coinsurance amount that is capped at the inpatient deductible.

After careful consideration of the need for the IPO list, CMS proposed to eliminate the IPO list over a transitional period beginning in 2021 and ending in 2024. For 2021, CMS proposed to remove musculoskeletal services from the IPO list for the following reasons:

- CMS has already removed two musculoskeletal services from the IPO list (total knee arthroplasty and total hip arthroplasty). Other musculoskeletal services will be similar clinically and in terms of resource cost which will allow for appropriate payment.
- Historically, requests for procedures to be removed from the IPO list commonly have been for musculoskeletal procedures.
- There is already a set of comprehensive APCs for musculoskeletal services for payment in the outpatient setting that will facilitate being able to make payment once these procedures are removed from the IPO list.

CMS proposed to remove 266 musculoskeletal services from the IPO list for 2021.

CMS requested comments on:

- Whether three years is an appropriate time frame for eliminating the IPO list;
- Whether there are other services that would be ideal candidates for removal from the IPO list in the near term;
- The order of removal of additional clinical families and/or specific services for each year between 2021 and 2024;
- Whether there need to be any APC changes to accommodate removal of services from the IPO list; and
- Whether any of the services removed from the IPO list can be added to the ASC list in 2021.

General Comments

Commenters supporting elimination of the IPO list indicated that CMS' efforts to remove regulatory barriers would provide patients with more choices for where to receive affordable care, decrease overall healthcare costs and improve clinical outcomes for patients. These commenters stated that there is no clinical difference between a surgery performed in an inpatient setting and an outpatient setting. Opponents of the proposed policy stated that the IPO list serves as an important programmatic safeguard for high-risk, invasive procedures that require post-operative monitoring that are not safe to perform on Medicare beneficiaries in the outpatient setting.

CMS responded that patient safety and quality of care will be safeguarded by the physician's assessment of the risk of a procedure or service to the individual beneficiary. Selection of the most appropriate setting of care will be based on this risk as well as state and local licensure requirements, accreditation requirements, hospital CoPs, medical malpractice laws, and CMS quality and monitoring initiatives and programs.

Pressure to Perform Services Outpatient

Some commenters stated that many hospitals and commercial payors make rules establishing outpatient status as the assumed baseline site of service for these procedures, regardless of patient characteristics or the physician's clinical assessment. These commenters requested that CMS issue clear guidance that encourages consideration of and deference to the judgment of the physician, professional societies, and hospital associations regarding the procedures that are appropriate to be performed in the HOPD.

CMS reiterates prior guidance that the decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician based on the beneficiary's individual clinical needs and on the general coverage rules requiring that any procedure be reasonable and necessary. It is not CMS' policy to require services that are removed from the IPO list only be performed in the outpatient setting. CMS' response also indicates that services newly removed from the IPO list beginning in 2021 will have an indefinite exception from the 2-midnight rule until there is data indicating that the procedure is more commonly performed in the outpatient setting than in the inpatient setting.

Criteria for Performing a Service Inpatient or Outpatient

Commenters urged CMS to develop national guidelines outlining when an inpatient or outpatient setting is the appropriate site of service, particularly for services that generally have a short length of stay (i.e. do not meet the 2- midnight benchmark).

CMS responded that the decision about the most appropriate care setting for a given surgical procedure is a complex medical judgment based on the beneficiary's individual clinical needs and on the general coverage rules requiring that any procedure be reasonable and necessary. Nevertheless, CMS also stated that it plans to provide information on appropriate site of service selection to support physicians' decision-making. These considerations will be for informational or educational purposes only and will not supersede physicians' medical judgment about whether a procedure should be performed in the inpatient or outpatient hospital setting.

Financial Impacts on Beneficiaries and Providers

Commenters stated that beneficiaries who require more than one outpatient hospital procedure delivered in separate episodes of care could be subject to multiple co-payments that may, when combined, exceed the inpatient deductible. Other commenters stated that a shift in site of service from the inpatient setting to the outpatient setting for numerous procedures could be financially disadvantageous for providers because the patients who would continue to receive these services as inpatients would likely be the more complex cases and more costly to treat.

CMS responded that it is very unlikely that outpatient coinsurance will ever exceed the inpatient deductible. Of the 298 services that are being removed from the IPO list beginning in 2021, only one will be a separately paid procedure. The large majority (261) will be assigned to a C-APC where the beneficiary will have a single copayment capped at the inpatient deductible. There will be 34 services that are unconditionally packaged and never paid separately and 2 services that

are conditionally packaged meaning they will only be paid separately if it is the only service provided.

With regard to stakeholder concerns about providers experiencing negative financial effects because of services transitioning from the inpatient setting to the lower cost outpatient setting, CMS expects that the volume of services currently being performed in the inpatient setting that can be appropriately performed in the outpatient setting will gradually shift as physicians and providers gain experience furnishing these services to the appropriate Medicare beneficiaries in the outpatient department. CMS believes this gradual shift will mitigate financial impacts on hospitals.

APC Assignments

Commenters expressed concern that CMS did not provide sufficient detail as to how the proposed APC placements were determined. Some commenters also believe that the proposed OPPS payment did not adequately reflect the costs associated with providing the procedure in the outpatient setting and that there was a significant differential between MS-DRG payment and OPPS payment for some procedures. Some commenters requested specific APC reassignments from those proposed by CMS.

CMS responded that it assigned services removed from the IPO list to APCs based on their similarity to other codes within the APC in terms of clinical characteristics and resource use based on claims data. The final rule indicates that the 266 musculoskeletal procedures are appropriately assigned to C-APCs but CMS will continue to monitor claims data as they become available to determine if assignment to other APCs is appropriate.

A few commenters suggested that procedures removed from the IPO list receive an interim assignment to a new technology APC to help collect claims data and subsequently assign the procedures to clinical APCs. These commenters suggested assigning a default 31 percent device offset for procedures removed from the IPO list that are low volume and are assigned to a device-intensive APC. These commenters felt that current APCs may need to be restructured due to the lack of appropriate comparison procedures to those procedures being removed from the IPO list.

CMS responded that it believes assigning procedures removed from the IPO list to existing clinical APCs that are similar in clinical characteristics and resource costs is appropriate. Procedures assigned to new technology APCs do not fit into existing APC groups, unlike the procedures transitioning from the IPO list. For procedures being removed from the IPO list in 2021, CMS will apply offset calculations and assessment in determining device intensive status at the HCPCS/CPT code level as it does for other procedures (81 FR 79657).

Centers for Medicare and Medicaid Innovation (CMMI) Payment Models

Commenters raised concerns about the effect of the elimination of the IPO list on the target pricing of payment models administered by CMMI. The commenters requested that CMS ensure that any changes to the IPO list do not unfairly penalize model participants.

CMMI will monitor the overall volume and complexity of cases performed in hospital outpatient departments to determine whether any future refinements to the Comprehensive Joint Replacement and Bundled Payments for Care Initiative BPCI Advanced Models are warranted.

3-Day Prior Hospitalization for Skilled Nursing Facility (SNF) Care

Commenters stated that the elimination of the IPO list may have a significant impact on Medicare beneficiaries' ability to obtain a 3-day prior inpatient stay to qualify for SNF care. CMS responded that it would not expect that Medicare beneficiaries who receive a surgical procedure in the outpatient setting would require SNF care following surgery.

Anesthesia and Other Additions to the List of Procedures Removed from the IPO List

Commenters noted that CMS proposed to remove some musculoskeletal procedures from the IPO list but not their related anesthesia procedures. Further, the Advisory Panel on Hospital Outpatient Payment (HOP Panel) recommended an additional 16 procedures be removed from the IPO list. CMS agreed with both of these comments. The additional anesthesia procedures are listed in Table 46 of the final rule. Table 47 lists the additional procedures recommended by the HOP Panel.

Timeframe for Eliminating the IPO List

Several commenters requested that CMS delay the elimination of the IPO list until it can address patient safety concerns and provide national guidelines outlining patients who are appropriate candidates for care in the inpatient hospital versus outpatient hospital setting. Commenters suggested various time frames for eliminating the IPO list that ranged from three years to seven years.

CMS is finalizing a three-year transition for removing procedures from the IPO list. This three-year timeframe provides a gradual transition that gives the public the opportunity to comment on the sequence in which services should be removed from the IPO list. A longer transition period would prevent providers who are ready to perform services in the outpatient department from doing so. Other providers are not required to perform services in the outpatient department. As CMS transitions procedures off of the IPO list, it will continue to actively monitor for impacts on patient safety and quality through analyzing claims and other relevant data

Final Decision: CMS is finalizing its proposal to eliminate the IPO list over the course of the next 3 years, starting with the proposed removal of 266 musculoskeletal-related services and 16 HOP Panel recommended services and related anesthesia codes, for a total of 298 services, as provided in Table 48 in 2021.

The agency will provide considerations for physicians and other health care providers when determining whether a service may be more appropriately performed in the inpatient or outpatient setting for a beneficiary, but again emphasizes that decisions regarding appropriate care setting are complex medical judgments.

CMS believes that the developments in surgical technique and technological advances in the practice of medicine, as well as the various safeguards discussed above, including, but not limited to, physician clinical judgment, state and local regulations, accreditation requirements, medical malpractice laws, hospital CoPs, and other CMS initiatives will ensure that procedures removed from the IPO list and provided in the outpatient setting will be done so safely.

X. Nonrecurring Changes

A. Supervision of Outpatient Therapeutic Services

In 2020, CMS changed the required level of supervision for most OPPTS services from direct to general. Direct supervision means:

the physician must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room where the procedure is performed. During a Public Health Emergency, as defined in §400.200 of this chapter, the presence of the physician includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider. (42 CFR 410.28(e)(1))

General supervision means “the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure.” (42 CFR 410.32(b)(3)(i))

For those services that retain direct supervision, CMS changed the supervision level to general during the COVID-19 public health emergency in an interim final rule issued on March 31, 2020. This policy was adopted to provide flexibility for Medicare beneficiaries to be able to receive medically necessary services without jeopardizing their health or the health of those who are providing those services, while minimizing the overall risk to public health. CMS believes that these policies are appropriate outside of the PHE and should apply permanently. Therefore, CMS proposed to change the required supervision level for the following categories of services:

1. Non-Surgical Extended Duration Therapeutic Services (NSEDTS). These non-surgical services have a significant monitoring component that can extend for a lengthy period of time. NSEDTS typically have a low risk of complications after the assessment at the beginning of the service. The minimum default supervision level for NSEDTS is direct supervision during the initiation of the service followed by general supervision at the discretion of the supervising physician or the appropriate nonphysician practitioner during the monitoring period.

CMS believes changing the level of supervision for NSEDTS permanently to general for the entirety of the service would be beneficial to patients and hospitals. General supervision for the entire service would improve access in cases where the direct supervision requirement may have otherwise prevented some services from being furnished due to lack of availability of the supervising physician or nonphysician practitioner. In addition, CMS’ experience indicates that

hospitals will provide similar quality for outpatient therapeutic services, including NSEDTS, regardless of whether the minimum level of supervision required under the Medicare program is direct or general. The requirement for general supervision does not preclude these hospitals from providing direct supervision for any part of the service when appropriate to do so. CMS further believes the CoPs will help ensure patient safety.

Beginning on or after January 1, 2021, CMS proposed to change the required level of supervision for the duration of NSEDTS from direct to general. Commenters supported CMS' proposal noting that practitioners, at their option, can furnish direct supervision at the initiation of an NSEDTS service and that CoPs and state scope of practice requirements may lead to a higher level of supervision for part or all of NSEDTS service. MedPAC encouraged CMS to monitor NSEDTS services performed under general supervision, especially some services that involve risk of serious complications. CMS is finalizing its proposal without modification.

2. Pulmonary, Cardiac and Intensive Cardiac Rehabilitation Services using Interactive Telecommunications Technology. Section 1861(eee)(2)(B) of the Act establishes that, for cardiac, intensive cardiac, and pulmonary rehabilitation programs, "a physician is immediately available and accessible for consultation and medical emergencies at all times items and services are being furnished under the program, except that, in the case of items and services furnished under such a program in a hospital, such availability shall be presumed." This statutory requirement is very similar to the requirement for direct supervision.

Recently, some stakeholders suggested that CMS has the authority to change the default minimum level of supervision for pulmonary, cardiac, and intensive cardiac rehabilitation services from direct to general supervision similar to the change for most other hospital outpatient therapeutic services. CMS disagrees. However, in the March 31, 2020 interim final rule (85 FR 19246), CMS established that the direct supervision requirement can be met for cardiac, intensive cardiac and pulmonary rehabilitation services by the virtual presence of the supervising physician through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks to COVID-19 for the beneficiary or health care provider.

CMS believes the virtual presence of the physician could continue to improve access for patients and reduce burden for providers after the end of the PHE. In some cases, depending upon the circumstances of individual patients and supervising physicians, CMS believes that telecommunications technology could be used in a manner that would facilitate the physician's immediate availability to furnish assistance and direction without necessarily requiring the physician's physical presence in the location where the service is being furnished. For pulmonary, cardiac, and intensive cardiac rehabilitation services, CMS proposed to specify that, beginning on or after January 1, 2021, direct supervision for these services includes the virtual presence of the physician through audio/video real-time communications technology subject to the clinical judgment of the supervising physician. Virtual presence required for direct supervision using audio/video real-time communications technology would not be limited to mere availability, but rather a real-time presence via interactive audio and video technology throughout the performance of the procedure.

Public commenters were concerned that CMS' proposal would require the supervising practitioner to observe a rehabilitation service during the entire time the service is being administered, which would be comparable to personal rather than direct supervision. There were also comments indicating that the proposal was inconsistent with the standard established in the 2021 PFS proposed rule (85 FR 50115 through 50116), requiring only immediate availability to engage using audio/visual technology to provide direct supervision. Commenters suggested an "immediately available" standard through audio/video technology rather than a "virtual presence."

CMS responded with concern that its proposal was inconsistent between the 2021 OPFS and PFS rules and could increase provider burden for providers having to accommodate different levels of virtual engagement depending on whether a rehabilitation service is furnished as an outpatient hospital service or a physicians' service. As indicated below, CMS is not finalizing its proposal to allow for a virtual presence to meet the supervision requirement for pulmonary, cardiac and intensive cardiac rehabilitation after the end of the PHE.

Other comments either opposed the proposal or wanted to place substantial limits on when direct supervision through virtual presence could be used to furnish pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services. These commenters were concerned that practitioners cannot adequately supervise procedures, especially complex and high-risk procedures, and meet all of a patient's clinical needs, unless they are physically available to participate in the administration of the medical service. Commenters requested that CMS only allow virtual presence as an option to meet the supervision requirement until the end of the PHE.

CMS responded that use of virtual presence to meet the supervision requirement is an option of the supervising physician. An in-person immediate availability presence may still be provided to meet the supervision requirements for pulmonary, cardiac rehabilitation and intensive cardiac rehabilitation. In response to concerns about quality, CMS indicated that it will monitor use of interactive audio/video real-time communications technology to meet the direct supervision requirement to determine whether there is a negative impact on the quality of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services.

Final Decision: CMS is not extending the virtual presence option to meet the supervision requirement for pulmonary, cardiac and intensive cardiac rehabilitation beyond the PHE. The rule will permit direct supervision of these services using virtual presence only until the later of the end of the calendar year in which the PHE ends or December 31, 2021. Specifically, direct physician supervision can be provided through virtual presence using audio/video real-time communications technology (excluding audio-only) subject to the clinical judgement of the supervising practitioner, as discussed in IFC-1 (85 FR 19246). CMS is clarifying that "virtual presence" does not require real-time presence or observation of the service via interactive audio and video technology throughout the performance of the procedure.

B. Medical Review of Certain Inpatient Hospital Admissions

Under the 2-midnight rule, services would generally be considered appropriate for inpatient hospital admission and Medicare Part A payment when the physician expects the patient to

require at least 2 midnights of hospital care. Services on the IPO list continue to be appropriate for inpatient hospital admission and payment under Medicare Part A regardless of the expected length of stay.

In some cases, an inpatient admission may be appropriate even if the patient needs less than 2 midnights of hospital care based on the physician's judgment considering:

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

For the inpatient stay to be considered reasonable and necessary, documentation in the medical record must support either the admitting physician's reasonable expectation that the patient will require hospital care spanning at least 2 midnights, or the physician's determination based on factors such as those identified above that the patient nonetheless requires care on an inpatient basis. The decision to formally admit a patient to the hospital is subject to medical review.

In 2020, CMS finalized a policy to exempt procedures that have been removed from the IPO list from eligibility for referral to Recovery Audit Contractors (RACs) for noncompliance with the 2-midnight rule within the 2 calendar years following their removal from the IPO list. Procedures removed from the IPO list will not be considered by the Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs) in determining whether a provider exhibits persistent noncompliance with the 2-midnight rule for purposes of referral to the RAC nor will these procedures be reviewed by RACs for "patient status." BFCC-QIOs will have the opportunity to review such claims in order to provide education for practitioners and providers regarding compliance with the 2-midnight rule during the 2-year period.

As stated in section IX., CMS proposed to eliminate the IPO list beginning in 2021 over a 3-year transitional period. The elimination of the IPO list would mean that procedures currently on the IPO list would be subject to the 2-midnight rule. With more services available to be paid in the hospital outpatient setting, CMS indicates that it will be increasingly important for physicians to exercise their clinical judgment in determining the appropriate clinical setting for their patient to receive a procedure, whether that be as an inpatient or on an outpatient basis. CMS stresses that removal of a service from the IPO list has never meant that a beneficiary cannot receive the service as a hospital inpatient—as always, CMS believes the decision to admit a patient is a complex medical judgment that the physician makes to determine the appropriate setting for care.

CMS proposed to retain the existing 2-year exemption from site-of-services denials in the proposed rule once a procedure is removed from the IPO list. However, given that many more services would be removed from the IPO list during the proposed transition, CMS requested comment on whether to retain, lengthen or shorten the 2-year exemption. Commenters were asked to indicate whether and why they believe the 2-year period is appropriate or if a longer or shorter exemption period is needed.

Length of the Exemption Period

Commenters suggested the 2-year exemption from site-of-service claim denials should be anywhere between 3 to 6 years or indefinitely. CMS should extend the medical review exemption period until there is data indicating that the procedure removed from the IPO list is more commonly performed on an outpatient basis. Other commenters stated that applying the 2-midnight rule to some procedures was not practical, as they are either exclusively performed on an inpatient basis or have an average length of stay of two days or longer. Many commenters stated that ending the exemption too early could create pressure on providers to perform a medical service in the outpatient setting despite medical judgement suggesting otherwise. A number of commenters suggested CMS provide criteria (age, dual-eligible status, presence of certain comorbidities, social factors, environmental factors, and patient body mass index) to assist in determining whether a procedure should be performed inpatient or outpatient.

CMS agreed, stating that the 2-year exemption might not be sufficient given the magnitude of the change for providers. Accordingly, CMS is finalizing an indefinite exemption period rather than the 2-year period proposed until there is data indicating that the procedure removed from the IPO list is more commonly performed on an outpatient basis. CMS is defining “more commonly performed” as being done more than fifty percent of the time in the outpatient setting.

As with the 2-midnight presumption, CMS will maintain the ability to conduct medical reviews where there is evidence of systemic fraud or abuse. CMS emphasizes that the 2-midnight rule does not prohibit procedures from being performed and billed on an inpatient basis. Whether a procedure has an exemption or not, does not change that site-of-service must be medically necessary for an individual beneficiary. Providers are expected to bill in compliance with the 2-midnight rule. The exemption is not from the 2-midnight rule but from certain medical review procedures and certain site-of-service claim denials.

Deference to Physician Judgment

Commenters indicated that CMS’ logic suggests that the 2-midnight rule and site-of-service audits be eliminated altogether. If it is the physician who should determine the correct level of care based upon individual patient needs and comorbidities, deference should be provided to the physician’s judgment on selection of site-of-service. CMS responded that use of the 2-midnight benchmark gives appropriate consideration to the medical judgment of physicians and furthers the goal of clearly identifying when an inpatient admission is appropriate for payment under Medicare Part A.

Burden Issues

Some commenters expressed concern that the elimination of the IPO list along with the continued application of the 2-midnight rule would increase paperwork and administrative burden. Hospitals would be burdened with justifying selection of an inpatient setting when the procedure can only be performed inpatient. CMS responded that indefinitely exempting procedures removed from the IPO list will mitigate this concern. Nevertheless, CMS continues to expect providers and physicians to document the medical necessity of any inpatient admission.

CMS believes that the documentation requirements for admitting physicians are not overly burdensome because they are consistent with Medicare's longstanding documentation requirements, which predate the adoption of the 2-midnight rule.

Provider Education

Many commenters stated that CMS has an essential role to play in the education of stakeholders. Providing hospitals and clinicians with clear and consistent standards against which they can perform will alleviate some of the administrative and financial burden otherwise associated with selecting patient site-of-service. CMS responded that it plans to provide considerations for the selection of site-of-service for a procedure to support physicians' decision-making. These guidelines will be for informational or educational purposes only and will not be intended to prohibit payment of procedures that were previously included on the IPO list in the outpatient setting.

BFCC-QIO and RAC Workload

Numerous commenters were concerned about how the BFCC-QIOs and RACs would handle the rapid influx of procedures now subject to review. CMS responded that it will work with the BFCC-QIOs as appropriate to address any issues as they arise. The BFCC-QIOs will continue to review claims even while procedures are exempt from denial based on site-of-service in order to provide education for practitioners and providers regarding compliance with the 2-midnight rule.

Final Decision: Procedures removed from the IPO list on or after January 1, 2021 will be indefinitely exempted from site-of-service claim denials for noncompliance with the 2-midnight rule until the procedure is more commonly performed in the outpatient setting than the inpatient setting. This exemption will end once Medicare claims data indicates that procedure was performed more than 50 percent of the time in the outpatient setting in a single calendar year. CMS will revisit in rulemaking whether and when an exemption for a procedure is ended.

The indefinite exemption will only apply to procedures removed from the IPO list beginning in 2021. CMS may revisit procedures that were removed from the IPO list prior to January 1, 2021 and extend their exemption if necessary. Conversely, CMS may shorten the exemption period for a procedure if necessary.

Providers are still expected to bill in compliance with the 2-midnight rule. It is standard practice that the factors supporting the determination that inpatient care is required will be documented in the medical records. The BFCC-QIOs will still have the opportunity to review claims for exempt procedures in order to provide education for practitioners and providers regarding compliance with the 2-midnight rule, but claims identified as noncompliant will not be denied based on site-of-service under Medicare Part A until the procedure is no longer subject to the exemption. Additionally, CMS may still conduct medical review in cases in which there is evidence of systemic fraud or abuse occurring.

XI. OPPS Payment Status and Comment Indicators

OPPS Payment Status Indicator Definitions

For 2021, CMS did not propose any changes to status indicators. Status indicators and their definitions can be found in Addendum D1 of the final rule. Each status indicator will identify whether a given code is payable under the OPPS or another payment system, and also whether particular OPPS policies apply to the code. The 2021 payment status indicator assignments for APCs and HCPCS codes are shown in Addenda A and B respectively.

Comment Indicator Definitions

For 2021, CMS is continuing to use the following comment indicators that are unchanged from 2020:

“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 the 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 the 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 the 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 2021 are listed in Addendum D2 of the proposed rule.

XII. Medicare Payment Advisory Commission (MedPAC) Recommendations

OPPS Update: MedPAC recommended that Congress update Medicare OPPS payment rates in 2021 by 2 percent, with the difference between 2 percent and the update amount specified in current law to be used to increase payments in a new recommended Medicare quality program, the “Hospital Value Incentive Program.” CMS indicates that MedPAC’s recommended update would require a change in law. CMS is adopting an OPPS update of 2.4 percent in this final rule.

ASC Update: MedPAC indicates that payments to ASCs are adequate and recommended no payment update. CMS is adopting an ASC update of 2.4 percent in the final consistent with its approach for updating hospital inpatient and outpatient services.

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. In 2019, CMS began using the hospital market-basket in place of the CPI-U to update ASC rates for five years.

ASC Cost Data: MedPAC recommended that Congress require ASCs to report cost data to enable the Commission to examine ASCs’ costs relative to Medicare payments over time to evaluate 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 did not propose any cost reporting requirements for ASCs.

XIII. Ambulatory Surgical Center (ASC) Payment System

Summary of Selected Key Elements of ASC Payment Rates for 2021		
	ASCs reporting quality data	ASCs not reporting quality data
2020 ASC Conversion Factor	\$47.747	
Wage index budget neutrality adjustment	1.0012	
2021 Update		
Hospital market basket update	2.4%	
Multi-factor productivity adjustment (MFP)	0.0%	
Net MFP adjusted update	2.4%	
Penalty for not reporting quality data	0.0%	-2.0%
Net MFP and quality adjusted update	2.4%	0.4%
2021 Final ASC Conversion Factor	\$48.952	\$47.996

CMS estimates that under the final rule, total ASC Medicare payments for 2021 will be approximately \$5.42 billion, an increase of \$120 million over 2020 levels inclusive of changes in enrollment, utilization, and case mix changes.

As with the rest of the OPPS final rule and other CMS rules, addenda related to the ASC section (and referenced in this summary) are available only on the CMS website, at <https://edit.cms.gov/medicaremedicare-fee-service-paymentascpaymentasc-regulations-and-notices/cms-1736-fc>. All ASC Addenda to the final rule are contained in the zipped folders entitled Addendum AA, BB, DD1, and DD2.

A. Background

Under current regulations, 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 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 included “surgery-like” procedures outside the CPT surgical range that meet the criteria to be on the ASC list.

B. ASC Treatment of New and Revised Codes

CMS evaluates new codes for inclusion on the ASC list or as separately paid ancillary services and whether to pay them as office-based services. CMS sets out discussion for new codes in two categories:

- Codes previously identified during the year in the quarterly update process and on which it sought comment in the proposed rule; and
- New codes for which it seeks comments in this final rule with comment period.

Table 52 in the final rule (shown below) provides the process and timeline for ASC list updates:

Comment and Finalization Timeframes for New or Revised HCPCS Codes (from Table 52)				
ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 1, 2020	HCPCS (CPT and Level II codes)	April 1, 2020	2021 OPPS/ASC proposed rule	2021 OPPS/ASC final rule with comment period
July 2020	HCPCS (CPT and Level II codes)	July 1, 2020		
October 2020	HCPCS (CPT and Level II codes)	October 1, 2020	2021 OPPS/ASC final rule with comment period	2022 OPPS/ASC final rule with comment period
January 2021	CPT Codes	January 1, 2021	2021 OPPS/ASC proposed rule	2021 OPPS/ASC final rule with comment period
	Level II HCPCS Codes		2021 OPPS/ASC final rule with comment period	2022 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 2020 for Which CMS Solicited Public Comments in the Proposed Rule

CMS, in April and July of 2020 change requests (CRs), made effective 67 new Level II HCPCS codes and 2 new Category III CPT codes describing covered ASC services that were not included in the 2020 OPPS final rule. Tables 49-51 in the final rule (reproduced below) set out the codes, descriptors, and the 2021 payment indicators. CMS did not receive any public comments on the proposed ASC payment indicator assignments for the new Level II HCPCS codes implemented in April 2020. CMS finalizes the ASC payment indicators for these codes, as proposed. It notes that several of the temporary drug HCPCS C-codes have been replaced with permanent drug HCPCS J-codes, effective January 1, 2021.

New Level II HCPCS Codes for Ancillary Services Effective on April 1, 2020 (Table 49)			
2020 HCPCS Code	2021 HCPCS Code	Long Descriptor	Final 2021 Payment Indicator
C9053*	J0791	Injection, crizanlizumab-tmca, 1 mg	K2
C9056**	J0223	Injection, givosiran, 0.5 mg	K2
C9057#	J1201	Injection, cetirizine hydrochloride, 1 mg	K2
C9058###	Q5120	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo) 0.5 mg	K2
*HCPCS code C9053, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J0791 (Injection, crizanlizumab-tmca, 5 mg) effective July 1, 2020.			
**HCPCS code C9056, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J0223 (Injection, givosiran, 0.5 mg) effective July 1, 2020.			
#HCPCS code C9057, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J1201 (Injection, cetirizine hydrochloride, 0.5 mg) effective July 1, 2020.			
###HCPCS code C9058, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code Q5120 (Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg) effective July 1, 2020.			

New Level II HCPCS Codes for Covered Surgical Procedures and Ancillary Services Effective on July 1, 2020 (Table 50)			
2020 HCPCS Code	2021 HCPCS Code	2020 Long Descriptor	Final 2020 PI
C1748	C1748	Endoscope, single-use (that is, disposable), upper GI,imaging/illumination device (insertable)	J7
C1849	C1849	Skin substitute, synthetic, resorbable, per square centimeter	N1
C9059	J1738	Injection, meloxicam, 1 mg	K2
C9061	J3241	Injection, teprotumumab-trbw, 10 mg	K2
C9063	J3032	Injection, eptinezumab-jjmr, 1 mg	K2
C9122	C9122	Mometasone furoate sinus implant, 10 micrograms (Sinuva)	K2
C9759	C9759	Transcatheter intraoperative blood vessel microinfusion(s)	N1
C9762	C9762	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with strain imaging	Z2

New Level II HCPCS Codes for Covered Surgical Procedures and Ancillary Services Effective on July 1, 2020 (Table 50)			
2020 HCPCS Code	2021 HCPCS Code	2020 Long Descriptor	Final 2020 PI
C9763	C9763	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with stress imaging	Z2
C9764	C9764	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed	G2
C9765	C9765	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed	J8
C9766	C9766	Revascularization, endovascular, open or percutaneous, any vessel (s); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed	G2
C9767	C9767	Revascularization, endovascular, open or percutaneous, any vessel (s); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel (s), when performed	J8
G2170*	G2170*	Percutaneous arteriovenous fistula creation (AVF), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow	J8
G2171**	G2171**	Percutaneous arteriovenous fistula creation (AVF), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures and fistulogram(s), angiography, enography, and/or ultrasound, with radiologic supervision and interpretation,	J8
J0223	J0223	Injection, givosiran, 0.5 mg	K2
J0691	J0691	Injection, lefamulin, 1 mg	K2
J0742	J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	K2
J0791	J0791	Injection, crizanlizumab-tmca, 5 mg	K2
J0896	J0896	Injection, luspatercept-aamt, 0.25 mg	K2
J1201	J1201	Injection, cetirizine hydrochloride, 0.5 mg	K2
J1429	J1429	Injection, golodirsen, 10 mg	K2
J1558	J1558	Injection, immune globulin (Xembify), 100 mg	K2
J7169	J7169	Injection, coagulation factor Xa (recombinant), inactivated-zhzo (Andexxa), 10 mg	K2
J7204	J7204	Injection, factor VIII, antihemophilic factor (recombinant), (esperoct), glycopegylated-exei, per iu	K2

New Level II HCPCS Codes for Covered Surgical Procedures and Ancillary Services Effective on July 1, 2020 (Table 50)			
2020 HCPCS Code	2021 HCPCS Code	2020 Long Descriptor	Final 2020 PI
J7333	J7333	Hyaluronan or derivative, visco-3, for intraarticular injection, per dose	N1
J9177	J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	K2
J9198	J9198	Gemcitabine hydrochloride, (Infugem), 100 mg	K2
J9246	J9246	Injection, melphalan (evomela), 1 mg	K2
J9358	J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	K2
Q4227# - Q4248#	Q4227# - Q4248#	Human cell, tissue, or cellular or tissue-based product. Combined here for brevity but listed separately in Table 50 in final rule. All have same comment and payment indicators.	N1
Q5119	Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg	K2
Q5120	Q5120	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg	K2
0594T	0594T	Osteotomy, humerus, with insertion of an externally controlled intramedullary lengthening device, including intraoperative imaging, initial and subsequent alignment assessments, computations of adjustment schedules, and management of the intramedullary lengthening device	J8
0596T	0596T	Temporary female intraurethral valve-pump (i.e., voiding prosthesis); initial insertion, including urethral measurement	R2
0597T	0597T	Temporary female intraurethral valve-pump (i.e., voiding prosthesis); replacement	R2
0600T	0600T	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous	J8
0601T	0601T	Ablation, irreversible electroporation; 1 or more tumors, including fluoroscopic and ultrasound guidance, when performed, open	J8
0614T	0614T	Removal and replacement of substernal implantable defibrillator pulse generator	J8
0616T	0616T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens	J8
0617T	0617T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with removal of crystalline lens and insertion of intraocular lens	J8
0618T	0618T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens	J8

New Level II HCPCS Codes for Covered Surgical Procedures and Ancillary Services Effective on July 1, 2020 (Table 50)			
2020 HCPCS Code	2021 HCPCS Code	2020 Long Descriptor	Final 2020 PI
		placement or intraocular lens exchange	
0619T	0619T	Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed	J8
<p>*HCPCS code C9754, which was effective January 1, 2019, was deleted June 30, 2020 and replaced with HCPCS code G2170 effective July 1, 2020. **HCPCS code C9755, which was effective January 1, 2019, was deleted June 30, 2020 and replaced with HCPCS code G2171 effective July 1, 2020. #HCPCS codes Q4227 through Q4248: The availability of an HCPCS code for a particular human cell, tissue, or cellular or tissue-based product (HCT/P) does not mean that that product is appropriately regulated solely under section 361 of the PHS Act and the FDA regulations in 21 CFR Part 1271.</p>			

New Category III CPT Code for Covered Ancillary Service Effective on July 1, 2020 (Table 51)			
2020 HCPCS Code	2021 HCPCS Code	CY 2020 Long Descriptor	2021 PI
0598T	0598T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (for example, lower extremity)	Z2
0599T	0599T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; each additional anatomic site (for example, upper extremity) (List separately in addition to code for primary procedure)	N1

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, 2020 and January 1, 2021 for Which CMS is Soliciting Public Comments in this Final Rule with Comment Period.

CMS continues to assign comment indicator “NI” in Addendum BB to the 2021 OPSS/ASC final rule for those new and revised Level II HCPCS codes that are effective October 1, 2020. This indicates that CMS has assigned the codes an interim OPSS payment status for 2021. CMS invites comments in this final rule with comment period on the interim payment indicators which CMS intends to finalize in the 2022 OPSS/ASC final rule with comment period.

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

CMS sought comment on proposed new and revised CPT codes effective January 1, 2021 that were received in time to be included in the proposed rule. Commenters addressed several of the new CPT codes that were assigned to comment indicator “NP” in Addendum B to the 2021 OPPTS/ASC proposed rule. CMS responded to those public comments in sections III.C. (New Technology APCs), III.D. (OPPTSAPC-Specific Policies), and IV. (OPPTS Payment for Devices) of this CY 2021 OPPTS/ASC final rule with comment period.

For the 2021 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.

CMS notes that it inadvertently omitted four new HCPCS codes, specifically, CPT codes 0627T, 0628T, 0629T, and 0630T, effective January 1, 2021 from Addendum AA of the 2021 OPPTS/ASC proposed rule. These codes have a comment indicator of “NI” and CMS invites public comment on the ASC payment indicators, which will be finalized in the 2022 OPPTS/ASC final rule with comment period.

C. Update to ASC Covered Surgical Procedures and Covered Ancillary Services Lists

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.

CMS finalizes its proposal, with modifications, to designate the procedures shown in Table 57 in the final rule (reproduced below) as temporarily office-based for 2021. Based on comments received and its own analysis, CMS removed the temporary office-based designation for CPT code 64624 and is finalizing a payment indicator of “G2” (Non office-based surgical procedure) instead. It found that this procedure was performed 23.9 percent of the time in an office setting, significantly less than the 50 percent threshold for a permanent office-based designation.

ASC Covered Surgical Procedures to be Designated as Temporarily Office-Based for 2021 (Table 57)		
2021 CPT/HCPCS Code	2021 Long Descriptor	2021 ASC Payment Indicator**
0402T	Collagen cross-linking of cornea, including removal of the corneal epithelium and intraoperative pachymetry, when performed (report medication separately)	R2**
0512T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	R2**

0551T	Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume	R2**
0566T	Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; injection of cellular implant into knee joint including ultrasound guidance, unilateral	R2**
0588T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve	R2**
0596T	Temporary female intraurethral valve-pump (i.e., voiding prosthesis); initial insertion, including urethral measurement	R2**
0597T	Temporary female intraurethral valve-pump (i.e., voiding prosthesis); replacement	R2**
64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed	P3**
65785	Implantation of intrastromal corneal ring segments	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 (e.g., retinopathy of prematurity), photocoagulation or cryotherapy	R2**
93985	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study	P2**
93986	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study	P2**

** Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the PFS final rates.

CMS also finalizes its proposal, without modifications, to designate the procedures shown in Table 58 in the final rule (reproduced below) as permanently office-based beginning 2021.

TABLE 58: ASC COVERED SURGICAL PROCEDURES TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2021

ASC Covered Surgical Procedures to be Newly Designated as Permanently Office-Based for 2021 (Table 58)		
2021 CPT/HCPCS Code	2021 Long Descriptor	2021 ASC Payment Indicator**
10007	Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion	P3**
10011	Fine needle aspiration biopsy, including mr guidance; first lesion	R2**

11102	Tangential biopsy of skin (e.g., shave, scoop, saucerize, curette); single lesion	P3**
11104	Punch biopsy of skin (including simple closure, when performed); single lesion	P3**
11106	Incisional biopsy of skin (e.g., wedge) (including simple closure, when performed); single lesion	P3**
11760	Repair of nail bed	P3**
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)	P3**
23077	Radical resection of tumor (e.g., sarcoma), soft tissue of shoulder area; less than 5 cm	R2**
44408	Colonoscopy through stoma; with decompression (for pathologic distention) (e.g., volvulus, megacolon), including placement of decompression tube, when performed	R2**
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy	P2**
67500	Retrobulbar injection; medication (separate procedure, does not include supply of medication)	P3**

** Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the PFS final rates.

Comment Solicitation on Office-Based Exemption for Dialysis Vascular Access Procedures

In the proposed rule, CMS discussed the office-based designation of two dialysis vascular access procedures: CPT codes 36902 and 36905 that first became effective in 2017. In 2019 and 2020, CMS believed it was premature to designate these codes with an office-based payment status based on the utilization data as the percentage of services being provided in the office was trending downward. In 2021, CMS' review of 2019 claims data indicates that office-based utilization is below 50 percent for both codes. Thus, CMS did not propose to designate CPT codes 36902 and 36905 as office-based procedures for 2021.

In the proposed rule, CMS discussed whether dialysis vascular access procedures should be permanently exempt from office-based designations similar to its exemption for radiology services that involve certain nuclear medicine procedures and radiology services that involve contrast agents. Commenters in the past had contended that an office-based designation for dialysis vascular access procedures (in particular CPT codes 36902 and 36905) would result in a lower ASC payment rate if frequently used additional services, which are often packaged under the ASC payment system but separately payable under the PFS, are factored in to the analysis. Commenters also contended that paying for these services based on the PFS could reduce beneficiary access and inadvertently encourage migration of these services to a more expensive hospital outpatient department setting.

Based on its comment solicitation, CMS received mixed perspectives on whether a permanent exemption was appropriate. CMS agrees with those commenters that such an exemption is not necessary at this time, but it may consider this issue for future rulemaking.

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 OPSS 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 OPSS 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 OPSS/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. CMS continues its policy to update the ASC list of covered surgical procedures that are eligible for payment according to the device-intensive payment methodology for 2021, reflecting the individual HCPCS code device offset percentages based on 2019 OPSS 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 notes that it inadvertently omitted language that its policy for partial credits would apply not just in 2019 (when finalized) but also in subsequent years. Specifically, for 2021 and subsequent calendar years, CMS finalizes continuing its existing policies that reduces the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device.

Additions to the List of ASC Covered Surgical Procedures

For 2021, CMS finalizes its proposal to add eleven procedures to the ASC covered procedures list (CPL) based on its standard review process under its current regulations. This includes total hip arthroplasty (THA), vaginal colpopexy, transcervical uterine fibroid ablation, and intravascular lithotripsy procedures, among others. CMS agrees with commenters who stated that advancements in clinical practice, less invasive techniques, patient selection, improved perioperative anesthesia, alternative postoperative pain management and expedited rehabilitation protocols have allowed these procedures to safely be performed in an ASC setting.

These surgical procedures are listed in Table 59 in the final rule (reproduced below).

Table 59- Final Additions to the List of ASC Covered Surgical Procedures for 2021 Under Standard Review Process		
2021 CPT/ HCPCS Code	2021 Long Descriptor	Final 2021 ASC Payment Indicator
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	J8
0268T	Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	J8
0404T	Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency	G2
21365	Open treatment of complicated (e.g., comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with internal fixation and multiple surgical approaches	G2
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft	J8
27412	Autologous chondrocyte implantation, knee	G2
57282	Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus)	G2
57283	Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy)	G2
57425	Laparoscopy, surgical, colpopexy (suspension of vaginal apex)	G2
C9764	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed	G2

Table 59- Final Additions to the List of ASC Covered Surgical Procedures for 2021 Under Standard Review Process		
2021 CPT/ HCPCS Code	2021 Long Descriptor	Final 2021 ASC Payment Indicator
C9766	Revascularization, endovascular, open or percutaneous, any vessel (s); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed	G2

In addition, CMS included two alternative proposals in the 2021 proposed rule. One alternative is to establish a nomination process for 2021, which would allow CMS to propose additional nominated procedures beginning in 2022. Under this proposal, external stakeholders, such as professional specialty societies, would nominate procedures that can be safely performed in the ASC setting based on the requirements in the ASC regulations along with suggested parameters and all other regulatory standards. CMS would review and finalize procedures through annual rulemaking.

Alternatively, CMS proposed to revise the ASC-CPL criteria under 42 CFR 416.166, retaining the general standard criteria and eliminating five of the general exclusion criteria. Using these revised criteria, CMS proposed to add approximately 267 potential surgery or surgery-like codes to the CPL that are not on the 2020 IPO list. It proposed to finalize only one of these alternative proposals and welcomed public comment as to which policy it should adopt in the final rule. CMS also sought comments on potential revisions to the ASC Conditions for Coverage (CfC) if Alternative 2 is adopted.

After consideration of comments, CMS finalizes its proposal, with modifications, that revises the ASC-CPL criteria under §416.166 by eliminating the general standards specified in §416.166(b) and the general exclusion criteria in §416.166(c)(1) through (c)(5). CMS' initial proposal had retained the general standards specified in §416.166(b) that required that a covered procedure not pose a significant safety risk when performed in an ASC and that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. CMS also eliminated the general exclusion criteria that excluded covered surgical procedures that generally result in extensive blood loss, are generally emergent or life-threatening in nature, among others. These seven criteria/requirements will now be physician considerations in §416.166(d). CMS did not adopt its other alternative approach that would have established a nomination process for 2021, which would have allowed CMS to propose additional nominated procedures beginning in 2022.

Under its finalized policy, a surgical procedure need only to meet the four requirements at revised §416.166(b) to be designated as a covered surgical procedure and placed on the ASC CPL. CMS will add 267 procedures to the ASC CPL, based upon these changes to its regulatory criteria. It states that it recognizes that physicians may consider certain safety factors when determining the most appropriate site of care for a specific patient (included in §416.166(d)). Finally, CMS adds new §416.166(e), which describes how CMS will add a surgical procedure to the ASC CPL, either on its own initiative or based on a notification from the public that a procedure not currently on the ASC CPL meets the criteria for addition to the ASC CPL. Table

60 in the final rule shows the final additions to the ASC CPL based on this approach.

Analysis of Comments

Adding the eleven procedures to the ASC CPL under the established process. Multiple commenters supported the eleven procedures CMS proposed to add to the ASC CPL based on the established process. Commenters stated that orthopedic surgeons in ASCs are increasingly performing these eleven procedures safely and effectively on non-Medicare-fee-for-service patients and appropriate Medicare patients. CMS received significant support for the addition of total hip arthroplasty (THA) and autologous chondrocyte knee implementation citing advancements in clinical practice, less invasive techniques patient selection, among others. Other commenters opposed the addition of THA due to the risk of jeopardizing patient safety as well as expanded beneficiary obligations; suggested that CMS inform in advance that, unlike under the OPPI, ASC cost sharing is not capped at the inpatient deductible and could exceed cost sharing in the hospital outpatient setting for the same procedure.

CMS states that based on its review of the clinical characteristics of the procedures and their similarity to other procedures that are currently included on the ASC CPL, it believes these eleven procedures can be safely performed in the ASC setting and notes that the physician should determine whether a particular beneficiary would be a good candidate to undergo a procedure in the ASC setting rather than the hospital setting based on the clinical assessment of the patient. It also acknowledges that beneficiaries may incur greater cost-sharing for THA procedures in an ASC setting under its proposal, but notes that this is not an occurrence that is unique to THA. CMS refers to its Outpatient Procedure Price Lookup tool available via the internet at <https://www.medicare.gov/procedure-price-lookup> as a resource that beneficiaries can use; this tool provides an estimated payment amount for the item or service under the OPPI and the ASC payment system and the estimated beneficiary liability. For these reasons, CMS does not believe a delay in the implementation of its proposed additions to the ASC CPL is warranted based on concerns relating to beneficiary safety or the potential for greater cost sharing expenses for beneficiaries.

Alternative Process to Revise Criteria and Add Codes to the ASC-CPL

Most commenters expressed concerns that the alternative proposal to revise the general exclusion criteria at 42 CFR 416.166(c) and add 267 potential surgery or surgery-like procedures that are not on the current IPO list to the ASC-CPL list would not give adequate consideration to patient safety or stakeholder input. Commenters pointed out that ASCs are not generally equipped to handle extensive blood loss or emergent and life-threatening procedures, the time waiting for emergency transport to a hospital would potentially place beneficiary life in jeopardy, and that these risks may occur even if a physician believes that the individual beneficiary's clinical condition would allow these procedures to be performed in an ASC. Other commenters supported this approach believing that medical research and technological advances have allowed for similar outcomes and a comparable quality of care for patients in both the outpatient hospital and ASC settings.

In its reply, CMS believes it is no longer necessary to apply these five exclusionary criteria because ASCs are currently and increasingly able to safely provide services with these characteristics. It also believes that it is important to adapt the ASC CPL to reflect the significant advances in medical practice, surgical techniques, and ASC capabilities. Further, it believes that it is important to support greater flexibility for physicians and patients to choose ASCs as the site of care. CMS still considers those five criteria important and will continue to include them in its regulations as “considerations” rather than requirements. It will be under a new paragraph (d) titled “Physician considerations beginning January 1, 2021,” at §416.166(d) for physicians to consider in selecting the most appropriate site of service for their patients. CMS places the burden on physicians to exercise their clinical judgement for each specific patient to assess whether a covered surgical procedure can be safely performed in the ASC setting. CMS also eliminates the general standards specified in §416.166(b) that required that a covered procedure not pose a significant safety risk when performed in an ASC and that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. This exclusion was not part of CMS’ original proposal. For all of the reasons above, CMS believes that physicians are better-positioned than CMS to determine that a surgical procedure is not expected to pose a significant safety risk. CMS states it is shifting the responsibility for these two considerations from CMS to physicians, as now reflected in §416.166(d)(1) and (2).

Alternative Proposal to Create a Nomination Process.

The majority of commenters supported the alternative proposal to establish a process for the public to nominate procedures for addition to the ASC CPL. These commenters generally supported this proposal because they believed it would better address beneficiary safety concerns than the alternative proposal to remove the general exclusion criteria at §416.166(c)(1) through (5). Several commenters noted that this alternative proposal would formalize the review process that occurs currently, provide transparency, and increase opportunity for engagement with providers and external stakeholders. CMS does not adopt this alternative proposal. It states that it does not believe that a full nomination process is necessary as CMS will now be applying only the four criteria listed in new §416.166(b)(2) to determine whether a surgical procedure is a covered surgical procedure. CMS states that it will add surgical procedures to the ASC CPL as it becomes aware of new surgical procedures that meet the four requirements, and that the public may also notify CMS of a surgical procedure at any time they believe it meets those criteria. CMS notes that the process it is finalizing is not a nomination process so much as a notification process, which it adds in its regulations at §416.166(e).

ASC Conditions for Coverage (CfC)

CMS received a few comments that specifically addressed CMS request for comments on whether it needed to expand the existing CfCs. CMS states in keeping with its efforts to reduce provider burden as well as prioritizing patient choice and physician judgement in determining the most appropriate site of service for a beneficiary, CMS declines to modify the ASC CfCs at this time. It states that it might revisit modifying these in the future should the need arise.

Comparison of Current Approach to Finalized Proposal

The table below summarizes the finalized proposal relative to the current approach and provides details on the criteria for inclusion on ASC-CPL list, the process, timeframe for implementation and additions to the list.

Changes to Approach Used to Update the List of ASC Covered Surgical Procedures for 2021

	Current Process	New Process: Revises Regulatory Criteria that Expands List of ASC Covered Surgical Procedure
Criteria for inclusion on list	<p>1. Meets general standards specified in 42 CFR 416.166 (b): Surgical procedures specified by Secretary and published in the Federal Register and/or via the Internet on the CMS website that are separately paid under OPPTS.</p> <ul style="list-style-type: none"> a. Not expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC b. Beneficiary would not typically expect to require active medical monitoring and care at midnight following the procedure <p>2. Follows the general exclusion criteria set out in 42 CFR 416.166(c): ASC covered surgical procedures do not include surgical procedures that : (1) generally result in extensive blood loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; (4) are generally emergent or life threatening in nature; (5) commonly require systemic thrombolytic therapy; (6) are designated as requiring inpatient care under 42 CFR 419.22(n); (7) can only be reported using a CPT unlisted surgical procedure code; or (8) are otherwise excluded under 42 CFR 411.15.</p>	<p>1. Eliminates the general standards specified in 42 CFR 416.166(b) and the general exclusion criteria in 42 CFR 416.166(c)(1) through (c)(5). These will now be physician considerations in §416.166(d).</p> <p>2. Effective for services furnished on or after January 1, 2021, covered surgical procedures are surgical procedures that are (1) separately paid under the OPPTS, and are NOT (2) designated as requiring inpatient care under §419.22(n) of this subchapter as of December 31, 2020; (3) only able to be reported using a CPT unlisted surgical procedure code; or (4) otherwise excluded under §411.15 of this chapter.</p>
Process	<p>CMS conducts an annual review of the HCPCS codes currently paid under the OPPTS, but not included on the ASC-CPL, and that meet the definition of surgery to determine its appropriateness for the ASC setting.</p>	<p>CMS can add surgical procedures to the ASC CPL either on its own initiative or based on a notification from the public that a procedure not currently on the ASC CPL meets the criteria for addition.</p>

	Current Process	New Process: Revises Regulatory Criteria that Expands List of ASC Covered Surgical Procedure
	<p>Reviews whether potential additions meet the general standards and general exclusion criteria.</p> <p>Publishes these potential additions in OPPS proposed rule for comment</p>	
Timeframe for implementation	No longer applicable	Begins January 1, 2021
Additions to the ASC-CPL	Adds eleven procedures (displayed in Table 59 in the final rule) based on the last year of its current process. Includes THA, vaginal colpopexy, transcervical uterine fibroid ablation, and intravascular lithotripsy procedures, among others.	Identified 267 potential surgery or surgery-like codes that CMS states meet its revised criteria. See Table 60 in the final rule for list of codes and payment indicators.

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

ASC Payment for Covered Surgical Procedures

CMS continues its policy to update payments for office-based procedures and device-intensive procedures using its established methodology and 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 2021 PFS non-facility practice expense payment amount, or the 2021 ASC payment amount. CMS continues its policy for device removal procedures – such procedures that are conditionally packaged in the OPPS would be assigned the current ASC payment indicators and continue to be paid separately under the ASC payment system.

Limit on ASC Payment for Low Volume Device-Intensive Procedures

Data anomalies for low-volume procedures can result in inappropriate payment rates using the standard ASC methodology for rate-setting. CMS continues its policy proposed in 2020 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. Based on their review of 2019 claims data, CMS did not find any low volume device-intensive procedures that would exceed the rate paid under the OPPS for the same procedure. CMS did find a single claim for CPT code 0308T, a low volume device-intensive procedure that was not able to be used in the rate setting process as it was packaged into a comprehensive APC. CMS finalizes its proposal to continue to use the 2020 final rule device offset percentage of 90.18 percent for CPT code 0308T in CY 2021.

Payment for Covered Ancillary Services

CMS notes that this section was inadvertently omitted from the 2021 OPPS/ASC Proposed Rule. It is not making any changes to prior year policies for how it determines payment for covered ancillary services.

Packaging Policy for Non-Opioid Pain Management Treatments

CMS continues to update payments and make changes necessary to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services. 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 has done extensive reviews of this topic and has come to the conclusion that CMS's packaging policies are not discouraging the use of non-opioid alternatives or impeding access to these products, with the exception of Exparel, the only non-opioid pain management drug that functions as a surgical supply in the ASC setting. Thus, CMS continues its policy to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for 2021.

In addition to Exparel, CMS will pay separately for Omidria in the ASC setting under this policy. Omidria is indicated for maintaining pupil size by preventing intraoperative miosis and reducing postoperative ocular pain in cataract or intraocular surgeries. While CMS was unconvinced that Omidria reduces use of fentanyl in cataract surgery, the rule states that it qualified as a non-opioid pain management drug that functions as a surgical supply when furnished in an ASC setting that is excluded from packaging.

E. New Technology Intraocular Lenses (NTIOL)

CMS did not receive any requests for review to establish a new NTIOL class for 2021 by the annual deadline (announced in the final rule). 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 proposed to continue using the current comment indicators “NP” and “CH.” Category I and III CPT codes that are new and revised for 2021 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 2021 proposed rule. For the 2021 update, CMS also proposed to add ASC payment indicator “K5” – Items, Codes, and Services for which pricing information and claims data are not available. CMS finalizes the proposed ASC payment and comments indicators without modification.

Addenda DD1 and DD2 provide a complete list of the ASC payment and comment indicators for 2021.

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

CMS continues to update ASC 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 2020 relative payment rates, to
- Total payments using the 2021 relative payment rates.

The resulting ratio, 0.8591, is the weight scaler for 2021. 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 2019 and the 2021 national payment rates after application of the weight scaler, CMS computes the ratio of:

- ASC payments using the 2020 ASC wage indices, to
- ASC payments using the 2021 ASC wage indices.

The resulting ratio, 1.0012, is the wage index budget neutrality adjustment to the conversion factor for 2021.

To update ASC rates, CMS would utilize the hospital market basket update of 2.4 percent (as published in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58796-7)) minus the MFP factor of 0.0 percent. This yields an update of 2.4 percent for ASCs meeting quality reporting requirements.

CMS continue its policy of reducing the update by 2.0 percentage points for ASCs not meeting the quality reporting requirements, yielding an update of 0.4 percent for such ASCs. The resulting 2021 ASC conversion factor is \$48.952 for ASCs reporting quality data, and \$47.996 for those that do not, computed as follows:

	ASCs reporting quality data	ASCs not reporting quality data
2020 ASC conversion factor	\$47.747	
Wage adjustment for budget neutrality	1.0012	
Net MFP-adjusted update	<u>x 1.024</u>	<u>x 1.004</u>
2021 ASC conversion factor	\$48.952	\$47.996

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 2019 claims data. (Table 80 of the final 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 for 2021. The second largest group, nervous system, is also estimated to see a 2 percent increase.

Table 80 – Estimated Impact of the 2021 Update to the ASC Payment System on Aggregate 2021 Medicare Program Payments by Surgical Specialty or Ancillary Items and Services Group		
Surgical Specialty Group	Estimated 2020 ASC Payments (in Millions)	Estimated 2021 Percent Change
Total	\$5,455	2%
Eye and ocular adnexa	\$1,815	3%
Nervous system	\$1,180	2%
Digestive system	\$909	4%
Musculoskeletal system	\$695	4%
Cardiovascular system	\$274	2%
Genitourinary system	\$201	5%

CMS provides estimated increases for 30 selected procedures in Table 81 in the final rule; the top 10 procedures are replicated below. CPT code 66984 (Extracapsular cataract removal with insertion of intraocular lens, 1 stage) is the largest aggregate payment procedure by far and is estimated to have a 3 percent increase in payment. The second largest aggregate payment procedures, CPT code 63685, is expected to see a 2 percent increase.

Excerpt from Table 81: Estimated Impact of the 2021 Update to the ASC Payment System on Aggregate Payments for the Top 10 Procedures			
CPT/ HCPS Code	Short Descriptor	Estimated 2020 ASC Payments (in Millions)	Estimated 2021 Percent Change
66984	Extracapsular cataract removal with insertion of intraocular lens, 1 stage	\$1,228	3%
63685	Insert/redo spine n generator	\$285	2%
45380	Colonoscopy and biopsy	\$240	4%
63650	Implant neuroelectrodes	\$186	-1%
43239	Egd biopsy single/multiple	\$180	4%
45385	Colonoscopy w/lesion removal	\$178	4%
0191T	Insert ant segment drain int	\$121	4%
64483	Inj foramen epidural l/s	\$118	2%
66982	Cataract surgery complex	\$90	3%
64635	Destroy lumb/sac facet jnt	\$85	1%

As noted at the beginning of this ASC section, Addenda tables available only on the website provide additional details; they are at <https://edit.cms.gov/medicaremedicare-fee-service-paymentascpaymentasc-regulations-and-notice/cms-1736-fc>. They include:

- AA – ASC Covered Surgical Procedures for 2021 (Including surgical procedures for which payment is packaged)
- BB – ASC Covered Ancillary Services Integral to Covered Surgical Procedures for 2021 (Including Ancillary Services for Which Payment is Packaged)
- DD1 – ASC Payment Indicators for 2021

- DD2 – ASC Comment Indicators for 2021
- EE – Surgical Procedures to be Excluded from Payment in ASCs for 2021

XIV. Hospital Outpatient Quality Reporting (OQR) Program

For the OQR Program, CMS updates the regulatory text to codify previously adopted policies, aligns deadlines for data submission and reconsideration applications to be consistent with federal law, and expands the review and corrections policy to apply to measures submitted via a web-based tool. No changes are made to the OQR Program measures, priorities for measure selection, retention and removal of measures, public display of measures, QualityNet account requirements, data submission requirements, data validation, extraordinary circumstances exceptions, or reconsiderations and appeals. A table at the end of this section shows the OQR Program measures previously adopted for payment determination in 2020 through 2023.

A. Codifications and Updates to Regulatory Text

CMS finalizes several changes to regulatory text regarding the OQR Program (42 CFR 419.46) to codify or update existing policies.

- A reference to the statutory authority for the OQR Program is added at a new §419.46(a). Table 61 in the final rule shows how cross references are modified as a result of this change and associated redesignations.
- The previously adopted policy that hospitals sharing the same CMS Certification Number must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes is codified at redesignated §419.46(d)(1).
- The term “security administrator” is replaced with “security official” to identify the individual responsible for security and management of the hospital’s QualityNet account, in newly redesignated §419.46(b)(2).
- Text regarding withdrawal from the OQR Program at redesignated §419.46(c) is modified to reflect previously adopted policy with respect to a hospital electing to participate in a future year of the OQR Program. References to a new participation form are removed; these hospitals must renew participation as specified in redesignated §419.46(b).
- The review and corrections policy is codified at a new §419.46(d) to reflect the expansion to include web-based measures discussed below. It states that for both chart-abstracted and web-based measures hospitals have a review and corrections period which runs concurrently with the data submission period. During this timeframe, hospitals can enter, review, and correct data submitted. After the submission deadline, these data cannot be changed.
- The existing educational review process associated with data validation is codified at a new §419.46(f) (§4). It states that hospitals selected for validation of chart-abstracted measures that receive a validation score may request an educational review within 30 days from the date the results are made available. If the educational review results indicate that a hospital’s medical records selected for validation were incorrectly scored, the corrected quarterly validation score will be used to compute the hospital’s final validation score at the end of the calendar year.

B. Alignment of Deadlines

The final rule aligns previously adopted data submission deadline policies at redesignated §419.46(d)(3) with statutory requirements.¹⁶ Specifically, all deadlines occurring on a Saturday, Sunday, legal holiday or other day for which all or part is declared by law or Executive Order to be a nonwork day for federal employees will be extended to the first day thereafter which is not such a weekend, holiday or nonwork day. Data submission deadlines for the 2023 payment determination, which occur during 2021, are shown in Table 63 of the proposed rule.

Similarly, the deadline for reconsideration at redesignated §419.46(g)(1) is modified to eliminate the reference to the “first business day on or after” and to state that the hospital must submit the reconsideration request no later than March 17, or, if March 17 falls on a non-work day, the first non-work day after March 17.

C. Expansion of Review and Corrections Period to Include Web-Based Measures

The existing review and corrections policy is expanded to apply to measures submitted via a web-based tool as well as chart-abstracted measures. Under the policy, a 4-month review and corrections period runs concurrently with the data submission period. That is, the review and corrections period begins at the time the submission period opens and ends on the submission deadline. During that time, a hospital can enter, review, and correct data submitted to CMS.

D. Summary Table of OQR Program Measures

The table below shows the previously finalized OQR Program measure sets for payment determination in 2020 through 2023. Specifications for OQR Program measures are available on the QualityNet website: <https://www.qualitynet.org/outpatient/oqr>. No changes to the measure set are made in this rule.

**SUMMARY TABLE OF HOSPITAL OQR PROGRAM MEASURES
Payment Determination for 2020-2023**

NQF		2020	2021	2022	2023
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED arrival	X	X	X	X
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention	X	X	X	X
0289 ⁺	OP-5: Median Time to ECG	X	Removed		
0514 ⁺	OP-8: MRI Lumbar Spine for Low Back Pain	X	X	X	X
	OP-9: Mammography Follow-up Rates	X	Removed		
	OP-10: Abdomen CT – Use of Contrast Material	X	X	X	X
0513	OP-11: Thorax CT – Use of Contrast Material	X	Removed		

¹⁶ Section 1872 of the Act incorporates for Medicare the definition in section 216(j) of the Act for “Periods of Limitation Ending on Nonwork Days.”

NQF		2020	2021	2022	2023
	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	Removed		
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery	X	X	X	X
	OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)	X	Removed		
0491+	OP-17: Tracking Clinical Results between Visits	X	Removed		
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients	X	X	X	X
0499+	OP-22: ED- Left Without Being Seen	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
0658	OP-29: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients	X	X	X	X
0659	OP-30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use	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
1822	OP-33: External Beam Radiotherapy for Bone Metastases	X	X	Removed	
	OP-35: Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	X	X	X	X
2687	OP-36: Hospital Visits After Hospital Outpatient Surgery	X	X	X	X
	OP-37 Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS-CAHPS) - 5 measures*	Delayed			

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

*Mandatory reporting on a set of OAS CAHPS measures, once scheduled to begin in 2018 for the 2020 payment determination, was indefinitely delayed (82 FR 59432). The measures are OP-37a: OAS CAHPS – About Facilities and Staff; OP-37b: OAS CAHPS – Communication About Procedure; OP-37c: OAS CAHPS – Preparation for Discharge and Recovery; OP-37d: OAS CAHPS – Overall Rating of Facility; and OP-37e: OAS CAHPS – Recommendation of Facility. CMS implemented a voluntary national reporting program for the OAS CAHPS Survey in January 2016. More information is available at <https://oascahps.org/General-Information/National-Implementation>

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

Existing policies with respect to computing and applying the 2.0 percentage point updated factor reduction for hospitals that fail to meet the Hospital OQR Program requirements are continued for the 2021 update factor. The final rule reduction ratio for hospitals that fail to meet OQR Program requirements, called the “reporting ratio”, is 0.9805. CMS states that it is calculated by dividing the reduced conversion factor of \$81.183 by the full conversion factor of \$82.797.

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

The reporting ratio is 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 2020 payment, 78 hospitals (out of 3,144) failed to meet the OQR Program requirements for a full update factor.

XV. Ambulatory Surgical Center Quality Reporting (ASCQR) Program

CMS makes several updates and additions to the regulatory text for the ASCQR Program. No changes are made to program measures, priorities for measure selection, retention and removal of measures, public display of measures, QualityNet account and security administrator requirements, data submission requirements, extraordinary circumstances exceptions, or reconsiderations and appeals. A table at the end of this section shows the previously adopted ASCQR Program measures for the 2020 through 2024 payment determinations.

A. Updates to Regulatory Text

- The term “security administrator” is replaced with “security official” to identify the individual responsible for security and management of the hospital’s QualityNet account at §416.310(c)(1)(i).
- The term “data collection time period” is replaced by “data collection period” everywhere it appears in §416.310(a) through (c). The terms are currently used interchangeably.

B. Alignment of Deadlines

The previously adopted data submission deadline policies at §416.310 are aligned with statutory requirements regarding deadlines falling on a nonwork day.¹⁷ Specifically, a new 416.310(f) is added to indicate that all deadlines occurring on a Saturday, Sunday, legal holiday or other day for which all or part is declared by law or Executive Order to be a nonwork day for federal employees are extended to the first day thereafter which is not such a weekend, holiday or nonwork day. Data submission deadlines are available at: <https://www.qualitynet.org/asc/data-submission#tab2>.

¹⁷ Section 1872 of the Act incorporates for Medicare the definition in section 216(j) of the Act for “Periods of Limitation Ending on Nonwork Days.”

C. Creation of Review and Corrections Period

Under the ASCQR Program, measures submitted via a CMS online data submission tool may be submitted from January 1 through May 15 of the calendar year subsequent to the data collection period. ASCs are encouraged to submit data early in the period so they can identify errors and resubmit data before the deadline.

In this rule, CMS formalizes the process and creates a review and corrections period similar to the one for Hospital OQR Program. (See section XIV.C above.) The review and corrections period will run concurrently with the data submission period beginning with the effective date of the final rule. During this review and corrections period, ASCs may enter, review, and correct data submitted directly to CMS. However, after the submission deadline, ASCs are not allowed to change these data. This finalized policy is codified at a new §416.310(c)(1)(iii).

D. Summary Table of ASCQR Program Measures

The table below shows the ASCQR Program measures previously adopted for payment determinations in 2020 through 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>.

ASCQR Program Measures by Payment Determination Year				
	2020	2021	2022/2023	2024
ASC-1: Patient Burn (NQF #0263) +	X		Suspended*	
ASC-2: Patient Fall (NQF #0266) +	X		Suspended*	
ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267)+	X		Suspended*	
ASC-4: All-Cause Hospital Transfer/Admission (NQF #0265)+	X		Suspended*	
ASC-9: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658)	X	X	X	X
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 (NQF #2539)	X	X	X	X
ASC-13: Normothermia Outcome	X	X	X	X
ASC-14: Unplanned Anterior Vitrectomy	X	X	X	X
ASC-15 Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS-CAHPS) - 5 measures**				
ASC-17: Hospital Visits After Orthopedic ASC Procedure (NQF #3470)			X	X
ASC-18: Hospitals Visits After Urology ASC Procedure (NQF #3366)			X	X

ASCQR Program Measures by Payment Determination Year				
	2020	2021	2022/2023	2024
ASC-19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at an ASC (NQF #3357)				X

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

* Data collection suspended until new method data collection developed.

**Mandatory reporting on a set of OAS CAHPS measures, once scheduled to begin in 2018 for the 2020 payment determination, was indefinitely delayed (82 FR 59450). The measures are OP-37a: OAS CAHPS – About Facilities and Staff; OP-37b: OAS CAHPS – Communication About Procedure; OP-37c: OAS CAHPS – Preparation for Discharge and Recovery; OP-37d: OAS CAHPS – Overall Rating of Facility; and OP-37e: OAS CAHPS – Recommendation of Facility. CMS implemented a voluntary national reporting program for the OAS CAHPS Survey in January 2016. More information is available at <https://oascahps.org/General-Information/National-Implementation>

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

CMS continues past 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 be 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 2020 payment determination, 195 of the 6,651 ASCs that met eligibility requirements for the ASCQR Program did not meet the requirements to receive the full annual payment update.

XVI. Overall Hospital Quality Star Rating Methodology

CMS makes changes to and codifies the Overall Hospital Quality Star Rating methodology used for publication beginning in 2021. One change is made from the proposed rule, regarding stratification of the readmission measures. The Overall Hospital Quality Star Rating (or Overall Star Rating) summarizes hospital quality performance by assigning a rating of one to five stars for posting on the *Hospital Compare* website. CMS explains that it used the OPPS/ASC rule to address the methodology for the Overall Star Rating even though it includes inpatient as well as outpatient measures because of the timeline needed to calculate and distribute Overall Star Rating results in time for hospitals to preview the ratings in advance of public release. CMS plans to reference policies for the Overall Star Rating in the FY 2022 IPPS rule.

A. Background

Since 2016, CMS has posted on the *Hospital Compare* website an Overall Star Rating, which uses performance on publicly reported quality measures to assign hospitals a rating of one to five

stars. The intention is to help consumer understanding of quality information through an easily understood summary measure. CMS views the overall star rating as a complement to the measure-specific performance data and the separate Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Star Rating also available on *Hospital Compare*.

The development and history of the Overall Star Rating methodology are reviewed in the final rule. The initial process was managed by a CMS contractor (Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation) with input from a Technical Expert Panel (TEP), Patient & Advocate Work Group and opportunities for public comment. These activities continued and expanded after introduction of the Overall Star Rating, which resulted in updates to the methodology in 2017 and 2019. A reevaluation of the methodology was undertaken in 2018 and 2019, which led to the more substantial changes adopted in this rule. CMS provides references for relevant historical materials. Some information on the methodology and updates is available on the QualityNet website at <https://www.qualitynet.org/inpatient/public-reporting/overall-ratings>.

Although CMS sought input from stakeholders during the development and implementation of the Overall Star Rating, it has not previously been the subject of notice and comment rulemaking.

B. Codification of the Overall Star Rating

CMS discusses the statutory basis for the Overall Star Rating, including the requirement that the Secretary make quality information public under the Hospital Inpatient Quality Reporting Program, the Hospital OQR Program, the Hospital Readmission Reduction Program, the Inpatient Hospital Value-based Purchasing Program, and the Hospital-Acquired Condition Reduction Program.

The final rule codifies the Overall Star Rating at a new §412.190. Beginning with publication of the Overall Star Rating in 2021 and subsequent years, CMS will continue to calculate the rating using quality data publicly reported on *Hospital Compare* or a successor CMS website from the programs identified above. Note that the *Hospital Compare* website has migrated to the CMS' new and broader *Care Compare* website.

The regulatory text states that the purpose of the Overall Star Rating is to summarize certain publicly reported hospital measure data for the benefit of stakeholders, such as patients, consumers, and hospitals. Under the guiding principles, CMS will strive to:

- Use scientifically valid methods that are inclusive of hospitals and measure information and able to accommodate underlying measure changes;
- Align with *Hospital Compare* or its successor website and CMS programs;
- Provide transparency of the methods for calculating the Overall Star Rating; and
- Be responsive to stakeholder input.

C. Inclusion of CAHs and Veterans Hospitals in the Overall Star Rating

In addition to subsection (d) hospitals, which are subject to the quality programs that underlie the data for the Overall Star Rating, CMS finalizes continued inclusion of CAHs that voluntarily report quality data and intends to extend the Overall Star Rating to include Veterans Health Administration (VHA) hospitals.

1. CAHs

CAHs that voluntarily report data under CMS hospital quality programs will continue to receive an Overall Star Rating if they meet the required reporting thresholds. CMS notes that about half of CAHs report sufficient data to receive a star rating. A CAH is included in the Overall Star Rating if it elects to voluntarily submit quality measures under CMS hospital programs and to publicly report these quality data on *Hospital Compare* or its successor site. CAHs that do not elect to participate or that elect to withhold data from public reporting are excluded from the Overall Star Rating. (See section XVI.G below.)

2. Veterans Health Administration Hospitals

Quality data from VHA hospitals would be included in the Overall Star Rating beginning in 2023. The details of this policy and its impacts will be addressed in future rulemaking. CMS notes that it has an existing interagency agreement with the VHA to publish their hospitals' quality measure data on *Hospital Compare* under the Veterans Access, Choice, and Accountability Act (Choice Act) of 2014 (Pub. L. 113-146). It further cites the authority in section 1704 of the Public Health Service (PHS) Act in support of this proposal. That provision authorizes the Secretary to conduct or support activities to make health information and education on the appropriate use of healthcare available to consumers, providers, and others. CMS believes that 2023 provides sufficient time for it to establish a methodology for hosting confidential reporting of the Overall Star Rating for VHA hospitals prior to public release.

To be eligible to receive a star rating, VHA data will be subject to the same reporting threshold as subsection (d) hospitals and CAHs. As discussed under Step 5 below this requires scores for three measure groups, one of which must be Mortality or Safety of Care, with at least three measures in each measure group.

While CMS anticipates that adding VHA hospital data to the Overall Star Rating calculation will influence national results, it states that this will not directly influence payment impacts under CMS-administered programs because VHA hospitals are not included in those determinations.

Most commenters opposed inclusion of VA hospitals because the patients they treat differ in case mix, demographics, and often care is targeted at select clinical conditions. CMS responds that the Veteran's Choice Act (P.L. 113-146) allows veterans to seek care at non-VA hospitals under certain circumstances, and inclusion of VHA hospitals in the star ratings will allow veterans to compare VHA and non-VHA hospitals when making decisions about where to seek care.

D. Overview of Changes to the Overall Star Rating Methodology

The final rule makes several changes to the methodology for calculating the Overall Star Rating, which are detailed in the six-step methodology discussion below. The changes are intended to address three areas for improvement:

- Simplicity of the methodology (i.e., reducing statistical complexity while maintaining a representative sample of hospital quality data so that stakeholders can better understand how the Overall Star Rating is calculated)
- Predictability of measure emphasis within the methodology over time (i.e., assigning similar measure weight over time)
- Comparability of ratings among acute care hospitals (i.e., comparing hospitals that are more similar to each other, such as the measures they report or services they provide)

Provisions discussed below that aim to simplify the methodology for providers to better understand or replicate the Overall Star Rating include: (1) regrouping measures into five measure groups, rather than seven, to account for measure removals (Step 2); and (2) using a simple average of measure scores to calculate measure group scores (Step 3).

In discussing the predictability of measure emphasis over time, CMS describes the July 2018 update (“refresh”) to the Overall Star Rating, which resulted in relatively large changes to ratings not because of hospital performance changes but because of the addition of two measures, removal of one measure and changes to measure specifications for another measure. The data were shared with hospitals during the confidential reporting period, but because of the large changes CMS did not publicly release this update.

Methodology updates that address the issue of predictability of measure emphasis include: (1) regrouping measures into five measure groups (Step 2); (2) use of a simple average to calculate measure group scores; and (3) requiring at least three measures in three measure groups, one of which must be Mortality or Safety of Care, to receive a star rating (Step 5).

CMS notes that providers had previously recommended that the Overall Star Rating account for differences in hospital case-mix or type to increase comparability. The methodology updates that address this issue include: (1) requiring at least three measures in three measure groups, one of which must be Mortality or Safety of Care, to receive a star rating (Step 5); and (2) peer grouping hospitals by number of measure groups (Step 5). As discussed below, CMS does not finalize its proposal to stratify the readmission measure group scores using the proportion of dual-eligible patients at each hospital within Step 3.

The final rule discusses the Overall Star Rating methodology in the following six steps, detailed further below.

- Step 1: Selection and standardization of measures
- Step 2: Assignment of measures to groups
- Step 3: Calculation of measure group score
- Step 4: Calculation of hospital summary score

- Step 5: Application of minimum thresholds for receiving a star rating
- Step 6: Application of clustering algorithm to assign star ratings

CMS lists features of the current methodology that are generally being retained:

- An annual publication cycle using data posted on *Hospital Compare* or its successor site from data publicly reported within the prior year (e.g., January 2020 *Hospital Compare* publication used data from the October 2019 refresh);
- Suppression policy for subsection (d) hospitals;
- Inclusion of measures publicly reported on *Hospital Compare* or its successor sites that meet specific inclusion and exclusion criteria and standardization of measure score within Step 1;
- Publicly displaying measure group level information for measure groups for which a hospital has at least three measures, use of weighted average of measure group scores to calculate summary scores and measure group reweighting to account for measure group scores which are not reported within Step 4; and
- Use of k-means clustering to assign hospitals that provide acute inpatient and outpatient care to one of five star ratings within Step 6.

CMS summarizes the methodology updates as follows:

- Regroup measures by combining the three process measure groups into one group, Timely and Effective Care, within Step 2;
- Update the calculation of measure group scores to include standardization of measure group scores and to use a simple average of measure scores, rather than latent variable modeling;
- Change the reporting thresholds required to receive a star rating to three measures within three measure groups, one of which must be Mortality or Safety of Care, within Step 5; and
- Apply peer grouping of acute care hospitals based on the number of measure groups between Step 5 and Step 6.

E. Modified Overall Star Rating Methodology

The overall star rating methodology newly codified as §412.190 is described in the final rule as a series of steps. Differences from the current methodology are highlighted.

Step 1: Selection and Standardization of Measures for Inclusion in the Overall Star Rating

Timeframe. For 2021 and subsequent years the current timeframe for the Overall Star Rating is retained with modification and codified in §412.190. The Overall Star Rating will continue to be published once a year. However, instead of using data from the same quarter as publication or the prior quarter, CMS will use publicly available measure results on *Hospital Compare* or a successor website from a quarter within the prior year. Measure results are generally updated on *Hospital Compare* quarterly in January, April, July, and October of each year. For a January 2021 Overall Star Rating release, for example, CMS would use data refreshed on *Hospital*

Compare in July or October of 2020. CMS believes that using these data will allow providers more time, beyond the standard 30-day confidential review period, to review their Overall Star Rating as well as the measure and measure group results that contribute to it.

Some commenters requested that instead of using data from the prior year, CMS prioritize using the most recently available data over giving hospitals more extra time to review their performance prior to publication of the star ratings. CMS responds that in previous public comments providers requested the use of data from the prior year¹⁸ to allow more time for review. In addition, it believes this approach will provide it with more flexibility in calculating the Overall Star Rating in the event of potentially compromised measure score calculation or a disruption at CMS like a public health emergency.

Measure selection. CMS continues (and codifies) the use of certain measures reported on *Hospital Compare* or a successor website through the specified CMS quality programs (Hospital Inpatient Quality Reporting Program, Hospital OQR Program, Hospital Readmission Reduction Program (HRRP), the Hospital Acquired Condition (HAC) Reduction Program, and the Inpatient Hospital Value-Based Purchasing (VBP) Program) to calculate the Overall Star Rating. It notes that these measures undergo a rigorous development process, including extensive measure testing, vetting by stakeholders, evaluation by the National Quality Forum, and rulemaking for inclusion in CMS programs and public reporting. Under the approach currently used and proposed, CMS does not make any changes to measures or measure scores specifically for the calculation of the Overall Star Rating. Any measures that are removed or suspended from one of the listed quality programs and not displayed on *Hospital Compare* are not included in the Overall Star Rating.

Measure exclusions. Certain measures will continue to be excluded from calculation of the Overall Star Rating; CMS believes that not all measure scores can be reliably or appropriately combined with others. All but one of the current exclusion rules is continued. The final exclusions, codified in §412.190, are:

- Measures that are publicly reported by no more than 100 hospitals.
- Structural measures or others that are not able to be standardized and otherwise not amenable to inclusion in a summary score calculation alongside process and outcome measures, or measures that cannot be combined in a meaningful way. This includes measures that cannot be as easily combined with other measures captured on a continuous scale with more granular data.
- Non-directional measures for which it is unclear whether a higher or lower score is better. Without directional scores these measures cannot be standardized to be combined with other measures and form an aggregate measure group score.
- Measures not required for reporting on *Hospital Compare* or its successor websites through CMS programs.
- Measures that overlap with another measure in terms of cohort or outcome; this includes component measures that are part of an already-included composite measure.

¹⁸ CMS cites a June 2019 Public Comment summary report, but the link provided is broken.

Because, as described in Step 3 below, the Latent Variable Model (LVM) is discontinued, the exclusion of measures with statistically significant negative loadings no longer applies.

Measure score standardization. Standardization of measure scores is continued. This step allows for measures that are expressed in different units and directions to be combined. Once measures are excluded, the remaining measures are standardized by calculating Z-scores prior to combining them into an aggregate measure group score. A Z-score is calculated by subtracting the national mean measure score from each hospital's measure score and dividing the difference by the measure's standard deviation. Table 65 in the final rule provides an example of standardizing measure scores.

Winsorization method. CMS does not continue using the Winsorization method.¹⁹ It has been using this technique to minimize the effects of extreme outliers on the performance of the LVM. As discussed further below, beginning in 2021, the LVM is replaced with simple averaging of measure scores and therefore the Winsorization step is also eliminated.

Step 2: Assignment of Measures to Groups

CMS modifies the assignment of measures to groups for the Overall Star Rating beginning in 2021 and codifies this at §412.190. The Mortality, Safety of Care, Readmission, and Patient Experience measure groups are unchanged. However, three previously used process measure groups – Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging – are combined into one group entitled Timely and Effective Care. These groups are merged because the number of publicly reported measures available for the Overall Star Rating has declined over time, from 64 measures in the first publication of the Overall Star Rating in 2016, to 51 measures for the most recent, January 2020 publication. CMS lists 12 process of care measures that have been finalized for removal from public reporting from 2019 to 2021. As a result, the current Timeliness of Care and Efficient Use of Medical Imaging measure groups now each have only three measures, which CMS says would not produce robust or predictable measure group scores.

CMS simulated the potential effects of these changes using October 2019 publicly reported measure data on *Hospital Compare*. Using the five measure groups, of the 4,576 acute care hospitals and CAHs, 180 more hospitals (3,780 hospitals total) and 157 more CAHs (1,307 total) would have met the current reporting thresholds (that is, at least three measures in at least three measure groups, one of which must be an outcome group) compared to the original seven measure groups. CMS notes that these estimates relate to measure regrouping; other changes in this final rule may also affect the number of hospitals meeting reporting thresholds.

¹⁹ Standardized measure scores were Winsorized at the 0.125th and 99.875th percentiles of a standard normal distribution so that all measure scores range from negative 3 to positive 3 (-3 to 3). CMS states that Winsorization is a common strategy used to set extreme outliers to a specified percentile of the data, and refers readers to Kwak, S.K., & Kim, J.H. (2017, July 27). "Statistical data preparation: management of missing values and outliers." Korean journal of anesthesiology 70.4: 407.

Step 3: Calculation of Measure Group Scores

CMS adopts a major change in how it calculates measure group scores for the Overall Star Rating. The LVM statistical approach will no longer be used; a simple average of measure scores will be used to calculate measure group scores instead. The measure group scores will be standardized.

Discontinued Use of LVM and Use of Simple Averaging. The final rule includes a detailed discussion of the LVM statistical method that has been used for the Overall Star Rating. This method allows measures that are more consistent with each other, measures with large denominators, and measures that are more commonly reported to have more influence on the measure group score. Information from the LVM is used to assign group performance categories on *Hospital Compare* that indicate whether a hospital's performance on a measure group is "above" "same as" or "below the national average." Specifically, the point estimate and standard error produced by the LVM is used to construct a confidence interval that was compared to the national mean measure group score to assign the performance category²⁰.

When the star rating was developed, the TEP favored the ability of the LVM to use data to account for the relationship between measures, measures which are not reported, and sampling variation. Based on stakeholder concerns, CMS made changes to the LVM in February 2019 to remove measures in the model with statistically significant negative loadings, where the loading is the measure's contribution to the group score. CMS "recognizes that LVM may be challenging for stakeholders to understand and explain to others."

In this rule, CMS discontinues use of the LVM for calculating measure group scores in favor of using a simple average of measure scores beginning in 2021. This change is codified at §412.190 and is made in response to provider requests for a less complex methodology that can be easily understood within their organizations, explained to patients, and used to identify areas for quality improvement. Of particular concern is that the LVM method results in large and unpredictable changes in how much each measure contributes to the Overall Star Rating. That is, while the measure loadings do not vary by hospital under the LVM, they can differ between publications of the Overall Star Rating due to the dynamics of measure methodologies, hospital performance, and the relationship between measures. While under simple averaging the weight for a given measure may vary between hospitals based on differences in the number of measures they report, this method would allow hospitals to anticipate equal measure weights and make it easier for them to understand, interpret and explain the methodology.

Under simple averaging, the weight for each measure within a measure group equals 100 percent divided by the number of measures reported by the hospital in the measure group. That weight is multiplied by the hospital's standardized measure score to obtain the weighted measure score, and the weighted measure scores in the measure group are summed to calculate the hospital's

²⁰ Measure group scores with confidence intervals that fall entirely above the national average are considered "above the national average", confidence intervals that include the national average are considered "same as the national average", and confidence intervals that fall entirely below the national average were considered "below the national average."

standardized measure group score. Tables 66 and 67 in the final rule provide numerical examples of the simple average approach to calculating measure group scores.

Measure group performance categories will not be available under the proposed simple average approach to calculating measure group scores. The information used to assign hospitals to these categories is an artifact of the LVM approach.

Some commenters noted disadvantages of the simple averaging approach and encouraged CMS to continue to consider alternatives to it, such as template matching and relative measure weighting. CMS responds by noting that various alternatives were considered and the simple averaging approach was vetted through a TEP, Provider Leadership Work Group, Patient & Patient Advocate Work Group meetings, a public input period and a CMS listening session. It notes that template matching may be infeasible given that the hospital-level measure scores are calculated without use of patient-level data, and might not meet the goal of using a methodology that is easily understood and explained by stakeholders. Measure weighting by volume could result in measure group scores dominated by a single measure such as PSI-90 or the Hospital-Wide Readmission measure, while weighting by evidence or importance to patients may be subjective and resource intensive for CMS and stakeholders to monitor and maintain. Further, the TEP noted relative measure weighting might have the unintended consequence of incentivizing hospitals to focus quality improvement only on a few measures.

Standardizing measure group scores. In order to put all measure group scores on a single scale, CMS standardizes the measure group scores using the same Z-score method used for standardizing individual measure scores. That is, the national mean measure group score is subtracted from each hospital's measure group score and then divided by the measure group's standard deviation across hospitals to obtain the standardized measure group score. Standardization occurs before measure group scores are combined to calculate summary scores. Standardization results in all measure group scores centered near zero with a standardized deviation of one. This is codified in §412.190.

Stratifying Readmission Measure Group Scores. CMS does not finalize its proposal to stratify the Readmission measure group based on hospitals' proportion of Medicare and Medicaid dual eligible patients. The proposal would have used the same dual eligibles variable and five peer group quintiles used for the HRRP, with non-HRRP hospitals assigned an HRRP peer group. CMS had offered this proposal in response to provider requests that it incorporate social risk factor adjustment and to provide consistency between the HRRP and the Overall Star Rating Readmission measure group. It had specifically sought comment on use of this stratification and an alternative of not doing so.

The decision not to proceed with stratification is based on several concerns. Many commenters objected to this approach, noting the limitations of using dual eligible status and the HRRP quintiles. CMS also acknowledges the potential for confusing and misleading patients, and notes that its analyses suggest that stratification may not have the intended effect given a strong correlation (0.967) between unadjusted and adjusted measure group scores and a finding that more hospitals lose a star than gain a star due to stratification. Further, rather than facilitating care decisions by dual eligible beneficiaries, CMS states that the TEP and work groups found

that stratification may obscure hospital quality results superficially for dual eligible beneficiaries. Finally, CMS notes the June 2020 HHS report to Congress²¹ recommending that hospital stratification by the proportion of dual eligibles approach eventually be removed from the HRRP. CMS is reviewing that report and considering how to incorporate its recommendations into its programs.

Step 4: Calculation of Hospital Summary Scores as a Weighted Average of Group Scores

General Approach and Weighting. CMS continues calculation of the hospital summary scores through a weighted average of measure group scores with a weighting scheme that continues to assign more weight to the outcome and patient experience measure groups and less weight to the process measure group. Specifically, for Overall Star Rating in 2021 and subsequent years, each of the outcome and patient experience measure groups – Mortality, Safety of Care, Readmission, and Patient Experience – will be weighted at 22 percent, and the combined process measure group, Timely and Effective Care will be weighted at 12 percent. Hospital summary scores are then calculated by multiplying the standardized measure group scores by the assigned measure group weight and then summing these amounts. This approach is codified in §412.190. Table 68 in the final rule offers an example of the summary score calculation.

An alternative considered by CMS is equal weighting of the five measure groups at 20 percent each. CMS decided against this approach because previous stakeholder feedback supports giving higher weight to outcome and patient experience measures.

Reweightings. Measure group scores will continue to be reweighted when a hospital does not have sufficient cases to report measures and therefore too few measures for a measure group score. Once the reporting thresholds are met (finalized below as having at least three measure groups each with at least three measures) a hospital must report at least one measure in each group and the weight of any measure group that does not have at least one measure will be re-distributed proportionally amongst the other measure groups to ensure the relative weight between groups is preserved. That is, the weight percentage of the missing groups is subtracted from 100 percent, and the weight percentage of each of the remaining groups then divided by the resulting percentage, giving new re-proportioned weights. This approach is codified in §412.190. Tables 69, 70, and 71 in the final rule offer numerical examples of the reweighting approach.

Responding to a comment, CMS reports that only in rare circumstances would a hospital meet the reporting thresholds and have only one measure in a measure group contribute a high weight toward its star rating. It states that for the October 2020 public reporting data, 3,356 hospitals received an Overall Star Rating; only 320 hospitals reported on a single measure in at least one measure group, and only 10 hospitals reported on a single measure for two measure groups. For 76 percent of hospitals no individual measure accounted for more than 10 percent of its Overall Star Rating. The maximum that a single measure contributed to the Overall Star Rating was 28 percent for the Mortality, Safety of Care or Readmission groups; 5 percent for Patient Experience and 15 percent for the Timely and Effective Care group.

²¹ HHS Assistant Secretary for Planning and Evaluation (ASPE). “Social Risk Factors and Performance in Medicare’s Value-Based Purchasing Programs.” June 29, 2020. <https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress>

Step 5: Application of Minimum Thresholds for Receiving a Star Rating

To receive a star rating, hospitals have to meet minimum reporting thresholds, and these are modified beginning with the 2021 Overall Star Rating. Under the current thresholds, a hospital must have a score for at least 3 measure groups, one of which is an outcome group (Mortality, Safety of Care, or Readmission), with at least three measures in each of the three groups. Since 2017, the thresholds are applied prior to assignment of hospital star ratings so that only hospitals meeting the thresholds are included in the algorithm that assigns the star rating.

Beginning with the 2021 Overall Star Rating, hospitals must report at least three measures for three measure groups, but one of the groups must be either the Mortality or Safety of Care outcome group. Once this reporting threshold is met, any additional measures or measure groups will contribute to the hospital's star rating. These policies are codified at §412.190.

CMS acknowledges that this change limits the number of hospitals eligible to receive a star rating, but it believes that mortality and safety of care are the most important aspects of quality to patients and reflective of performance under the hospital's control. In the data for the January 2020 Overall Star Rating, 125 hospitals would not have met the new threshold (i.e., did not report at least three measures in either the Mortality or Safety of Care measure groups). Of this total, 48 were safety net hospitals, 68 were CAHs, and 16 were specialty hospitals.

Approach to Peer Grouping Hospitals

CMS finalizes its proposal to assign hospitals to one of three peer groups before calculating the Overall Star Rating, beginning with 2021. The peer groups are based on the number of measure groups for which the hospital has at least three measures: (1) three measure groups, (2) four measure groups, or (3) five measure groups. Hospitals are assigned to peer groups after the minimum reporting thresholds are applied. Once grouped, k-means clustering is applied within each peer group to assign hospital summary scores to star ratings (as discussed below). This policy is codified at §412.190.

Using the January 2020 Overall Star Rating release data, CMS found 348 (10 percent) hospitals reported at least 3 measures in 3 groups, 583 (17 percent) reported 4 groups, and 2,509 (73 percent) reported all 5 groups. It notes that peer groupings by measure are stable over time; hospitals are assigned to the same peer group 96 to 98 percent of the time over 5 years of data.

Some commenters did not support the peer groups as proposed as not responsive to stakeholder concerns about comparing hospitals by characteristics such as safety net status, size, and patient case-mix. CMS responds that it evaluated many variables and notes a lack of consensus among stakeholders, particularly providers, regarding the most suitable variable for peer grouping. In addition, CMS notes that few variables are available and consistently captured for all hospitals nationally. Further, CMS reiterates its belief that the peer groupings by number of measure groups indirectly captures differences in hospital size, case mix and services provided.

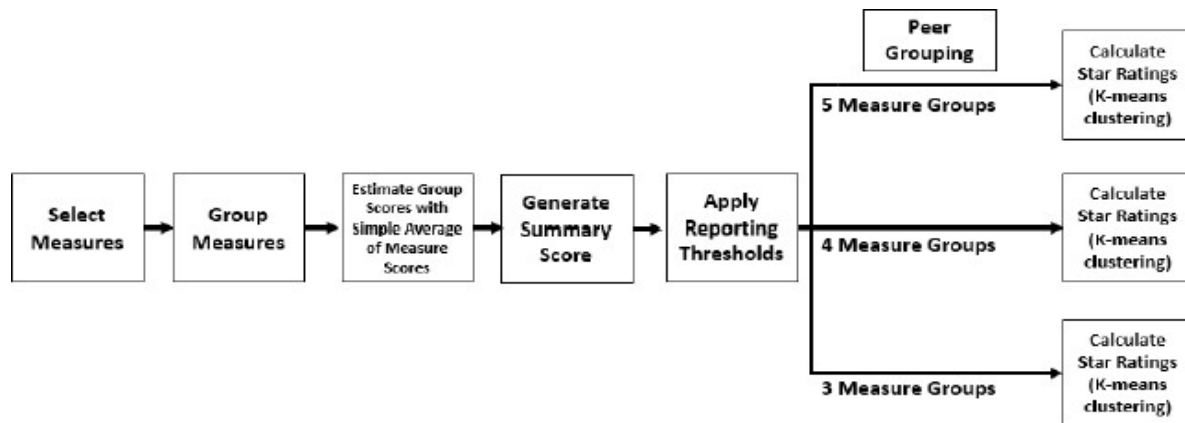
CMS commits to examining alternative peer grouping approaches as stakeholder input evolves and data become available. This is true for peer grouping in the calculation and also for public display of the Overall Star Rating.

Step 6: Application of Clustering Algorithm to Assign Star Rating

CMS will continue to use the k-means clustering algorithm to establish the cutoffs, or range of summary scores, that group hospitals into the five star rating categories in which one star is the lowest and five stars is the highest. Specifically, for the Overall Star Rating beginning in 2021, it will use k-means clustering with complete convergence without Winsorization²² of hospital summary scores to group hospitals into five clusters to assign star ratings. This policy is codified at §412.190.

K-means clustering results in groupings where the summary scores in the one-star rating category would be more similar to each other and less similar to summary scores in other star rating categories. Responding to commenters, CMS acknowledges that k-means clustering may not be as predictable as fixed cutoffs but notes that it minimizes within-category differences and maximizes between-category differences in summary scores. Further, this approach aligns with the clustering approach used for the HCAHPS Star Ratings.

Figure 2 in the final rule, reproduced below, summarizes the methodology for calculation of the Overall Star Rating for 2021 and subsequent years.



Each time it publishes a new Overall Star Rating CMS will continue to publicly post the Overall Star Rating input file and SAS pack on the QualityNet website and Overall Star Rating results on

²² Since December 2017, for the Overall Star Rating, CMS has used an application of k-means clustering by running the summary scores through the clustering algorithm multiple times, a statistical method called complete convergence, to provide more reliable and stable star rating assignments. Prior that point, CMS performed Winsorization of hospital summary scores to limit the influence of extreme outliers. Because running k-means clustering to complete convergence results in a broader distribution of star ratings, CMS states that it negates the need for Winsorization of hospital summary scores.

data.cms.gov, which will include all specifications and results of the Overall Star Rating calculations.

F. Preview Period

CMS will continue its current process regarding the preview period for the Overall Star Rating, which is codified at §412.190. Under that process, a few months prior to public release of the Overall Star Rating, CMS will issue to hospitals a confidential hospital-specific report detailing the hospital's measure and measure group scores, summary score, and star rating. Hospitals have at least 30 days to preview their results, and if necessary, contact CMS with questions about the methodology and results.

G. Overall Star Rating Suppressions

Policies for suppression of the Overall Star Rating are adopted separately for subsection (d) hospitals and CAHs. These will begin with 2021 and are codified at §412.190. Previously, CMS has only suppressed the Overall Star Rating for a subsection (d) hospital when there were errors in the calculation of the Overall Star Rating or in the calculation of individual measure scores, which would first need to be addressed within the Medicare quality program. There has been no separate corrections process for the Overall Star Rating.

CMS responds to commenters concerned about the impact of the COVID-19 public health emergency on the Overall Star Ratings. It is currently assessing the effect of the exemptions it granted under Medicare quality reporting and value-based purchasing programs in guidance issued on March 27, 2020 and policies adopted in a September 2, 2020 Interim Final Rule with Comment Period (85 FR 54820). The IFC provided that CMS may not score facilities under the Hospital VBP Program, HRRP and HAC Reduction Program if it does not have sufficient data to reliably compare hospital performance on program measures. In this rule, CMS states that it will consider suppression of the Overall Star Rating if it determines that underlying measure data were substantially affected.

1. Subsection (d) Hospitals

CMS will consider suppressing the Overall Star Rating only under extenuating circumstances that affect numerous hospitals as determined by CMS or when CMS is at fault. This includes circumstances when (1) there is an Overall Star Rating calculation error by CMS, (2) there is a systemic error at the CMS quality program level that substantively affects the Overall Star Rating calculation, for example, if there is a CMS quality program level error for one or more calculations that affects a substantial number of hospitals, or (3) a Public Health Emergency substantially affects the underlying measure data.

Consistent with past practices, CMS will not suppress an individual hospital's Overall Star Rating because the hospital or one of its agents (e.g., authorized vendors, representatives, or contractors) submitted inaccurate data to CMS, including inaccurate underlying measure data and claims records. Established processes under the hospital quality programs allow hospitals to review and correct individual measure scores.

2. CAHs

CAHs, which submit quality measures voluntarily, may continue to withhold their Overall Star Rating from public release on *Hospital Compare* or its successor website if the request for withholding is made no later than during the proposed Overall Star Rating preview period. CAHs may make this request by submitting the “Request Form for Withholding/Footnoting Data for Public Reporting.” (This is the same form used for withholding data from CMS quality programs.) If a CAH requests withholding of any of the measures included within the Overall Star Rating from public reporting on *Hospital Compare* or its successor website through this form, all of its measure scores will be withheld from the Overall Star Rating calculation. However, individual measure scores will still be included in the public input file which is posted upon the public release of the Overall Star Rating because there would not be sufficient time for CMS to remove these data and recalculate the Overall Star Rating for all affected hospitals.

CAHs that do not want their voluntarily submitted measure data publicly reported on *Hospital Compare* may submit the same form during the 30-day confidential preview period provided for the applicable quality program. In this case, measure data withheld from *Hospital Compare* will not be included in the Overall Star Rating.

Finally, using the same form, CAHs may request to have their Overall Star Rating and their data withheld from the public input file which is posted upon the public release of the Overall Star Rating and used by stakeholders to replicate the calculation of star ratings, so long as the request is made during the CMS quality program-level 30-day confidential preview period for the *Hospital Compare* refresh used to calculate the Overall Star Rating. As an example, readers are referred to the discussion in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51608).

Some commenters objected to allowing CAHs to withhold the Overall Star Rating from publication. CMS reports that historically only a few CAHs have exercised the ability to request withholding of measure data and star ratings from publication.

H. Impact of Changes to the Overall Star Rating Methodology

CMS estimates the cost to hospitals of reviewing the preview reports for the Overall Star Rating to total \$397,710 across 4,500 hospitals; \$100,890 of this total to be borne by 1,300 CAHs.

Tables 89 through 92 in the final rule display the estimated impacts of changes made to the Overall Star Rating methodology. The estimates are updated from the proposed rule, and were prepared using data from the October 2020 *Hospital Compare* data.

The tables examine the proposals separately and in combination. In all the tables, the effects of three proposals are combined (“combined methodology proposals”): (1) grouping measures into five, rather than seven, measure groups; (2) using a simple average of measure scores to calculate measure group scores; and (3) updating the reporting thresholds to require at least three measure groups, one of which must be Mortality or Safety of Care, with at least three measures in each group to receive a star rating, compared to the current methodology. The proposals for

peer grouping and readmission stratification are examined individually and in combination with the combined methodology proposals and each other.

Among the observations highlighted by CMS from these impact tables are the following:

- The final Overall Star Rating methodology results in 3,350 (74 percent) hospitals receiving a star rating and shows a similar distribution of star ratings to the current methodology, with more three- and four-star ratings and fewer one, two- and five-star ratings (Table 89).
- Compared with the current methodology, 50 percent of hospitals (n=1585) receive the same star rating under the final methodology, 45 percent (n = 1423) shift up or down one star, 5 percent (n = 150) shift up or down two stars, and 0.3 percent (n = 9) shift up or down three stars. (Table 90).
- Under the final rule methodology, CMS finds that the distribution of hospitals across the star rating categories by hospital type is generally similar to the overall distribution of hospitals, and notes a series of exceptions to that finding, including that a relatively high proportion of specialty hospitals and non-DSH hospitals receive 5 stars. About 56 percent of DSH hospitals receive three stars or less compared with 42 percent of hospitals overall. The pattern of having more hospitals with 1 or 2 stars and fewer with 4 or 5 stars increases with the DSH quintiles. (Table 92).

While not highlighted by CMS, comparison of the distribution of star ratings under the current methodology shown in Table 91 to the final rule distribution by hospital type shown in Table 92 shows a higher proportion of major teaching hospitals receiving 4 or 5 stars under the new methodology (42 percent compared to 33 percent) and fewer receiving one or two stars (31 percent compared with 45 percent). By comparison, the overall percentage of hospitals receiving one or two stars only shifts from about 18 percent to 20 percent under the new methodology and the shift in hospitals receiving 4 or 5 stars is from 31 percent to 32 percent.

XVII. Prior Authorization

A. Background

Citing authority under section 1833(t)(2)(F) of the Act to control unnecessary increases in the volume of covered OPD services, in the 2020 OPPS/ASC final rule CMS established a prior authorization process as a condition of payment for certain hospital-based services. The regulations include provisions relating to the process by which hospitals must obtain prior authorization, the lists of the specific service categories for which prior authorization is required,²³ the process for adding new service categories using notice and comment rulemaking, the agency's discretion to exempt certain providers, and the agency's discretion to suspend the process generally or for a particular service. Table 73 in the rule lists all the service categories and services to which prior authorization currently applies.

²³ The five service categories finalized in the 2020 OPPS/ASC final rule are blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation.

B. Addition of Two New Service Categories

Effective for dates of services on or after July 1, 2021, CMS proposed to add the following two services categories to the prior authorization list: Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators. CMS would clarify that prior authorization for the existing 5 service categories had an effective date of July 1, 2020.

CMS also proposed to identify the list of covered OPD services for these new service categories in Table 72 of the final rule (reproduced below).

Code	Beginning for service dates on or after July 1, 2021
	(i) Cervical Fusion with Disc Removal
22551	Fusion of spine bones with removal of disc at upper spinal column, anterior approach, complex, initial
22552	Fusion of spine bones with removal of disc in upper spinal column below second vertebra of neck, anterior approach, each additional interspace
	(ii) Implanted Spinal Neurostimulators
63650	Implantation of spinal neurostimulator electrodes, accessed through the skin
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver

For the proposed rule, CMS updated the analysis done for the 2020 OPPS/ASC final rule. It reviewed more than 1.2 billion claims from 2007 through 2018, and determined an overall average rate of utilization increase of 2.8 percent. This reflects a slight decrease from the 3.2 percent average utilization rate increase the agency found for the 2020 OPPS/ASC final rule. CMS also found an average annual rate-of-increase in Medicare allowed charges of 7.8 percent. Based on its analysis, CMS found higher than expected volume increases for the proposed two new service categories. CMS believes that the increase in volume of these services is unnecessary because the data show the 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 might contribute to clinically valid volume increases. CMS reviewed clinical and industry-related literature and did not find any indication that justifies the increases. CMS concludes that the increases are due to financial motives.

1. Implanted Spinal Neurostimulators

The annual average rates of increase in volume for the three CPT codes (65630, 63685, and 63688) were 6.5 percent, 10.2 percent²⁴, and 8.8 percent, respectively. All three were higher than the 2.8 percent rate for all OPPS services over the same period. CMS says it fully accounted for changes that occurred in 2014 (related to electrodes being incorporated into CPT code 63650) which did not show a corresponding claims volume change that explains the large increases noted over time when compared to all OPPS services.

²⁴ When examining the volume of CPT code 63685 only during 2016 through 2018, CMS found an average annual rate of increase of 17 percent.

2. Cervical Fusion with Disc Removal

The annual average rates of increase in volume between 2012 and 2018 for the two CPT codes (22551 and 22552) were 124.9 percent²⁵ and 174.9 percent, respectively. CMS notes that the use of 22551 almost tripled in 2012 and that it significantly increased each year thereafter. Those increases became more dramatic when the APC for CPT 22551 was changed to a higher level beginning in 2016.

General Comments

Commenters reiterated that prior authorization processes add burden and costs, can result in unnecessary delays in care, and interfere with the physician-patient care decision or otherwise negatively affect patient care. Some commenters stated that prior authorization is contrary to CMS' Patients Over Paperwork initiative and referenced CMS Administrator Seema Verma's comments related to prior authorization. Other commenters requested information regarding how prior authorization will impact advance beneficiary notices (ABNs) and continued to express concern regarding the inability to appeal the outcome of prior authorization requests.

CMS responded that it has structured the OPSS prior authorization processes to build on already established prior authorization programs for durable medical equipment, prosthetics, orthotics and supplies and ambulances. The agency remains fully committed to the Patients over Paperwork initiative and does not believe prior authorization is inconsistent with this initiative. While Administrator Verma noted concerns about potential burden related to prior authorization, she also recognized that prior authorization "is an important utilization management tool."

The response further adds that the agency has established timeframes for contractors to render decisions on prior authorization requests, as well as an expedited review process when the regular review timeframe could seriously jeopardize the beneficiary's health. Additionally, the prior authorization policy does not create any new documentation or administrative requirements. Instead, it just requires the same documents that are currently required to be submitted earlier in the process.

CMS also believes that some assurance of payment and protection from future audits will ultimately reduce burdens associated with denied claims and appeals. Because the prior authorization process is not a final determination and a provider has the ability to resubmit a prior authorization request multiple times, it is not necessary to provide appeal rights. Appeal rights still exist once a claim is actually denied. The prior authorization process does not change a provider's obligation with regard to ABNs. An ABN is used to advise a beneficiary in advance that the provider expects Medicare payment to be denied.

Legal Issues and Questioning Whether Utilization Growth is Unnecessary

Some commenters continue to question whether section 1833(t)(2)(F) of the Act grants CMS the authority to establish a prior authorization process. Other commenters suggested that adding new

²⁵ When examining the volume of CPT code 22551 only during 2016 through 2018, CMS found an increase of 736 percent.

procedures to the prior authorization program is arbitrary and capricious because exceeding baseline growth is not a sufficient basis for concluding that utilization growth is unnecessary. Some commenters indicated that outpatient utilization growth for cervical fusion is directly correlated with the procedure's removal from the inpatient only list. Other commenters suggested growth in use of implantable neurostimulators reflects a shift from reliance on opioids to control chronic pain.

CMS responded that section 1833(t)(2)(F) of the Act gives the Secretary discretion to determine the appropriate methods to control unnecessary increases in the volume of covered OPD services. It says extensive data analysis included in this year's proposed rule demonstrates that there have been unnecessary increases for each of the two proposed new service categories. While the cervical fusion codes were removed from the IPO list in 2012, the more significant increases in volume occurred years later, when the reimbursement changed for the procedure. Similarly, CMS disagrees that the 174.6 percent increase between 2007 and 2018 for implanted spinal neurostimulators is due solely to efforts to avoid use of opioids.

Including Only Hospitals

Commenters questioned why ASCs and physicians are exempt from prior authorization stating services may shift to ASCs, physicians' offices, or even inpatient hospitals. CMS explained that its statutory authority for prior authorization only applies to the outpatient hospital department. CMS will monitor whether there are utilization shifts from the outpatient department to ASCs and physician offices in response to prior authorization.

Other Utilization Control Tools

Several commenters suggested using National Coverage Decisions (NCDs) and Local Coverage Determinations (LCDs), prepayment and post-payment reviews, and provider outreach and education, to control unnecessary increases in volume rather than prior authorization. CMS recognizes the utility of NCDs and LCDs but stated that they do not guarantee compliance with policy. Further, a broad program integrity strategy must use a variety of tools to best account for potential fraud, waste and abuse and unnecessary increases in volume.

Prior Authorization Principles

Some commenters suggested that CMS require specific credentials for MAC medical reviewers to ensure the accuracy of MAC decisions. Others asked CMS to adopt a 2018 Consensus Statement on Improving the Prior Authorization Process that include the following principles: applying prior authorization only to outliers; adjustment of prior authorization lists to remove low-value services; transparency of requirements; protections of patient continuity of care; and automation to improve process efficiency.

CMS responded that its prior authorization process is consistent with these principles. MACs are required to maintain specific medical staffing to undertake reviews. Prior authorization includes established timeframes for both initial and resubmitted requests, as well as an expedited process when regular timeframes could impact the health of the beneficiary.

The final rule also states that CMS has established a process with specific requirements for providers to demonstrate compliance with Medicare requirements for performing these services that will exempt them from the prior authorization process. CMS also indicates that it is committed to incorporating automation into the prior authorization process although the majority of providers submit requests and medical information via facsimile.

Concerns about MAC Timeliness

Several commenters stated that the MACs have not demonstrated the ability to timely handle the volume of prior authorization requests since the process began on July 1, 2020 for outpatient services. These commenters stated that MACs have taken longer than the 10 days specified for communicating the results of prior authorization requests. CMS responded that it has intervened on occasions when a few of the MACs were not able to issue decisions within required timeframes. As the prior authorization process has only recently been implemented, CMS has minimal data to evaluate contractor performance. However, experience with other prior authorization programs has shown MACs exceeded their required review timeframe only 16 times of 62,000 initial prior authorization requests submitted in FY 2020 (less than 0.01 percent).

Final Decision: CMS is finalizing its proposal without modification. Table 74 includes the overall list of services subject to prior authorization with the effective dates for each service (either July 1, 2020 or July 1, 2021).

C. Regulatory Impact

Based on other prior authorization programs, CMS estimates savings based on a 50 percent reduction in improper payments, using a 10 percent improper payment rate. For the first six months, CMS believes there will be savings of \$15,922,194 overall. Annually, it estimates an overall gross savings of \$31,844,388.

CMS estimates the time burden per case of compliance with prior authorization will be 0.5 hours. Public commenters disputed this estimate. The volume estimates are 15,884 and 5,214 initial and resubmissions respectively by fax and electronic means; 6,808 and 2,234 initial and resubmissions by mail according to CMS for the first year (six months).

XVIII. Revisions to Laboratory Date of Service (DOS) 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 the 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 OPSS service payment or, if separately payable, must be billed by the hospital.

Most clinical diagnostic laboratory tests (CDLTs) are packaged as integral, ancillary, supportive, dependent, or adjunctive to the primary service or services provided in the hospital outpatient setting during the same outpatient encounter and billed on the same claim. Medicare only pays

separately for a CDLT when it is: (1) the only service provided to a beneficiary during an outpatient encounter; or (2) considered a preventive service.

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

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

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

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

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

For hospital outpatients only, the DOS for molecular pathology tests or advanced diagnostic laboratory tests (ADLTs)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.

Protein-based Multianalyte Assays with Algorithmic Analyses (MAAAs) laboratory tests are not considered molecular pathology tests subject to the above policy. However, several stakeholders have suggested that they believe the pattern of clinical use of some of these protein-based MAAAs make them relatively unconnected to the primary hospital outpatient service.

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

CMS agrees that cancer-related protein-based MAAAs may be relatively unconnected to the primary hospital outpatient service during which the specimen was collected from the patient and are instead used to guide future treatment through surgical procedures or chemotherapeutic interventions. As indicated in section II.A.3., CMS proposed to make protein-based MAAA CPT codes 81500, 81503, 81535, 81536, 81538 and 81539 separately payable rather than packaged.

For the same reasons that CMS proposed to no longer package cancer-related protein-based MAAAs, CMS proposed a modification to the DOS rule to apply the same DOS to these tests as molecular pathology tests and ADLTs. This proposed revision to the laboratory DOS policy would require laboratories performing cancer-related protein-based MAAAs to bill Medicare directly for those tests instead of seeking payment from the hospital when the service is not packaged and the DOS rule described above is met.

Commenters generally supported the proposed revisions to the laboratory DOS policy although there were comments asking that CMS expand the policy to include all CPT Proprietary Laboratory Analysis (PLA) test codes that may have similar characteristics to AMA CPT MAAA test codes but are not currently categorized as CPT MAAA test codes. Other commenters requested that CMS expand the policy to metabolite-based MAAA tests as well as protein-based tests and diseases other than cancer that have a distinct pattern of clinical use that make them relatively unconnected to a patient's hospital encounter.

There were comments requesting that CMS make the following PLA tests subject to the DOS exception: OVERA test from Aspira Labs (CPT 0003U), EPI assay by Bio-Techne (CPT 0005U), TissueCypher assay from Cernostics (CPT 0108U), and KidneyIntelX (0105U). Commenters asserted that the results of these tests are used to determine longer-term care treatment for the patient, and are typically discussed at a follow up appointment with the ordering physician.

With regard to PLA tests, CMS responded the PLA category as a whole does not address the clinical use of the test. Therefore, in order for CMS to consider certain PLA tests as potential additions to the DOS exception policy, CMS would need to establish that they are appropriately separable from the hospital outpatient encounter. At this time, CMS cannot establish that every PLA test, MAAA test, or "MAAA-like" PLA test, including those that are protein-based, are generally used to guide treatment outside of the outpatient clinical encounter and have a distinct pattern of clinical use that make them relatively unconnected to a patient's hospital encounter. However, if a protein-based MAAA test is designated by CMS as an ADLT, it would be eligible for the laboratory DOS exception

In response to the specific PLA tests commenters asked to be subject to the DOS exception, CMS responded that these PLA tests are relatively new, with minimal to no Medicare utilization. At this time CMS does not have a sufficient understanding of how these tests may be used to guide treatment outside of the outpatient encounter and whether they should be unpackaged under OPSS and subject laboratory DOS exception policy.

Several commenters recommended that CPT code 81490 be subject to the DOS exception. Commenters asserted that this rheumatoid arthritis (RA) test is unconnected to the hospital

outpatient encounter during which the specimen is collected and is instead used to determine potential future interventions outside of the hospital outpatient encounter. The test is used by the rheumatologist to make longer-term changes in RA treatment. CMS agreed and will include this test among those that are subject to the laboratory DOS exception.

Final Decision: CMS finalizes its proposal to add CPT codes 81500, 81503, 81535, 81536, 81539 and 81490 to the list of codes subject to the laboratory DOS exception. Cancer-related protein-based MAAAs that do not currently exist, but that are developed in the future will also be subject to this policy. CMS intends to continue studying the list of tests included in the laboratory DOS exception policy to determine whether any additional changes are warranted. If changes are warranted, CMS will propose future changes to this policy through notice-and-comment rulemaking.

XIX. Physician-Owned Hospitals

A. Background

The physician self-referral law prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies. It also prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third-party payer) for those referred services. Two exceptions apply under the physician self-referral law for physician-owned hospitals—the rural exception and the whole hospital exception.

B. Prohibition on Facility Expansion

Section 1877(i) of the Act prohibits hospitals subject to the rural exception and the whole hospital exception from increasing the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed (referred to as its “baseline number”) on specific dates. The Secretary is permitted to provide exceptions to the limits on facility expansion to an “applicable hospital” or “high Medicaid facility.”

Certain of the statutory provisions regarding expansion of facility capacity apply only to applicable hospitals, not high Medicaid facilities. For instance, the statute explicitly limits applications for an exception to the expansion limit up to once every 2 years to an applicable hospital. Further, the law only explicitly requires CMS to provide an opportunity for public input on the exception from applicable hospitals. However, CMS extended these provisions to high Medicaid facilities under its regulatory authority. If granted an exception, CMS’ regulations limit the increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed to the extent such increase does not exceed 200 percent of its baseline number. By regulation, the increases may only occur on the hospital’s main campus.

As the Congress did not explicitly mandate the regulatory policies described above to high Medicaid facilities, CMS has reconsidered its policies as part of the Patients over Paperwork initiative. CMS believes that its current regulations limiting high Medicaid facilities to up one expansion exception request every two years imposes unnecessary burden on high Medicaid

facilities. For this reason, CMS proposed to permit a high Medicaid facility to request an exception to the prohibition on expansion of facility capacity at any time. To preserve CMS resources and to continue to maintain an orderly and efficient exception process, CMS proposed that a high Medicaid facility may submit only one exception request at a time. Under the proposed change, a high Medicaid facility may not request a second exception for facility expansion if there is one pending for which CMS has not issued a decision.

CMS further proposed to not apply the exception expansion limit to 200 percent of the baseline number to high Medicaid facilities or that the expansion be limited to the hospital's main campus. Under the proposal, these restrictions would apply only to applicable hospitals.

CMS further considered whether it should eliminate the opportunity for community input in the review process with respect to high Medicaid facilities only (as the statute expressly requires this provision to apply to applicable hospitals). Comments were specifically solicited on the importance of community input, which allows for confirmation of (or disagreement with) the data provided by a high Medicaid facility seeking an exception to the prohibition on expansion of facility capacity. CMS requested comment regarding how it could obtain independent confirmation of the data provided in the absence of the community input. The proposed rule indicated that independent confirmation could delay or add complexity to the review process and result in greater burden or cause greater harm to high Medicaid facilities than continuing to permit community input on the expansion exception requests submitted by these hospitals.

General Comments

Commenters supported and opposed CMS' proposal to allow for expansion of physician-owned specialty hospitals. Supporters of the proposal suggested that expanded capacity of physician-owned hospitals could increase competition and choice, as well as patient access to high-quality care. Opponents of the proposal stated that a high Medicaid physician-owned specialty hospital could qualify for the exception by having a higher Medicaid percentage than other hospitals in its county even though they have very low Medicaid discharge percentages overall. As expansion is not limited to the hospital's main campus, these hospitals could then expand into markets without large Medicaid patient populations. Such hospitals could temporarily meet the high Medicaid facility threshold to qualify for expansion and then reject Medicaid patients as there is no requirement for a physician-owned hospital to maintain its status as a high Medicaid facility following the approval of an exception request.

CMS responded that the statute does not impose the same limitations on the expansion of high Medicaid facilities and, in its view, the regulatory limitations are burdensome and unnecessary. For this reason, CMS is finalizing its proposal to allow high Medicaid physician-owned specialty hospitals to expand. While CMS acknowledges the scenario raised as a concern in the comment, it is not prohibited by either the statute or the regulations, and CMS will not be adopting a policy to prohibit such activity.

The final rule emphasizes that any expansion of facility capacity must be part of the hospital for which the exception is approved (e.g. the expansion site must meet the provider-based rules). CMS further states that to qualify as an applicable hospital or a high Medicaid facility, a hospital

may not discriminate against beneficiaries of federal health care programs and may not permit physicians practicing at the hospital to discriminate against such beneficiaries. Further, other federal and state laws and regulations, such as the Emergency Medical Treatment and Labor Act and state Medicaid program rules and regulations, prohibit a hospital from refusing to care for or otherwise discriminate against Medicaid patients.

Academic Studies

Opponents of physician-owned specialty hospitals cited studies showing that they present a risk of program or patient abuse, have greater per capita utilization of services, have higher costs for the Medicare program, cherry-pick patients by avoiding Medicaid and uninsured patients, treat fewer medically complex patients and have margins nearly three times those of nonphysician-owned hospitals. Supporters of physician-owned specialty hospitals cited studies showing they have similar quality and costs of care when compared to nonphysician-owned hospitals or outperform other hospitals in the Medicare value-based purchasing program and that patients benefit when traditional hospitals have greater competition.

CMS acknowledged the conflicting conclusions in these studies and reiterated that the plain language of the statute does not impose the same limitations on the expansion of high Medicaid facilities as it does the expansion of applicable hospitals, and it believes that the existing regulations impose unnecessary burden on high Medicaid facilities.

Community Input

Commenters (including those that supported removing the restrictions on high Medicaid physician-owned specialty hospitals) supported retaining the process for obtaining community input before undergoing an expansion. One commenter opposed obtaining community input but did not provide an alternative method for CMS to obtain independent confirmation of data provided by a high Medicaid facility.

CMS agrees that community input is vital to the expansion exception process and that it was the Congress' intent to include it. Moreover, CMS believes that it would significantly lengthen the expansion exception process to eliminate community input, as CMS would need to engage in additional independent verification of information in the physician-owned hospital's expansion application. CMS is not revising its regulations to eliminate the requirement for community input related to the request of a high Medicaid facility for an exception to the prohibition on expansion of facility capacity.

C. Deference to State Law to Determine the Number of Licensed Beds

To qualify for the rural provider or whole hospital exception, a hospital may not increase the aggregate number of operating rooms, procedure rooms, and beds above its baseline number as of a specific date (March 23, 2010 or December 31, 2010 depending the circumstances of the hospital). Stakeholders have asked what CMS would consider to be the baseline number for which the hospital was licensed on either of these dates. CMS has responded to this question

through formal advisory opinions and frequently asked questions posted on its website.²⁷ For purposes of applying this provision of the physician self-referral law, CMS generally defers to the number of operating rooms, procedure rooms, and beds for which the hospital was licensed by the state on either March 23, 2010 or December 31, 2010. In extraordinary circumstances, CMS may include additional beds when determining a hospital’s baseline.²⁸

In order to ensure stakeholders’ awareness of a hospital’s baseline number licensed by the state as of either March 23, 2010 or December 31, 2010, CMS proposed to include the following sentence in the regulations:

For purposes of determining the number of beds in a hospital’s baseline number of operating rooms, procedure rooms, and beds, a bed is included if the bed is considered licensed for purposes of State licensure, regardless of the specific number of beds identified on the physical license issued to the hospital by the State.

CMS specifically requested comment on whether the inclusion of this language is necessary or could be perceived as inadvertently limiting the definition of “baseline number of operating rooms, procedure rooms, and beds.” Commenters supported this clarification of the regulations. There were no comments in opposition to the proposal. CMS is finalizing the proposal without modification.

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

Medicare provides indirect medical education (IME) and direct graduate medical education (DGME) payments to hospitals based on the number of residents the hospitals trains. The hospital’s payment is based on a cap at the number of residents trained in 1996. Section 5506 of the Affordable Care Act instructed the Secretary to establish a process to redistribute residency slots after a hospital closes. The final rule notifies the public about the closure of Westlake Community Hospital in Melrose Park, Illinois and Astria Regional Medical Center in Yakima, Washington. Combined Table 75/76 below contains the identifying information and IME and DGME FTE resident caps for the closed teaching hospitals to be redistributed. CMS describes the redistribution process for each hospital as rounds 18 and 19 respectively.

Available Resident Cap FTEs

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME Resident Cap	DGME Resident Cap
140240	Westlake Community Hospital	Melrose Park, IL	16984	08/14/2019	36.33	39.28
500012	Astria Regional Medical Center	Yakima, WA	49420	01/15/2020	12.03	13.02

²⁷ <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2019-01-Redacted.pdf>; <https://www.cms.gov/files/document/cms-ao-2020-01.pdf>; and <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/FAQsPhysician-Self-Referral-Law.pdf>.

²⁸ https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.

Application Process for Available Resident Slots

The application period for hospitals to apply for slots under section 5506 is 90 days following notification to the public of a hospital closure. The application deadline is not included in the rule but is stated as “90 days from date of display in the Federal Register.” CMS confirmed that this date is March 4, 2021. Hospitals must submit an application form to the CMS Central Office by March 4, 2021 to be eligible to receive slots from these closed hospitals. The mailing address for the CMS Central Office is included on the application form. Applications must be received by the CMS Central Office by the deadline date. **It is not sufficient for applications to be postmarked by this date.** The application is available at:

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

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

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

On behalf of [insert hospital name and Medicare CCN#], I, [insert your name], am sending this email to notify CMS that I have mailed to CMS a hard copy of a section 5506 application under [Round 17 or Round 18 due to the closure of Westlake Community Hospital in Melrose Park, Illinois or Astria Regional Medical Center in Yakima, Washington]. If you have any questions, please contact me at [insert phone number] or [insert your email address].”

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

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

XXI. Radiation Oncology (RO) Model

On September 29, 2020, CMS published a final rule in the *Federal Register* (85 FR 61114) entitled “Specialty Care Models to Improve Quality of Care and Reduce Expenditures” that finalized the Radiation Oncology Model (RO Model). To ensure that participation in the RO Model during the PHE for COVID-19 pandemic does not further strain RO participants' capacity, CMS is revising the RO Model's performance period to begin on July 1, 2021 and end December 31, 2025 in the interim final rule with comment period. CMS states that this will give RO participants an additional 6 months necessary to learn the RO billing requirements and train staff on new procedures for 2021, and as a consequence of the revised RO Model performance

period, an additional 12 months to prepare for required quality measure and clinical data element reporting beginning in 2022.

The interim final rule with comment period revised the following RO Model policies as described in the table below. It waives proposed rulemaking based on the continuing PHE. CMS notes there is a 60-day public comment period to comment on these final amendments to its regulations.

RO Model Issue	Policy Revision	Comments
Model performance period at §512.205	4.5 years, beginning on July 1, 2021, and ending on December 31, 2025. PY1 will be 6 months, and each subsequent PY will be a calendar year (CY).	This will not affect the list of participating ZIP Codes posted on the RO Model website.
Low volume opt-out eligibility timeframe at §512.210©	PY1 – Episodes from CY 2019 PY2 – Episodes from CY 2020 PY3 – Episodes from first 6 months of CY 2020 and RO episodes for the last 6 months of CY 2021. PY4 – RO episodes from CY 2022 PY5 – RO episodes from CY 2023	Both episodes and RO episodes from 2021 will be used to determine eligibility for the low volume opt-out for PY3.
Review and certification of the individual practitioner list at §512.217	Excludes PY1 from use in determining Qualifying APM Participant determinations or for a MIPS APM under the QPP in PY1.	RO Model will not meet the criteria to be either an Advanced APM or a MIPS APM under the QPP in PY1.
Included RO episodes at §512.245	Any RO episode that begins on or after July 1, 2021, and ends on or before December 31, 2025, is included in the Model performance period.	Clarifies episodes included in model.
Quality requirements	Quality measures requirements will be delayed to PY 2.	RO model will not meet the criteria to be either an Advanced APM or a MIPS APM under the QPP in PY1. Expects this designation starting in PY2.
Form, manner, and timing policy for data reporting	RO participants must, beginning in PY2, submit in March 2023 quality measures data from January 1, 2022 through December 31, 2022.	PY2 will include three pay-for-performance measures: (1) Plan of Care for Pain; (2) Screening for Depression and Follow-up Plan; and (3) Advance Care Plan. The fourth measure, Treatment Summary Communication, will be a pay-for-performance measure.
CAHPS contractor start date	Administer the CAHPS® Cancer Care Survey for Radiation Therapy beginning in October 2021.	Replaces the April 2021 date.
Quality withhold at §512.255(c)(10)	No quality withhold in PY1.	Delays the quality reporting until PY2, thus not quality withhold

RO Model Issue	Policy Revision	Comments
Reconciliation process at §512.285(d)	Professional participants and Dual participants will have a quality reconciliation amount only for PY2 through PY5.	Reconciliation amount for PY1 will be based solely on the incorrect episode payment reconciliation amount and any stop-loss reconciliation amount, if applicable.
CEHRT requirements at §512.220(b)	CEHRT measure requirements will be delayed to PY 2.	RO participants will not be eligible for the 5 percent APM Incentive Payment for QPs in PY 1 based on their participation in the RO Model.

XXII. Reporting COVID-19 Therapeutic and Acute Respiratory Illness Data

A. Reporting COVID-19 Therapeutic Acute Respiratory Illness Data

Under its CoP authority and regulations, CMS is requiring hospitals and CAHs to report data elements that must include, the following: (1) the hospital’s (or the CAH’s) current inventory supplies of any COVID-19-related therapeutics that have been distributed and delivered to the hospital (or CAH) under the authority and direction of the Secretary; and (2) the hospital’s (or the CAH’s) current usage rate for any COVID-19-related therapeutics that have been distributed and delivered to the CAH under the authority and direction of the Secretary.

CMS is also requiring hospitals and CAHs to report information with a frequency, and in such standardized format as specified by the Secretary during the COVID-19 PHE, on acute respiratory illness (including, but not limited to, seasonal influenza virus, influenza-like illness, and severe acute respiratory infection). Examples of data elements that are to be reported include diagnoses, admissions, and counts of patients currently hospitalized who have diagnoses of acute respiratory illnesses (including, but not limited to, seasonal influenza virus, influenza-like illness, and severe acute respiratory infection). The new rules make reporting a requirement of participation in the Medicare and Medicaid programs and CMS says the required reporting is needed to support broad surveillance of COVID-19 in conjunction with other acute respiratory illnesses that may further burden and strain hospital and CAH resources.

CMS believes that universal acute respiratory illness reporting, in tandem with the current COVID-19 reporting, by all hospitals and CAHs, will be an important tool for supporting surveillance of COVID-19, as well as for future planning to prevent the spread of these respiratory viruses and infections, especially to those most vulnerable and at-risk. New reporting data that will be requested by the Secretary will include reporting channel options similar to, if not the same as, those currently in place for COVID-19, to make submission of data as user-friendly as possible to reduce the potential strain and burden on hospitals and CAHs. The new standards will ask hospitals and CAHs to report information on acute respiratory illness in a standardized format, frequency, and manner specified by the Secretary.

CMS is waiving notice and comment rulemaking procedures to adopt this provision citing the COVID-19 public health emergency as its good cause. The reporting requirements are effect on December 4, 2020.

B. Enforcement of Reporting Requirements

Should a hospital or CAH consistently fail to report data related to patient diagnoses of acute respiratory illness (including, but not limited to, seasonal influenza virus, influenza-like illness, and severe acute respiratory infection) throughout the duration of the PHE for COVID-19, it will be non-compliant with the hospital and the CAH CoPs and subject to termination. While CMS implies that it would prefer to impose civil monetary penalties (CMPs) as intermediate step short of termination to enforce compliance with this new CoP requirement, it indicates that the statute does not give it authority to do so. However, CMS will continue to utilize all enforcement and payment authorities available to incent and promote compliance with all health and safety requirements, as allowed by statute and regulation.

XXIII. Files Available to the Public via the Internet

Addenda for the 2021 OPPS final rule are available on the following CMS website: [CMS-1736-FC | CMS](#)

Note that CMS has added a column to Addenda A and B entitled “Copayment Capped at the Inpatient Deductible of \$1,408.” An asterisk will appear in this column signifying that outpatient coinsurance is capped at the inpatient deductible for that year.

For addenda related to 2021 ASC final payments, please see: [CMS-1736-FC | CMS](#)

TABLE 79—ESTIMATED IMPACT OF 2021 OPPS CHANGES

	(1)	(2)	(3)	(4)	(5)
	Number of Hospitals	APC Recalibration (All Changes)	New Wage Index and Provider Adjustments	All Budget Neutral Changes (Combined cols 2&3 with Market Basket Update)	All Changes
ALL PROVIDERS *	3,665	0.0	0.2	2.6	2.4
ALL HOSPITALS	3,558	0.0	0.2	2.7	2.4
(excludes hospitals held harmless and CMHCs)					
URBAN HOSPITALS	2,806	0.0	0.2	2.6	2.4
LARGE URBAN (GT 1 MILL.)	1,449	0.0	0.2	2.6	2.4
OTHER URBAN (LE 1 MILL.)	1,357	0.1	0.2	2.7	2.4
RURAL HOSPITALS	752	0.0	0.4	2.9	2.5
SOLE COMMUNITY	367	0.0	0.5	3.0	2.6
OTHER RURAL	385	0.0	0.2	2.7	2.4
BEDS (URBAN)					
0 - 99 BEDS	961	0.2	0.3	2.9	2.6
100-199 BEDS	786	0.3	0.3	2.9	2.6
200-299 BEDS	447	0.3	0.2	2.9	2.7
300-499 BEDS	386	0.2	0.2	2.8	2.5
500 + BEDS	226	-0.4	0.0	2.1	2.0
BEDS (RURAL)					
0 - 49 BEDS	330	0.0	0.5	2.9	2.5
50- 100 BEDS	256	0.1	0.5	3.1	2.6
101- 149 BEDS	90	0.0	0.3	2.6	2.3
150- 199 BEDS	38	-0.1	0.4	2.8	2.6
200 + BEDS	38	0.0	0.2	2.6	2.5
REGION (URBAN)					
NEW ENGLAND	132	-0.3	1.0	3.1	2.0
MIDDLE ATLANTIC	327	-0.2	0.1	2.4	2.3
SOUTH ATLANTIC	455	0.1	0.1	2.6	2.6
EAST NORTH CENT.	440	-0.1	-0.1	2.3	2.2
EAST SOUTH CENT.	163	0.0	-0.1	2.3	2.3
WEST NORTH CENT.	186	0.0	0.5	2.9	1.9
WEST SOUTH CENT.	474	0.5	0.1	3.0	3.0
MOUNTAIN	213	0.2	0.1	2.8	2.1
PACIFIC	368	0.1	0.2	2.8	2.7
PUERTO RICO	48	0.2	-0.2	2.4	2.3
REGION (RURAL)					
NEW ENGLAND	20	-0.3	0.1	2.2	2.1
MIDDLE ATLANTIC	50	-0.2	0.1	2.4	2.4
SOUTH ATLANTIC	113	0.0	-0.2	2.2	2.1
EAST NORTH CENT.	120	0.2	0.6	3.3	3.2
EAST SOUTH CENT.	146	0.0	0.0	2.5	2.4
WEST NORTH CENT.	91	0.0	1.1	3.5	2.4
WEST SOUTH CENT.	141	0.5	0.0	2.9	2.8

	(1)	(2)	(3)	(4)	(5)
	Number of Hospitals	APC Recalibration (All Changes)	New Wage Index and Provider Adjustments	All Budget Neutral Changes (Combined cols 2&3 with Market Basket Update)	All Changes
MOUNTAIN	48	-0.2	2.2	4.4	2.4
PACIFIC	23	-0.2	-0.2	2.0	2.0
TEACHING STATUS					
NON-TEACHING	2,391	0.3	0.2	2.9	2.7
MINOR	792	0.2	0.3	3.0	2.6
MAJOR	375	-0.5	0.1	2.0	1.9
DSH PATIENT PERCENT					
0	13	0.1	-0.3	2.1	2.0
GT 0 - 0.10	267	0.6	0.0	3.0	2.7
0.10 - 0.16	241	0.4	0.2	3.1	2.8
0.16 - 0.23	579	0.5	0.2	3.1	2.8
0.23 - 0.35	1,101	0.0	0.3	2.7	2.4
GE 0.35	899	-0.3	0.1	2.3	2.1
DSH NOT AVAILABLE **	458	0.0	0.1	2.5	2.3
URBAN TEACHING/DSH					
TEACHING & DSH	1,048	-0.1	0.2	2.5	2.3
NO TEACHING/DSH	1,307	0.4	0.1	2.9	2.7
NO TEACHING/NO DSH	13	0.1	-0.3	2.1	2.0
DSH NOT AVAILABLE2	438	0.0	0.1	2.5	2.3
TYPE OF OWNERSHIP					
VOLUNTARY	1,976	0.0	0.2	2.6	2.3
PROPRIETARY	1,132	0.9	0.3	3.5	3.2
GOVERNMENT	450	-0.3	0.1	2.2	2.2
CMHCs	39	9.7	-0.1	12.2	11.9

Column (1) shows total hospitals and/or CMHCs

Column (2) includes all final CY 2021 OPPS policies and compares those to the CY 2020 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the final FY 2021 hospital inpatient wage index and the non-budget neutral frontier adjustment. The final rural SCH adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the cancer hospital adjustment is 1.0000 because in CY 2021 the final target payment-to-cost ratio is the same as that of CY 2020 (0.90 and reduced to 0.89 in accordance with the 21st Century Cures Act)

Column (4) shows the impact of all budget neutrality adjustments and the addition of the 2.4 percent OPD fee schedule update factor (2.4 percent reduced by 0.0 percentage point for the productivity adjustment).

Column (5) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate, and adding estimated outlier payments. Note that previous years included the frontier adjustment in this column, but we have the frontier adjustment to Column 3 in this table.

These 3,665 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.

** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.