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

The Centers for Medicare & Medicaid Services (CMS) released the calendar year 2021[1] proposed rule for Medicare's hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system on August 4, 2020. Policies in the proposed rule will generally go into effect on January 1, 2021 unless otherwise specified. The proposed rule will be published in the August 12th issue of the *Federal Register*. **The public comment period will end on October 5, 2020.**

While the final rule would normally be published by November 2, 2020 to allow for a 60-day delay in the effective date in accord with the Congressional Review Act, CMS is waiving the 60-day delay because of the COVID-19 public health emergency (PHE). CMS expects to provide a 30-day delay in the effective of the final rule which means that it would likely be published no later than December 2, 2020.

The proposed rule updates OPPS payment policies that apply to outpatient services provided to Medicare beneficiaries by general acute care hospitals, inpatient rehabilitation facilities, inpatient psychiatric facilities, long-term acute care hospitals, children's hospitals, and cancer hospitals, as well as for partial hospitalization services in community mental health centers (CMHCs). Also included is the 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, proposed 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: https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1736-p. Unless otherwise noted, this weblink can be used to access any information specified as being available on the CMS website.

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

I. Overview

A. Estimated Impact on Hospitals

The total 2021 increase in OPPS spending due only to changes in the 2020 OPPS proposed rule is estimated to be approximately $1.61 billion. Taking into account estimated changes in enrollment, utilization, and case-mix for 2021, CMS estimates that OPPS expenditures, including beneficiary cost-sharing will be approximately $83.9 billion, which is approximately $7.5 billion higher than estimated OPPS expenditures in 2020.

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

The proposed update equals the market basket of 3.0 percent reduced by a multifactor productivity adjustment of 0.4 percentage points. The net proposed update is 2.6 percent. Hospitals that satisfactorily report quality data will qualify for the full update of 2.6 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 OPPS increase factor.

Medicare makes payments under the OPPS to approximately 3,628 facilities (3,523 hospitals excluding CMHCs and cancer and children's hospitals held harmless to their pre-OPPS payment to cost ratios). Table 55 in the proposed rule (reproduced in the Appendix to this summary) includes the estimated impact of the proposed rule by provider type. It shows an estimated increase in expenditures of 2.5 percent for all facilities and 2.6 percent for all hospitals (all facilities except cancer and children's hospitals, and CMHCs). The following table shows components of the 2.5 percent total:

	% Change All Facilities
Fee schedule increase factor	2.6
Difference in pass through estimates for 2020 and 2021	-0.05
Difference from 2020 outlier payments (1.01% vs. 1.0%)	-0.01
All changes	2.5

The proposed fee schedule increase factor is 2.6 percent (3.0 percent for the hospital market basket less 0.4 percentage points for multifactor productivity). CMS estimates that pass-through spending for drugs, biologicals and devices for 2021 will be $783.2 million, or 0.930 percent of OPPS spending. For 2020, CMS estimates pass-through spending would be 0.880 percent of OPPS spending. The -0.05 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 1.01 percent of total OPPS payments compared to the 1.0 percent set aside, a -0.01 percentage point change in 2021 payments.

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

Although CMS projects an estimated increase of 2.5 percent for all facilities, the proposed rule impacts vary depending on the type of facility. Impacts will differ for each hospital category based on the mix of services provided, location and other factors. Impacts for selected categories of hospitals are shown in the table below:

Facility Type	2021 Impact
All Hospitals	2.6
All Facilities (includes CMHCs and cancer and children's hospitals)	2.5
Urban	2.5
Large Urban	2.5
Other Urban	2.4
Rural	3.2
Beds	
0-99 (Urban)	3.4
0-49 (Rural)	3.5
500+ (Urban)	1.6
200+ (Rural)	3.0
Major Teaching	1.4
Type of ownership:	
Voluntary	2.4
Proprietary	4.1
Government	2.2

The above table includes CMS' proposal to make payment for 340B drugs at average sales price (ASP)-28.7 percent beginning in 2021 instead of ASP-22.5 percent. The proposed adjustment is expected to decrease payments by $427 million. To offset this decrease, CMS is proposing to

increase payments for all non-drug OPPS services by 0.85 percent (1.0085). Increases in the above table that are smaller than the 2.6 percent average across all hospitals are generally accounted for by the 340B policy. For instance, large urban hospitals over 500 beds and major teaching hospitals are estimated to lose 0.6 percent as a result of the proposed 340B policy. Conversely, increases that are larger than the 2.6 percent average across all hospitals are generally accounted for by the budget neutrality offset for the reductions in payment from the 340B policy. Proprietary hospitals, for instance, are ineligible for the 340B discounts and will see no decline in payment from the additional reduction in ASP pricing. However, these hospitals will benefit from the increase in payments to all non-drug services that is made to ensure the proposed 340B policy is budget neutral. The higher increases for rural hospitals are also generally a result of the proposed 340B policy.

B. Estimated Impact on Beneficiaries

CMS estimates that the aggregate beneficiary coinsurance percentage will be 18.1 percent for all services paid under the OPPS in 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 ($1,408 in 2020) which accounts for the aggregate coinsurance percentage being less than 20 percent.

II. Updates Affecting OPPS Payments

A. Recalibration of APC Relative Payment Weights

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

1. Database Construction

a. Database Source and Methodology

For the 2021 proposed rule, CMS proposes to use hospital final action claims for services furnished from January 1, 2019 through December 31, 2019 processed through the Common Working File as of March 30, 2020. Proposed 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. (https://www.cms.gov/files/document/2021-nprm-opps-claims-accounting.pdf)

Continuing past years' methodology, CMS proposes to calculate the cost of each procedure only from single procedure claims. CMS proposes to create "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 proposed rule, CMS proposes to bypass the 173 Healthcare Common Procedure Coding System (HCPCS) codes identified in Addendum N. CMS indicates the list of bypass codes may include codes that were reported on claims in 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 proposes to multiply the charges by a hospital-specific CCR associated with each revenue code and cost center. To calculate CCRs for 2021, CMS proposes 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 OPPS/ASC final rule with comment period (78 FR 74840 through 74847), CMS created distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. However, in response to public comment, CMS removed claims from providers that use a cost allocation method of "square feet" to calculate CCRs used to estimate costs associated with the CT and MRI APCs (78 FR 74847) because of concerns about the accuracy of this cost allocation method. CMS indicated that it would provide hospitals with 4 years to transition to a more accurate cost allocation method and would use cost data from all providers, regardless of the cost allocation statistic employed, beginning in 2018. CMS later extended the transition policy through 2018 and 2019.

Table 1 of the proposed rule shows the relative effect on imaging APC payments after removing cost data for providers that report CT and MRI standard cost centers using square feet as the cost allocation method. Table 2 of the proposed rule provides statistical values based on the CT and MRI standard cost center CCRs using the different cost allocation methods. 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	-2.6%
5522	Level 2 Imaging without Contrast	5.5%
5523	Level 3 Imaging without Contrast	4.1%
5524	Level 4 Imaging without Contrast	5.5%
5571	Level 1 Imaging with Contrast	6.7%
5572	Level 2 Imaging with Contrast	8.3%
5573	Level 3 Imaging with Contrast	2.1%
8005	CT and CTA without Contrast Composite	13.9%
8006	CT and CTA with Contrast Composite	10.9%

APC	APC Descriptor	% Change Excluding Sq. Ft. CCRs
8007	MRI and MRA without Contrast Composite	7.0%
8008	MRI and MRA with Contrast Composite	7.3%

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	0.0347	0.0491	0.0764	0.1016
Square Feet Only	0.0286	0.0444	0.0665	0.0928
Direct Assign	0.0472	0.0564	0.0935	0.1183
Dollar Value	0.0414	0.0553	0.0858	0.1128
Direct Assign and Dollar Value	0.0415	0.0555	0.0866	0.1131

The proposed rule indicates that the number of valid MRI CCRs has increased by 18.5 percent to 2,195 providers and the number of valid CT CCRs has increased by 16.3 percent to 2,275 providers since CMS adopted its policy in 2014 of excluding providers that use the square foot cost allocation method. As shown in Table 1 below, eliminating these hospitals from the OPPS rate setting methodology increases the payment for all but one of the imaging APCs because hospitals that use the square foot allocation have lower CCRs for their imaging cost centers. CMS believes that because many providers continue to use the "square feet" cost allocation methodology, it is valid for attributing costs.

In the 2020 OPPS 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 feet CCRs) and 50 percent of the standard methodology (including square feet CCRs). For 2021, CMS proposes 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 OPPS final rule.

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

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

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 proposing to continue following 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 physician fee schedule 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 proposes 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 proposing to continue to include blood and blood products in the comprehensive APCs, which provide all-inclusive payments covering all services on the claim. HCPCS codes and their associated APCs for blood and blood products are identified with a status indicator of "R" (Blood and Blood Products) in Addendum B of the proposed rule.

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 is proposing to unconditionally package HCPCS code P9099 because it is not possible to accurately determine an appropriate rate for multiple products with varying costs. CMS believes 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 proposed CY 2021 payment rate of $8.02 per unit. CMS rejected this option as the cross-walked payment rate could be significantly lower than the cost of the 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 mm^2. For 2020, CMS proposed to set the payment rate for HCPCS code C2645 at $1.02 per mm^2 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 mm^2 for 2020. As CMS has only one claim in the 2019 data to set a rate for HCPCS code C2645, it is proposing to continue the rate of $4.69 per mm^2 for 2021.

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.

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 OPPS, CMS is not proposing to convert any conventional APCs to C-APCs in 2021. The full list of C-APCs, the data CMS used to evaluate APCs for being a C-APC, and C-APC complexity adjustments are found in Addendum J. C-APCs with a status indicator of "J1" or "J2" (only for the Comprehensive Observation Services C-APC) can be found in other Addenda as well.

c. Calculation of Composite APC Criteria-Based Costs

Since 2008, CMS has used composite APCs to make a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. CMS is proposing to continue unchanged composite policies for mental health services and multiple imaging services for 2021.

3. Changes to Packaged Items and Services

Except as described below for protein-based Multianalyte Assays with Algorithmic Analyses (MAAAs) laboratory tests, CMS is not proposing 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 OPPS to ensure that there are not financial incentives to use opioids instead of non-opioid alternatives. CMS reviews prior analysis done under the SUPPORT Act and is not proposing any changes to its packaging policies for 2021 for non-opioid treatment alternatives.

Stakeholders have suggested that some protein-based MAAAs to diagnose cancer should not be packaged into OPPS payment. These commenters state that these MAAAs are similar to DNA and RNA-based MAAA tests that are separately paid under the OPPS. 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 is proposing to exclude cancer-related protein-based MAAAs from the OPPS 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 proposes 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 is 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 is excluding 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.

4. Calculation of OPPS Scaled Payment Weights.

As in past years, CMS proposes to standardize the relative weights based on APC 5012 and HCPCS code G0463 (a hospital outpatient clinic visit) which is the most commonly billed OPPS service. CMS proposes giving APC 5012 a relative weight of 1.0 and dividing the geometric mean costs of all other APCs by the geometric mean cost for APC 5012 to determine its associated relative payment weight. Even though CMS is paying for clinic visits furnished in off-campus PBDs at a PFS equivalent rate under a site neutral policy, CMS is proposing 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 is proposing to follow its past practice to determine budget neutrality for changes in the OPPS 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 proposes adopting a weight scaler of 1.4443. 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 is proposing 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. CMS does not show the details of this calculation in the proposed rule but it can be found on page 24 of the claims accounting at the weblink shown at the beginning of the summary and is shown in the below table:

2020 Conversion Factor	**$80.7930**	**Resulting CF**
Remove pass-through and outliers from prior year CF	1.0192	82.341
Wage Index Budget Neutrality	1.0027	82.563
Budget Neutrality Wage Index Cap	0.9990	82.480
Cancer Hospital Adjustment	1.0000	82.480
Rural Hospital Adjustment	1.0000	82.480
340B Budget Neutrality	1.0085	83.181
Update	1.0260	85.344
Pass-Through and Outlier Adjustment	0.9807	83.697
2021 Conversion Factor		83.697

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 1.0027 (0.0.27 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 0.9990 (-0.10 percent). The cancer and rural hospital adjustments are 1.0000 (0.0 percent). The update of 1.026 (2.6 percent) equals the market basket of 3.0 percent less 0.4 percentage points for multifactor productivity. CMS estimates that pass-through spending for drugs, biologicals and devices for 2021 will be $783.2 million or 0.93 percent of OPPS spending. The outlier adjustment is 0.99 (-1.0 percent). The combined adjustment for pass-through and outliers is 0.9807 (-1.93 percent).

CMS reports that the reduced conversion factor for hospitals not meeting the OQR requirements will be $82.0650 which is determined using the factors in the table above and substituting 1.006 for the 1.0260 for the update.

C. Wage Index Changes

CMS is proposing to continue using a labor share of 60 percent and the fiscal year IPPS post-reclassified wage index for the OPPS in 2021. It also proposes 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 may affect hospital wage indexes. Consistent with the policy adopted in the FY 2021 IPPS proposed rule, CMS proposes 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.

For non-IPPS hospitals paid under the OPPS for 2021, CMS is proposing 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.

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

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

In cases where there is no data to calculate a hospital's CCR, CMS proposes 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 proposes 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 is updating 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 OPPS rule. CMS says it is available at the link provided at the beginning of this summary but it is actually at https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppsannual-policy-files/2021.

E. Sole Community Hospital (SCH) Adjustment

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

F. Cancer Hospital Adjustment

Eleven cancer hospitals meeting specific statutory classification criteria are exempt from the IPPS. Medicare pays these hospitals under the OPPS for covered outpatient hospital services. The 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 OPPS 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 proposed rule shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals, with increases in OPPS payments for 2021 ranging from 11.2 percent to 44.8 percent. No additional budget neutrality adjustment is required for the cancer hospital adjustment in 2021 compared to 2020.

G. Outpatient Outlier Payments

CMS makes OPPS outlier payments on a service-by-service basis when the cost of a service exceeds the outlier threshold. For 2021, CMS is proposing to continue setting aside 1.0 percent of the estimated aggregate total payments under the OPPS for outlier payments. It is proposing to calculate the fixed-dollar threshold using the same methodology that was used to set the threshold for 2020 and previous years. CMS is proposing 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 calculates a fixed-dollar threshold of $5,300 (compared to $5,075 in 2020).

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

Hospitals that fail to report data required for the quality measures selected by the Secretary incur a 2.0 percentage point reduction to their OPPS annual payment update factor, resulting in reduced OPPS payments for most services. For hospitals failing to satisfy the quality reporting requirements, CMS proposes 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.

To model hospital outlier payments and set the outlier threshold for the proposed rule, CMS applied the hospital-specific overall ancillary CCRs available in the April, 2020 update to the Outpatient Provider-Specific File after adjustment using a CCR inflation adjustment factor of 0.975271 to approximate 2021 CCRs and a charge inflation factor of 1.131096 to approximate 2021 charges from 2019 claims.

H. Calculation of an Adjusted Medicare Payment

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

I. Beneficiary Coinsurance

Medicare law provides that the minimum coinsurance is 20 percent. The statute also limits a beneficiary's actual cost-sharing amount for a service to the inpatient hospital deductible for the applicable year, which is $1,408 in 2020. 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. OPPS Ambulatory Payment Classification (APC) Group Policies

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

CPT and Level II HCPCS code changes that affect the OPPS are published through the annual rulemaking cycle and through the OPPS 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 OPPS final rule. The proposed status indicators, APC assignments, and payment rates can be found in Addendum B of this proposed rule.[2]

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

1. April 2020 Codes - CMS Solicits Public Comments in this Proposed Rule

In the April 2020 OPPS quarterly update, CMS made effective 13 new Level II HCPCS codes and assigned them to interim OPPS status indicators and APCs (Table 6 in the proposed rule). For the April 2019 update, there were no new CPT codes.

2. July 2020 HCPCS Codes - CMS Solicits Public Comments in this Proposed Rule

In the July 2020 OPPS quarterly update, CMS made 102 new codes effective and assigned them to interim OPPS status indicators and APCs (Table 7).

3. October 2020 HCPCS Codes - CMS Will Be Soliciting Public Comments in the 2021 Final Rule with Comment Period

CMS proposes to provide interim payment status indicators, APC assignments and payment rates, if applicable, for HCPCS codes that will become effective October 1, 2020 in Addendum B to the 2021 final rule. These codes will be flagged with comment indicator "NI" in Addendum B, indicating that CMS has assigned the codes an interim OPPS payment status for 2021. CMS proposes that these status indicators and APC assignments would be applicable in 2021. **CMS will invite 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 final rule.

4. January 2021 HCPCS Codes

a. New Level II HCPCS Codes – CMS Will Be Soliciting Public Comments in the 2021 Final Rule with Comment Period

CMS will solicit comments on the new Level II HCPCS codes that will become effective January 1, 2021 in the 2021 OPPS 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 proposed rule, most Level II HCPCS codes are not released until November to be effective January 1 and CMS is not able to include them in the proposed rule.

New Level II HCPCS codes that will be effective January 1, 2021 will be flagged with comment indicator "NI" in Addendum B, indicating that CMS has assigned the codes an interim OPPS payment status for 2021. CMS proposes that these status indicators and APC assignments will be applicable in 2021. **CMS will invite 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 Will Be Soliciting Public Comments in This 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 this proposed rule (available in Addendum B of this proposed rule). CMS will continue to assign a new comment indicator "NP" and is requesting comments on the

proposed APC assignment, payment rates and status indicators. (NP indicates that the code is new for the next CY or the code is an existing code with substantial revision to its code descriptor in the next CY as compared to the current CY, with a proposed APC assignment and that comments will be accepted on the proposed APC assignment and status indicator.) CMS proposes to finalize the status indicators and APC assignments for these codes in the 2021 OPPS final rule.

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

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
	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 recommendations for specific services for the 2021 OPPS and CMS' responses will be discussed in the 2021 OPPS final rule.

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

2. Proposed APC Exceptions to the 2 Times Rule

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

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

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

Table 9 (reproduced below), lists the 18 APCs that CMS proposes to exempt from the 2 times rule for 2021based on claims data from January 1, 2019, through December 31, 2019 and processed on or before December 31, 2019. For the final rule, CMS plans to use 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.

TABLE 9: PROPOSED CY 2021 APC EXCEPTIONS TO THE 2 TIMES RULE	
Proposed CY 2021 APC	**Proposed CY 2021 APC Title**
5051	Level 1 Skin Procedures
5055	Level 5 Skin Procedures
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5112	Level 2 Musculoskeletal Procedures
5301	Level 1 Upper GI Procedures
5311	Level 1 Lower GI Procedures
5521	Level 1 Imaging without Contrast

TABLE 9: PROPOSED CY 2021 APC EXCEPTIONS TO THE 2 TIMES RULE	
Proposed CY 2021 APC	**Proposed CY 2021 APC Title**
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5571	Level 1 Imaging with Contrast
5612	Level 2 Therapeutic Radiation Treatment Preparation
5627	Level 7 Radiation Therapy
5691	Level 1 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5821	Level 1 Health and Behavior Services
5823	Level 3 Health and Behavior Services

C. New Technology APCs

1. New Technology APC Groups

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

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

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

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

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

services using its equitable adjustment authority. For 2021, CMS proposes to continue this policy:

- Use 4 years of claims data to establish a payment rate for each applicable service both for assigning a service to a New Technology APC and for assigning a service to a regular APC at the conclusion of payment for the service through a New Technology APC;
- Use the geometric mean, the median, or the arithmetic mean to calculate the cost of furnishing the applicable service;
- 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 proposes 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) (APCs 1575, 5114 and 5414)

There are four CPT/HCPS 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 has 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 meets the definition for a low-volume new technology service, CMS proposes to assign the service to a clinical APC. CMS determined that the most appropriate APC would be the Neurostimulator and Related Procedures APC series (APC 5461- 5464). Based on the geometric mean cost of CPT code 0398T ($12,798.38), CMS is concerned that the payment rate for APC 5462 ($6,169.27) would be too low and the payment rate for APC 5463 would be too high ($19,737.37) for this procedure. CMS proposes to restructure this APC family and create an additional payment level (also discussed below in section D). CMS creates a proposed Level 3, “Proposed APC 5463”, with a payment rate of approximately $12,286. CMS proposes to reassign CPT code 0398 to “Proposed APC 5463” (Table 10 in the proposed rule).

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

For 2021, CMS has 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 fall within the cost band for New Technology APC 1908, with an estimated cost between $145,001 and $160,000. CMS proposes to maintain the assignment of CPT code 0100T to APC 1908 (New Technology – Level 52 ($145,0001-$152,000)). CMS notes that the proposed payment rate includes both the surgical procedure (CPT code 0100T) and the use of the Argus II device (HCPCS code C1841).

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 proposes to establish a new HCPCS code C97X1 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) to describe this procedure. For 2021, CMS proposes to assign C97X1 to APC 1561 (New Technology Level 24 ($3001- $3500)) (Table 11).

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 proposes 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.(Table 12).

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 does not propose this reassignment and instead proposes to reassign CPT code 0503T to New Technology APC 1510 (New Technology Level 10 ($801- $900) with a proposed payment rate of $850.50.

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 proposes to continue to maintain the 2020 assignment for 2021 (Table 13).

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 notes that P9100 has been assigned to a new technology APC since July 2107 and believes it has 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 proposes to reassign P9100 to APC 5732 with a geometric mean of approximately $33.

h. V-Wave Interatrial Shunt Procedure (HCPCS code C758; APC 1589)
CMS discusses 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)) (Table 14).

i. Supervised Visits for Esketamine Self-Administration (HCPCS codes G2082 and G2083); APCs 1508 and 1511)

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 proposes to continue to assign HCPCS code G2082 to New Technology APC 1508 and assign HCPCS code G2083 to New Technology APC 1511 (Table 15).

D. APC-Specific Policies

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

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

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

Based on the available 2019 claims data, CMS believes it is appropriate to create an additional Neurostimulator and Related Procedures level, between the Level 2 and 3 APCs. CMS states this will allow for a smoother distribution of the costs between the different levels based on their resource costs and clinical characteristics. Table 16, reproduced below, provides information about the five proposes APCs.

TABLE 16: PROPOSED NEUROSTIMULATOR AND RELATED PROCEDURES APCs FOR CY 2021

APC	APC Descriptor	SI	CY 2020 OPPS Final Geometric Mean Cost	CY 2021 Proposed Geometric Mean Cost
5461	Level 1 Neurostimulator and Related Procedures	J1	$3,080.60	$3,370.70
5462	Level 2 Neurostimulator and Related Procedures	J1	$6,053.71	$6,105.05

TABLE 16: PROPOSED NEUROSTIMULATOR AND RELATED PROCEDURES APCs FOR CY 2021				
APC	**APC Descriptor**	**SI**	**CY 2020 OPPS Final Geometric Mean Cost**	**CY 2021 Proposed Geometric Mean Cost**
5463	Level 3 Neurostimulator and Related Procedures	J1	$18,863.68	$12,286.43
5464	Level 4 Neurostimulator and Related Procedures	J1	$28,490.84	$20,032.49
5465	Level 5 Neurostimulator and Related Procedures	J1	N/A	$28,876.14

2. 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 there will be a new CPT code 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 believes the test is 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 proposes to assign the new CPT code associated with IDx-DR to APC 5732 and status indicator "Q1" (Table 17).

3. 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 proposes to assign 0308T a payment weight based on the most recently available data from the 2020 OPPS final rule, and maintain the assignment to APC 5495.

4. Musculoskeletal Procedures (APCs 5111 through 5116)
Prior to the 2016 OPPS, 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 proposes to maintain the APC structure. Table 18 (reproduced below) displays the proposed 2021 Musculoskeletal Procedures APC series' structure and APC geometric mean costs. CMS states as a result of its proposal to remove codes that were previously on the Inpatient Only List and assign them to clinical APCs (discussed below in section IX), many of these codes are being proposed assignment to the Musculoskeletal Procedure APC series and may impact the geometric means for these APCs.

Table 18: Proposed Musculoskeletal Procedures APCs for CY 2021

APC	Group Title	Number of Codes Assigned to the APC in the 2021 OPPS/ASC proposed rule	2020 Final APC Geometric Mean Cost	Proposed 2021 APC Geometric Mean Cost
5111	Level 1 Musculoskeletal Procedures	103	$210.99	$206.66
5112	Level 2 Musculoskeletal Procedures	136	$1,326.17	$1,367.39
5113	Level 3 Musculoskeletal Procedures	411	$2,678.42	$2,777.09
5114	Level 4 Musculoskeletal Procedures	445	$5,852.95	$6,136.58
5115	Level 5 Musculoskeletal Procedures	120	$11,644.09	$12,101.07
5116	Level 6 Musculoskeletal Procedures	50	$15,602.23	$15,711.96

CMS also discusses the assignment of CPT code 22869 (insertion of interlaminar/interspinous process stabilization/distraction device) to APC 5115. For the 2020 OPPS final rule, commenters believed the code was inappropriately assigned to APC 5115 due to one hospital inaccurately reporting its costs and charges. In response, CMS stated it generally does not judge the accuracy of hospital coding and charging for purposes of ratesetting. For 2021, the geometric mean cost of CPT code 228699 has increased slightly to $12,788.56 and CMS continues to believe it is appropriate to assign CPT code 22869 to APC 5115.

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

Beginning July 1, 2020, two new CPT codes (CPT codes 0598T and 599T)[3] are effective for reporting noncontact real-time fluorescence wound imaging for bacterial presence in chronic and acute wounds. CMS notes that it recently 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.

CMS notes that the new technology application indicated a higher projected cost. **CMS requests comments from hospital-based providers that use MolecuLight on the appropriate OPPS payment, particularly on the cost of providing the service in the hospital outpatient setting**.

[3] The codes and their long descriptors are listed in Table 7 in the proposed rule.

6. Pathogen Test for Platelets/Rapid Bacterial Testing (APC 5732)
For 2021, CMS proposes to revise the APC assignment for HCPCS code P9100 from New Technology APC 1494 to clinical APC 5732 (Level 2 Minor Procedures) (discussed above in Section III.C.)

7. Urology and Related Services (APCs 5371 through 5378)
In the 2020 OPPS 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.

Currently there are seven levels of APCs for urology services. 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) has continued to increase. Based on this analysis, CMS proposes 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 (reproduced below) displays the proposed 2021 Urology and Related Services APC series' structure and APC geometric mean costs.

Table 19: Proposed CY 2021 Geometric Mean Cost for the Urology and Related APC 5371-5378

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 notes the proposed re-organization reassigns 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.

The proposed 2021 payment rate for all the urology APCs can be found in Addendum A to this proposed rule.

IV. OPPS Payment for Devices

A. Pass-Through Payments for Devices

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

CMS follows the statutory requirements that a category of devices is eligible for transitional pass-through payments for at least 2, but not more than 3 years. To allow a pass-through payment period that is as close to a full 3 years as possible, in the 2017 OPPS final rule (81 FR 79655), CMS finalized a policy change to allow for quarterly expiration of pass-through payments status for devices. 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 20 (reproduced below) lists the devices and their pass-through expiration.

Table 20: 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
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 be classified as a Category B device by the FDA), or meets another appropriate FDA exemption from premarket approval or clearance; and the pass-through application must be submitted within 3 years form the date of the initial FDA approval or clearance, if required, unless there is a documented, verifiable delay in the US market availability in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability;
2. The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury to improve the functioning of a malformed body part; and
3. The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion.

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

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

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

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

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 in terms of the current substantial clinical improvement criterion, but need to meet the other requirements for pass-through payment status.

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

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

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

b. Applications Received for Device Pass-Through Payments for 2020

CMS received five applications by the March 1, 2019 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: CUSTOM*FLEX*® ARTIFICIAL*IRIS* (effective January 1, 2020) and EXALT™ Model D Single-Use Duodenoscope (effective July 1, 2020).

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

i. Alternative Pathway Device Pass-Through Applications

(l) CUSTOM*FLEX*® ARTIFICIAL*IRIS*

VEO Ophthalmics submitted an application for the CUSTOM*FLEX*® ARTIFICIAL*IRIS* 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.

Newness. The FDA granted the CUSTOM*FLEX*® ARTIFICIAL*IRIS* 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 CUSTOM*FLEX*® ARTIFICIAL*IRIS* 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 CUSTOM*FLEX*® ARTIFICIAL*IRIS.*

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 CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets all the cost criteria.

CMS invites comments on whether the CUSTOM*FLEX*® ARTIFICIAL*IRIS* should continue to receive transitional pass-through payment under the alternative pathway.

(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 states 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.

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.

CMS invites comments on whether the CUSTOM*FLEX*® ARTIFICIAL*IRIS* should continue to receive transitional pass-through payment under the alternative pathway.

(3) BAROSTIM NEO™ System[4]

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 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 is concerned that the BAROSTIM NEO™ System may be appropriately described by existing pass-through payment category, C1767 and invites comments on this issue.

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

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

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

CMS invites comments on this application.

ii. Traditional Device Pass-Through Applications

(1) Hemospray® Endoscopic Hemostat[5]

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.

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 summarizes this information and discusses specific concerns with the submitted information. CMS notes that the majority of studies lack a comparator and may not provide strong evidence of substantial clinical improvement. It notes several issues with one randomized study including the small sample size of 20 patients. CMS is concerned that the samples in the studies may 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 is also concerned about the potential for adverse events from Hemospray® and notes that the evaluation of adverse events in the studies was limited.

CMS notes that Cook Medical is voluntarily recalling the Hemospray® because of complaints about the device handle breaking and, in some cases, causing the carbon dioxide cartridge to exit the handle. Cook Medical is investigating the issue and will determine appropriate corrective actions. It received one report of a superficial laceration to the user's hand requiring basic first aid but, no reports of laceration, infection, or permanent damage to users or patients due to the carbon dioxide cartridge existing the handle. Although the recall restricts availability of the device, Cook Medical wants to continue their application because they believe the use of the device significantly improves clinical outcomes for certain patient populations.

[5] The applicant also submitted an application for a hospital inpatient new technology add-on payment for FY 2021.

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

CMS invites comments on whether the Hemospray® Endoscopic Hemostat meets the device pass-through payment criteria.

(2) The SpineJack® Expansion Kit[6]

Styrker, 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 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 has identified one existing pass-through payment category that may be applicable to the device, HCPCS code C1821 (interspinous process, distraction device (implantable)).

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.

[6] The applicant also submitted an application for a hospital inpatient new technology add-on payment for FY 2021.

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 fractures[7] 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.

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

CMS invites comments on whether the SpineJack® Expansion Kit meets the device pass-through payment criteria.

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).

CMS is clarifying in this proposed rule that the same policy applies for purposes of the OPPS alternative pathway policy. Specifically, CMS clarifies 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 makes the

7 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.,Bouxsein 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

following conforming change to 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 has 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, CMS is requesting comments on whether it should adjust future payments for devices currently eligible to receive transitional pass-through payments that may have been impacted by the PHE and how it should implement that adjustment, including the duration of the adjustment. Specifically, **CMS is requesting comment on utilizing 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.

CMS states that any rulemaking on this issue would be included in the CY 2022 OPPS/ASC proposed rule. CMS notes that done of the devices with less than three years of pass-through payment status at the start of the PHE have pass-through payments status that end before December 31, 2021.

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, 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.[8] Once claims data are available for a new procedure requiring the implantation of a medical device, device-intensive status is applied to the code if the HCPCS code-level device offset is greater than 30 percent.

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

For 2021 CMS is not proposing 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 proposed rule on the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospital/OutpatientPPS/index.html. The full listing of proposed 2020 device-intensive procedures provided in Addendum P.[9]

8 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.

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

For 2021, CMS is not proposing any changed to the device edit policy.

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

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

In the 2014 OPPS final rule (78 FR 75005 through 75007), CMS adopted a policy of reducing OPPS 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 OPPS final rule, CMS finalized that the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC be calculated using the median cost instead of the geometric mean cost. For 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 proposes to continue this policy. CMS notes that for CY 2021, this policy will not apply to any procedure. CMS received no claims data for CPT code 0308T and proposes to assign this CPT code to APC 5495 (Level 5 Intraocular Procedures). In the absence of 2019 claims data, CMS proposes to use 2018 claims data to establish a device offset percentage for 0308T of 82.21 percent.

V. OPPS 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 OPPS. 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 21 of the proposed rule lists 28 drugs and biologicals for which CMS is proposing to end pass-through payment in 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 will expire on September 30, 2020.

CMS proposes to end pass-through payment in 2021 for 26 drugs and biologicals listed in Table 22. Each of the products will have received at least the full 3 years of pass-through payments once the additional payments expire.

Table 23 lists 46 drugs and biologicals where CMS proposes to continue pass-through payment in 2021. For 2021, CMS proposes to 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.

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 proposes that 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 proposes to pay for diagnostic and therapeutic radiopharmaceuticals receiving pass-through payment at ASP+6 percent. As diagnostic radiopharmaceuticals are also policy packaged, CMS proposes a payment offset from the associated APC. If ASP data are not available, CMS proposes to provide pass-through payment at wholesale acquisition cost (WAC)+3 percent. If WAC information also is not available, CMS proposes to provide payment for pass-through drugs and biologicals at 95 percent of their most recent average wholesale price (AWP).

Table 24 lists the APCs where CMS proposes to 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: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files. (Offset amounts for 2021 are not posted as of the writing of this summary.)

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

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

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

Cost Threshold for Packaging of "Threshold-Packaged Drugs"

"Threshold-packaged drugs" under the OPPS are drugs, non-implantable biologicals and therapeutic radiopharmaceuticals whose packaging status is determined by the packaging threshold. If a drug's average cost per day exceeds the annually determined packaging threshold, it is separately payable and, if not, it is packaged. For 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 proposes 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 proposes adopting a packaging threshold for 2021 of $130.

CMS proposes to 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 proposed rule, CMS uses ASP+6 percent for each HCPCS code with manufacturer-submitted ASP data from the 4th quarter of 2019 (data that were used for drugs and biologicals payment in physicians' offices effective April 1, 2020). For products that do not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, CMS proposes to use their mean unit cost derived from the 2019 hospital claims data. CMS is proposing to package products with a per day cost of less than or equal to $130 and pay separately for items with a per day cost greater than $130 in 2021.

CMS proposes to continue using 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 proposing to continue 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 proposing to apply 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.

Policy Packaged Drugs, Biologicals, and Radiopharmaceuticals

CMS is not proposing any changes for policy packaged drugs, biologicals and radiopharmaceuticals.

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

For 2021, CMS proposes to continue its policy of making packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis in the case of multiple HCPCS codes describing the same drug or biological but with different dosages. The codes to which this policy applies, and their packaging status, are listed in Table 25 of the proposed rule.

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

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

Consistent with policy in the PFS, CMS is again proposing 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 is proposing 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 proposes that drugs that are 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 proposes 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.

CMS also proposes to continue to include payments for separately payable drugs and biologicals in determining budget neutrality adjustments (i.e., the budget neutral weight scaler). Following established policy, CMS proposes to not, however, apply the budget neutral weight scaler in determining payments for these separately paid drugs and biologicals 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 proposed 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). Payment rates will be updated quarterly throughout 2021.

Payment rates for drugs and biologicals in Addenda A and B of the proposed rule for which there was no ASP information available for the 4th quarter of 2019 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.

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 is proposing to pay for the biosimilar at ASP minus 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 proposes that the add-on will be +3 percent or +6 percent of the product's own 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.

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 2nd 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.

3. Payment Policy for Therapeutic Radiopharmaceuticals

For 2021, CMS proposes to continue paying for therapeutic radiopharmaceuticals at ASP+6 percent. For therapeutic radiopharmaceuticals for which ASP data are unavailable, CMS also proposes to determine 2021 payment rates based on 2019 geometric mean unit cost.

4. Payment for Blood Clotting Factors

For 2021, CMS is proposing to continue paying for blood clotting factors at ASP+6 percent and updating the furnishing fee by the Consumer Price Index (CPI) for medical care. The CPI won't be available until after publication of the 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 proposing to continue 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 proposes to pay for these products using ASP+6 percent if ASP is reported, WAC+6 percent if a WAC is available and at 95 percent of AWP if ASP and WAC are unavailable. The proposed 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 proposed 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 OPPS.
- 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.[10] 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 adopt a policy it believes would be consistent with the district court decision. In the 2020 OPPS 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 OPPS 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.

[10] 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 proposed rule and could not be found in the district court decision.

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.[11] CMS indicates it considered GAO's conclusion that the 2005 survey created "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 (n=100) responded using the detailed survey; 55 percent (n=780) responded using the quick survey option; and the remaining 38 percent (n=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. Proposed 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 is proposing to use

[11] GAO Report to Congress: Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS, 4 (April 2006).

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 proposes to apply a single uniform reduction to all drugs acquired under the 340B program. CMS further indicates that a single uniform reduction will protect the confidentiality of ceiling prices for individual drugs under section 1927(b)(3)(D) of the Act.

Methodological Issues: Based on its analysis of the available information, CMS estimates that the typical acquisition cost for 340B drugs for hospitals paid under the OPPS 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 proposes to apply a geometric mean as the averaging methodology. Among the averaging methodologies evaluated (before making the additional methodological determinations described below), use of the geometric mean would produce the lowest reduction to ASP (-58.3 percent).

- Volume Weighting. CMS proposes to volume weight the survey results using 2018 and 2019 utilization data under the OPPS. Volume weighting reduces 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 proposes 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 reduces 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 believes 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 proposes to exclude penny pricing. Excluding penny pricing reduces 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 was more than three standard deviations from the geometric mean. This proposal reduces the adjustment to -34.7 percent.

Table 26 of the proposed 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 OPPS averaging methodologies.

Determining an Add-on Payment for 340B Drugs Under the OPPS. 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 is, nonetheless, proposing 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 says 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 is proposing to pay WAC-28.7 percent. For AWP priced drugs, CMS is proposing 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 proposes to continue exempting CAHs, children's hospitals, cancer hospitals, 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 minus 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 proposes 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.

7. <u>High/Low Cost Threshold for Packaged Skin Substitutes</u>

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

For 2021, CMS proposes 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 proposes using 2019 data for this purpose.

The proposed 2021 MUC threshold is $47 per cm^2 (rounded to the nearest $1) and the proposed 2021 PDC threshold is $936 (rounded to the nearest $1). A skin substitute with a MUC or a PDC that exceeds either the MUC threshold or the PDC threshold will be assigned to the high cost group. If the product is assigned to the high cost group in 2020, CMS proposes to continue assigning it to the high cost group in 2021. Otherwise, CMS proposes assigning the skin substitute to the low-cost group.

Table 27 displays the proposed 2021 cost category assignment for each skin substitute product. For 2021, CMS is proposing to continue 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.

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 is proposing to include synthetic products in addition to biological products in its in its 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.

VI. Estimate of OPPS Transitional Pass-Through Spending

CMS estimates total pass-through spending for drug and device pass-through payments during 2021 will be approximately $783.2 million, or 0.934 percent of total OPPS projected payments for 2021 (approximately $84 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 $473.4 million in 2021 for drugs and biologicals—$463.4 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.

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 is proposing to continue paying 40 percent of the full OPPS 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 the district court in 2019 but that decision was reversed by the appeals court on July 17, 2020. As appeals court reversed the district court decision, CMS' rule has been upheld.

VIII. Partial Hospitalization Program (PHP) Services

A. PHP APC Update for 2021

For 2021, CMS proposes to continue its established policies to calculate the PHP APC per diem payment rates for Community Mental Health Centers (CMHCs) and hospital-based PHP providers based on geometric mean per diem costs using the most recent claims and cost data for each provider type, with one exception. As described further below, CMS proposes 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.

CMS would continue to use CMHC APC 5853 (Partial Hospitalization (3 or more services per day)) and hospital-based PHP APC 5863 (Partial Hospitalization (3 or more services per day)) using actual claims data from 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 OPPS/ASC final rule (80 FR 70462-70466) as modified in the 2017 OPPS/ASC final rule, including the application of a ±2 standard deviation trim on costs per day for all CMHCs and a CCR greater than 5 (CCR>5) trim for hospital-based PHP providers.

CMS analyzes 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 proposed PHP geometric mean per diem costs. CMS proposes to continue its policy to exclude data from any CMHC when the CMHC's costs are more than ±2 standard deviations from the geometric mean cost per day for all CMHCs and to exclude hospital-based PHP service days when a CCR>5 is

used to calculate costs for at least one of the component services. CMS also proposes to default any CMHC CCR that is greater than 1 to the statewide hospital ancillary CCR.

CMS did not exclude any CMHCs nor adjust the CCR for any CMHCs; all 38 CMHCs were included in the 2021 calculation. CMS removed 212 CMHC claims which left 9,369 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 $104 which represents a decrease of roughly 14.5 percent from the 2020 geometric mean per diem cost ($121.62) for all CMHCs. 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 does not believe that the costs of furnishing these services have gone down over time and instead attributes the decrease to the impact of the six providers. CMS is concerned generally by any significant fluctuation in the geometric mean per diem costs over time, and it worries about the impact of such a substantial decrease on beneficiary access to PHP services from CMHCs. Thus, it proposes to use the 2020 CMHC geometric mean per diem cost of $121.62 as a floor for 2021 and each subsequent year. If the most recent data used in the final rule results in a CMHC geometric mean per diem cost below the 2020 CMHC geometric mean per diem cost, CMS will finalize the geometric mean per diem cost of $121.62 for PHP services furnished in 2020.

For hospital-based PHP providers, CMS excluded 73 providers as follows: two 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. The calculated geometric mean per diem cost for 2021 for all hospital-based PHP providers for providing 3 or more services per day is $243.94 which represents an increase of 4.5 percent from the 2020 geometric mean per diem cost for these providers ($233.52). CMS is nonetheless concerned about potential fluctuations in costs of providing hospital-based PHP services, and it proposes to use the 2020 hospital-based PHP provider geometric mean per diem cost as a floor for 2021 and each subsequent year.

CMS also considered using 3- or 4-year rolling averages calculated using the final PHP geometric mean per diem costs for CMHCs and hospital-based PHP providers in lieu of its floor policy. The alternatives still resulted in lower geometric mean per diem costs for 2021, and they would not have addressed the fluctuation in costs over time that concerns CMS. CMS estimates the difference in the (prescaled) CMHC geometric mean per diem costs for 2021 from its floor policy rather than the calculated costs without the floor policy is $1.3 million.

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

2020 APC	Group Title	Proposed PHP APC Geometric Mean Per Diem Costs*	Proposed Payment Rates**
5853	Partial Hospitalization (3 or more services per day) for CMHCs	$121.62	$ 126.22
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	$243.94	$ 253.17

* Table 28 of the proposed rule shows the proposed PHP APC geometric mean per diem costs.
** The proposed payment rates are from Addendum A to the proposed rule.

B. PHP Service Utilization

CMS has previously expressed concern about the low frequency of individual therapy in PHP services. CMS believes that appropriate treatment for PHP patients includes individual therapy, and its analysis of 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. Hospital-based PHPs rates of individual therapy for days with 3 and with 4 or more services have slightly decreased though CMS notes that the overall decrease is less than one-tenth of one percent. Table 29 of the proposed rule shows claims data from 2016 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.

C. Outlier Policy for CMHCs

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

CMS proposes to designate less than 0.01 percent of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs for PHP outliers. CMS proposes to set the cutoff point for the outlier payments for CMHCs for 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 proposes to continue this policy for 2021. This payment cap only impacts CMHCs.

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

D. Regulatory Impact

CMS estimates that payments to CMHCs will increase by 1.3 percent in 2021. 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 OPPS 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 OPPS 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 OPPS 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 proposes to continue this 2-year exemption from site-of-service claim denials for procedures that are removed from the IPO list. CMS is also seeking 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, 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 requests 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 is proposing to eliminate the IPO list over a transitional period beginning in 2021 and ending in 2024. For 2021, CMS is proposing 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 proposes to remove 266 musculoskeletal services from the IPO list for 2021. These services are listed on table 31 of the proposed rule.

CMS requests 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.

X. Nonrecurring Changes

A. Supervision of Outpatient Therapeutic Services

In 2020, CMS changed the required level of supervision for most OPPS 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 is proposing 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 proposes to change the required level of supervision for the duration of NSEDTS from direct to general.

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 proposes 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.

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 is proposing 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 to the physician to determine the appropriate setting for care.

CMS continues to believe that a 2-year exemption from certain medical review activities by the BFCC-QIOs for services removed from the IPO list under the OPPS in 2021 and subsequent years is appropriate. Accordingly, CMS is proposing to retain the existing 2-year exemption even in the event that it finalizes the proposal to eliminate the IPO list. However, given that many more services would be removed from the IPO list during the proposed transition, CMS is seeking comment on whether to retain, lengthen or shorten the 2-year exemption. Commenters may indicate whether and why they believe the 2-year period is appropriate or if a longer or shorter exemption period is needed.

C. Comment Solicitation on Specimen Collection for COVID-19 Tests

As result of the COVID-19 public health emergency (PHE), CMS established HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), any specimen source). HCPCS code C9803 is assigned to APC 5731- Level 1 Minor Procedures for the duration of the COVID19 PHE with a payment rate of $22.98 for 2020. HCPCS code C9803 is conditionally packaged

meaning that it will only be paid separately if it is the only service provided or it is billed with a clinical diagnostic laboratory test that is separately payable.

CMS is requesting comment on the APC and status indicator assignment for HCPCS code C9803 for 2021 in the event the PHE extends into next year. In addition, CMS is requesting comment on whether the HCPCS code C9803 (and its APC assignment and status indicator) should be retained beyond the COVID-19 PHE to support COVID–19 testing.

XI. OPPS Payment Status and Comment Indicators

OPPS Payment Status Indicator Definitions

For 2021, CMS is not proposing any changes to status indicators. Status indicators and their definitions can be found in Addendum D1 of the proposed rule. Each status indicator will identify whether a given code is payable under the OPPS or another payment system, and also whether particular OPPS policies apply to the code. The 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 proposing to continue 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 current calendar year for which CMS is requesting comments in the proposed rule, final APC assignment; comments will not be accepted on the final APC assignment for the new code.
‘‘NI’’—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.
‘‘NP’’—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.

The definitions of the OPPS comment indicators for 2021 are listed in Addendum D2 of the proposed rule.

XII. MedPAC Recommendations

OPPS Update: MedPAC recommends 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 proposed an update of 2.6 percent or the hospital market basket of 3.0 percent less 0.4 percentage points for multifactor productivity.

ASC Update: MedPAC indicates that payments to ASCs are adequate and recommended no payment update. CMS proposed an ASC update of 2.6 percent equal to the hospital market basket less 0.4 percentage points for multifactor productivity consistent with the law.

CMS has the authority to select the market basket used in the update but once selected is required to use that market basket less multifactor productivity in the update. 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 is not proposing 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	0.9999	
2021 Update		
Hospital market basket update	3.0%	
Multi-factor productivity adjustment (MFP)	-0.4%	
Net MFP adjusted update	2.6%	
Penalty for not reporting quality data	0.0%	-2.0%
Net MFP and quality adjusted update	2.6%	0.6%
2021 Proposed ASC Conversion Factor	$48.984	$48.029

CMS estimates that under the proposed rule, total ASC Medicare payments for 2021 will be approximately $5.45 billion, an increase of $160 million over 2020 levels inclusive of changes in enrollment, utilization, and case mix changes.

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

A. Background

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

CMS provides quarterly update change requests (CRs) for ASC services throughout the year and makes new codes effective outside the formal rulemaking process via these quarterly updates. The annual rulemaking process is used to solicit comments and finalize decisions.

Until 2019, CMS 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 proposals for new codes in two categories:

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

Table 35 in the proposed rule (shown below) provides the process and timeline for ASC list updates:

Comment and Finalization Timeframes for New or Revised HCPCS Codes (from Table 35)				
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 OPPS/ASC	2021 OPPS/ASC

Comment and Finalization Timeframes for New or Revised HCPCS Codes (from Table 35)				
ASC Quarterly Update CR	**Type of Code**	**Effective Date**	**Comments Sought**	**When Finalized**
		2021	proposed rule	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 is Soliciting Public Comments in this 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 32-34 in the proposed rule (reproduced below) set out the codes, descriptors, and the 2021 payment indicators.

New Level II HCPCS Codes for Ancillary Services Effective on April 1, 2020 (Table 32)			
2020 HCPCS Code	**Long Descriptor**	**Proposed CY 2021 Comment Indicator**	**Proposed CY 2021 Payment Indicator**
C9053*	Injection, crizanlizumab-tmca, 1 mg	CH	K2
C9056**	Injection, givosiran, 0.5 mg	CH	K2
C9057#	Injection, cetirizine hydrochloride, 1 mg	CH	K2
C9058##	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo) 0.5 mg	CH	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 33)			
2020 HCPCS Code	**2020 Long Descriptor**	**Proposed 2020 CI**	**Proposed 2020 PI**
C1748	Endoscope, single-use (that is, disposable), upper GI,imaging/illumination device (insertable)	NP	J7
C1849	Skin substitute, synthetic, resorbable, per square centimeter	NP	N1
C9059	Injection, meloxicam, 1 mg	NP	K2
C9061	Injection, teprotumumab-trbw, 10 mg	NP	K2

New Level II HCPCS Codes for Covered Surgical Procedures and Ancillary Services Effective on July 1, 2020 (Table 33)			
2020 HCPCS Code	**2020 Long Descriptor**	**Proposed 2020 CI**	**Proposed 2020 PI**
C9063	Injection, eptinezumab-jjmr, 1 mg	NP	K2
C9122	Mometasone furoate sinus implant, 10 micrograms (Sinuva)	NP	K2
C9759	Transcatheter intraoperative blood vessel microinfusion(s)	NP	N1
C9762	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with strain imaging	NP	Z2
C9763	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with stress imaging	NP	Z2
C9764	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed	NP	G2
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	NP	J8
C9766	Revascularization, endovascular, open or percutaneous, any vessel (s); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed	NP	G2
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	NP	J8
G2170*	Percutaneous arteriovenous fistula creation (AVF), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow	NP	J8
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,	NP	J8
J0223	Injection, givosiran, 0.5 mg	NP	K2
J0691	Injection, lefamulin, 1 mg	NP	K2
J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	NP	K2
J0791	Injection, crizanlizumab-tmca, 5 mg	NP	K2
J0896	Injection, luspatercept-aamt, 0.25 mg	NP	K2
J1201	Injection, cetirizine hydrochloride, 0.5 mg	NP	K2
J1429	Injection, golodirsen, 10 mg	NP	K2
J1558	Injection, immune globulin (Xembify), 100 mg	NP	K2
J7169	Injection, coagulation factor Xa (recombinant), inactivated-zhzo (Andexxa), 10 mg	NP	K2

New Level II HCPCS Codes for Covered Surgical Procedures and Ancillary Services Effective on July 1, 2020 (Table 33)			
2020 HCPCS Code	**2020 Long Descriptor**	**Proposed 2020 CI**	**Proposed 2020 PI**
J7204	Injection, factor VIII, antihemophilic factor (recombinant),(esperoct), glycopegylated-exei, per iu	NP	K2
J7333	Hyaluronan or derivative, visco-3, for intraarticular injection, per dose	NP	N1
J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	NP	K2
J9198	Gemcitabine hydrochloride, (Infugem), 100 mg	NP	K2
J9246	Injection, melphalan (evomela), 1 mg	NP	K2
J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	NP	K2
Q4227# - Q4248#	Human cell, tissue, or cellular or tissue-based product. Combined here for brevity but listed separately in Table 33 in proposed rule. All have same comment and payment indicators.	NP	N1
Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg	NP	K2
Q5120	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg	NP	K2
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	NP	J8
0596T	Temporary female intraurethral valve-pump (i.e., voiding prosthesis); initial insertion, including urethral measurement	NP	R2
0597T	Temporary female intraurethral valve-pump (i.e., voiding prosthesis); replacement	NP	R2
0600T	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous	NP	J8
0601T	Ablation, irreversible electroporation; 1 or more tumors, including fluoroscopic and ultrasound guidance, when performed, open	NP	J8
0614T	Removal and replacement of substernal implantable defibrillator pulse generator	NP	J8
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	NP	J8
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	NP	J8
0618T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens placement or intraocular lens exchange	NP	J8
0619T	Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed	NP	J8

New Level II HCPCS Codes for Covered Surgical Procedures and Ancillary Services Effective on July 1, 2020 (Table 33)			
2020 HCPCS Code	**2020 Long Descriptor**	**Proposed 2020 CI**	**Proposed 2020 PI**
*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.			

New Category III CPT Code for Covered Ancillary Service Effective on July 1, 2020 (Table 34)			
2020 HCPCS Code	**CY 2020 Long Descriptor**	**Proposed 2021 CI**	**Proposed 2021 PI**
0598T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (for example, lower extremity)	NP	Z2
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)	NP	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 will be Soliciting Public Comments in the 2021 OPPS/ASC Final Rule with Comment Period.

CMS proposes to continue to assign comment indicator "NI" in Addendum BB to the 2021 OPPS/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 OPPS payment status for 2021. CMS will invite comments in the 2021 OPPS/ASC final rule with comment period on the interim payment indicators which will then be finalized in the 2022 OPPS/ASC final rule with comment period.

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

CMS seeks comment on proposed new and revised CPT codes effective January 1, 2021 that were received in time to be included in this proposed rule. They will be finalized in the 2021 OPPS/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.

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. Based on its review of 2019 volume and utilization data, CMS proposed to permanently designate six additional procedures as office-based (shown in Table 36 in the proposed rule).

ASC Covered Surgical Procedures Proposed to Be Newly Designated as Permanently Office-Based for 2021 (Table 36)			
2021 CPT Code	**2021 Long Descriptor**	**2020 ASC Payment Indicator**	**Proposed 2021 ASC Payment Indicator***
11760	Repair of nail bed	G2	P3*
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)	J8	P3*
23077	Radical resection of tumor (e.g., sarcoma), soft tissue of shoulder area; less than 5 cm	G2	P2*
44408	Colonoscopy through stoma; with decompression (for pathologic distention) including placement of decompression tube, when performed	G2	P2*
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy	G2	P2*
67500	Retrobulbar injection; medication (separate procedure, does not include supply of medication)	G2	P3*
* Payment indicators are based on a comparison of the proposed rates according to the ASC standard rate setting methodology and the PFS proposed rates.			

CMS also reviewed 2019 volume and utilization data for 18 procedures finalized for temporary office-based status in last year's final rule. CMS found that there were very few or no claims data for 11 of these procedures and proposed to maintain the temporary office-based designations for these codes (CPT codes 64454, 64624, 65785, 67229, 0402T, 0512T, 0551T, 0566T, 0588T, 93985 and 93986) for 2021. The volume and utilization data for five of the seven procedures (10007, 10011, 11102, 11104, and 11106) was sufficient to indicate that these procedures are performed predominately in physicians' offices and thus CMS proposes to assign them one of the office-based indicators.. Table 37 and Table 38 in the proposed rule lists the procedures and CMS' proposed payment indicators for 2021.

CMS proposes to designate two new 2021 CPT codes as ASC covered surgical procedures as temporary office-based, using a 5-digit CMS placeholder code. Table 39 in the proposed rule (reproduced below) lists the procedures and proposed payment indicators.

Proposed 2021 Payment Indicators for New 2021 CPT Codes for ASC Covered Surgical Procedures Designated as Temporarily Office-based (Table 39)		
2021 OPPS/ASC proposed rule 5-digit CMS placeholder code	**CY 2021 Long Descriptor**	**Proposed 2021 ASC Payment Indicator****
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**
**Payment indicators are based on a comparison of the proposed rates according to the ASC standard rate setting methodology and the PFS proposed rates.		

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

CMS discusses 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 with an office-based payment status based on the utilization data as 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 is not proposing to designate CPT codes 36902 and 36905 as office-based procedures for 2021.

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 contend 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 contend 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.

CMS seeks comment on whether it might be justified in establishing a permanent exemption from PFS nonfacility PE RVU amounts for dialysis vascular access procedures under §416.171(d) in 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 OPPS payment. The service portion of the ASC payment for device-

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

In the 2019 OPPS/ASC final rule, CMS lowered the device offset percentage threshold from 40 percent to 30 percent, and aligned the device-intensive policy with the criteria used for device pass-through status. CMS proposes 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 proposed individual HCPCS code device offset percentages based on 2019 OPPS claims and cost report data.

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

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

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

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

- When the device is furnished with partial credit of 50 percent or more of the cost of the new device, the contractor would reduce payments to the ASC by 50 percent of the device offset amount. In order to report a partial credit, the ASC would have the option of either submitting the claim after the procedure, but prior to manufacturer acknowledgement of credit for the device, and having the contractor make a claim adjustment, or holding the claim for payment until a determination is made by the manufacturer. The ASC would then submit the claim with a "FC" modifier if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the replacement device. Beneficiary coinsurance would be based on the reduced payment amount.

CMS 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 proposes to reduce 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 proposes 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. These are detailed in Table 40 in the proposed rule (reproduced below).

Table 40- Proposed Additions to the List if ASC Covered Surgical Procedures for 2021 Under Standard Review Process

2021 CPT/ HCPCS Code	2021 Long Descriptor	Proposed 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)	G2
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
C9766	Revascularization, endovascular, open or percutaneous, any vessel (s); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed	J8

In addition, CMS includes two alternative proposals that it may finalize for 2021. 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, revised as described in this proposed rule along with suggested parameters and all other regulatory standards. CMS would review and finalize procedures through annual rulemaking.

Alternatively, CMS proposes 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 proposes to add approximately 270 potential surgery or surgery-like codes to the CPL that are not on the 2020 IPO list. **It proposes to finalize only one of these alternative proposals and welcomes public comment as to which policy should be adopted in the final rule. CMS also seeks comments on potential revisions to the ASC Conditions for Coverage (CfC) if Alternative 2 is adopted.**

After consideration of priorities discussed above, CMS believes that these proposed policies strike an appropriate balance of between flexibility for physicians to exercise their complex medical judgment in factoring in patient safety considerations and flexibility for patients to choose from more settings of care in which to receive surgical procedures.

The table below examines the two alternative proposals and current approach and provides details on the criteria for inclusion on ASC-CPL list, the process, timeframe for implementation, proposed additions to the list, and comments sought on specific issues.

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

	Current Process	Alternative One: Nomination Process for Adding New Procedures	Alternative Two: Broader Approach by Revising Regulatory Criteria
Criteria for inclusion on list	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 OPPS. 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 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.	1. Keeps general standards specified in 42 CFR 416.166(b) 2. Eliminates the general exclusion criteria in 42 CFR 416.166(c)(1) through (c)(5). 3. Retains the criteria at §§416.166(c)(6) through (8). This would continue to prohibit certain procedures designated as requiring inpatient care under 42 CFR 419.22(n) as of December 31, 2020, and any procedures that are otherwise excluded under 42 CFR 411.15.	1. Keeps general standards specified in 42 CFR 416.166(b) 2. Eliminates the general exclusion criteria in 42 CFR 416.166(c)(1) through (c)(5). 3. Retains the criteria at §§416.166(c)(6) through (8).

	Current Process	Alternative One: Nomination Process for Adding New Procedures	Alternative Two: Broader Approach by Revising Regulatory Criteria
Process	CMS conducts an annual review of the HCPCS codes currently paid under the OPPS, but not included on the ASC-CPL, and that meet the definition of surgery to determine its appropriateness for the ASC setting. Reviews whether potential additions meet the general standards and general exclusion criteria. Publishes these potential additions in OPPS proposed rule for comment	CMS would solicit recommendations from external stakeholders, such as medical specialty societies and other members of the public for suitable candidates to add to the ASC-CPL. Nomination process would occur annually through the proposed rule (nomination received by March 1st) and final determinations regarding nominated procedures would be decided in the final rule. CMS would add the procedure that meet the requisite criteria to the ASC-CPL in the final rule.	CMS would use a similar process as under the standard review process. The use of different criteria results in more procedures being added to the ASC-CPL list.
Timeframe for implementation	Current process	Nomination process would begin in 2021 for surgical procedures that could be added to the ASC-CPL beginning in 2022.	Could be implemented for 2021, if finalized.
Proposed additions to the ASC-CPL	Proposes to add eleven procedures (displayed in Table 40 in the proposed rule). Includes THA, vaginal colpopexy, transcervical uterine fibroid ablation, and intravascular lithotripsy procedures, among others.	None for 2021 – process would begin in 2022 – CMS would likely use the standard ASC-CPL review process for 2021.	Identified 270 potential surgery or surgery-like codes that CMS believes could meet the proposed revised criteria. See Table 41 in the proposed rule for list of codes

	Current Process	Alternative One: Nomination Process for Adding New Procedures	Alternative Two: Broader Approach by Revising Regulatory Criteria
			and payment indicators.
Comments sought on specific issues	Seeks comments on the proposed additions to the ASC-CPL	CMS proposes certain parameters for stakeholders to consider when nominating procedures to add to the ASC-CPL and seeks comments and suggestions on these. This includes the following themes: • Risk of life-threatening complications • Need for specialized resources, not generally available in an ASC to mitigate the risk of one or more life-threatening complications. • Average length of time for patients to be stabilized (needs to be at least 90 minutes) for transport to another facility. • Availability of resources and providers required for intervention nearby.	Seeks comment on the list of potential additions and whether any of the procedures would typically require care after midnight, and thus should not be added to list. Seeks comments on potential revisions to the ASC CfCs including whether: • quality measures should change in response to expanded range of services. • risk evaluations should be more prescriptive and attest that an individual patient can safely undergo the procedure in an ASC • CMS should add an additional CfC at §416.46 to require and adequate number of nurses be on duty in the ASC. • CMS should require the presence of staff certified to provide Advance Cardiac Life Support (ACLS) in the ASC

	Current Process	Alternative One: Nomination Process for Adding New Procedures	Alternative Two: Broader Approach by Revising Regulatory Criteria
			for life threatening emergencies • CMS would make specific requirements in the CfC regulations at 42 CFR 416.52(a) for particular patient conditions or more complex and invasive surgical procedures ASCs would need to meet.

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

Proposed ASC Payment for Covered Surgical Procedures

CMS proposes to continue its policy to update payments for office-based procedures and device-intensive procedures using its established methodology and using its modified definition for device-intensive procedures for all but low volume device-intensive procedures. Payment for office-based procedures will be the lesser of the 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.

Proposed Limit on ASC Payment for Low Volume Device-Intensive Procedures

Data anomalies for low-volume procedures can result in inappropriate payment rates using the standard ASC methodology for rate-setting. CMS 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 proposes to apply a payment rate of $20,994.57 for CPT code 0308T and to continue the 2020 final rule device offset percentage of 90.18 percent.

Proposed Payment for Covered Ancillary Services

CMS proposes to update payments and make changes necessary to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services. It is not making any changes to prior year policies for how it determines payment for covered ancillary services. Based on its quarterly updates for April and July 2020, CMS proposes to add CPT codes 0598T, 0599T, C9762, and C7963 as covered ancillary services.

Under a new policy adopted in 2019, opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting are unpackaged and paid separately at ASP+6. CMS notes that it 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 proposes to continue 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 CY 2021.

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 proposes 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.

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

- Total payments using the 2020 relative payment rates, to
- Total payments using the 2021 relative payment rates.

The resulting ratio, 0.8494, is the proposed 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, 0.9999, is the proposed wage index budget neutrality adjustment to the conversion factor for 2021.

To update ASC rates, CMS would utilize the hospital market basket update of 3.0 percent minus the MFP factor of 0.4 percent. This yields an update of 2.6 percent for ASCs meeting quality reporting requirements.

CMS would continue its policy of reducing the update by 2.0 percentage points for ASCs not meeting the quality reporting requirements, yielding an update of 0.6 percent for such ASCs. The resulting proposed 2021 ASC conversion factor is $48.984 for ASCs reporting quality data, and $48.029 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	x 0.9999	
Net MFP-adjusted update	x 1.026	x 1.006
2021 ASC conversion factor	$48.984	$48.029

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 56 of the proposed rule and reproduced below). The eye and ocular adnexa group remains the largest source of payments, with 3 percent increase in payments attributable to the changes proposed for 2021. The second largest group, nervous system, is also estimated to see a 3 percent increase.

Table 56 – Estimated Impact of the Proposed 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	**$5,446**	**3%**
Eye and ocular adnexa	$1,811	3%
Nervous system	$1,178	3%
Digestive system	$908	4%
Musculoskeletal system	$693	4%
Cardiovascular system	$270	3%
Genitourinary system	$201	5%

CMS provides estimated increases for 30 selected procedures in Table 57 in the proposed rule; the top 10 procedures are replicated below. CPT code 66984 (Cataract surgery with intraocular lens, 1 stage) is the largest aggregate payment procedure by far and is estimated to have a 3

percent increase in payment. The second largest aggregate payment procedures, CPT code 63685, is expected to see a 4 percent increase.

Excerpt from Table 57: 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)	Estimate 2021 Percent Change
66984	Cataract surg w/iol, 1 stage	$1,259	3%
63685	Insert/redo spine n generator	$295	4%
45380	Colonoscopy and biopsy	$247	3%
63650	Implant neuroelectrodes	$189	2%
43239	Egd biopsy single/multiple	$185	3%
45385	Colonoscopy w/lesion removal	$184	3%
0191T	Insert ant segment drain int	$125	4%
64483	Inj foramen epidural l/s	$120	1%
66982	Cataract surgery complex	$92	3%
64635	Destroy lumb/sac facet jnt	$86	1%

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

- AA – Proposed ASC Covered Surgical Procedures for 2021 (Including surgical procedures for which payment is packaged)
- BB – Proposed ASC Covered Ancillary Services Integral to Covered Surgical Procedures for 2021 (Including Ancillary Services for Which Payment is Packaged)
- DD1 – Proposed ASC Payment Indicators for 2021
- DD2 – Proposed 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 proposes to update regulatory text to codify previously adopted policies, align deadlines for data submission and reconsideration applications to be consistent with federal law, and expand the review and corrections policy to apply to measures submitted via a web-based tool. No policy changes are proposed 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 proposes 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 would be added at a new §419.46(a). Table 42 in the proposed rule shows how cross references would be 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 submitted across their multiple campuses for all clinical measures for public reporting purposes would be codified at redesignated §419.46(d)(1).
- The term "security administrator" would be 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) would be 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 would be removed; these hospitals must renew participation as specified in redesignated §419.46(b).
- The review and corrections policy would be codified at a new §419.46(d) to reflect the expansion to include web-based measures discussed below. It would state that for 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 would be codified at a new §419.46(f)(§4). It would state 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 year.

B. Alignment of Deadlines

CMS proposes that the previously adopted data submission deadline policies at redesignated §419.46(d)(3) be aligned with statutory requirements.[12] 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 would 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 are shown in Table 44 of the proposed rule.

Similarly, the deadline for reconsideration at redesignated §419.46(g)(1) would be 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.

12 Section 1872 of the Social Security Act incorporates for Medicare the definition in section 216(j) of the ACT for "Periods Of Limitation Ending On Nonwork Days."

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

CMS proposes to expand the existing review and corrections policy 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 proposed 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		
	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		

NQF		2020	2021	2022	2023
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*				

+ 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 would be continued for the 2021 update factor. The proposed 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 $82.065 by the full conversion factor of $83.697. 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 would continue to be applied to the national unadjusted payment rates and minimum unadjusted and national unadjusted copayment rates of all applicable services for hospitals that fail to meet the OQR Program reporting requirements. All other applicable standard adjustments to the OPPS national unadjusted payment rates apply, and OPPS outlier eligibility and outlier payment would be based on the reduced payment rates. Beneficiaries and secondary payers share in the reduced payment to hospitals that are subject to the payment reduction.

CMS reports that for 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 Program (ASCQR)

CMS proposes several updates and additions to the regulatory text for the ASCQR Program. No changes are proposed 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" would be 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" will be replaced by "data collection period" everywhere it appears in §416.310(a) through (c). The terms are currently used interchangeably.

B. Alignment of Deadlines

CMS proposes that the previously adopted data submission deadline policies at §416.310 be aligned with statutory requirements regarding deadlines falling on a nonwork day.[13] Specifically, a new 416.310(f) would be 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 would be 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

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 proposes to formalize the process and create a review and corrections period similar to the one for Hospital OQR Program. (See section XIV.C above.) A review and corrections period would be implemented to run concurrently with the data submission period beginning with the effective date of the final rule. During this review and corrections period, ASCs could enter, review, and correct data submitted directly to CMS. However, after the submission deadline, ASCs would not be allowed to change these data. The proposal would be codified at a new §416.310 (c)(1)(iii).

13 Section 1872 of the Social Security Act incorporates for Medicare the definition in section 216(j) of the ACT for "Periods Of Limitation Ending On Nonwork Days."

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.

CMS invites comments on new measures for its future consideration that address care quality in the ASC setting as well as on additional measures that could facilitate comparison of care between ASCs and hospitals.

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
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

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

CMS proposes to continue 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 is applied to ASCs that fail to meet the requirements. The reduction applies to services calculated using the ASC conversion factor with the payment indicators of A2, G2, P2, R2, Z2, and the service portion of device-intensive procedures identified by J8. The reduction does not apply to services that are assigned other status indicators for which payments are not calculated using the conversion factor, including separately payable drugs and biologicals, pass through devices that are contractor-priced, brachytherapy sources that are paid based on OPPS payment rates, and others. When the update reduction is applied to a facility, beneficiary copayments are based on the reduced payment rate.

CMS reports that for the 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 proposes to modify and codify the Overall Hospital Quality Star Rating methodology used for publication beginning in 2021. 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 is using this OPPS/ASC rule to propose 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 proposed 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 proposed 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 proposed rule would codify the Overall Star Rating at a new §412.190. CMS proposes that beginning with publication of the Overall Star Rating in 2021 and subsequent years, it would continue to calculate the rating using quality data publicly reported on *Hospital Compare* or a successor CMS website from the programs identified above.

The regulatory text would state 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 proposed guiding principles, CMS would 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

CMS proposes that in addition to subsection (d) hospitals, which are subject to the quality programs that underlie the data for the Overall Star Rating, CMS proposes to continue to include CAHs that voluntarily report quality data and to extend the Overall Star Rating to include Veterans Health Administration (VHA) hospitals.

1. CAHs

Under the proposal, CAHs that voluntarily report data under CMS hospital quality programs would 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 would be 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 would be excluded from the Overall Star Rating. (See section XVI.G below.)

CMS cites section 1704 of the Public Health Service (PHS) Act as providing it authority to continue to include voluntary data from CAHs in the Overall Star Rating. This 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 including these data are important because many CAHs are located in remote areas and are often one of the only options for patients seeking care.

CMS notes that its proposal to peer group hospitals (discussed in XVI.F below) is dependent on CAH participation in the Overall Star Rating; CAHs make up about half of the hospitals within the proposed three measure peer group. Excluding CAHs from the Overall Star Rating would result in an insufficient amount of hospitals to make peer group comparisons.

2. Veterans Health Administration Hospitals

Quality data from VHA hospitals would be included in the Overall Star Rating beginning in 2023. (This proposal is made in the preamble but not reflected in the proposed regulatory text.) 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 PHS Act in support of this proposal. CMS believes that 2023 provides it time 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 would be subject to the same reporting threshold as subsection (d) hospitals and CAHs (proposed in Step 5 below as 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 would influence national results, it states that this would not have direct influence on payment impacts under CMS-administered programs because these hospitals would not be included in those determinations. CMS intends to provide more information about the statistical impact of adding VHA hospitals to the Overall Star Rating and discuss procedural aspects in a future rule.

D. Overview of Changes to the Overall Star Rating Methodology

The proposed rule would make 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)

Proposals 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 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.

Proposed methodology updates that would 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 have highly recommended that the Overall Star Rating account for differences in hospital case-mix or type to increase comparability. The proposed methodology updates that address this issue include (1) stratifying the readmission measure group according to proportion of dual-eligible patients at each hospital; (2) 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 (3) peer grouping hospitals by number of measure groups, discussed below in section XVI.F.

The proposed 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 under its proposal:

- 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 proposed 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;
- Stratify the readmission measure group scores using the proportion of dual-eligible patients at each hospital within Step 3;
- 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. Current and Proposed Overall Star Rating Methodology

The proposed overall star rating methodology that would be codified in new §412.190 is described in the proposed 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 CMS proposes that the current timeframe for the Overall Star Rating would be retained with modification and codified in §412.190. The Overall Star Rating would continue to be published once a year. However, instead of using data from the same quarter as publication or the prior quarter, CMS would 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. Under the proposal, for a January 2021 Overall Star Rating release, for example, CMS could use data refreshed on *Hospital Compare* in July or October of 2020. CMS believes that using these data would allow providers more time, beyond the standard 30-day confidential review period, to review their Overall Star Raring as well as the measure and measure group results that contribute to it.

Measure selection. CMS proposes to continue (and codify) the use of certain measures reported on *Hospital Compare* or a successor website through the specified CMS quality programs (Hospital IQR Program, Hospital OQR Program, HRRP, HAC Reduction Program, and Hospital 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 would 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 other measure scores. All but one of the current exclusion rules would be continued. The proposed exclusions, which would be codified in §412.190, are:

- Measures that are publicly reported by no more than 100 hospitals. CMS says these would not produce reliable measure group scores.
- 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.

CMS does not propose to continue to exclude measures with statistically significant negative loadings estimated by the Latent Variable Model (LVM). As discussed further below, CMS proposes to calculate group scores using a simple average instead of using the LVM. If that proposal is not finalized and the use of LVM is retained CMS would continue the current exclusion of measures with statistically significant negative loadings estimated by the LVM.
.
In general, CMS would determine which measures to include or exclude based on the level of information provided by the measure. It says, for example, that it would include a composite measure, such as PSI-90, over the component measures, such as PSI-03. It would include the excess days in acute care (EDAC) measures over the readmission measures, because the EDAC measures capture a broader outcome for the same cohort, including emergency department visits and observation stays in addition to the unplanned readmissions captured by both measures.

Measure score standardization. Standardization of measure scores would be continued under the proposal. 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 46 in the proposed rule provides an example of standardizing measure scores.

Winsorization method. CMS is not proposing to continue using the Winsorization method[14] because 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, CMS is proposing to use simple averaging of measure scores in place of the LVM and therefore the Winsorization step would also be eliminated. However, if the proposal to use averaging is not finalized and the LVM is continued, CMS would continue to Winsorize measure scores to minimize the impact of outliers.

Step 2: Assignment of Measures to Groups

CMS proposes to modify the assignment of measures to groups for the Overall Star Rating beginning in 2021 and codify this at §412.190. The Mortality, Safety of Care, Readmission, and Patient Experience measure groups would be unchanged. However, three previously used process measure groups – Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging – would be combined into one group entitled Timely and Effective Care. The merging of these groups is proposed 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 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 proposals using October 2019 publicly reported measure data on *Hospital Compare* to determine how many hospitals would be eligible to receive a star under the proposed measure grouping. Using the proposed 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 the measure regrouping proposal; other proposals may also affect the number of hospitals meeting reporting thresholds. It believes that this proposal aligns with the guiding principles of the Overall Star Rating, which include being inclusive of hospitals and measure information, accommodating changes in the underlying measures, and accounting for the heterogeneity of available measures.

[14]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 proposes a major change in how it calculates measure group scores for the Overall Star Rating. The LVM statistical approach would no longer be used; a simple average of measure scores would be used to calculate measure group scores instead. The measure group scores would be standardized, and the readmission measure group scores would be stratified based on the proportion of dual-eligible discharges.

Discontinued Use of LVM and Use of Simple Averaging. The proposed rule includes a detailed discussion of the LVM statistical method currently in use 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 category[15].

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 proposes to discontinue use of the LVM for calculating measure group scores and to use a simple average of measure scores instead beginning in 2021. This proposal responds 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.

CMS says that the proposed use of a simple average of measure scores, which would be codified at §412.190, is in response to stakeholder requests that CMS increase the simplicity of methods and predictability of measure emphasis between publications of the Overall Star Rating. While 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.

[15] 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."

Under the proposal, the weight for each measure within a measure group would equal 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 standardized measure group score. Tables 47 and 48 in the proposed rule provide numerical examples of how the simple average approach to calculating measure group scores would work.

Measure group performance categories would 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. If the simple averaging approach is not finalized and the LVM continued, CMS would also continue the measure group performance categories.

Standardizing measure group scores. In order to put all measure group scores on a single scale, CMS proposes to standardize the measure group scores using the same Z-score method used for standardizing individual measure scores. That is, the national mean measure group score would be 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 would occur before measure group scores are combined to calculate summary scores. Standardization would result in all measure group scores centered near zero with a standardized deviation of one. This would be codified in §412.190. Table 49 in the proposed rule shows how measure group scores would be calculated using a simple average of measure scores and how the measure group scores would be standardized. If the proposal to use simple averaging to compute measure group scores is not finalized, measure group scores would not need to be standardized. (In using the LVM statistical modeling approach, standardization is not necessary.)

CMS notes that standardizing measure group scores would not impact hospital performance within the measure group or the natural distribution of hospital scores. CMS simulated the effects of standardization using data from the January 2020 publication of the Overall Star Rating and found that hospital summary scores with and without standardization are highly correlated (Pearson correlation of 0.975).

Stratifying Readmission Measure Group Scores. To date, CMS has not stratified or adjusted any of the Overall Star Rating measures, measure groups, summary scores or star ratings by social risk factors. Throughout the development and reevaluation of the Overall Star Rating, some stakeholders, mostly providers, have requested incorporation of social risk factor adjustment while others have expressed concerns about doing so in general or with respect to the specific variables available for adjustment.

CMS proposes to stratify only the Readmission measure group based on hospitals' proportion of Medicare and Medicaid dual eligible patients using the same dual eligibles variable and five peer group quintiles used for the HRRP[16]. Non-HRRP hospitals would be assigned an HRRP peer

[16] For FY 2019, the proportion of dual-eligible patients within the five peer groups are: 0 to 13.69 percent, 13.70 to 18.40 percent, 18.41 to 23.23 percent, 23.24 to 30.98 percent, 30.99 to 100 percent for peer groups one, two, three,

group. A hospital for which data on the proportion of dual eligible patients is missing would receive an unadjusted Readmission measure group score. These policies would be codified in §412.190.

Because the number of hospitals included in the Overall Star Rating includes CAHs and is greater than those participating in the HRRP, the star rating peer groups under the proposal would not be exact quintiles. For the 2020 Overall Star Rating release, 4,384 hospitals had a Readmission measure group score, while 3,077 hospitals received a readmission score for the HRRP.

CMS emphasizes that this proposal is meant to provide consistency between the HRRP and the Overall Star Rating Readmission measure group and is not intended to suggest a new policy direction with respect to social risk factor adjustment more broadly. If the HRRP stratification approach is changed, CMS may consider similar changes to the Overall Star Rating in future rulemaking. The proposal is made in response to concerns of some stakeholders that some hospitals face unique challenges preventing readmissions among patients with complex social risk factors. CMS notes that the readmissions measures publicly reported on *Hospital Compare* are not adjusted for social risk factors.

A June 2020 HHS report to Congress[17] recommends that hospital stratification by the proportion of dual eligibles approach eventually be removed from the HRRP, and more broadly recommends not adjusting outcome measures for social risk factors. The report recommends instead that measures be reported separately for dual-eligibles and other beneficiaries in order to monitor disparities over time. Other recommendations are made, and CMS is reviewing that report and considering how to incorporate the recommendations into its programs. Further, CMS states that it would be inappropriate to apply social risk factor adjustment to measure scores for the Overall Star Rating because the rating relies on measures as specified and calculated for the hospital quality programs and publicly reported on *Hospital Compare.* CMS also notes that stakeholders agree that social risk factor adjustment is not appropriate for all measures, such as those for healthcare-associated infections.

As an alternative, CMS considered creating new peer group quintiles based on all the hospitals in the Overall Star Rating data set, instead of using the HRRP quintiles. But because hospitals scored for both could potentially be placed in different quintiles, CMS chose to propose using the same ones for both purposes. Its analysis of the January 2020 Overall Star Rating release data showed that 155 hospitals would be in a lower peer group than they are in for the HRRP, including 23 that would move to the lowest peer group from the second-lowest peer group. Among the 1,307 non-HRRP hospitals, 90 would be in a lower peer group using all hospitals than they would be if the HRRP peer groups were used.

CMS specifically seeks comment on its proposal to stratify the Readmission measure group based on the proportion of dual-eligible patients and on the alternative not to do so. While

four, and five, respectively.

[17] 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

it makes the proposal to respond to some stakeholders it notes that others expressed concern that stratification would misrepresent quality of care for dual-eligible patients and would be confusing to consumers. CMS also notes a high correlation (0.967) between unadjusted and adjusted Readmission measure group scores using the January 2020 Overall Star Rating data. That is, it finds the effect of stratification is modest or negligible. (Each of these words is used in a different place in the proposed rule.)

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

General Approach and Weighting. CMS proposes to continue to calculate hospital summary scores through a weighted average of measure group scores with a similar 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 – would be weighted at 22 percent, and the proposed combined process measure group, Timely and Effective Care would be weighted at 12 percent. Hospital summary scores would then be calculated by multiplying the standardized measure group scores by the assigned measure group weight and then summing these amounts. This approach would be codified in §412.190. Table 49 in the proposed rule offers an example of the proposed 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.

Reweighting. Measure group scores would 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 (proposed below as having at least three measure groups each with at least three measures) a hospital would need to 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 would be subtracted from 100 percent, and the weight percentage of each of the remaining groups would then be divided by the resulting percentage, giving new re-proportioned weights. This approach would be codified in §412.190. Tables 50, 51, and 52 in the proposed rule offer numerical examples of how the reweighting approach would work.

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

To receive a star rating, hospitals have to meet minimum reporting thresholds, and CMS proposes to modify these beginning with the 2021 Overall Star Rating. The current thresholds are that the 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, CMS proposes that 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 would contribute to the hospital's star rating. These policies would be codified at §412.190.

CMS believes that this proposal would increase the comparability of hospitals in the Overall Star Rating and would ensure that in order to receive a star rating hospitals must have information available on mortality and patient safety, which are important to patients making healthcare decisions.

CMS acknowledges that this proposal would limit the number of hospitals eligible to receive a star rating. This would be particularly true for small, low volume hospitals without sufficient cases to report the individual measures; CAHs are not required to report safety measures under the HAC Reduction Program. In the data for the January 2020 Overall Star Rating, 125 hospitals did not meet the proposed 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. CMS makes the proposal because, as recommended by the TEP, mortality and safety of care are the most important aspects of quality to patients and reflective of performance under the hospital's control.

Approach to Peer Grouping Hospitals

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

CMS believes that the proposed peer groupings would capture the hospital differences that are important to stakeholders. These include differences in size, patient volume, case mix, and service mix. CMS offers the example that larger hospitals with more diverse case mix and service mix, such as large urban teaching hospitals, report a greater number of measures, and therefore measure groups, and would be grouped separately from smaller hospitals with less diverse patient cases and service mix, which tend to report fewer measures and measure groups.

CMS simulated the effects of the peer grouping proposal using the January 2020 Overall Star Rating release data, and 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 vetted these group sizes with the TEP and workgroups.

CMS also assessed the stability of the peer groups over time and found that hospitals tend to report the same number of measure groups over time and demonstrate similar within-peer group

hospital reporting profiles. Using data over five previous years, hospitals would have been assigned to the same peer groups of three, four, or five measure groups 96 to 98 percent of the time, indicating a high level of consistency over time. Regarding within-group reporting profiles, hospitals with three measure groups tend to almost always report at least three measures in the Mortality (86 percent), Readmission (86 percent), and Timely and Effective Care (96 percent) measure groups but tend to seldom report at least three measures in the Safety of Care (15 percent) and Patient Experience (17 percent) measure groups. Similar consistent patterns were found for hospitals with four and five measure groups. CMS believes these results confirm that peer grouping results in the grouping of hospitals with similar reporting profiles and characteristics and may address stakeholder concerns about the comparability of hospital star ratings.

Because CAHs account for about half the hospitals in the three-measure peer group, CMS makes adoption of the peer group proposal contingent on the inclusion of CAHs in the Overall Star Rating. It says that exclusion of CAHs would not result in peer groups with a sufficient number of hospitals for comparison. If CAHs were not included in the three-measure peer group, the difference in summary score between a two-star and three-star hospital in the three-measure peer group may be modest and not truly reflective of differences in hospital quality.

Peer groups have not been used before for the Overall Star Rating, and CMS believes that its proposed approach would address stakeholder concerns about the comparability of hospital star ratings by assigning star ratings relative only to similar hospitals. CMS notes, however, that the peer grouping proposal would change the historical, conceptual comparative nature of the Overall Star Rating. Hospitals with the same summary score but in different peer groups could receive different star ratings because they would only be compared to hospitals in their peer group. Although comparability within peer groups would be increased under the proposal, comparability across peer groups would be decreased for patients comparing hospitals in the same geographic area that fall within different peer groups.

CMS explains that its proposal to apply peer grouping after the calculation of summary scores and before the assignment of star ratings makes hospital summary scores equivalent and comparable among all hospitals, regardless of peer grouping. CMS says this would provide transparency and allow stakeholders to review measure group and summary score results comparable to all other hospitals in the nation. This could be accomplished by hospitals using confidential hospital-specific reports during the 30-day confidential preview period for quality improvement purposes or by using the *Hospital Compare* public downloadable database. CMS states that this approach would also provide minimal sensitivity of measure-level differences between peer groups on star ratings, and a hospital's final star rating would only be in comparison to hospitals that have a similar number of measure groups.

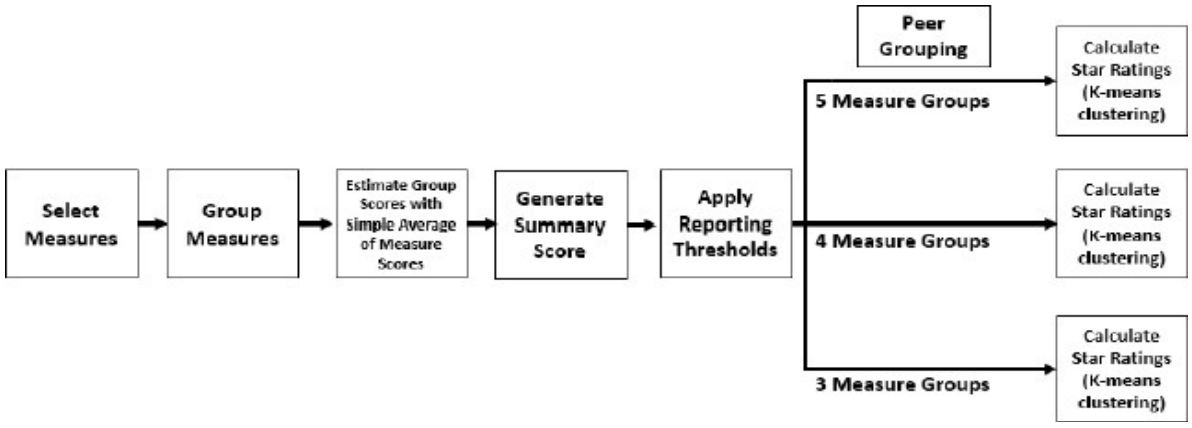
Step 6: Application of Clustering Algorithm to Assign Star Rating

CMS proposes to 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, CMS proposes to continue use k-means clustering with complete convergence without

Winsorization[18] of hospital summary scores to group hospitals into five clusters to assign star ratings. This policy would be 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. CMS considered other methods and presented them to the TEP and for public comment, including percentiles, statistically significant cutoffs, and clustering algorithms. K-means clustering is preferred because it is data driven, minimizes within-category differences, maximizes the between-category differences and is similar to the algorithm used for the HCAHPS Star Rating. CMS states that stakeholders have generally supported the use of k-means clustering to assign star ratings over other methods.

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



F. Preview Period

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

[18] 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.

G. Overall Star Rating Suppressions

Policies for suppression of the Overall Star Rating are proposed separately for subsection (d) hospitals and CAHs. These would begin with 2021 and be 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 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.

1. Subsection (d) Hospitals

CMS proposes to consider suppressing Overall Star Rating only under extenuating circumstances that affect numerous hospitals as determined by CMS or when CMS is at fault. This would include 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 proposes that it would 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, would continue to be allowed 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 would 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 would be withheld from the Overall Star Rating calculation. However, individual measure scores would 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* could submit the same form during the 30-day confidential preview period provided for the applicable quality program. Measure data withheld from *Hospital Compare* would not be included in the Overall Star Rating.

Finally, CMS also proposes that 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).

H. Impact of Changes to the Overall Star Rating Methodology

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

Tables 64 through 75 in the proposed rule display the estimated impacts of proposed changes to the Overall Star Rating methodology. The estimates were prepared using data from the January 2020 Overall Star Rating publication (data publicly reported on *Hospital Compare* in October 2019). 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.

CMS reminds readers that the actual impacts will be affected by changes in the measures included in the underlying quality programs and publicly reported as well as hospital performance on the measures.

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

- The combined methodology proposals alone and in combination with the peer grouping and readmission stratification proposals all result in 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 64).
- Under the combined methodology proposals alone, 53 percent of hospitals would receive the same star rating, 43 percent would shift up or down one star, 4 percent would shift up or down two stars, 0.3 percent would shift up or down three stars, and one hospital would shift up or down four stars (Table 65).
- When the peer group proposal is added to the combined methodology proposals, 50 percent of hospitals would receive the same star rating, 43 percent would shift up or down one star, 5 percent would shift up or down two stars, 0.3 percent would shift up or down three stars, and one hospital would shift up or down four stars (Table 66).
- When the readmission stratification proposal is added to the combined methodology proposals, 50 percent of hospitals would receive the same star rating, 45 percent would shift up or down one star, 5 percent would shift up or down two stars, 0.2 percent would

shift up or down three stars, and one hospital would shift up or down four stars (Table 67).

- When all proposals are combined, 51 percent of hospitals would receive the same star rating, 43 percent would shift up or down one star, 5 percent would shift up or down two stars, 0.2 percent would shift up or down three stars, and one hospital would shift up or down four stars (Table 68).
- Under the combined methodology proposals alone, the distribution of hospitals across the star rating categories is similar by hospital type, except that more specialty hospitals would receive at least three stars; more DSH hospitals would receive three stars or less and fewer would receive five stars, a pattern increasing with DSH quintile; more CAHs would receive four or five stars; and the share of hospitals with one or two stars increases with bed size (Table 72).
- When the peer group proposal is added to the combined methodology proposals, the distribution of hospitals across the star rating categories is similar by hospital type, except that more specialty hospitals would receive at least three stars; more DSH hospitals would receive two stars and fewer would receive four and five stars, a pattern increasing with DSH quintile (Table 73).
- When the readmission stratification proposal is added to the combined methodology proposals, the distribution of hospitals across the star rating categories is similar by hospital type, except that more specialty hospitals would receive four or five stars; more CAHs would receive four or five stars; more DSH Quintile 5 hospitals than Quintile 1 hospitals would receive one and two stars and fewer DSH hospitals would receive four and five stars as DSH quintiles increase; more hospitals would receive one and two stars as bed size increases (Table 74).
- When all the proposals are combined, the distribution of hospitals across the star rating categories is similar by hospital type, except that more specialty hospitals would receive four or five stars; more CAHs would receive four or five stars; more DSH hospitals would receive three stars or less and fewer would receive five stars, a pattern increasing with DSH quintile; and more hospitals receive one and two stars as bed size increases (Table 75).

XVII. Prior Authorization Process

A. Background

Citing the 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. Regulations for the prior authorization process are found at §§419.80 through 419.89. 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,[19] 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

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

service. Table 54 in the proposed rule lists all the service categories and services to which prior authorization currently applies.

B. Proposed Addition of Two New Service Categories

Effective for dates of services on or after July 1, 2021, CMS proposes to add the following two services categories to the prior authorization list: Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators. They would be added as new sections §§419.83(a)(2)(i) and (ii), respectively. CMS would clarify that the existing 5 service categories had an effective date of July 1, 2020.

CMS also proposes to identify the list of covered OPD services for these new service categories in Table 53 of the proposed 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 this 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 that the overall rate of OPD claims increased each year by an average rate of 2.8 percent. This reflects a slight decrease from the 3.2 percent average rate the agency found for the 2020 OPPS/ASC final rule. CMS also found an average annual rate-of-increase in the Medicare allowed amount 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 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 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 percent[20], and 8.8 percent, respectively. All three were higher than

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

the 2.8 percent rate for all OPD 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 OPD services.

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 percent[21] 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.

CMS seeks comment on the proposed new service categories.

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.

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 OPPS 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

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

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)[22] 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.

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 proposes 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 proposes to no longer package cancer-related protein-based MAAAs, CMS is proposing a modification to the date of service rule to apply the same date of service 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

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

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.

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 proposes 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 proposes 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 proposes 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 is further considering 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 are 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 seeks comments regarding how it could obtain independent confirmation of the data provided in the absence of the community input. The proposed rule indicates 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.

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.[23] 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.[24]

In order to ensure stakeholders' awareness of its baseline number licensed by the state as of either March 23, 2010 or December 31, 2010, CMS proposes 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 seeks 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."

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[23] https://www.cms.gov/Medicare/Fraud-andAbuse/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.

[24] https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.

XX. Files Available to the Public via the Internet

Addenda for the 2021 OPPS proposed rule are available on the following CMS website:

https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1736-p

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 proposed payments, please see:

https://www.cms.gov/medicaremedicare-fee-service-paymentascpaymentasc-regulations-and-notices/cms-1736-p

TABLE 55—ESTIMATED IMPACT OF PROPOSED OPPS CHANGES FOR 2021

	(1)	(2)	(3)	(4)	(5)	(6)
	Number of Hospitals	APC Recalibration (all changes	New Wage Index and Provider Adjustment	340B Adjustment	All Budget Neutral Changes (combined col 2-4) with Market Basket Update	All Changes
ALL PROVIDERS *	3,628	0.0	0.2	0.0	2.8	2.5
ALL HOSPITALS	3,523	0.1	0.2	0.0	2.9	2.6
(excludes hospitals held harmless and CMHCs)						
URBAN HOSPITALS	2,772	0.0	0.2	-0.1	2.8	2.5
LARGE URBAN	1,431	0.1	0.2	-0.1	2.8	2.5
(GT 1 MILL.)						
OTHER URBAN	1,341	0.0	0.2	-0.1	2.8	2.4
(LE 1 MILL.)						
RURAL HOSPITALS	751	0.1	0.4	0.4	3.6	3.2
SOLE COMMUNITY	368	0.1	0.5	0.7	4.0	3.5
OTHER RURAL	383	0.1	0.2	0.0	2.9	2.7
BEDS (URBAN)						
0 - 99 BEDS	927	0.3	0.3	0.5	3.7	3.4
100-199 BEDS	789	0.3	0.2	0.3	3.4	3.1
200-299 BEDS	449	0.2	0.2	0.1	3.2	2.9
300-499 BEDS	383	0.1	0.3	0.0	2.9	2.6
500 + BEDS	224	-0.3	0.0	-0.6	1.7	1.6
BEDS (RURAL)						
0 - 49 BEDS	324	0.3	0.5	0.5	3.9	3.5
50- 100 BEDS	262	0.3	0.5	0.5	3.9	3.4
101- 149 BEDS	88	0.0	0.3	0.3	3.2	2.8
150- 199 BEDS	38	0.0	0.4	0.1	3.1	2.9
200 + BEDS	39	-0.1	0.3	0.3	3.1	3.0
REGION (URBAN)						
NEW ENGLAND	133	-0.1	0.7	-0.2	3.0	2.0
MIDDLE ATLANTIC	325	-0.2	0.0	-0.1	2.3	2.2
SOUTH ATLANTIC	452	0.1	0.1	-0.1	2.7	2.7
EAST NORTH CENT.	436	0.0	-0.1	0.0	2.5	2.4
EAST SOUTH CENT.	162	-0.1	0.0	-0.3	2.2	2.1
WEST NORTH CENT.	183	-0.1	0.7	-0.2	2.9	1.9
WEST SOUTH CENT.	461	0.3	0.2	0.2	3.4	3.3
MOUNTAIN	204	0.2	0.2	-0.1	3.0	2.3
PACIFIC	367	0.2	0.2	-0.1	2.9	2.8
PUERTO RICO	49	0.7	-0.3	0.8	3.7	3.7

	(1)	(2)	(3)	(4)	(5)	(6)
	Number of Hospitals	APC Recalibration (all changes	New Wage Index and Provider Adjustment	340B Adjustment	All Budget Neutral Changes (combined col 2-4) with Market Basket Update	All Changes
REGION (RURAL)						
NEW ENGLAND	20	0.0	-0.1	0.3	2.8	2.7
MIDDLE ATLANTIC	50	0.0	0.3	0.4	3.2	3.2
SOUTH ATLANTIC	114	0.1	0.0	0.2	2.9	2.8
EAST NORTH CENT.	120	0.1	0.7	0.5	4.0	3.8
EAST SOUTH CENT.	146	0.2	0.0	0.0	2.9	2.8
WEST NORTH CENT.	91	0.0	1.0	0.6	4.3	3.1
WEST SOUTH CENT.	139	0.3	0.1	0.6	3.7	3.6
MOUNTAIN	48	0.0	2.0	0.6	5.2	3.1
PACIFIC	23	0.2	-0.3	0.3	2.8	2.7
TEACHING STATUS						
NON-TEACHING	2,367	0.3	0.2	0.3	3.5	3.2
MINOR	779	0.2	0.4	0.1	3.2	2.8
MAJOR	377	-0.4	0.0	-0.6	1.6	1.4
DSH PATIENT PERCENT						
0	11	0.5	-0.1	0.8	3.8	3.7
GT 0 - 0.10	268	0.5	0.2	0.8	4.1	3.8
0.10 - 0.16	241	0.3	0.0	0.7	3.7	3.4
0.16 - 0.23	591	0.4	0.2	0.7	4.0	3.7
0.23 - 0.35	1,081	0.0	0.3	-0.1	2.7	2.4
GE 0.35	906	-0.2	0.2	-0.6	2.0	1.8
DSH NOT AVAILABLE **	425	-1.0	0.2	0.7	2.5	2.3
URBAN TEACHING/DSH						
TEACHING & DSH	1,041	-0.1	0.2	-0.3	2.4	2.1
NO TEACHING/DSH	1,313	0.4	0.1	0.3	3.4	3.2
NO TEACHING/NO DSH	11	0.5	-0.1	0.8	3.8	3.7
DSH NOT AVAILABLE2	407	-0.9	0.2	0.7	2.6	2.4
TYPE OF OWNERSHIP						
VOLUNTARY	1,971	0.0	0.2	-0.1	2.7	2.4
PROPRIETARY	1,099	0.7	0.3	0.8	4.4	4.1
GOVERNMENT	453	-0.1	0.1	-0.3	-0.3	2.2
CMHCs	38	-2.0	0.1	0.9	1.5	1.3

Column (1) shows total hospitals and/or CMHCs.
Column (2) includes all proposed 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 proposed FY 2021 hospital inpatient wage index and the non-budget neutral frontier adjustment. The proposed 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 proposed 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 the proposed CY 2021 OPPS changes to 340B drug payment and the corresponding budget neutrality adjustment.
Column (5) shows the impact of all budget neutrality adjustments and the addition of the 2.6 percent OPD fee schedule update factor (3.0 percent reduced by 0.4 percentage point for the productivity adjustment).

Column (6) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate, and adding estimated outlier payments.
Note that previous years included the frontier adjustment in this column, but we have the frontier adjustment to Column 3 in this table.
These 3,628 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