hfma
healthcare financial management association

Medicare Program: 2023 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs Proposed Rule Summary

The Centers for Medicare & Medicaid Services (CMS) released the calendar year 2023[1] proposed rule for Medicare's hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system (CMS-1772-P) on July 15, 2022. Policies in the proposed rule will generally go into effect on January 1, 2023 unless otherwise specified. The proposed rule will be published in the July 26, 2022 issue of the *Federal Register*. **The public comment period will end on September 13, 2022.**

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.

In this proposed rule, CMS discusses how it plans to modify payment for separately payable outpatient drugs acquired by hospitals in the 340B drug discount program. A recent Supreme Court decision found CMS' policy to be contrary to law. CMS also proposes additional policies to implement the Rural Emergency Hospitals (REH) program. The proposed rule includes a number of other issues including a proposed method of accounting for research organs that will improve payment accuracy and lower the costs to procure and provide research organs to the research community; making data publicly available on hospital and skilled nursing facility mergers, acquisitions and consolidations; and other issues.

Addenda containing relative weights, payment rates, wage indices and other payment information are available on the CMS website at: https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1772-p. Unless otherwise noted, this weblink can be used to access any information specified as being available on the CMS website.

TABLE OF CONTENTS

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

I. Overview

A. Estimated Impact on Hospitals

The increase in OPPS spending due only to changes in the 2023 OPPS proposed rule is estimated to be approximately $1.79 billion. Taking into account estimated changes in enrollment, utilization, and case-mix for 2023, CMS estimates that OPPS expenditures, including beneficiary cost-sharing, will be approximately $86.2 billion, which is approximately $6.2 billion higher than estimated OPPS expenditures in 2022.

CMS estimates that the update to the conversion factor net of the total factor productivity (TFP) will increase payments 2.7 percent in 2023 (market basket of 3.1 percent less 0.4 percentage points for TFP). Including changes to outlier payments, pass-through payment estimates and the application of the frontier state wage adjustment, CMS estimates a 2.9 percent increase in payments between 2022 and 2023.

Hospitals that satisfactorily report quality data will qualify for the full update of 2.7 percent, while hospitals that do not will be subject to an update of 0.7 percent (a statutory reduction of 2.0 percentage points). All other adjustments are the same for the two sets of hospitals. Of the approximately 3,356 hospitals that meet eligibility requirements to report quality data, CMS determined that 88 hospitals will not receive the full OPPS increase factor.

Medicare makes payments under the OPPS to approximately 3,502 facilities (3,411 hospitals excluding CMHCs, cancer and children's hospitals held harmless to their pre-OPPS payment to cost ratios). Table 84 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 2.9 percent for all facilities and hospitals. The following table shows components of the 1.6 percent total:

	% Change All Facilities
Fee schedule increase factor	2.7
Difference in pass through estimates for 2022 and 2023	0.34
Difference from 2022 outlier payments (1.29% vs. 1.0%)	-0.29
Change to Rural SCH Off-Campus Policy & N95 Masks	0.15
All changes	2.9

CMS estimates that pass-through spending for drugs, biologicals and devices for 2023 will be $772 million, or 0.9 percent of OPPS spending.[2] For 2022, CMS estimates pass-through spending would be 1.24 percent of OPPS spending. The difference between these figures (0.90 - 1.24 = 0.34 percentage point) is the required adjustment to ensure that pass-through spending remains budget neutral from one year to the next.

In addition, CMS estimates that actual outlier payments in 2022 will represent 1.29 percent of total OPPS payments compared to the 1.0 percent set aside, a -0.29 percentage point change in 2023 payments.

CMS does not precisely quantify the increase payments for the change to payment policy for off-campus rural SCHs but elsewhere indicates that the budget neutral change to provide subsidies for N95 masks accounts for 0.01 percent of OPPS payments. Taken together as a residual to explain the 2.9 percent increase across all facilities, these two factors represent a 0.15 percent change in payment to all facilities.

[2] As explained further in section V. B., a large portion of pass-through spending is associated with 340B drugs. As a result of a recent Supreme Court decision, CMS expects to change its 340B payment policy in the final rule to pay a higher amount for drugs acquired under the 340B program. The increase in payment will result in lower pass-through payment and less of a budget neutrality adjustment.

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

Although CMS projects an estimated increase of 2.9 percent for all facilities, the rule's 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	2023 Impact
All Hospitals	2.9%
All Facilities (includes CMHCs and cancer and children's hospitals)	3.0%
Urban	2.9%
Large Urban	2.9%
Other Urban	3.0%
Rural	3.2%
Beds	
0-99 (Urban)	3.4%
0-49 (Rural)	3.0%
500+ (Urban)	2.6%
200+ (Rural)	3.0%
Major Teaching	2.6%
Type of ownership	
Voluntary	2.9%
Proprietary	3.5%
Government	2.8%

The payment impacts are largely consistent between the different categories of hospitals. Generally, an increase or decrease larger than the average will be accounted for by recalibration of APC weights or changes to the wage index. The higher increase for proprietary hospitals is accounted for by recalibration of the relative weights. Similarly, recalibration of the relative weights appears to also benefit smaller hospitals on average. The rural hospital category shows a larger increase due to CMS' policy of exempting rural SCHs from the reduction in payment for off-campus provider-based departments.

B. Estimated Impact on Beneficiaries

CMS estimates that the aggregate beneficiary coinsurance percentage will be 17.8 percent for all services paid under the OPPS in 2023. 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 ($1,556 in 2022) which accounts for the aggregate coinsurance percentage being less than 20 percent.

II. Updates Affecting OPPS Payments

A. Recalibration of Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

For 2023, CMS is returning to its normal processing of using the latest available claims data to set the OPPS relative weights—2021 hospital final action claims for services furnished from January 1, 2021 through December 31, 2021 processed through the Common Working File as of March 31, 2022 (approximately 93 million claims).

CMS is continuing to use cost reports that precede the COVID-19 Public Health Emergency (PHE) for cost-to-charge ratios (CCR) that are used to adjust charges on claims to cost. CMS proposes to use cost report data from the June 2020 Hospital Cost Report Information System data set, which only includes cost report data through CY 2019 for 2023 OPPS rate setting purposes. For additional discussion of this issue, please see section X.D.

In a separate document available on the CMS website, CMS provides a detailed description of the claims preparation process and an accounting of claims used in the development of the proposed rule payment rates, including the number of claims available at each stage of the process: https://www.cms.gov/files/document/2023-nprm-opps-claims-accounting.pdf.

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

For the 2023 proposed rule, CMS is bypassing the 174 HCPCS codes identified in Addendum N. There are seven new bypass codes are identified with an asterisk in column D. CMS indicates the list of bypass codes may include codes that were reported on claims in 2021 but were deleted for 2022.

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

To convert billed charges on outpatient claims to estimated costs, CMS is multiplying the charges on the claim by a hospital-specific CCR associated with each revenue code and cost center. To calculate CCRs for 2023, CMS is employing the same basic approach used for APC rate construction since 2007. CMS applies the relevant hospital-specific CCR to the hospital's charges at the most detailed level possible based on a revenue code-to-cost center crosswalk containing a hierarchy of CCRs for each revenue code. The current crosswalk is available for review and continuous comment on the CMS website at the link provided at the beginning of this summary.

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. For 2023, CMS proposes not to use nonstandard cost centers on cost report lines that do not correspond to the cost center number because of concerns about how use of data reported in this way will affect a small number of APCs. CMS will further investigate the accuracy of the cost reports and accept comments on this issue before including such data in the rate-setting process.

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

In past years, to determine each APC's relative weight, CMS takes single procedure claims and adjusts charges to costs for each procedure within an APC and then calculates the APC's geometric mean cost. The relative weight is the geometric mean cost of the APC divided by the geometric mean cost across all APCs. CMS standardizes the relative weights to the APC for G0463, an outpatient hospital visit—the most commonly furnished service billed under the OPPS. CMS is continuing to follow this basic process for 2023. The 2021 claims data that CMS is using for 2023 includes data from off-campus provider-based departments paid at a physician fee schedule (PFS) comparable amount under section 603 of the Bipartisan Budget Act (BBA) of 2015. As these claims are not paid under the OPPS, CMS eliminates these claims from the relative weight calculation.

a. Calculation of single procedure APC criteria-based costs

The calculation of geometric mean costs for some APCs follows various special rules, as described below.

Blood and blood products

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

Brachytherapy sources

The statute requires the Secretary to create APCs for brachytherapy consisting of a seed or seeds (or radioactive source) – i.e., "brachytherapy sources" – separately from other services or groups of services, in order to reflect the number, isotope, and radioactive intensity of the brachytherapy sources furnished. Since 2010, CMS has used the standard OPPS payment methodology for brachytherapy sources, with payment rates based on source-specific costs as required by statute. CMS proposes no changes to its brachytherapy policy for 2023.

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 through 2022, 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. CMS has no 2021 claims data for HCPCS code C2645 to set a proposed rate for 2023. For this reason, CMS proposes to continue the rate of $4.69 per mm^2 for 2023 for HCPCS code C2645.

In section III.D. below, there is more information on CMS' universal low volume APC policy to use up to four years of claims data for APCs with fewer than 100 single procedure claims in a year that can be used for rate-setting. For these APCs, CMS will determine the relative weight based on the higher of the arithmetic mean cost, median cost, or geometric mean cost. CMS proposes to price four low volume brachytherapy APCs under this policy (excluding those that are priced using external data).

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

b. Comprehensive APCs (C-APCs) for 2023

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.

CMS also adopted an exception to the C-APC policy in the November 6, 2020 interim final rule with comment (IFC) titled "Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency" for drugs and biologicals approved by the Food and Drug

Administration (FDA) to treat COVID-19 for use in the outpatient department or not limited for use in inpatient settings. Such drugs and biologicals will be paid separately outside of the C-APC for the duration of the COVID-19 PHE.

For 2023, CMS is proposing a new policy to exclude HCPCS Code C9399 (Unclassified drugs or biologicals) from the C-APC policy. Consistent with section 1833(t)(15) of the Act, this code allows for pricing at 95 percent of average wholesale price (AWP) before a specific HCPCS code is assigned to a new drug or biological. Since the implementation of the C-APC policy in 2015, payment for drugs and biologicals described by HCPCS code C9399 has been included in the C-APC payment when these products appear on a claim with a primary C-APC service.

Excluding HCPCS code C9399 from the C-APC policy will ensure that drugs that do not yet have a specific HCPCS code will be priced at 95 percent of AWP. CMS is also proposing to add a new definition to status indicator "A" to include unclassified drugs and biologicals that are reportable with HCPCS code C9399 (also see section XI. for a description of the status indicator proposal).

As a result of its annual review of the services and APC assignments under the OPPS, CMS proposes to add one new C-APCs in 2023: C-APC 5372 (Level 2 Urology and Related Services). The full list of C-APCs, the data CMS used to evaluate creating 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. At this time, CMS' composite APC policy applies only for mental health services and multiple imaging services. CMS is not proposing any changes to its composite APC policies for 2023.

3. Changes to Packaged Items and Services

CMS is not proposing any changes to its packaging policies and separate payment for nonopioid treatment alternatives. However, it is soliciting potential modifications to its packaging policies in ASCs. See section XIII.E. for more information.

4. Calculation of OPPS Scaled Payment Weights

As in past years, CMS is standardizing 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 will give APC 5012 a relative weight of 1.0 and divide 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 an off-campus provider-based department at a PFS equivalent rate under a site neutral policy, CMS will

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.

CMS is following its past practice of using utilization from the preceding year (2021) to determine budget neutrality for changes in the OPPS relative weights for the proposed rule year (2023). (For 2022, CMS deviated from the practice of using the preceding year's utilization to avoid using 2020 utilization affected by the COVID-19 PHE.)

Holding all other variables constant, CMS multiplies the 2022 final relative weights and the 2023 proposed relative weights respectively for each APC by its associated volume from 2021. It sums the 2022 and proposed 2023 relative weights respectively, and divides the 2023 proposed aggregate relative weights by the 2022 aggregate relative weights to determine the weight scaler. Using this process, CMS is adopting a weight scaler of 1.4152. The unscaled proposed 2023 relative payments are multiplied by 1.4152 to determine the proposed 2023 scaled relative weights that are shown in Addendum A and B.

Specified covered outpatient drugs (SCODs) are included in the budget neutrality calculation to ensure that the relative weight changes between 2022 and 2023 do not increase or decrease expenditures. However, SCODs are not affected by the budget neutrality adjustment.

B. Conversion Factor Update

The proposed 2023 conversion factor is $86.7850 for hospitals receiving the full update for outpatient quality reporting. The components of the update are shown below:

	Full Update		Reduced Update	
2022 Conversion Factor (CF)	**$84.1770**	**Resulting CF**	**$84.1770**	**Resulting CF**
Remove pass-through & outliers from prior year CF	1.0229	$86.1060	1.0229	$86.1060
Wage Index Budget Neutrality	1.0010	$86.1920	1.0010	$86.1920
Cap on Wage Index Reductions	0.9995	$86.1490	0.9995	$86.1490
Cancer Hospital Adjustment	1.0000	$86.1490	1.0000	$86.1490
Rural Hospital Adjustment	1.0000	$86.1490	1.0000	$86.1490
340B Adjustment	1.0000	$86.1490	1.0000	$86.1490
Update	1.0270	$88.4750	1.0070	$86.7520
Pass-Through/Outlier/N95 Adjustment	0.9809	$86.7850	0.9809	$85.0930
2023 Conversion Factor		$86.7850		$85.0930

CMS removes the prior year's pass-through and outlier adjustment from the 2022 conversion factor which equals 1.0229 (2.29 percent). Wage index budget neutrality is 1.0010 (0.10 percent) for 2023. There is a cap on reductions to the wage index that requires a budget neutrality adjustment of 0.9995 (-0.05 percent) for 2023. CMS indicates no additional budget neutrality adjustment is needed for the cancer and rural hospital adjustments or 340B policies for 2023.[3]

[3] The proposed rule assumes the 340B policy is unchanged from 2022. However, in response to a Supreme Court case decided shortly before the proposed rule, CMS indicates that it plans to pay ASP+6 percent in place of ASP-22.5 percent for drugs acquired under the 340B program. The final rule policy will require a budget neutrality adjustment to offset the higher payments for drugs acquired under the 340B program.

The update of 1.027 (2.7 percent) equals the market basket of 3.1 percent less 0.4 percentage points for TFP (0.7 percent for hospitals that do not receive the full update) for 2023. CMS estimates that pass-through spending for drugs, biologicals and devices for 2023 will be $772 million, or 0.90 percent of OPPS spending.[4] The outlier adjustment is 0.99 (-1.0 percent). CMS estimates a budget neutrality adjustment of 0.9999 (-0.01 percent) is needed for the N95 payment policy. The combined adjustment for pass-through, outliers and CMS' N95 policy is 0.9809 (-1.91 percent).

The proposed 2023 conversion factor for hospitals that submit quality data is $86.7850. The conversion factor for hospitals that do not submit quality data is subject to all of the same adjustments except the update is 1.0000 (0.0 percent) instead of 1.0200 (2.0 percent). The proposed conversion factor for hospitals that do not submit quality data is $85.0930 (HPA calculates a slightly higher conversion factor of $85.0950). CMS applies the reduced update as the "reporting ratio" to the full payment rate for hospitals that do not submit quality data or the ratio of the reduced CF to the full CF ($85.0930/$86.7850=0.9805).

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 2023. The propose rule directs readers to the IPPS rule for more details regarding specific policies affecting the proposed 2023 wage index. In the FY 2023 IPPS rule, CMS proposed to apply a 5 percent cap on reductions to a hospital wage index for any reason. CMS is proposing to adopt this same policy under the OPPS for 2023. As noted in the prior section, CMS proposes to make this change budget neutral necessitating -0.05 percent budget neutrality adjustment to the conversion factor.

For non-IPPS hospitals paid under the OPPS for 2023, 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 not the out-migration adjustment, which only applies to hospitals.

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

In cases where there are 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

[4] This amount will change in the final rule. Nearly $593 million of these pass-through amounts are associated with drugs that will be paid ASP+6 percent instead of ASP-22.5 percent under CMS' 340B drug payment policy. However, CMS indicates that in the final rule it will no longer apply the ASP-22.5 percent policy and will pay all separately payable drugs at ASP+6 percent. This will change the pass-through amount to $179.3 million or 0.21 percent of total OPPS spending necessitating a pass-through adjustment of -0.9979 (-0.21 percent) in the final rule in place of the 0.9910 (-0.90 percent) in the proposed rule.

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. Consistent with other policies to not use cost report data that span the COVID-19 PHE, CMS proposes to continue using the same default statewide average CCRs for 2023 that it used for 2021. The table of statewide average CCRs can be found at: https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppsannual-policy-files/2023-0

E. Sole Community Hospital (SCH) Adjustment

For 2023, CMS proposes 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. Rather than using the latest available cost reports that would include data that span the COVID-19 PHE, CMS proposes to continue using the same target PCR it used for 2021 and 2022. Under the proposed policy for 2023, the target PCR would remain at 0.89.

Table 4 in the proposed rule shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals, with increases in OPPS payments for 2022 ranging from 12.9 percent to 69.2 percent. CMS indicates that no additional budget neutrality adjustment is required for the cancer hospital adjustment in 2023 compared to 2022.

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 2023, CMS proposes to continue setting aside 1.0 percent of the estimated aggregate total payments for OPPS outlier payments. It proposes calculating the fixed-dollar threshold using the same methodology that was used to set the threshold for 2022 and previous years. CMS proposes to continue setting the 2023 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.

CMS proposes to set aside a portion of the 1.0 percent outlier pool, specifically an amount equal to less than 0.01 percent of outlier payments, for CMHCs for partial hospitalization program outlier payments. 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, a hospital's costs for the service are compared to the reduced payment level for purposes of determining outlier eligibility and payment amount.

CMS is proposing to use 2021 Medicare claims data to set the 2023 outlier threshold. To model hospital outlier payments and set the outlier threshold for the proposed rule, CMS applied a charge inflation factor of 1.13218 to approximate 2023 charges from 2021 claims.

The proposed rule indicates that CMS is proposing to use hospital-specific overall ancillary CCRs from the April 2022 update to the Outpatient Provider-Specific File (OPSF) to determine the 2023 proposed rule outlier threshold. However, CMS is proposing to use June 2020 cost report data for determining the 2023 OPPS relative weights. CMS explains that since the April 2022 OPSF contains cost data primarily from 2021 and 2022 and is the basis for determining current 2022 OPPS outlier payments, CMS believes the April 2022 OPSF provides a more updated and accurate data source for determining the CCRs that will be applied to 2023 hospital outpatient claims. Section X.D. explains why CMS believes using pre-2020 cost reports are the better data source for determining the 2023 relative weights. CMS proposes to adjust the April 2022 CCRs by 0.974495 to approximate 2023 CCRs.

For 2023, CMS proposes a fixed dollar threshold of $8,350 (compared to $6,175 in 2022). CMS indicates that this fixed dollar threshold, combined with the multiplier threshold of 1.75 times the APC payment rate, will allocate 1.0 percent of aggregated total OPPS payments to outlier payments.

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 one that does not.

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 $1,556 in 2022. The inpatient hospital deductible limit is applied to the *actual* co-payment amount after adjusting for the wage index (e.g., the national estimated coinsurance amount could be above the inpatient deductible but could come below the capped amount once adjusted for the wage index). Addenda A and B include a column with an asterisk to designate those APC and HCPCS codes where the deductible limit applies.

III. OPPS Ambulatory Payment Classification (APC) Group Policies

A. Treatment of New and Revised 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 (CR). 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.[5]

1. April 2022 Codes - CMS Solicits Public Comments in this Proposed Rule

In the April 2021 OPPS quarterly update, CMS made effective 48 new Level II HCPCS codes and assigned them to interim OPPS status indicators and APCs (Table 5). 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 2023.

2. July 2022 HCPCS Codes - CMS Solicits Public Comments in this Proposed Rule

In the July 2022 OPPS quarterly update, CMS made 63 new codes effective and assigned them to interim OPPS status indicators and APCs (Table 6). 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 2023.

3. October 2022 HCPCS Codes - CMS Will Be Soliciting Public Comments in the 2023 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, 2022 in Addendum B to the 2023 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 2023. CMS proposes that these status indicators and APC assignments would be applicable in 2023. **CMS will invite public comment in the 2023 OPPS/ASC final rule** about the status indicators, APC

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

assignments, and payment rates for these codes and this information will be finalized in the 2024 OPPS/ASC final rule.

4. January 2022 HCPCS Codes

a. New Level II HCPCS Codes – CMS Will Be Soliciting Public Comments in the 2023 Final Rule with Comment Period

CMS will solicit comments on the new Level II HCPCS codes that will become effective January 1, 2023 in the 2023 OPPS/ASC 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, 2023 will be flagged with comment indicator "NI" in Addendum B, indicating that CMS has assigned the codes an interim OPPS payment status for 2023. CMS proposes that these status indicators and APC assignments will be applicable in 2023. **CMS will invite public comment in the 2023 OPPS/ASC final rule** about the status indicators, APC assignments, and payment rates for these codes and this information will be finalized in the 2024 OPPS/ASC final rule.

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

For the 2023 OPPS update, CMS received the CPT codes that will be effective January 1, 2023 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 2023 OPPS/ASC 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 7 (reproduced below) summarizes the process used by CMS for updating codes.

Table 7: Comment Timeframe for New or Revised HCPCS codes

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	Finalized
April 2022	HCPCS (CPT and Level II Codes)	April 1, 2022	2023 OPPS/ASC proposed rule	2023 OPPS/ASC final rule with comment period
July 2022	HCPCS (CPT and Level II Codes)	July 1, 2022	2023 OPPS/ASC proposed rule	2023 OPPS/ASC final rule with comment period

Table 7: Comment Timeframe for New or Revised HCPCS codes				
OPPS Quarterly Update CR	**Type of Code**	**Effective Date**	**Comments Sought**	**Finalized**
October 2022	HCPCS (CPT and Level II Codes	October 1, 2022	2023 OPPS/ASC final rule with comment period	2024 OPPS/ASC final rule with comment period
January 2023	CPT Codes	January 1, 2023	2023 OPPS/ASC proposed rule	2023 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2023	2022 OPPS/ASC final rule with comment period	2024 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 2023 OPPS and CMS' responses will be discussed in the 2023 OPPS/ASC final rule.

For 2023, 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 2023 are related to changes in costs of services that were observed in the 2021 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 8 (reproduced below) lists the 23 APCs that CMS proposes to exempt from the 2 times rule for 2022 based on claims data from January 1, 2021, through December 31, 2021 and processed on or before December 31, 2021.

Table 8: Proposed 2023 APC Exceptions to the 2 Times Rule

Proposed CY 2023 APC	Proposed CY 2023 APC Title
5012	Clinic Visits and Related Services
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5301	Level 1 Upper GI Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5571	Level 1 Imaging with Contrast
5611	Level 1 Therapeutic Radiation Treatment Preparation
5612	Level 2 Therapeutic Radiation Treatment Preparation
5627	Level 7 Radiation Therapy
5673	Level 3 Pathology
5691	Level 1 Drug Administration
5692	Level 2 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5734	Level 4 Minor Procedures
5741	Level 1 Electronic Analysis of Devices
5791	Pulmonary Treatment
5811	Manipulation Therapy
5821	Level 1 Health and Behavior Services
5822	Level 2 Health and Behavior Services
5823	Level 3 Health and Behavior Services

C. New Technology APCs

1. New Technology APC Groups

Currently, there are 52 levels of New Technology APC groups with two parallel status indicators; one set with a status indicator of "S" (S = Significant procedure, not discounted when multiple) and the other set with a status indicator of "T" (T = Significant procedure, multiple

reduction applies). The New Technology APC levels range from the cost band assigned to APC 1491 (New Technology – Level 1A ($0 - $10)) through the highest cost band assigned to APC 1908 (New Technology – Level 52 ($145,001 - $160,000)). Payment for each APC is made at the mid-point of the APC's assigned cost band. The proposed payment rates for these New Technology APCs are included in Addendum A to this proposed rule.

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

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

In the 2019 OPPS/ASC final rule, CMS finalized a payment methodology low-volume services assigned to a New Technology APC using its equitable adjustment authority at section 1833(t) of the Act to determine costs for low-volume services. Beginning in 2022, CMS adopted a policy to use the equitable adjustment authority to determine costs for all low-volume services. CMS also designated clinical APCs and brachytherapy APCs with fewer than 100 single claims that can be used for rate-setting as low volume. For low volume APCs, CMS determines the relative weight based on the higher of the APC's geometric mean, median, or the arithmetic mean.

For 2023, CMS proposes to designate three new procedures assigned to New Technology APCs as low-volume procedures.

3. Procedures Assigned to New Technology APC Groups for 2023

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. Retinal Prosthesis Implant Procedure (Argus II Retinal Prosthesis System)
In 2022, CMS learned that the manufacturer of the Argus II devis discontinued the devise in 2020. CMS found there were no OPPS claims billed for this surgical procedure (CPT code 0100T) in 2020 and 2021.

For 2023, CMS proposes to make changes to the OPPS SI for the HCPCS (C1841) and CPT codes related to the device and the procedure to indicate that Medicare payment is no longer available (Table 9).

b. Administration of Subretinal Therapies Requiring Vitrectomy
Effective January 1, 2021, CMS established C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) and assigned this HCPCS code to New Technology APC 1561 (New Technology Level 24 ($3001- $3500)) based on a crosswalk to HCPCS code 67036. This procedure may be used to describe the administration of HCPCS code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes). Voretigene 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. This therapy is administered by a subretinal injection. For 2022, using its equitable adjustment authority, CMS continued to assign C9770 to New Technology APC 1561.

For 2023, there are 11 single claims available for ratesetting for HCPCS code C97770 and CMS proposes to base the payment rate on claims data rather than on using a crosswalk to HCPCS code 67036. For 2023, CMS proposes to assign HCPCS code C9770 to APC 1562 (Table 10).

c. Bronchoscopy with Transbronchial Ablation of Lesion(s) by Microwave Energy
Effective January 1, 2019, CMS established HCPCS code C9751 for bronchoscopy with transbronchial microwave ablation for treatment of lung cancer. For 2022, CMS continued to assign HCPCS code C9751 to APC 1562.

There were no claims reported in 2020 or 2021 for this procedure. For 2023, CMS proposes to continue to assign HCPCS code C9751 to APC 1562 (Table 11).

d. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies
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). For 2022, CMS did not receive any claims with these CPT codes and continued to maintain the 2021 assignment for 2022.

For 2023, CMS proposes to use 2021 claims data to determine the payment rates for these codes. CPT code 78431 had over 18,000 single frequency claims in 2021. CMS proposes to reassign CPT code 78431 from APC 1522 to APC 1523. CPT code 78432 had only 5 single frequency claims in 2021. CMS proposes to apply its universal low volume APC policy and assigned CPT code 78432 from APC 1523 to APC 1520. CPT code 78433 had 954 single frequency claims in 2021. CMS proposes to reassign CPT code 78433 from APC 1523 to APC 1521 (Table 12).

e. V-Wave Interatrial Shunt Procedure
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 (Unlisted cardiovascular procedure), would be included

on the claims for participants receiving the interatrial shunt. As a result, for 2020, CMS created a temporary HCPCS code, C9758[6], to describe the V-wave interatrial shunt procedure for both the experimental and control group in the study. For 2022, CMS continued to assign C9758 to APC 1590).

For 2023, there were no claims from 2021 billed with HCPCS code C9758. CMS proposes to continue to assign this procedure to APC 1590 (Table 13).

f. Corvia Medical Interatrial Shunt Procedure
Corvia Medical pivotal trial for their interatrial shunt procedure started in Quarter 1 2017 and continued through Quarter 3 of 2021. CMS established HCPCS code C9760 to facilitate the implantation of the Corvia Medical interatrial shunt.[7] For 2022, CMS continued to assign HCPCS code C9760 to New Technology APC 1592.

For 2023, there are no claims from 2021 billed with HCPCS code C9760. For 2023, CMS proposes to continue to assign this procedure to APC 1592 (Table 14).

g. Supervised Visits for Esketamine Self-Administration (HCPCS codes G2082 and G2083);
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 2022, CMS continued to assign HCPCS code G2082 to New Technology APC 1508 and assign HCPCS code G2083 to New Technology APC 1511.

For 2023, CMS proposes to use 2021 claims data to determine the payment rates for HCPCS codes G2082 and G2083. For 2023, CMS proposes to reassign HCPSC codes G2082 from APC 1508 to APC 1511 HCPCS code G2083 from APC 1511 to 1516 (Table 15).

[6] The long descriptor for HCPCS code C9758 is Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography/intracardiac echocardiography, and all imaging with or without guidance performed in an approved IDE study.
[7] The long descriptor for HCPCS code 9760 is non-randomized, non-blinded procedure for NYHA class II -IV heart failure; transcatheter implantation of interatrial shunt including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography/intracardiac echocardiography, and all imaging with or without guidance performed in an approved IDE study.

h. DARI Motion Procedure
The DARI Motion Procedure consist of eight cameras that surround a patient to obtain a live video that is analyzed to create a 3D reconstruction of the patient. The technology is intended to guide providers on surgical interventions, physical therapy and rehabilitation. CPT code 0693T was effective January 1, 2022. For 2022, CMS assigned CPT code 0693T to New Technology APC 1505.

For 2023, CMS proposes to continue to assign CPT code 0693T to APC 1505 (Table 16).

i. Histotripsy Service
Histotripsy is a non-invasive, non-thermal, mechanical process that uses a focused beam of sonic energy to destroy targeted cancerous liver tumors. CPT code 0686T was effective July 1, 2021. For 2022, CMS assigned CPT code 0686T to New Technology APC 1575.

For 2023, CMS proposes to continue to assign CPT code 0686T to APC 1575 (Table 17).

j. LiverMultiscan Service
LiverMultiScan is a Software as a medical Service (SaaS) that aids in the diagnosis and management of chronic liver disease. The SaaS receives MR images, analyzes them using their proprietary AI algorithms, and then sends the provider a quantitative metric report of the patient's liver fibrosis and inflammation. CPT codes 0648T and 0649T were effective July 1, 2021. For 2022, CMS assigned CPT code 0648T to New Technology APC 1511 (the same APC assignment for HeartFlow). CMS finalizes CPT code 0649T, an add-on code, as a packaged service (status indicator "N").

For 2023, CMS proposes to continue to assign CPT code 0648T to APC 1511 (Table 18).

k. Minimally Invasive Glaucoma Surgery (MIGS)
For 2022, two new Category I CPT codes were created for extracapsular cataract removal with insertion of intraocular lens prosthesis (66989 and 66991) and deleted Category III code (0671T) for insertion of anterior segment aqueous drainage device. CMS assigned CPT codes 66989 and 6691 to New Technology APC 1526. CPT code 0671T to APC 5491.

For 2023, CMS proposes to continue to assign CPT codes 66989 and 66991 to APC 1526 (Table 19).

l. Scalp Cooling
CPT code 0662T describes initial measurement and calibration of a scalp cooling device for use during chemotherapy; the code was effective July 1, 2021. CPT guidance states that CPT code 0662T should be billed once per chemotherapy session; CMS interprets this to mean once per course of chemotherapy regardless of the number of session. CMS assigned CPT code 0662T to APC New Technology 1520.

For 2023, CMS proposes to continue to assign CPT code 0662T to APC 1520 (Table 20).

m. Optellem Lung Cancer Prediction (LCP)
The Optellum LCP applies an algorithm to a patient's CT scan to produce a raw risk score for a patient's pulmonary nodule to quantify the risk of lung cancer. CPT code 0721T became effective July 1, 2022. For 2022, CMS assigned CPT code 0721T to APC New Technology 1508.

For 2023, CMS proposes to continue to assign CPT code 0721T to APC 1508 (Table 21).

n. Quantitative Magnetic Resonance Cholangiopancreatography (QMRCP)
The QMRCP is a SaaS that performs quantitative assessment of the biliary tree and gallbladder. It uses a proprietary algorithm that produces a three-dimensional reconstruction of the biliary tree and pancreatic duct and also provide quantitative information about biliary tree volume and duct metrics. CPT code 0723T became effective July 1, 2022. For 2022, CMS assigned CPT code 0723T to APC New Technology APC 1511.

For 2023, CMS proposes to continue to assign CPT code 0723T to APC 1511 (Table 22).

o. CardiAMP
The CardiAMP cell therapy IDE studies are two randomized, double-blinded, controlled IDE studies: the CardiAMP Cell Therapy Chronic Myocardial Ischemia Trial and the CardiAMP Cell Therapy Heart Failure Trial. The two trials are designed to investigate the safety and efficacy of autologous bone marrow mononuclear cell treatment for patients with (1) medically refractory and symptomatic ischemic cardiomyopathy and (2) patients with refractory angina pectoris and chronic myocardial ischemia. HCPCS code C9782 became effective April 1, 2022 and CMS assigned this code to APC New Technology 1590.

For 2023, CMS proposes to continue to assign HCPCS code C9782 to APC 1590 (Table 23).

D. Universal Low Volume APC Policy for Clinical and Brachytherapy APCs

Beginning in 2022, CMS adopted a policy to use the equitable adjustment authority at section 1833(t)(2)(E) of the Act to determine costs for low-volume services. For 2022, CMS designated clinical APCs and brachytherapy APCs with fewer than 100 single claims that can be used for rate-setting as low-volume. CMS is using up to four years of data (but not data than spans the COVID-19 PHE) to make determinations when a clinical APC or brachytherapy APC is designated as low volume. For clinical and brachytherapy APC designated as low volume, CMS determines the relative weight based on the higher of the APC's geometric mean, median, or the arithmetic mean. CMS does not apply this policy to APC 5853 Partial Hospitalization for CMHCs or APC 5863 Partial Hospitalization for Hospital-based PHPs because of the different nature of policies that affect partial hospitalization programs. APC 2698 and 2999 for brachytherapy sources "not otherwise specified" are excluded from this policy and prices using external data sources.

For 2023, CMS proposes to apply this policy to four clinical APCs and four brachytherapy APCs, all of which are low-volume for 2022 (Table 24).

E. APC-Specific Policies

1. 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, CMS identified 3,188 claims with 465 single frequency claims. Using its standard methodology, CMS determined a geometric mean cost of $804.35 and proposed to assign CPT code 0503T to New Technology APC 1510 (New Technology Level 10 ($801- $900) with a proposed payment rate of $850.50. Based on comments from providers and other stakeholders indicating that the FFRCT service costs $1,100 and the need for providers to learn how to bill for artificial intelligence services, CMS assigned CPT code 0503T to New Technology APC 1511 (New Technology – Level 11 ($901-$1000). For 2022, CMS proposes to continue to assign CPT code 0503T to New Technology APC 1511 (New Technology – Level 11 ($901-$1000), with a payment rate of $950.50 (Table 12).

For 2023 CMS has claims data from 2018 (101 single frequency claims), 2019 (465 single frequency claims), and 2021 (1,681 single frequency claims) to determine whether there is an appropriate clinical APC to assign the HeartFlow services. CMS notes that the cost data has been stable for HeartFlow and it calculates a geometric mean cost of $827 for HCPCS code 0503T. For 2023, CMS proposes to assign CPT code 0503T to clinical APC 5714 (Table 25).

2. Neurostimulators and Related Procedures (APCs 5461-5465)

CMS reviews the restructuring of the neurostimulator procedure-related APCs. In the 2015 OPPS/ASC final rule, CMS developed a four-level series and in the 2021 OPPS/ASC, finalized a five-level APC structure for the Neurostimulator and Related Procedure series.

CMS notes that commenters have raised concerns about the clinical and resource cost similarity in the Level 5 Neurostimulator and Related Procedure APC and requested creation of a Level 6 for this series. Based on the data reviewed for this proposed rule, CMS believes that the five-level structure for this series remains appropriate. The proposed geometric mean cost for the Level 5 APC is $30,198.36 with the geometric means of codes with significant volume ranging from approximately $28,000 to $36,000. CMS notes this range is well within the 2 times rule. CMS also believes the clinical characteristics of the services in the APC support the current structure.

For 2023, CMS proposes to maintain the current 5-level structure. **Given commenters' concerns about the current APC levels, CMS solicits comments on the potential creation of**

a new Level 6 APC from the current Level 5 within the Neurostimulator and Related Procedures APC series (Table 26, reproduced below).

Table 26: Proposed 2023 Neurostimulator and Related Procedures APC				
APC	**Group Title**	**SI**	**Proposed CY 2023 Proposed APC Geometric Mean Cost**	**6-Level Alternative APC Geometric Mean Cost**
5461	Level 1 Neurostimulator and Related Procedures	J1	$3,491.49	$3,491.49
5462	Level 2 Neurostimulator and Related Procedures	J1	$6,808.24	$6,808.24
5463	Level 3 Neurostimulator and Related Procedures	J1	$12,980.43	$12,980.43
5464	Level 4 Neurostimulator and Related Procedures	J1	$22,059.02	$22,059.02
5465	Level 5 Neurostimulator and Related Procedures	J1	$30,198.36	$29,434.26
5466	Level 6 Neurostimulator and Related Procedures	J1	N/A	$33,947.12

Level 6 would include the following codes:

- 0266T (Implantation or replacement of carotid sinus baroreflex activation device; total system);
- 0268T (Implantation or replacement of carotid sinus baroreflex device; pulse generator only);
- 0424T (Insertion or replacement of neurostimulator system for treatment of central apnea; complete system);
- 0431T (Removal and replacement of neurostimulator system for treatment of central apnea; pulse generator only); and
- 64568 (Open implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator)

3. Urology and Related Services (APCs 5371-5378)

In the 2021 OPPS/ASC final rule, CMS finalized a reorganization of the Urology and Related Services APCs from a seven-level to an eight-level series. For 2022 ratesetting, CMS used the 2019 claims data and did not finalize any APC reassignments.

For 2023, based on the 2021 claims data, CMS identified eight procedures from APC 5375 whose geometric mean ranged between the geometric means for APC 5375 and APC 5376. For 2023, CMS proposes to reassign these services from APC 5375 to APC 5376: CPT 50576, HCPCS C9769, CPT 51860, CPT 0549T, CPT 53449, CPT 54344, CPT 54316, and CPT 5580 (Table 27).

4. Unlisted Dental Procedure/Services (APC 5871)

CPT code 41899 (Unlisted procedures, dentoalveolar structures) is assigned to APC 5161 (Level 1 ENT Procedures). Because of the lack of specificity, unlisted codes are generally assigned to the lowest level within the most appropriate clinically related APC groups. CMS believes that APC 5161 is not the most clinically appropriate APC series for this code. For 2023, CMS proposes to reassign HCPCS code 41899 to clinical APC 5871, which is the only APC group that specifically describes dental procedures.

5. COVID-19 Vaccine and Monoclonal Antibody Administration Services

a. Payment for COVID-19 Vaccine Administration Services Under the OPPS

Under the OPPS, separate payment is made for the COVID-19 vaccine and its administration. Except when the provider receives the vaccine for free, providers are paid for COVID-19 vaccines at reasonable cost, similar to influenza and pneumococcal vaccines. The payment rates for the COVID-19 vaccine administration HCPCS codes are based on the APCs to which the codes are assigned. CMS established APC 9397 (COVID-19 Vaccine Admin Dose 1 of 2) and APC 9398 (COVID-19 Vaccine Admin Dose 2 of 2); the 2022 payment rate for these APCs is $40.

For 2023, CMS proposes to use its equitable adjustment authority at 1833(t)(2)(E) to maintain the payment rate of $40 for the COVID-19 vaccine administration APCs 9397 and 9398. Table 29 lists the proposed 2023 payment rates for the COVID-19 vaccine administration HCPCS codes. CMS also proposes to maintain the payment rate for the administration of the COVID-19 vaccines when provided under certain circumstances in the patient's home at $35.50.

b. Use of Alternative Site-Neutral Methodology to Update Payment Rates for COVID-19 Vaccine Administration Services for 2023

The current payment rates for COVID-19 vaccine administration services are site-neutral across most outpatient and ambulatory settings. In the 2023 PFS proposed rule (scheduled to be published in the July 29, 2022 *Federal Register*), CMS proposes to update the payment rate for the administration of preventive vaccines (other than for COVID-19 and other than for services paid under other payment systems as the OPPS) using the annual increase to the Medicare Economic Index (MEI).

CMS requests comments on whether as an alternative to maintaining current OPPS payment rates, it should use the rate finalized through PFS rulemaking that generally applies under the preventive vaccine benefit, or an alternative method suggested by commenters which would likely require use of its equitable authority.

c. Comment Solicitation of the Appropriate Payment Methodology for Administration of Preventive Vaccine Post PHE

Under the OPPS, codes describing the administration of the influenza, pneumococcal, and hepatitis b vaccines are assigned to APC 5691 with a payment rate of $40. CMS notes that given the statutory benefit for Medicare Part B preventive vaccines and their administration is based on 1861(s)(10) of the Act, CMS seeks comments on whether it should adopt a different methodology to make payment for these services other than the one for covered OPD services under its equitable adjustment authority.

CMS seeks comments on the appropriate payment methodology for the administration of Part B preventive vaccines, including COVID-19 vaccine post PHE.

d. COVID-19 Monoclonal Antibody Products and Their Administration Services Under OPPS

COVID-19 monoclonal antibody products are paid based on reasonable costs under the OPPS, except when the products are free. Payment for the administration depends on the route of administration and whether the product is furnished in a healthcare setting or in the beneficiary's home.[8]

For 2023, CMS proposes to use the equitable adjustment authority at 1833(t)(2)(E) to maintain the 2022 New Technology APC assignments (APCs 1503-1507, or 1509) and corresponding payment rate for each of the COVID-19 monoclonal antibody product administration HCPCS codes, for as long as these products are considered to be covered and paid under the Medicare Part B vaccine benefit. Thus, if the PHE ends, the benefit category and payment methodology under the OPPS will remain site neutral.

CMS notes that once these products are no longer considered to be covered and paid under the Medicare Part B vaccine benefit, it expects that COVID-19 monoclonal antibody product administration services to be paid similar to biologics. As discussed in the 2023 PFS proposed rule[9], CMS clarifies that the COVID-19 monoclonal antibody products would be covered and paid for under the Medicare Part B vaccine benefit until the end of the calendar year in which the March 27, 2020 EUA declaration for drugs and biologics is terminated.

CMS proposes to continue to pay for monoclonal antibody COVID-19 pre-exposure prophylaxis products and their administration under the Part B vaccine benefit even after the EAU

[8] COVID-19 Vaccines and Monoclonal Antibodies. CMS Website. https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodes.

[9] In the 2023 PFS proposed rule, CMS discusses the distinctions between a PHE declared under section 319 of the Public Health Service (PHS) Act and an EUA under section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act. A PHE declaration authorizes the Secretary to take a variety of discretionary actions to respond to the PHE under the statues HHS administers. Under section 564 of the FD&C Act, the Secretary may make a declaration that circumstances exist justifying an EUA of unapproved drugs, devices or biological products, or of approved drugs, devices, or biological products for an unapproved use. Declarations under section 319 of the PHS Act generally last for 90 days but may be extended by the Secretary. In contrast, an EUA continues until specifically terminated and may remain in effect beyond the duration of the section 319 PHE declaration.

declaration for drugs and biological products is terminated, as long as such products have market authorization.

IV. Payment for Devices

A. Pass-Through Payments for Devices

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

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

In the 2022 OPPS/ASC final rule, due to the PHE, CMS used 2019 claims data rather than 2020 claims data for ratesetting. CMS utilized its equitable adjustment authority at section 1833(t)(2)(E) of the Act to provide up to four quarters of separate payment for one device category (C1823) whose pass-through payment status expired between December 31, 2021 and September 30, 2022. Because CMS proposes to resume the regular update process of using claims from the year 2 years prior to the year it is setting rates, (e.g., 2021 outpatient claims for 2023 OPPS ratesetting), CMS proposes not to provide any additional quarters of separate payment for device categories whose pass-through payment status will expire between December 31, 2022 and September 30, 2023 (discussed in section X.B). CMS seeks comments on how the circumstances for 2023 are similar to 2022, when it adopted the equitable authority to continue pass-through status.

Currently, there are 11 device categories eligible for pass-through payment. Separate payment for HCPCS code C1823 under the equitable adjustment authority will end on December 31, 2022, Table 30 (reproduced below) lists the devices and their pass-through expiration.

Table 17: Expiration of 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	12/31/2022*
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

Table 17: Expiration of Pass-Through Payments for Certain Devices			
HCPCS Codes	**Long Descriptor**	**Effective Date**	**Pass-Through Expiration Date**
C1748	Endoscope, single-use (that is, disposable), Upper GI, imaging/illumination device (insertable)	7/1/2020	6/30/2023
C1052	Hemostatic agent, gastrointestinal, topical	1/1/2021	12/31/2023
C1062	Intravertebral body fracture augmentation with implant	1/1/2021	12/31/2023
C1825	Generator, neurostimulator (implantable) nonrechargeable with carotid sinus baroreceptor simulation lead(S)	1/1/2021	12/1/2023
C1761	Catheter, transluminal intravascular lithotripsy, coronary	7/1/2021	6/30/2024
*CMS used its equitable adjustment authority to provide separate payment for C1823 for four quarters of 2022 for C1823 whose pass-through payment status expired on December 31, 2021. Adjusted separate payment for HCPCS code C1823 will end on December 31, 2022.			

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 all of the following:
  (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, or, for devices for which pass-through payment status will begin on or after January 1, 2020, as an alternative pathway to demonstrating substantial clinical improvement, a device is part of the FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.

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.

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.

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

CMS received nine complete applications by the March 1, 2021 quarterly deadline, the last quarterly deadline in time for this proposed rule; two of the applications were for devices eligible under the alternative pathway. One applications was approved under the alternative pathway: the aprevo™ Intervertebral Body Fusion, effective October 1, 2021.

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

(1) Aprevo™ Intervertebral Body Fusion Device[10]

Carlemed, INC. submitted an application for the Aprevo Intervertebral Body Fusion Device (aprevo) , an interbody fusion implant that stabilizes the lumbar spine column and facilitates fusion during lumbar fusion procedures for the treatment of spinal deformity. The implant device is custom made for patient-specific features by using CT scans to create 3D virtual models of the deformity.

Eligibility

Newness. The aprevo device received Breakthrough Device designation under the name "Corra" on July 1, 2020 for the Corra Anterior, Corra Transforaminal and Cora Lateral Lumbar Fusion System interbody device intended for use in anterior lumbar interbody fusion (ALIF), lateral lumber interbody fusion (LLIF) and transforaminal lumbar interbody fusion (TLIF). The applicant was granted FDA 510(k) clearance as a Class II medical devise for the ALIF and LLIF indications on December 3, 2020. The Transforaminal Intervertebral Body Fusion (IBF) received FDA 510(k) clearance on June 30, 2021. CMS received the pass-through application for aprevo

[10] In the FY 2022 IPPS final rule, Aprevo™ Intervertebral Body Fusion Device was approved for a New Technology (NTAP) under the Alternative Pathway for Breakthrough Devices.

on May 27, 2021, which is within 3 years of the date of the initial FDA marketing authorization of both indications.

Additional eligibility criteria. According to the applicant, the aprevo meets all the eligibility requirements.

Establishing a New Device Category
(i) Existing payment category. CMS has not identified an existing pass-through payment category that describes aprevo.

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

(iii) Cost. CMS believes aprevo meets all the cost criteria.

The aprevo Intervertebral Body Fusion received preliminary approval for transitional pass-through payment effective October 1, 2021. CMS invites comments on whether this device should continue to receive transitional pass-through payments under the alternative pathway.

(2) MicroTransponder® ViviStim® Paired Vagus Nerve Stimulation (VNS) System (ViviStim® System)[11]

Micro Transponder submitted an application for ViviStim System, a vagus nerve stimulation therapy intended to stimulate the vagus nerve during rehabilitation therapy to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment. The ViviStim System is comprised of an Implantable Pulse Generator (IPG), an implantable stimulation Lead, and an external paired stimulation controller which is composed of the external Wireless Transmitter (WT) and the external Stroke Application and Programming Software (SAPS). The applicant stated the SAPS and WT enable the implanted components to stimulate the vagus nerve during rehabilitation.

Eligibility
Newness. The ViviStim System was designated as a Breakthrough Device on February 10, 2021 for use in stimulating the vagus nerve during rehabilitation therapy to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment. The ViviStim System received FDA premarket approval on August 27, 2021 as a Class III implantable device for the Breakthrough Device designation. CMS received the pass-through application on September 1, 2021, which is within 3 years of the date of the initial FDA marketing authorization.

Additional eligibility criteria. According to the applicant, the ViviStim System meets all the eligibility requirements.

[11] In the FY 2023 IPPS final rule (87 FR 28349-28350), CMS proposed to approve the ViviStim Paired VNS System for new technology add-on payments for FY 2023.

CMS notes that the external non-implantable components SAPS and WT may be an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered and may considered depreciable assets as described in §419.66(b)(4). **CMS invites comments on whether ViviStim System meets this eligibility requirement**s.

Establishing a New Device Category

(i) Existing payment category. The applicant stated there are five HCPCS device category codes describing neurostimulation devices that are similar to the ViviStim System, listed in Table 32 (reproduced below). The applicant believes these codes do not encompass the ViviStim System because none of the codes have an external paired stimulation controller to actively pair stimulation with rehabilitation by the clinician. In addition, the ViviStim System does not include a rechargeable battery or charging device. The applicant specifically discusses why the ViviStim System is not encompassed by each of the existing device categories.

Table 32: HCPCS Codes Reported with the ViviStim System

HCPCS Code	Long Descriptor	Status Indicator	APC
C1767	Generator, neurostimulator (implantable), non-rechargeable	N	N/A
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system	N	N/A
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system	N	N/A
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads	H	2993
C1825	Generator, neurostimulator (implantable), non- rechargeable with carotid sinus baroreceptor stimulation lead(s)	H	2030

CMS notes that the applicant asserted that the ViviStim System is distinct from HCPCS codes C1820, C1822, C1823, and C1825 due to distinguishing features unique to these codes. These unique features include rechargeable batteries, high frequency stimulation, transvenous sensors and stimulators, and unique placement of stimulators. CMS disagrees with the applicant's argument that C1767 does not encompass the ViviStim System. According to the applicant, the ViviStim System is not "always on" and is paired to an external stimulation controller to allow for clinician controlled stimulation during rehabilitation; therefore, the device is not like the non-rechargeable implantable neurostimulation of the VNS Therapy® System (LivaNova) described by C1767. CMS believes that implantable neurostimulators for epilepsy and depression are not "always on" but are programmed to turn on and off in specific cycles as determined by a clinician. In addition, for epilepsy treatment, a neurostimulator can be turned on by the patient with a handheld magnet if an impending seizure is sensed, and the neurostimulator can be similarly turned off by the patient during certain activities, such as speaking or exercises. The application indicates the IPG of the ViviStim System can also be patient-engaged with a magnetic card, allowing the patient to continue at home. CMS believes the ViviStim System may be similar devices currently described by C1767 and therefore appropriately described by C1767.

CMS invites public comment on whether the ViviStim System meets the device category criterion.

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

(iii) Cost. CMS believes ViviStim meets all the cost criteria.

CMS invites comments on whether the ViviStim System meets the device pass-through payment criteria.

ii. Traditional Device Pass-through Applications

(1) The Brain Scope TBI model (Ahead 500)

BrainScope Company submitted an application for the BrainScope TBI, a handheld medical device and decision-support tool that use artificial intelligence (AI) to identify objective brain-activity based biomarkers of structural and functional brain injury in patients with suspected mild traumatic brain injury (mTBI). The BrainScope TBI is composed of two elements: (1) the Ahead 500, a disposable forehead-only-8-electrode headset temporarily applied to the patient's skin to assess brain injury which records electroencephalogram (EEG) signals; and (2) a reusable handheld device (referred to as the "Handheld Device") which includes a standard commercial off-the-shelf handheld computer attached to a custom manufactured Data Acquisition Board (DAB) via a permanently attached cable. The disposable headset is attached to the DAB, which collects the EEG signal and passes it as a digital signal to the Handheld Device to perform the data processing and analysis. According to the applicant, the BrainScope TBI is intended to record, measure, analyze, and display brain electrical activity utilizing the calculation of standard quantitative EEG parameters from the patient's frontal region of the brain. The applicant states the device can be used as a screening tool and aid in determining the medical necessity of head computerized tomography (CT) scanning.

Newness. The BrainScope TBI received FDA 510(k) clearance on September 11, 2019 as a Class II device used as an adjunct to standard clinical practice to aid in the evaluation of patients who have sustained a closed head injury and have a Glasgow Coma Score (CGS) of 13-15 (including patients with mTBI). CMS received the application on February 23, 2022 , which is within 3 years of the date of the initial FDA market authorization.

Eligibility. With respect to the eligibility criteria at §419.66(b)(3), the applicant states the BrainScope TBI is integral to the service provided and is used for only one patient. CMS notes that neither the Ahead 500 or the Handheld Device, is surgically implanted or inserted or applied in or on a wound or other skin lesion, as required by §419.66(b)(3). CMS also questions whether the components of this device may be an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered (§419.66(b)(4). The applicant did not indicate if the BrainScope TBI is a supply or material furnished incident to a service.

CMS invites comments on whether the BrainScope TBI meets the eligibility criteria.

Establishing a New Device Category.
Existing Payment Category. CMS has not identified any existing pass-through payment category that may be applicable to the BrainScope TBI. The applicant did note that another marketed medical device, the COGNISION, would also fit in the proposed device category as BrainScope TBI. COGNISION is cleared by the FDA for use by qualified clinical professionals for acquisition, display, analysis, storage, reporting and management of EEG and auditory evoked potentials.

Substantial Clinical Improvement. The applicant stated that the BrainScope TBI represents a substantial clinical improvement because it is associated with (1) decreased rate of repeat/subsequent diagnostic or therapeutic interventions; (2) more rapid beneficial resolution of the disease process treated; and (3) reduced recovery time when used for the treatment of mTBI.

The applicant provided ten articles to support the assertion of substantial clinical improvement. CMS summarizes this information and discusses specific concerns with the submitted information. CMS is concerned that most of the articles are prospective observational or retrospective review articles, and most findings appear to be suggestive, instead of being conclusive of an associated or significant benefit. CMS notes that these types of studies can be associated with selection bias and that confounding may result in misinterpretation of the observed relationships between the dependent and independent variables. Most of the studies provided did not address potential confounding issues which makes it difficult to determine in the BrainScope was effective. CMS also notes the small sample size of the studies. CMS is also concerned that the retrospective clinical validation studies describe findings for previous BrainScope technology and no information is provided about the comparative outcomes data between all the BrainScope devices.

CMS is also concerns that although the applicant identified COGNISION as another existing device, but no information is provided comparing these technologies. CMS also notes that there are two additional FDA-cleared potential alternative therapies[12] that could be relevant but no information was provided about these devices.

Cost. CMS believes the BrainScope TBI meets all the cost criteria.

CMS invites comments on whether the BrainScope TBI meets the device pass-through payment criteria.

(2) NavSlim™ and NavPencil

Elucent Medical submitted an application for the NavSlim and NavPencil (referred to collectively as "the Navigators"), single-use (disposable) devices for real-time, stereotactic, 3D navigation for the excision of pre-defined soft tissue specimens. The FDA 510(k) Summary (K1834000) indicates that the Navigators are a component of the applicant's Navigation System which is intended only for the non-imaging detection and localization (by navigation) of a SmartClip™ Soft Tissue Marker (SmartClip) that has been implanted in a soft tissue biopsy site or a soft tissue site intended for surgical removal (SmartClip is discussed as a separate

[12] https://www.mobilehealthnew.com/news/syncthink-scores-fda-clearance-ai-system-aid-concussion-diagnosis

application for 2023). The applicant stated there are two types of Navigators: the NavSlim allows integration with a broad range of electrosurgical tools and the NavPencil which incorporates a small screen that mimics the Navigation System operating room monitor. According to the applicant, the Navigators enable intraoperative visualization by displaying real-time stereotactic 3D guidance from the tip of the surgical tool enabling minimally invasive removal of predefined tissue specimen (tumor and margin).

Newness. The EnVisio™ Navigation System,[13] which includes the Navigators received 510(k) clearance on March 22, 2019, for the non-imaging detection and localization (by navigation) of a SmartClip™ implanted in a soft tissue biopsy site or a soft tissue site for surgical removal. CMS received the application on February 28, 2022 which is within 3 years of the date of the initial FDA marketing authorization.

Eligibility. The applicant stated the Navigators are an integral part of the service furnished and are used for only one patient. The applicant did not indicate whether the Navigators come in contact with human tissue and are surgically implanted or inserted or applied in or on a wound or other skin lesion, as required at §419.66(b)(3). CMS notes the FDA 510(k) Summary states the Navigator is a sterile, non-patient contacting, single -use device. The applicant also did not indicate whether the Navigators meet the requirements at §419.66(b)(4).

Establishing a New Device Category.
Existing Payment Category. CMS has not identified any existing pass-through payment category that may be applicable to the Navigators.

Substantial Clinical Improvement. The applicant stated the Navigators represent a substantial clinical improvement because it (1) decreases the rate of subsequent interventions by reducing positive margin and re-excision rates; (2) reduces the rate of device-related complications, including surgical site infections and wire migration and transection; and (3) improving the surgical approach.

The applicant provided articles, including an abstract of an article, and case reports addressing these issues. CMS summarizes this information and discusses specific concerns with the submitted information. CMS notes that the abstract provided of an article appears to be a feasibility study for a potentially larger randomized control study; CMS also wonders if this article has been published or submitted to a peer-reviewed journal. CMS highlights that the authors of this study stated that further studies are required to compare the Navigator technology to other non-wire localization techniques to refine which technology is best for breast conservation surgery. In addition, CMS notes that none of the articles and case reports provided conclusive evidence that the use of the Navigators reduces surgical site infection rates or the risks of tissue marker migration.

Cost. CMS believes the Navigator meets all the cost criteria.

[13] The FDA 510(k) Summary for the EnVisio Navigation System states that the "equipment components" are the Console, Heads Up Display, Patient Pad and Foot Pedal. The Navigator is listed as a separate, sterile, non-patient contacting, single-use system component.

CMS invites comments on whether the Navigator meets the device pass-through payment criteria.

(3) SmartClip™ Soft Tissue Marker

Elucent Medical, submitted any application for the SmartClip, an electromagnetically activated, single-use, sterile soft tissue marker used for anatomical surgical guidance. The FDA 510(k) Summary indicates the SmartClip can be implanted into various types of soft tissue, such as lung and breast, and can subsequently be detected using the EnVisio Navigation System or by means of radiology (including mammographic imaging), ultrasound, and MRI.

Newness. The SmartClip received FDA 510(k) clearance on June 4, 2019 but the applicant requested that CMS use the FDA clearance data for the Navigation System, March 22, 2019. The applicant submitted its application on February 28, 2022 which is more than 3 years from the date of the initial FDA marketing authorization. The applicant stated that the SmartClip could not be marketed until May 2019 because it is utilized with the EnVisio Navigation System and it did not pursue marketing the device without the Navigation System. In addition, the applicant states the impacts of the PHE limited breast cancer surgery. CMS notes that the FDA Summary and Indications for Use of the SmartClip indicate that it can be used through the use of standard imaging guidance.

CMS invites comments on whether the SmartClip meet the newness criterion.

Eligibility. The applicant stated the SmartClip is an integral part of the service furnished and used for only one patient. The applicant did not indicate whether the SmartClip meets the device eligibility requirements at §419.66(b)(4), which provide the device may not be any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets; or (2) a material or supply furnished incident to a service (e.g., a suture, customized surgical kit, or clip, other than radiological site marker).

CMS invites comments on whether the SmartClip meet the eligibility criteria at §419.66(b).

Establishing a New Device Category

Existing Payment Category. The applicant identified three devices or device categories that are most closely related to the SmartClip including HCPCS code A4648 (Tissue marker, implantable, any type, each). The applicant discussed the differences between the SmartClip and tissue markers described by A4648. CMS notes that although A4648 is not an existing pass-through payment category, a previous equivalent code C1879 (Tissue marker (implantable)) was a pass-through payment category in effect between August 1, 2000 and December 31, 2002.[14] CMS also provided instructions that effective July1, 2013, when using implantable tissue markers with any services provided in the OPPS, providers should report the use and cost of the implantable tissue marker with A4648 only.15

[14] Medicare Claims Processing Manual, Ch.4, section 60.4.2
[15] Change Request 8338, June 7, 2013 and Medicare Claims Processing Manual, Ch. 4. Section 60.4.3.

CMS invites comments on whether the SmartClip meets the device category criterion.

Substantial Clinical Improvement. The applicant stated the SmartClip represents a substantial clinical improvement because it (1) decreases the rate of subsequent interventions by reducing positive margin and re-excision rates; (2) reduces the rate of device-related complications, including surgical site infections and wire migration and transection; and (3) improving the surgical approach.

The applicant provided articles, including an abstract of an article, and case reports addressing these issues; some of this information was also submitted with the Navigators application. CMS summarizes this information and discusses specific concerns with the submitted information, which incorporate several of the concerns previously discussed with the Navigators application. CMS reiterates the authors of the study summarized as an abstract stated that further studies are required to compare the Navigator technology to other non-wire localization techniques to refine which technology is best for breast conservation surgery. In addition, CMS reiterates that none of the articles and case reports provided conclusive evidence that the use of the Navigators or the SmartClip reduces surgical site infection rates or the risks of tissue marker migration.

Cost. CMS believes the SmartClip meets all the cost criteria.

CMS invites comments on whether the SmartClip meets the device pass-through payment criteria.

(4) Evoke® Spinal Cord Stimulation (SCS) System

Saluda Medical submitted an application for the Evoke SCS System, a rechargeable, upgradeable, implantable spinal cord stimulation system that provides closed-loop stimulation controlled by measured evoked compound action potentials (ECAPs). According to the applicant in closed-loop stimulation, the system automatically measures the impact of the prior stimulation signal on the nerve and adjusts the next stimulation signal accordingly to maintain the prescribed physiologic response. The applicant states the device is used in treatment of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, intractable low back pain, and leg pain. The Evoke SCS System is comprised of 5 implanted and 12 external components.

Newness. The Evoke SCS System received PMA approval from the FDA on February 28, 2022 as an aid in the management of chronic intractable pain of the truck and/or limbs including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain. The applicant submitted its application on March 1, 2022, which is within the 3 years date of the initial FDA marketing authorization.

Eligibility. The applicant stated the Evoke SCS System is integral to the service furnished and are used for only one patient. CMS notes that the external components of the Evoke SCS System are not implanted in a patient and do not come in contact with human tissue as required at §419.66(b)(3). The applicant also did not indicate whether the Evoke SCS Systems meets the requirements at §419.66(b)(4). CMS notes that some of the external components (e.g., clinical

system transceiver and pocket console) may be considered capital equipment as specified under §419.66(b)(4).

CMS invites comments on whether the Evoke SCS System meets the eligibility criteria at §419.66(b).

Establishing a New Device Category

Existing Payment Category. The applicant provided a list of current and prior device categories for pass-through payments for other SCS systems (Table 36) and explained why each category does not describe the Evoke SCS System. In general, the applicant stated that the existing codes do not adequately describe the Evoke SCS System because these codes apply to devices that only provide open-loop stimulation, are non-rechargeable and provide stimulation to organs other than the spinal cord. After reviewing the applicant's information, CMS agrees that there aren't any existing pass-through payment categories that might apply to the Evoke SCS System.

Substantial Clinical Improvement. The applicant stated that the Evoke SCS System's closed-loop stimulation provides substantial clinical improvement over the open-loop stimulation systems for ten reasons including (1) a greater responder rate in overall chronic leg and back pain with no increase in baseline pain medications in comparison to open-loop SCS; (2) greater percentage change in back pain and greater incidence of 50 percent reduction in back and leg pain.

The applicant provided two published studies and one study pending publication in peer-reviewed journals. CMS summarizes this information and discusses specific concerns. CMS notes that none of the studies provided compared the Evoke SCS System to other currently available technologies, specifically open-loop SCS products. CMS acknowledges that in the pivotal clinical study, the open-look SCS system was compared with the Evoke SCS System as some of the devices were set to closed loop which allowed testing between different aspects of the Evoke SCS System. The applicant asserts the Evoke SCS System is the only available closed-loop SCS. CMS is also concerned about the small sample size and that two studies were done in Australia. CMS requests additional details about how these results would be generalizable to the U.S. population.

CMS invites public comment on whether there are existing technologies which may be appropriate comparators to the Evoke SCS System.

Costs. The data submitted by the applicant indicates that the Evoke SCS System meets all the cost criteria. CMS is concerned however that the external components do not meet the criteria required at §419.66(b)(3) and only the costs of the eligible internal components should be used in the cost analysis. CMS notes that if the cost of the internal components is sufficiently less than the whole system, the cost criterion might not be met.

CMS invites comments on whether the Evoke SCS System meets the device pass-through payment criteria.

(5) Pathfinder® Endoscope Overtube

Neptune Medical submitted an application for the Pathfinder Endoscope Overtube (the Pathfinder), a flexible, single use, overtube with stiffening capabilities that is used to manage endoscope looping and improve tip control of the endoscope. The applicant stated the handle rotator has two positions: a flexible position and a rigid position.

Newness. The Pathfinder received FDA 510(k) clearance on August 20, 2019 as a Class II device used with an endoscope to facilitate intubation, changes of endoscopes, and treatment in the GI tract in adult patients (22 years of age and older). The applicant submitted its application on November 30, 2021 which is within the 3 years date of the initial FDA marketing authorization.

Eligibility. According to the applicant, the Pathfinder meets all the eligibility requirements.

Establishing a New Device Category
Existing Payment Category. The applicant provided a list of all established device categories that describe related or similar products and explained why the categories did not encompass the Pathfinder. CMS reviewed this information and has not identified any existing pass-through payment category that may be applicable to the Pathfinder.

Substantial Clinical Improvement. The applicant stated that the Pathfinder provides a substantial clinical improvement because it: (1) minimizes scope looping and associated complications, (2) reduces endoscopist's workload, (3) provides endoscopic tip stabilization, (4) enables endoscopic procedures in patients with altered anatomy, (5) enables crossing of anastomosis and (6) enables antegrade and retrograde enterostomy.

The applicant provided eleven articles which include several case reports. CMS summarizes this information and discusses specific concerns. CMS notes that the majority of the articles are clinical case series which do not necessarily allow for a comparison with other treatments. The applicant did not provide studies comparing the efficacy of the Pathfinder with other rigidization devices although the applicant has discussed these devices. CMS is also concerned that the articles related to endoscopists' workload is limited to the same study center with only two participating endoscopists. CMS believes it is difficult to make comparisons with these limited studies.

CMS seeks comments on whether the Pathfinder shows superiority over existing devices or existing methods used in cases of endoscopic looping and abnormal anatomy.

Cost. CMS believes the Pathfinder meets all the cost criteria.

CMS invites comments on whether the Pathfinder meets the device pass-through payment criteria.

(6) The Ureterol

STERIS submitted an application for the Ureterol, a sterile, single-use, disposable flexible ureteroscope. According to the applicant , the Ureterol™ Ureteroscope System consists of the Ureterol and a touch screen camera control unit, Vision 1. The Ureterol is used to visualize organs, cavities, and canals in the urinary tract and can be used with endoscopic accessories to perform various diagnostic and therapeutic procedures.

Newness. The Ureterol received FDA 510(k) clearance on November 23, 2021 to market the Ureterol to visualize the urinary tract via transurethral or percutaneous access routes. CMS received the application on March 1, 2022, which is within 3 years of the date of the initial FDA marketing authorization.

Eligibility. The applicant states the Ureterol meets all the eligibility criteria.

Establishing a New Device Category
Existing Payment Category. The applicant has not identified any existing pass-through payment category that may be applicable to the Ureterol.

Substantial Clinical Improvement. The applicant stated that the Ureterol provides substantial clinical improvement for nine reasons predominately related to prevention of infection transmission. The applicant provided five articles, an FDA advisory letter, and a set of manufacturer's instructions for cleaning and reprocessing flexible endoscopes. CMS summarizes this information and discusses specific concerns. CMS notes that most of the evidence provided supports the need to follow established reprocessing guidelines for reusable devices. In addition, none of the studies reference another disposable device as a comparator. CMS requests additional evidence demonstrating a comparison of the Ureterol's performance against other similarly disposable devices.

Cost. CMS believes the Ureterol meets all the cost criteria.

CMS invites comments on whether the Ureterol meets the device pass-through payment criteria.

B. Public Posting of Device Pass-through Applications

CMS discusses the information it summarizes for each application for OPPS transitional pass-through status for medical devices ("OPPS device-passthrough) in the proposed rule.[16] CMS tries to ensure that sufficient information is provided to facilitate public comments on whether the device meets the PSS device-pass though criteria under §419.66. CMS notes that it generally does not take into consideration information that is marked as confidential when determining the decision.

CMS has received requests from the public to access and review OPPS device pass-through applications a to facilitate comment on whether the payment criteria are met. CMS believes that

[16] The OPPS device pass-through application is currently undergoing the Paperwork Reduction Act reapproval process and a 60-day notice was published in the *Federal Register* on April 29, 2022 (87 FR 25488).

public posting the applications and certain related materials online may help foster additional comments on these applications. CMS also believes that posting the applications online, reduces the risk that CMS may have inadvertently omit or misrepresentative relevant information from summaries in the rules. As the number and complexities of the applications has increased, this process would also streamline CMS' evaluation process.[17]

Beginning with applications submitted on or after January 1, 2023, CMS proposes to post online the completed application forms and certain related materials (e.g., attachments and uploaded supportive materials) it receives from applicants. CMS also proposes to post information acquired subsequent to the application submission. CMS proposes it would publicly post all completed application forms and related materials at the same time the proposed rule is issued. CMS notes that it is proposing to continue its policy that applicants whose applications are not approved through the quarterly review process may elect to withdraw their application from consideration in the next applicable rulemaking cycle.

For copyrighted material, CMS proposes that on the application form, the applicant would be asked to provide a representation that the applicant owns the copyright or otherwise has the appropriate license to make all the copyrighted material included with its application public with the exception of materials by the applicant as not releasable to the public. For material included in the application that is not releasable to the public, CMS proposes that the applicant must either provide a link to where the material can be accessed or provide an abstract or summary of the material that CMS can make public. CMS plans to post this information online, along with the other posted application material.

Currently, applicants may include information marked as proprietary or trade secret information along with its device pass-through application. The current application specifies that data provided by the applicant may be subject to disclosure and instructs the applicant to mark any proprietary or trade secret information so that CMS can attempt, to the extent allowed under Federal law, to keep the information protected from public view.

CMS notes that it has received applications in which all the data and information are marked proprietary or confidential, or certain information in support of a claim of substantial clinical improvement, is marked as proprietary or confidential. CMS reiterates that it generally would not be able to consider that data and information when determining whether a device meets the device pass-through criteria because the process requires public input.

CMS notes this proposal would not change the timeline or evaluation process for device pass-through payments. CMS also does not expect added burdens on prospective applicants since it is not proposing to fundamentally change the information collected in the application.
CMS does expect to make changes in the summaries that appear in the annual proposed and final rule. CMS will continue to provide sufficient information in the rules to facilitate public comments on whether a device meets the pass-through payment criteria. CMS expects it would include at a high level the following information in the proposed and final rule: the medical device and applicant name; a description of the what the device does; the cost significance

[17] This proposal would also streamline the effort required from anyone summarizing these applications.

calculation; the FDA approval/clearance information; and a summary of the applicant's assertions. CMS also expects to provide a more succinct summary regarding the applicant's assertions of how the medical service or technology meets the criteria. CMS would continue to provide discussion of concerns or issues for applications submitted and in the final rule, CMS would continue to provide an explanation of CMS' determination.

If this proposal in adopted in the final rule, CMS would begin publicly posting applications in the 2024 rulemaking cycle, depending on when they are received. Applications received as of December 31, 2022 would follow the current process and be discussed fully in the proposed rule and applications received after the effective date of January 1, 2023 would be summarized in the proposed rule with a cross-reference to the publicly posted application. If the proposal was finalized effective January 1, 2023, CMS would allow applicants that submit a device pass-through application prior to December 31, 2022 to elect to have the information summarized and publicly posted instead of a full CMS write-up. **CMS seeks comments on whether it should consider an alternative implementation date of March 1, 2023**; this would allow all device pass-through applications discussed in the 2024 OPPS proposed and final rules follow the current process. Under this alternative proposal, CMS would begin publicly posting all device pass-through applications and summarize and cross-reference applications beginning in the 2025 rules.

CMS notes it included a similar proposal in the FY 2023 IPPS proposed rule.[18] Beginning with FY 2023 CMS proposed publicly posting the new technology add-on payment applications and certain related material.

CMS seeks public comments on the proposal to post online the completed application forms, supporting information, and updated application information submitted subsequent to the initial application submission for OPPS device-pass through payment, beginning January 1, 2023. CMS also proposes March 1, 2023 as an alternative effective date.

C. 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 finalized that device-intensive procedures would be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device-offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost.

[18] 87 FR 28355-28357

To align the device-intensive policy with the criteria used for device pass-through status, CMS also finalized 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.[19] 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 uses the 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. Additional information about new HCPCS codes, such as pricing data or invoices from a manufacturer, should be directed to the Division of Outpatient Care, Mail Stop C4-01-26, CMS, 7500 Security Blvd, Baltimore, Md 21244-1850 or electronically at outpatientpps@cms.hhs.gov.

For 2023, consistent with CMS' broader proposal to use 2021 claims for 2023 OPPS/ASC ratesetting purposes, CMS proposes to use 2021 claims information for determining device offset percentages and assigning device-intensive status.

[19] 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.

The full listing of proposed 2020 device-intensive procedures provided in Addendum P.[20]

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 2023, CMS did not propose any changes 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.

For 2023, CMS is not proposing any changes to this policy.

V. Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

CMS currently pays for drugs, biologicals, and radiopharmaceuticals in one of three ways: packaged (either policy packaged or threshold packaged); separately paid above a cost threshold; or on pass-through. When a drug, biological or radiopharmaceutical is packaged into the payment for the associated service or separate payment (individual APCs), hospitals do not receive a separate payment for the packaged items. Hospitals 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.

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

Some drugs are policy packaged meaning they are always packaged into payment for the APC except when paid on pass-through. Policy packaged drugs and biologicals include:

- Anesthesia;
- Medical and surgical supplies and equipment;
- Surgical dressings; devices used for external reduction of fractures and dislocations;
- Drugs, biologicals, 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.

Other drugs are threshold packaged meaning that their per day costs must exceed a fixed threshold ($130 for 2022) to be paid separately. For a separately payable drug that exceeds the packaging threshold, CMS will make payment at average sales price (ASP)+6 percent (unless the drug or biological is acquired under the 340B drug discount program).

Other drugs and biologicals may be paid transitional pass-through payments.

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. Proposed pass-through drugs and biologicals for 2023 and their designated APCs are assigned status indicator "G" in Addenda A and B of the proposed rule. For 2023, CMS proposes to continue using ASP+6 percent as payment for pass-through drugs and biologicals. CMS also proposes to pay for diagnostic and therapeutic radiopharmaceuticals receiving pass-through payment at ASP+6 percent.

CMS approves pass-through payments quarterly and 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. Table 39 of the proposed rule lists 32 drugs and biologicals where CMS proposes to expire pass-through payment at the end of 2022. Table 40 lists 43 drugs and biologicals where CMS proposes to end pass-through payment status in 2023. Each of the products will have received at least the full 3 years of pass-through payments once the additional payments expire. Table 41 of the proposed rule lists 32 drugs where CMS proposes to continue pass-through payment for all 2023.

Some of the products listed in Table 39 received extended pass-through payment for additional time in 2022 under CMS' use of its equitable adjustment authority. For these products, CMS felt extended pass-through payment was warranted due to the COVID-19 PHE and CMS' decision not to use 2020 Medicare utilization to set 2022 rates. As CMS was continuing to use 2019 utilization to set 2022 rates, the costs of these pass-through drugs were not yet incorporated into the data that CMS uses for rate-setting.

When policy packaged or threshold drugs and biologicals are paid on pass-through, CMS makes an offset to the APC payment for the cost of the predecessor drug products. As diagnostic radiopharmaceuticals are also policy packaged, CMS will apply a payment offset to the associated APC. No offset is required for a separately payable drug paid on pass-through as there is no payment included in the APC for the drug. Table 42 of the proposed rule lists the APCs where CMS will apply an offset for policy packaged drugs paid on pass-through.

CMS directs readers to the following link for a file of APC offset amounts used to evaluate cost significance for candidate pass-through device categories and drugs and biologicals and for establishing any appropriate APC offset amounts: https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppsannual-policy-files/2023-0. However, the actual file does not appear to be available at the time of this writing.

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

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

Cost Threshold for Packaging of "Threshold-Packaged Drugs"

For 2023, CMS is proposing to establish a packaging threshold of $135 for drugs, biologicals, and radiopharmaceuticals that are not new and do not have pass-through status. The packaging threshold was initially set at $50 in 2005. To calculate the 2023 threshold, CMS used 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) to trend the $50 threshold forward from the third quarter of 2005 to the third quarter of 2023. CMS rounds the resulting dollar amount ($133.73) to the nearest $5 increment ($135).

CMS proposes to continue using the following process to determine the 2023 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 2021 claims data processed through March 31, 2022,[21] 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 2021 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 2021 (data that will be used to pay for drugs and biologicals in physicians' offices effective April 1, 2022). For products that do not have an ASP, such as some therapeutic radiopharmaceuticals, CMS will use their mean unit cost derived from 2021 hospital claims data. CMS proposes to package payment for products with a per day cost of $135 or less and pay separately for items with a per day cost greater than $135 in 2023.

[21] The proposed rule indicates that CMS will use claims processed and paid through June 30, 2021 but this is likely a typographical error and CMS meant to say March 31, 2022 consistent with past practice. HPA has queried CMS about the accuracy of this sentence.

CMS uses quarterly ASP updates as follows:

- 4th quarter of 2021: Per day cost, budget neutrality estimates, packaging determinations, impact analyses, and Addenda A and B for the 2023 OPPS proposed rule;
- 2nd quarter of 2022: Per day cost, budget neutrality estimates, packaging determinations, impact analyses, and Addenda A and B for the 2023 OPPS final rule; and
- 3rd quarter of 2022: Payment rates effective January 1, 2023 for separately payable drugs and non-implantable biologicals; these are the same ASP data used to calculate payment rates effective January 1, 2023 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 2023 final rule will be subject to quarterly updates.

As in past years, CMS is proposing to apply the following policies to determine the 2023 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 2022 and were proposed for separate payment in 2023 are separately payable in 2023 even if the updated data used for the 2023 final rule indicate per day costs equal to or less than the $135 threshold.
- HCPCS codes that are packaged in 2022, proposed for separate payment in 2023, and have per day costs equal to or less than $135 based on the updated data used for the 2023 final rule are packaged in 2023.
- HCPCS codes for which CMS proposed packaged payment in 2023 and have per day costs greater than $135 based on the updated data used for the 2023 final rule are separately payable in 2023.

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

For 2023, CMS is proposing 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 43 of the proposed rule.

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

As indicated above, CMS proposes to pay for separately payable drugs and biologicals at ASP+6 percent in 2023. For drugs acquired under the 340B drug discount program, the proposed rule reflects that CMS will continue to pay ASP-22.5 percent. However, CMS indicates that it plans

to pay for these drugs at ASP+6 percent in the final rule. CMS' reasoning for using ASP-22.5 percent in the proposed rule even though it intends to pay at ASP+6 percent in the final rule is explained in more detail later in this section. Medicare's payment represents the combined acquisition and pharmacy overhead payment for drugs and biologicals.

Consistent with policy in the PFS, CMS will pay for drugs and biologicals under the OPPS during an initial sales period (2 quarters) for which ASP pricing data are not yet available from the manufacturer at wholesale acquisition cost (WAC)+3 percent. The WAC+3 percent payment under the OPPS will only apply to new drugs and biologicals in an initial sales period. Other drugs and biologicals where ASP data are not available will continue to be paid at WAC+6 percent. If ASP and WAC are unavailable, Medicare will pay 95 percent of AWP.

CMS will continue to include payments for separately payable drugs and biologicals in determining budget neutrality adjustments (i.e., the budget neutral weight scaler). However, the weight scaler is not applied to separately payable drugs 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, 2023. Payment rates effective January 2023 will be released near the end of December 2022 and will be based on ASP data submitted by manufacturers for the third quarter of 2022 (July 1, 2022 through September 30, 2022).

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 2021 (used for payment in physician's offices for the 2nd quarter of 2022) are based on mean unit cost in the available 2021 claims data. If ASP information becomes available for the quarter beginning in January 2022, 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 policies that parallel those used 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.

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

CMS proposes to continue all of its biosimilar policies unchanged for 2023.

3. Payment Policy for Therapeutic Radiopharmaceuticals

For 2023, CMS proposes to continue paying for therapeutic radiopharmaceuticals at ASP+6 percent. For therapeutic radiopharmaceuticals for which ASP data are unavailable, CMS proposes to determine 2023 payment rates based on 2021 geometric mean unit cost.

4. Payment for Blood Clotting Factors

For 2023, CMS proposes to continue paying for blood clotting factors at ASP+6 percent and is updating the $0.239 per unit furnishing fee from 2022 by the Consumer Price Index (CPI) for medical care. The CPI won't be available until after publication of the 2023 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/Medicare3.2-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 2023 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' proposed policy is to pay for these products using ASP+6 percent if ASP is reported, WAC+6 percent if WAC is available and at 95 percent of AWP if ASP and WAC are unavailable.

6. OPPS Payment Methodology for 340B Purchased Drugs

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 based on findings of the General Accountability Office and MedPAC that hospitals acquire drugs at a significant discount under the 340B program.
- 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. While the initial decision applied only to CMS' 2018 policy, the district court later made the same finding for CMS' 2019 policy.
- On July 31, 2020, the United States Circuit Court for the District of Columbia entered an opinion reversing the district court's judgment.
- On June 15, 2022, the United States Supreme Court held that the Secretary may not vary payment rates for drugs and biologicals among groups of hospitals in the absence of having conducted a survey of hospitals' acquisition costs.

In the proposed rule, CMS indicates the Supreme Court's decision is only applicable to 2018 and 2019 but "obviously has implications for 2023 payment rates." Given the timing of the Supreme Court's decision, CMS lacked the necessary time to reflect a payment policy other than the one it

was intending to propose—ASP-22.5 percent—in the payment rates, tables, and addenda for the proposed rule.

However, CMS fully anticipates adopting ASP+6 percent in the final rule for drugs acquired under the 340B program and has provided alternate supporting data files on the impact of removing the 340B program payment policy for 2023. It will also accept comments on the propriety of maintaining differential payment for 340B-acquired drugs in the future subject to the constraints of the Supreme Court's recent decision.

The Supreme Court did not specify a remedy for prior years. CMS is still evaluating how to apply the Supreme Court's recent decision to prior cost years and is interested in public comments on the best way to craft any proposed, potential remedies affecting calendar years 2018-2022. Even though the Supreme Court decision does not apply to any year after 2019, CMS makes clear that it intends to reverse its 340B policy retroactively to also apply to 2020-through 2022

The proposed rule indicates that to maintain budget neutrality under the anticipated final policy where OPPS drugs purchased under the 340B program are paid at ASP+6 percent in 2023, CMS would need to determine the change in estimated OPPS spending associated with the alternative policy. Based on separately paid line items with the "JG" modifier in the 2021 claims, the estimated payment differential would be an increase of approximately $1.96 billion in OPPS drug payments.

To ensure budget neutrality under the OPPS after applying this alternative payment methodology for drugs and biologicals purchased under the 340B Program, CMS would apply a budget neutrality adjustment of 0.9596 (-4.04 percent) to offset these additional $1.96 billion in OPPS drug payments. The revised conversion factor would be $83.279. Public comments on the budget neutrality adjustment are welcome and will be carefully considered.[22]

CMS describes this process as reversing the budget neutrality increase that was applied to the OPPS CF to offset the decrease in OPPS drug payments when this policy was adopted in 2018. The amount of this adjustment would potentially change in the final rule due to updated data, potential modifications to the estimate methodology, and other factors. A table detailing the impact on hospital outpatient payment rates of removing the payment differential for 340B drugs and the corresponding budget neutrality adjustment for 2023 is included in the 340B alternative data supporting files.

[22]CMS applied an adjustment of 1.032 (3.2 percent) in 2018 to make the reduction in drug and biological payments for drugs acquired under the 340B budget neutral. Public comments on the 2021 and 2022 OPPS rule requested CMS revisit the initial budget neutrality adjustment using claims data with JG modifier that indicate the precise situations where the payment reduction is applied. CMS declined this request. Therefore, CMS applied a +3.2 percent adjustment in 2018 and is now proposing a -4.04 percent adjustment for budget neutrality even though the initial adjustment was never revised.

7. High/Low-Cost Threshold for Packaged Skin Substitutes

CMS has been packaging skin substitutes as drugs and biologicals that function as supplies when used in a surgical procedure since 2014. The packaging methodology also divides skin substitutes into high- and low-cost groups in order to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures. Skin substitutes assigned to the high-cost group are billed with HCPCS codes 15271, 15273, 15275 and 15277. Skin substitutes assigned to the low-cost group are billed with HCPCS codes C5271, C5273, C5275 and C5277. Based on the geometric mean costs, these HCPCS codes are assigned to APCs as follows:

APC	HCPCS	2022 Geometric Mean Cost
5053 (Level 3 Skin Procedures)	C5271, C5275, C5277	$596.39
5054 (Level 4 Skin Procedures	C5273, 15271, 15275,15277	$1,774.73
5055 (Level 5 Skin Procedures)	15273	$3,326.39

For 2023, CMS proposes to determine the high-cost/low-cost status for each skin substitute product based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold. CMS proposed to use 2019 data for this purpose.[23]

The proposed 2023 MUC threshold was $47 per cm^2 rounded to the nearest $1, and the proposed 2023 PDC threshold was $837 rounded to the nearest $1. CMS proposes to assign a skin substitute with a MUC or a PDC that exceeds either the MUC threshold or the PDC threshold to the high-cost group. If the product is assigned to the high-cost group in 2022, CMS proposed to continue assigning it to the high-cost group in 2023. Otherwise, CMS proposed assigning the skin substitute to the low-cost group.

For 2023, CMS proposed 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, or 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.

The proposed rule notes that there is a proposal in the 2023 physician fee schedule proposed rule to treat all skin substitute products consistently across healthcare settings as incident-to supplies rather than as biologicals. If this proposed policy is finalized, manufacturers would not report ASPs for skin substitute products starting in 2023. CMS will determine whether a product should

[23] HPA has queried CMS whether the proposed rule is accurate on the use of 2019 data as CMS is using 2021 data for most other purposes for calculating proposed 2023 OPPS rates and policies.

be assigned to the high-cost group or the low-cost group using WAC and AWP pricing when cost data for a product is not available.

Table 44 of the proposed rule lists the high/low-cost group assignment for each skin substitute.

CMS proposes to retire HCPCS code C1849. This code was initially used for a single synthetic skin substitute product but later was used for multiple products and assigned to the high-cost group. There are now HCPCS A-codes available for synthetic graft skin substitute products that can be billed under the OPPS making code C1849 no longer needed. As products previously using code C1849 are currently assigned to the high-cost group for 2022, these products will continue to be assigned to the high-cost group in 2023 whether they currently have a product-specific code or will be assigned a product-specific code in the future. CMS also created code A4100 for an unclassified skin substitute product. Consistent with policy for other unclassified skin substitute codes, CMS proposes to assign this code to the low-cost group.

In the proposed rule, CMS further notes complaints from interested parties regarding inconsistent treatment of skin substitutes. These parties indicate that:

1. All skin substitutes should receive product-specific Q codes and payment under the ASP+6 percent methodology; and
2. The recent assignment of A codes has created confusion among Medicare contractors and lead to uncertainty among physicians whether they will be paid for skin substitute products that do not have national pricing.

In response to these concerns, CMS indicates that it intends to reform its substitute policies over the next one to five years with the following objectives:

1. Ensuring a consistent payment approach across the physician office and hospital outpatient department settings;
2. Ensuring that all products are assigned an appropriate HCPCS code;
3. Using a uniform benefit category across products within the physician office setting regardless of whether the product is synthetic or biological; and
4. Maintaining clarity for interested parties.

Consistent with these goals, CMS proposes to treat skin substitutes as medical supplies in the 2023 physician fee schedule rule. All Q codes for skin substitutes will be retired by January 1, 2024 and manufacturers of these products can apply for a medical supplies A code during the intervening period. Effective January 1, 2024, these products will be contractor-priced in physician offices. CMS indicates it intends to use the next 1 to 5 years working on payment reform for skin substitutes to pay them consistently across sites (with the implication being that CMS would bundle payment for skin substitutes into the physician fee schedule application procedure analogous to the OPPS packaging policy).

CMS also proposes to use the term “wound care management products” in place of “skin substitutes.” The proposed rule indicates that these products do not actually function like human

skin that is grafted onto a wound. Instead, these products are applied to wounds to aid healing through various mechanisms of action to regenerate lost tissue.

"Wound care management products" do not include bandages or standard dressings that are assigned to either the high-cost or low-cost wound care product groups under the OPPS. Bandages and standard dressings are not reported with either CPT codes 15271 through 15278 or HCPCS codes C5271 through C5278 that are for application of a wound care management product.

The proposed rule indicates that the terms "care management" or "management" are not intended include E/M or care management codes (99424-99427, 99437, 99439, 99487, 99489, 99490-99491), or G-codes that describe care management services. The proposed terms would describe a category of items or products, not a type of service.

8. Radioisotopes Derived from Non-Highly Enriched Uranium (non-HEU) Sources

Beginning in CY 2013, CMS finalized a policy to provide an additional payment of $10 for the marginal cost for radioisotopes produced by non-HEU sources (77 FR 68323). CMS expected that this additional payment would be needed for the duration of the industry's conversion to alternative methods to producing radioisotopes without HEU.

The Secretary of Energy issued a certification on January 2, 2022 stating that there is a sufficient global supply of molybdenum-99 (Mo-99 is source material for the radioisotope Technetium-99 (Tc-99m)) produced without the use of HEU available to meet the needs of patients in the United States. The Department of Energy also expects that the last HEU reactor that produces Mo-99 for medical providers in the United States will finish its conversion to a non-HEU reactor by December 31, 2022. Therefore, CMS believes that the conversion to non-HEU sources of Tc-99m has reached a point where a reassessment of the policy of paying an add-on payment of $10 for non-HEU radioisotopes is necessary.

In the proposed rule, CMS indicates that non-HEU isotopes are more expensive than HEU isotopes. As these isotopes are used in diagnostic imaging procedures that are policy packaged, CMS believes the policy of paying an extra $10 for non-HEU isotopes should be extended for two more years to ensure the Medicare claims data that is used to value the APCs that use these products fully accounts for their costs (e.g., two years beyond the date that the U.S market has fully transitioned to use of non-HEU sources).

The conversion to non-HEU sourced radioisotopes is expected to be completed by the end of 2022. Medicare will use claims data from 2023 data to set 2025 OPPS payment rates. At that point, the data will reflect the full cost of Tc-99m diagnostic radiopharmaceuticals that will be used by providers. For this reason, CMS proposes to continue the additional $10 payment for diagnostic radiopharmaceuticals containing Tc-99m through December 31, 2024.

C. Reporting Discarded Amounts for Single Use Vial Drugs

Effective January 1, 2023, section 1847A of the Act requires Part B drug manufacturers to refund discarded drug amounts exceeding 10 percent of total charges for the drug or biological in a given calendar quarter. CMS is implementing this provision through the 2023 physician fee schedule rule.

CMS' proposal will require that hospital outpatient departments and ASCs report the JW modifier or any successor modifier to identify discarded amounts of refundable single-dose container or single-use package drugs or biologicals that are separately payable under the OPPS or ASC payment system. In addition, CMS proposes to require hospitals and ASCs (and others subject to the policy) to use a separate modifier, JZ, in cases where no billing units of single use container were discarded.

The 2023 OPPS/ASC proposed rule advises interested parties to direct their comments on this issue to the 2023 physician fee schedule proposed rule. More information on this proposal can be found at: https://public-inspection.federalregister.gov/2022-14562.pdf. Discussion begins on page 491 or section III.A.

VI. Estimate of Transitional Pass-Through Spending

CMS estimates proposed pass-through spending for 2023 in two ways—including the proposed policy of paying for drugs and biologicals acquired under the 340B program at ASP-22.5 percent and with their expected final rule policy of paying for drugs and biologicals acquired through the 340B program at ASP+6 percent. As pass-through drugs and biologicals acquired under the 340B program are paid at ASP+6 percent instead of ASP-22.5 percent, there is a large difference in estimated pass-through payments from these two policy options.

- Paying for 340B Drugs at ASP-22.5 percent: $622.6 million for drugs and biologicals and $149.4 million for devices with total pass-through spending equaling $772 million.
- Payment for 340B Drugs at ASP+6 percent: $29.9 million for drugs and biologicals and $149.4 million for devices with total pass-through spending equaling $179.30 million.

A. Devices

CMS estimates pass-through spending of $149.4 million in 2023 for devices—$48 million for those recently eligible for pass-through payments that will continue for 2023 and $101.4 million for those CMS knows or projects could be approved for pass-through status in 2023.

B. Drugs and Biologicals

With a policy to pay for 340B drugs and biologicals at ASP-22.5 percent, CMS estimates pass-through spending of $622.6 million in 2023 for drugs and biologicals—$612.6 million for those recently eligible for pass-through payments that will continue for 2023 and $10 million for those CMS knows or projects could be approved for pass-through status in 2023.

With a policy to pay for 340B drugs and biologicals at ASP+6 percent, CMS estimates pass-through spending of $29.9 million in 2023 for drugs and biologicals—$19.9 million for those recently eligible for pass-through payments that will continue for 2023 and $10 million for those CMS knows or projects could be approved for pass-through status in 2023.

VII. Hospital Outpatient Visits and Critical Care Services

CMS is soliciting comments but not proposing any changes to the current clinic and emergency department hospital outpatient visits payment policies or to the payment policy for critical care services when these services are provided on the campus of a hospital for 2023. For off-campus provider-based departments being paid a physician fee schedule equivalent rate, CMS proposes to continue paying 40 percent of the full OPPS rates. Beginning in 2023, CMS proposes to exempt rural sole community hospitals from being paid the physician fee schedule equivalent rate as described in section X.I.

VIII. Partial Hospitalization Program (PHP) Services

A. Background

CMS describes the evolution of its payment policies for partial hospitalization program (PHP) services. In the past two rulemaking cycles, it adopted policies to protect against significant reductions in payment rates for PHP services, and, in response to the COVID-19 pandemic, it provided greater flexibility for the delivery of PHP services by Community Mental Health Centers (CMHCs) and hospital-based providers.

In the 2020 OPPS/ASC final rule (84 FR 61339 through 61350), it calculated the 2020 CMHC geometric mean per diem cost and the 2020 hospital-based PHP geometric mean per diem cost consistent with its existing methodology, but it established a cost floor equal to the 2019 final geometric mean per diem costs as the basis for developing the 2020 PHP APC per diem rates. Similarly, in the 2021 rulemaking cycle, it proposed, for 2021 and subsequent years, to use the 2021 CMHC geometric mean per diem cost calculated using its existing methodology, but with a cost floor equal to the per diem cost calculated for 2020 ratesetting as the basis for developing the 2021 CMHC APC per diem rate. Because the final calculated geometric mean per diem costs for both CMHCs and hospital-based PHPs were significantly higher than each proposed cost floor, the floors were not necessary; thus, the agency did not finalize the proposed cost floors in the final rule.

In the 2022 OPPS/ASC final rule (86 FR 63665 through 63666), CMS observed significant decreases in utilization and in the number of hospital-based PHP providers who submitted CY 2020 claims; this was attributed to the impact of the COVID-19 PHE. In response, the PHP per diem costs were calculated using the year of claims consistent with the calculations that would be used for other OPPS services (i.e., by using the CY 2019 claims and the cost reports that were used for CY 2021 final rulemaking to calculate the CY 2022 PHP per diem costs). CMS also used cost and charge data from the Hospital Cost Report Information System (HCRIS) as the source for the CMHC cost-to-charge ratios (CCRs), instead of using the Outpatient Provider Specific File (OPSF).

B. PHP APC Update for 2023

For 2023, CMS proposes to use its established policies to calculate the PHP APC per diem payment rates for CMHCs and hospital-based PHP providers based on geometric mean per diem costs using the most recent claims and cost data for each provider type, with some modifications. As it did for 2022, CMS proposes for 2023 only to use the cost data that was available for the 2021 rulemaking (which is the same cost data used for the 2022 rulemaking). CMS proposes to use the geometric mean per diem cost of $131.71 for CMHCs as the basis for developing the 2023 CMHC APC per diem rate, and to use the geometric mean per diem cost of $264.06 as the basis for developing the 2023 hospital-based APC per diem rate.

CMS proposes to 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)) 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.

As discussed in detail in section X.D. of the proposed rule, cost and claims information for 2020 and 2021 were analyzed to understand the impact of the COVID-19 PHE on outpatient services and to identify the best data to use in ratesetting for 2023. CMS continues to note significant declines in the number of PHP days in its trimmed 2021 claims dataset (18 percent less and 32 percent less for hospitals and CMHCs, respectively) from its trimmed 2020 claims dataset. The agency has noted that Medicare outpatient service volumes are returning to more normal pre-pandemic levels. While anticipating the continued effects of COVID-19 on Medicare claims and cost report data as well as future variants, CMS nonetheless believes that the more recently available 2021 claims data would better represent the volume and mix of claims for the 2023 OPPS. Therefore, it proposes to use 2021 PHP claims for 2023 ratesetting. However, as CMS did for 2022, it proposes to use cost report data from the June 2020 HCRIS data set (which only includes cost report data through 2019).

CMS proposes to exclude data from nonstandard cost centers reported on lines that do not correspond to the cost center number in its 2023 PHP ratesetting; one example of this is hospital reporting of Psychiatric/Psychological Services. **Comment is sought on whether there are any specific concerns with regards to the accuracy of data from these nonstandard cost center lines that it should consider before including them in future OPPS ratesetting**.

1. CMHCs

CMS continues its policy of excluding data from any CMHC when the CMHC's costs are more than ±2 standard deviations from the geometric mean cost per day for all CMHCs. CMS also defaults any CMHC CCR that is greater than 1 to the statewide hospital ancillary CCR. For the proposed rule, CMS used HCRIS as the source for CMHC cost information used for calculating the geometric mean per diem cost for CMHC APC 5853 for 2023.

Of the 40 CMHCs in the PHP claims data file, CMS excludes data from two CMHCs with geometric mean costs per day of more than ±2 standard deviations from the geometric mean cost per day for all CMHCs (one higher and one lower). No CMHC is excluded for missing wage index data, and one provider is excluded from ratesetting because it had no days containing 3 or more units of PHP-allowable services. CMS adjusts the CCR for 5 CMHCs to the applicable statewide hospital CCR based on its urban/rural designation and state location; one CMHC had a CCR greater than one, and 4 CMHCs were missing CCR information.

Thirty-seven CMHCs were included in the 2023 calculation. CMS removed 330 CMHC claims which left 3,314 CMHC claims for the 2023 ratesetting. The 2023 geometric mean per diem cost for all CMHCs for providing 3 or more services per day is $131.71 (an increase from $129.93 calculated for 2022).

2. Hospital-based PHP Providers

CMS proposes to continue its policy of excluding hospital-based PHP service days when a CCR>5 is used to calculate costs for at least one of the component services. No hospital-based PHP providers had a CCR greater than 5. Of the hospital-based PHP providers, CMS removes 6 with no PHP payment, one because none if its days included allowable PHP HCPCS codes, and one provider with geometric mean costs per day outside the ± 3 standard deviation limits.

Thus, 326 hospital-based PHP providers were included in the data used to calculate rate setting. The calculated geometric mean per diem cost for 2023 for all hospital-based PHP providers for providing 3 or more services per day is $265.97 which is a significant increase from the 2022 geometric mean per diem cost for these providers of $253.02.

The final 2023 geometric mean per diem costs and payment rates are as follows:

2023 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	$131.71	$130.54
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	$264.06	$261.73

* Table 45 of the proposed rule shows the 2023 PHP APC geometric mean per diem costs.
** The 2023 proposed payment rates are from Addendum A to the proposed rule.

C. Remote Non-PHP Mental Health Services after the COVID-19 PHE

1. Background

In the April 30, 2020 interim final rule with comment period, effective as of March 1, 2020 and for the duration of the COVID-19 PHE, hospital and CMHC staff may furnish certain outpatient therapy, counseling, and educational services (including certain PHP services), incident to a physician's services, to beneficiaries in temporary expansion locations, including the

beneficiary's home, so long as the location meets all conditions of participation to the extent not waived. Additionally, a hospital or CMHC may furnish such services using telecommunications technology to a beneficiary in a temporary expansion location if that beneficiary is registered as an outpatient.

However, all other PHP requirements are unchanged and still in effect, including that all services furnished under the PHP still (1) require an order by a physician, (2) must be supervised by a physician, (3) must be certified by a physician, and (4) must be furnished in accordance with coding requirements by a clinical staff member working within his or her scope of practice. CMS also noted that the longstanding requirements for documentation in the medical record of the reason for the visit and the substance of the visit still apply. Notwithstanding CMS' expectation that PHP services should be furnished using both audio and video telecommunications Technology, it permits in limited cases (i.e., where a beneficiary does not have access to video communication technology) for PHP services to be furnished exclusively with audio.
Some commenters have expressed support for continuing the flexibility that permits PHP services to be furnished to beneficiaries in their homes via telecommunication technology after the COVID–19 PHE. The commenters believe these flexibilities, especially the use of audio-only telecommunications technology, increases access to mental health services, especially in rural areas and for vulnerable populations.

2. Outpatient Non-PHP Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes after the COVID-19 PHE

In section X.A.5 of the proposed rule (described below), CMS proposes to designate certain remote services provided for the purposes of diagnosis, evaluation, or treatment of a mental health disorder furnished by clinical staff of a hospital using communications technology to beneficiaries in their homes as hospital outpatient services that are covered and paid for under the OPPS. However, CMS is not proposing to recognize these proposed OPPS remote services as PHP services. However, it clarifies that none of the PHP regulations would preclude a patient that is under a PHP plan of care from receiving other reasonable and medically necessary non-PHP services from a hospital if that proposal is finalized.

CMS reminds stakeholders that partial hospitalization services are in lieu of inpatient hospitalization, and all PHP patients should have the cognitive and emotional ability to participate in the active treatment process and should be able to tolerate the intensity of the PHP. Thus, if the proposal at Section X.A.5 is finalized, physicians would be expected to update the patient's PHP plan of care to reflect any change to the type, amount, duration, or frequency of the therapeutic services planned for that patient when a PHP patient receives non-PHP remote mental health services from a hospital outpatient department. The medical documentation should continue to support the patient's eligibility for participation in a PHP.

Noting that CMHCs may not bill Medicare for any remote mental health services furnished by clinical staff of the CMHC in an individual's home, CMS observes that if the proposal at Section X.A.5 is finalized, a PHP patient who typically receives PHP services at a CMHC could receive non-PHP remote mental health services from a hospital outpatient department.

3. Request for Information Regarding Remote PHP Services Furnished by Hospital Outpatient Departments and CMHCs during the COVID-19 PHE

Seeking a better understanding of the use of remote mental health services for PHP patients during the COVID-19 PHE as well as the potential need for PHP services in the future among PHP patients who receive care from CMHCs and HOPDs, **CMS seeks comments in response to the following questions**:

- How have CMHCs and HOPDs used the flexibilities allowing the provision of remote PHP services and incorporated remote PHP services into their operations during the COVID-19 PHE?
- What are the needs and circumstances in which remote PHP services have most often been used? What situations and patient populations have these flexibilities best served? How have these needs, circumstances, and patient populations differed between HOPDs and CMHCs?
- What, if any, barriers would there be to access to remote mental health services for PHP patients of a CMHC? What if any possible pathways do commenters believe might exist to minimize these barriers, while taking into consideration section 1861(ff)(3)(A) of the Act?

D. Outlier Policy for CMHCs

For 2023, 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. CMS provides a more detailed explanation of the steps involved in calculating the CMHC outlier percentage in the preamble to the final rule.

CMS projects that CMHCs will receive 0.02 percent of total hospital outpatient payments in 2023 (excluding outlier payments), and it 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 continue to set the cutoff point for outlier payments for CMHCs for 2023 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 calculates 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.

CMS proposes to continue to use its established outlier reconciliation policy to address charging aberrations related to OPPS outlier payments established in the 2009 OPPS/APC final rule (73 FR 68594 through 68599). The policy requires outlier reconciliation for providers whose outlier payments meet a specified threshold ($500,000 for hospitals and any outlier payments for CMHCs) and whose overall ancillary CCRs change by ±10 percentage points or more, pending approval of the CMS Central Office and Regional Office.

In the 2017 OPPS/ASC final rule (81 FR 79692 through 79695), CMS implemented an outlier payment cap of 8 percent; thus, an individual CMHC may not receive more than 8 percent of its total per diem payments in outlier payments. CMS continues this policy for 2023 which only impacts CMHCs.

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

E. Regulatory Impact

CMS estimates that payments to CMHCs will decrease by -8.4 percent in 2023. The estimate includes the impact of the trimming methodology, wage index, and other adjustments.

IX. Inpatient Only (IPO) List

A. Background

The IPO list was created based on the premise that Medicare should not pay for procedures furnished as outpatient services that are not reasonable and necessary to be performed in any other setting than inpatient. Services on the IPO list are highly invasive, result in major blood loss or temporary deficits of organ systems (such as neurological impairment or respiratory insufficiency), or otherwise require intensive or extensive postoperative care.

CMS has historically worked with interested stakeholders, including professional societies, hospitals, surgeons, hospital associations, and beneficiary advocacy groups, to evaluate the IPO list and to determine whether services should be added or removed. Stakeholders were encouraged to request reviews for a particular code or group of codes. CMS has asked that requests include evidence that demonstrates that the procedure can be performed on an outpatient basis in a safe and appropriate manner in a variety of different types of hospitals.

Prior to 2021, CMS traditionally used the following five criteria to determine whether a procedure should be removed from the IPO list:

1. Most outpatient departments are equipped to provide the service to the Medicare population.
2. The simplest procedure described by the code may be furnished in most outpatient departments.
3. The procedure is related to codes that have already been removed from the IPO list.
4. The procedure is being furnished in numerous hospitals on an outpatient basis.
5. The procedure can be appropriately and safely furnished in an ASC and is on the list of approved ASC services or has been proposed for addition to the ASC list.

A procedure is not required to meet all of the established criteria to be removed from the IPO list but it should meet at least one of these criteria.

In the 2021 OPPS final rule with comment period (85 FR 86084 through 86088), CMS adopted a policy to eliminate the IPO list over three years. As part of the first phase of eliminating the IPO

list, CMS removed 298 codes from the list beginning in 2021. The removed procedures were not assessed against the above criteria.

In 2022 OPPS final rule, CMS halted the elimination of the IPO list and returned most services removed in 2021 back to the IPO list beginning in 2022 after evaluating the removed procedures against the above criteria. CMS codified in regulation the above criteria as those it will use to determine whether a procedure may be removed from the IPO list effective with 2023.

B. Changes to the IPO List for 2023

Using the five criteria listed above, CMS is proposing to remove 10 codes from the IPO list in 2023 as shown in the below table. The table provides the code, short descriptor, proposed status indicator, proposed APC assignment, and the basis upon which CMS proposes to remove the code from the IPO list.

Code	Short Descriptor	Proposed Status Indicator	Proposed APC Assignment	Criteria Met to be Removed
16036	Escharotomy addl incision	N	N/A (add-on)	2 and 3 (base code not IPO)
22632	Arthrd pst tq 1ntrspc lm ea	N	N/A (add-on)	2 and 3 (base code not IPO)
21141	Lefort i-1 piece w/o graft	J1	5165	1, 2 and 3
21142	Lefort i-2 piece w/o graft	J1	5165	1, 2 and 3
21143	Lefort i-3/> piece w/o graft	J1	5165	1, 2 and 3
21194	Reconst lwr jaw w/graft	J1	5165	1, 2 and 3
21196	Reconst lwr jaw w/fixation	J1	5165	1, 2 and 3
21347	Opn tx nasomax fx multple	J1	5165	1, 2 and 3
21366	Opn tx complx malar w/grft	J1	5165	1, 2 and 3
21422	Treat mouth roof fracture	J1	5165	1, 2 and 3

CMS also proposed to add eight new surgical procedure codes to the IPO list effective January 1, 2023 on the basis that they will require a hospital admission or stay.

X. Nonrecurring Policy Changes

A. Mental Health Services Furnished to Patients in their Homes

a. Background

In an interim final rule with comment (IFC) period published in the Federal Register on May 8, 2020, CMS waived regulations to allow a patient's home to be considered provider-based to a hospital so long as the hospital can ensure the location meets all the conditions of participation, to the extent they are not waived. The waived regulations will remain so as long as the COVID-19 PHE remains in effect.

As a condition of payment, most therapeutic services paid under the OPPS are subject to general supervision (the physician or nonphysician practitioner supervising the service does not have to be immediately available while hospital staff are performing the service). CMS made clear in the IFC that when a hospital's clinical staff are furnishing hospital outpatient mental health services

to a patient in the hospital (which can include the patient's home so long as it is provider-based to the hospital), and the patient is registered as an outpatient of the hospital, CMS will consider the general supervision requirements to be met.

After the PHE ends, absent changes to regulations, the beneficiary would need to physically travel to the hospital to continue receiving outpatient hospital mental health treatment services from hospital clinical staff. CMS is concerned that this could have a negative impact on access to care in areas where beneficiaries may only be able to access mental health services provided remotely by hospital staff. In these areas, beneficiaries have become accustomed to receiving these services in their homes during the PHE. Therefore, CMS proposes to designate certain services provided for the purposes of diagnosis, evaluation, or treatment of a mental health disorder performed remotely by clinical staff of a hospital using communications technology to beneficiaries in their homes as hospital outpatient services for which payment can be made under the OPPS.

To effectuate payment for these services, CMS proposes to create OPPS-specific coding. The proposed code descriptors specify that the beneficiary must be in their home and that there is no associated professional service billed under the PFS. Consistent with the conditions of participation for hospitals, all hospital staff must be licensed to furnish these services in compliance with all applicable state laws regarding scope of practice. CMS further proposes that the hospital clinical staff be physically located in the hospital when furnishing services remotely using communications technology for purposes of meeting the general supervision requirements for being furnished in the hospital or CAH.

CMS proposes to create codes CXX78 for 15 to 29 minutes of mental health services provided by outpatient hospital staff to a patient located remotely in the home via telecommunications technology. Code CXX78 would be for 30 to 60 minutes of service and code CXX80 would be for each additional 15 minutes service beyond 60 minutes. CMS uses the PFS facility payment rates for CPT codes 96158 (Health behavior intervention, individual, face-to-face; initial 30 minutes) and 96159 (Health behavior intervention, individual, face-to-face; each additional 15 minutes) as comparators for assigning CXX78 and CXX79 to APCs.

As these codes pay approximately $60 and $20 respectively, CMS proposes assigning codes CXX78 and CXX79 to APC 5822 (Level 2 Health and Behavior Services) and APC 5821 (Level 1 Health and Behavior Services), respectively that have proposed payments of $77 and $30. As CXX80 is an add-on code, payment would be packaged and the code would not be assigned to an APC. Although CMS describes these services as being payable under the OPPS, they would be applicable to CAHs even though CAHs are not paid under the OPPS.

b. Periodic In-Person Visits

Section 123 of the CAA 2021 added the home of the individual as a permissible originating site for telehealth services billed under the PFS when furnished for the purposes of diagnosis, evaluation, or treatment of a mental health disorder. The CAA provision requires that there be an in-person service within 6 months prior to or after the furnishing of the telehealth service.

Under the PFS, CMS requires that after the first mental health telehealth service in the patient's home, there must be an in-person, non-telehealth service within 12 months of each mental health telehealth service. However, if the patient and practitioner agree that the benefits of an in-person, non-telehealth service within 12 months of the mental health telehealth service are outweighed by risks and burdens associated with an in-person service, and the basis for that decision is documented in the patient's medical record, the in-person visit requirement will not apply for that 12-month period. The same policies apply to mental health visits furnished through communications technology for RHCs and FQHCs.

CMS is proposing these same policies for the provision of remote mental services furnished by hospitals and CAHs. Exceptions to the in-person visit requirement should involve a clear justification documented in the beneficiary's medical record including the clinician's professional judgment that the patient is clinically stable and/or that an in-person visit has the risk of worsening the person's condition, creating undue hardship on the person or their family, or would otherwise result in disengaging with care that has been effective in managing the person's illness. Hospitals must also document that the patient has a regular source of general medical care and has the ability to obtain any needed point of care testing, including vital sign monitoring and laboratory studies.

The Consolidated Appropriations Act, 2022 delayed requirements for an in-person visit under the physician fee schedule and for an RHCs and FQHC within 6 months prior to the initial mental health telehealth service, and at subsequent intervals as determined by the Secretary, until the 152nd day after the end of the COVID-19 PHE. CMS is proposing the same delay for in-person visit requirements for remote outpatient mental health services provided by hospitals and CAHs.

c. Audio-only Communication Technology

Statutory and regulatory provisions require telehealth services to be provided by an interactive telecommunications system that includes audio and video communications between the patient and distant site physician or practitioner. During the PHE for COVID-19, CMS temporarily waived the audio/video requirements to allow telehealth services to be furnished via audio telecommunications only.

In the 2022 physician fee schedule final rule, CMS allowed practitioners to provide mental health telehealth services via audio only communications where the beneficiary is not capable of, or did not consent to, use of two-way, audio/video technology. Similar rules apply to RHCs and FQHCs. CMS is proposing a similar policy for mental health services furnished remotely by hospital clinical staff to beneficiaries in their homes through communications technology. Specifically, CMS proposes that hospital clinical staff must have the capability to furnish two-way, audio/video services but may use audio-only communications technology given an individual patient's technological limitations, abilities, or preferences.

B. Comment Solicitation on Treatment of Substance Use Disorders (SUD)

There are a range of services described by existing coding under the PFS and OPPS that can be billed for treatment of mental health conditions, including SUD, such as individual, group, and family psychotherapy. Over the past several years, in collaboration with interested parties and the public, CMS has provided additional coding and payment mechanisms for mental health care services paid under the PFS and OPPS.

The proposed rule discussion focuses largely on SUD and opioid use disorder and the potential for creating access to intensive outpatient mental health treatment for clients seeking primary treatment; step-down care from inpatient, residential, and withdrawal management settings; or step-up treatment from individual or group outpatient treatment. Intensive outpatient treatment includes a prearranged schedule of core services (e.g., individual counseling, group therapy, family psychoeducation, and case management) for a minimum of nine hours per week for adults or six hours per week for adolescents

CMS is seeking comment on whether these services are described by existing CPT codes paid under the OPPS, or whether there are any gaps in coding that may be limiting access to needed levels of care for treatment of mental health disorders or SUDs for Medicare beneficiaries. CMS is also interested in additional, detailed information about intensive outpatient services, such as the settings of care in which these programs typically furnish services, the range of services typically offered, the range of practitioner types that typically furnish those services, and any other relevant information, especially to the extent it would inform CMS' ability to ensure that Medicare beneficiaries have access to this care.

C. Remote Direct Supervision of Cardiac and Pulmonary Rehabilitation Services

Cardiac (CR), intensive cardiac (ICR) and pulmonary rehabilitation (PR) services can be provided via telehealth under the physician fee schedule until December 31, 2023. Until 151 days after the end of the COVID-19 PHE, these services may originate from a patient's home in any area of the country, and the physician supervision of these services may take place via interactive telecommunications systems including audio only. One hundred fifty-one days after the end of the PHE, CR, ICR and PR service must originate from health care setting and a rural area to be paid via telehealth under the physician fee schedule until December 31, 2023. After that time, CR, ICR and PR services cannot be provided via telehealth.

Under current OPPS policy, CR, ICR and PR may be provided in the hospital with the physician direct supervision being provided to a patient via a virtual presence. The virtual supervision policy will end with the conclusion the COVID-19 PHE. After that time, the physician must be immediately available for the direct supervision requirement to be met for the hospital to be paid for CR, ICR and PR. CMS is requesting comments on whether to allow for virtual direct supervision for the physician through the end of 2023 comparable to the physician fee schedule.

D. Use of Claims Data for 2023 Rate-Setting Due to the PHE

CMS deviated from its normal practice of using the latest available claims and cost report data for setting the 2022 OPPS rates because of concerns about the impact of the COVID-19 PHE on the data. These concerns included an overall aggregate decrease in claims volume (particularly those associated with visits); significant increases in HCPCS code Q3014 (Telehealth originating site facility fee) in the hospital outpatient claims; and increases in certain PHE-related services, such as HCPCS code C9803, which describes COVID-19 specimen collection and services assigned to APC 5801 (Ventilation Initiation and Management). As a result of the concerns, CMS believed that 2019 data, as the most recent complete calendar year of data prior to the COVID-19 PHE, were a better approximation of expected 2022 hospital outpatient service utilization than 2020 data. Therefore, CMS established rate-setting for the 2022 OPPS using 2019 claims data and cost reports prior to the PHE.

For 2023 rate-setting, CMS continues to see limited effects of the PHE, with service volumes generally about halfway between those in the 2019 (pre-PHE) claims and 2020 (beginning of the PHE) claims. At the aggregate level, there continues to be a decrease in the overall volume of outpatient hospital claims during the PHE, with approximately 10 percent fewer claims usable for rate-setting purposes when compared to the 2019 outpatient claims volume. This number compares to the 20 percent reduction observed last year in the 2020 claims. Similarly, this moderate return to more normal volumes extends across claims volume and applies to a majority of the clinical APCs in the OPPS, suggesting that, while clinical and billing patterns have not quite returned to their pre-PHE levels, they are beginning to do so.

After carefully considering the effects of new variants of COVID-19 emerging, CMS believes it is reasonable to assume that there will continue to be some effects of the COVID-19 PHE on the outpatient claims used for OPPS rate-setting, similar to the patterns found in the 2021 claims data. For this reason, CMS believes the 2021 data, with an exception noted below, will be a reasonable approximation of the 2023 utilization. As a result, CMS proposes to use the 2021 claims for 2023 OPPS rate-setting.

CMS does note, however, that HCPCS code C9803 was made effective for services furnished on or after March 1, 2020 for COVID-19 specimen collection. In the 2021 claims data available for rate-setting for this proposed rule, CMS indicates that this code accounted for 93 percent of the claims used to set the payment rate for APC 5731 (Level 1 Minor Procedures). Given that C9803 is a temporary code only in use for the duration of the PHE, CMS proposes to exclude claims for C9803 to determine the payment for APC 5731 for 2023.

For cost reports, CMS proposes to use the same set originally used to set rates for 2021—which in most cases included those beginning in 2018 and ending before the PHE began in 2020. If CMS were to use the latest set of cost reports, it would be using approximately 1,000 cost reports with the fiscal year ending in 2020. CMS observed a significant impact at the service level when incorporating these cost reports into rate-setting and the effects on billing/clinical patterns, similar to those observed in the 2020 claims when reviewing them for the 2022 rulemaking cycle. For this reason, CMS believes it is appropriate to continue to use the same set of cost reports that were used in developing the 2021 OPPS. As noted in the outlier section, CMS will

continue to use later cost reports to develop CCRs and charge inflation factors to determine the 2023 outlier threshold.

As it did for 2022, CMS is making available all of the supporting data files used for both determining the proposed rule relative weights as well as an alternative of using the latest available cost report data. The alternative cost report data would be cost report data extracted from HCRIS in December 2021, which in most cases included cost reporting periods beginning in CY 2018. The files specific to this alternative configuration will be identified by the word "Alternative" in the filenames.

E. Nonphysician Practitioner Supervision of Hospital and CAH Diagnostic Services

Prior to 2020, Medicare only allowed physicians to supervise diagnostic tests as condition of payment in the hospital outpatient department of both hospitals and CAHs. In the May 8, 2020 IFC, CMS allowed diagnostic tests furnished in outpatient departments to also be supervised by non-physician practitioners (NPPs)[24] to the extent they are authorized under their scope of practice and applicable state law. The May 8, 2020 IFC only provided for a temporary change to the supervision rules but the 2021 physician fee schedule final rule made the changes permanent.

In this proposed rule, CMS has identified inconsistencies in the regulations for when a diagnostic test may only be supervised by a physician and when they may be supervised by both physicians and NPPs. Under the general rule and specified exceptions in 42 CFR §410.32(b)(1) and (2) respectively, supervision may be furnished by a physician or NPP. However, under the 42 CFR §410.32(b)(3) definitions of the supervision levels, only direct supervision may be provided by a physician or NPP while personal and general supervision must be furnished by a physician.

The above referenced regulations apply to services paid under the physician fee schedule. However, parallel supervision requirements for both diagnostic and therapeutic services applicable to the outpatient department services of hospitals and CAHs reference these regulations (42 CFR §§ 410.27 and 410.28). CMS proposes to modify 42 CFR §§ 410.27 and 410.28 to include NPPs as supervising practitioners in addition to physicians for diagnostic and therapeutic services furnished under personal or direct supervision to the extent that they are authorized to do so under their scope of practice and applicable state law.

F. Coding and Payment: Category B Investigational Device Exemption Clinical Trials

Medicare may make payment for routine care items and services furnished in FDA-approved studies if CMS determines that the Medicare coverage criteria are met. However, Medicare does not make payment for the Category A investigational device exemption (IDE) but may make payment for a Category B IDE device. A Category A IDE device refers to a device where initial questions of safety and effectiveness have not been resolved. A Category B IDE device refers to a device where initial questions of safety and effectiveness have been resolved, or it is known

[24] For this purpose, NPPs are nurse practitioners, physician assistants, clinical nurse specialists, certified nurse midwives and certified register nurse anesthetists.

that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type.

In the past, CMS has responded to concerns about coding of Category B IDE devices that could unblind the participant receiving the experimental item relative to those receiving a placebo. To address these concerns, CMS created a single temporary HCPCS code to describe the device in both the experimental group and the control group. For 2023, CMS proposes to make a single blended payment, and establish a new HCPCS code or revise an existing HCPCS code for devices and services in Category B IDE studies when the Medicare coverage IDE study criteria are met as necessary to preserve scientific validity of a study. The proposal is intended to preserve the scientific validity by avoiding differences in Medicare payment methods that would otherwise reveal the group (treatment or control) to which a patient has been assigned.

The single blended payment rate would be dependent on the specific trial protocol and would account for the frequency with which the investigational device is used compared to placebo. For example, in a study for which CMS determines the Medicare coverage IDE study criteria in 42 CFR § 405.212 are met and where there is a 1:1 assignment of the device to placebo (no device), Medicare's payment rate would prospectively average the payment for the device with the zero payment for the placebo in a 1:1 ratio. Furthermore, costs for routine care items and services in the study would be included in the single blended payment.

G. OPPS Payment for Software as a Service

1. Background on Clinical Software and OPPS Add-on Codes Policy

New clinical software—which includes clinical decision support software, clinical risk modeling, and computer aided detection—is becoming increasingly available to providers. These technologies rely on complex algorithms or statistical predictive modeling to aid in the diagnosis or treatment of a patient's condition. CMS refers to these algorithm-driven services that providers pay for, either on a subscription or per-use basis, as Software as a Service (SaaS).

The first SaaS service that CMS paid for under the OPPS was Fractional Flow Reserve Derived from Computed Tomography (FFRCT), also known by the trade name HeartFlow. HeartFlow uses a proprietary data analysis process performed at a central facility to develop a three-dimensional image of a patient's coronary arteries, which allows physicians to identify the fractional flow reserve to assess whether patients should undergo further invasive testing (that is, a coronary angiogram). Analytics like HeartFlow are typically add-on services to a base code (in this case, CT test) that are not paid separately under the OPPS.

CMS, however, decided to pay separately for HeartFlow because the analytics are performed by a separate entity rather than the provider performing the CT scan. Since CMS began paying for Heartflow, it has paid separately for other SaaS procedures (IDx-Dr, an artificial intelligence system to detect diabetic retinopathy; and EyeBOX, an aid in the diagnosis of concussion).

HeartFlow, IDx-DR, and the EyeBox System are each described by single CPT codes. But for a procedure known by the tradename LiverMultiScan, the CPT editorial panel created two CPT codes for 2022, a primary code (0648T) and an add-on code (0649T). The first code is used to

analyze already existing images, while the add-on code is adjunctive to the acquisition of the MR images. CMS does not pay separately for add-on codes as they represent a continuation of a primary procedure. Consistent with this policy, CMS packaged the second—CPT code 0649T—rather than paying for it separately as it does for the first CPT code—code 0648T.

2. Recent CPT Codes for SaaS Procedures

The AMA has continued to establish new CPT codes that describe SaaS procedures using two codes: a primary code that describes the standalone clinical software service and an add-on code that describes a clinical software service that is adjunctive to and billed concurrent with a diagnostic imaging service. The standalone code is billed when no additional imaging is required because raw images from a prior scan are available for the software to analyze, while the add-on code is billed with an imaging service when a prior imaging scan is unavailable, or the prior images are insufficient. If a patient needs a SaaS procedure and has no existing diagnostic images, the patient would undergo the diagnostic imaging (i.e., CT or MRI), and the SaaS procedure. In this scenario, the provider would report the diagnostic imaging service code and the SaaS add-on code on the same day of service. In contrast, if a patient has pre-existing diagnostic images, the provider would only need to perform the SaaS procedure and would only report the standalone SaaS code.

3. 2023 Proposal for SaaS Add-on Codes

CMS has heard from stakeholders that the services described by the SaaS add-on codes should be paid separately because the technologies are new and associated with significant costs. The proposed rule states that the SaaS add-on codes created by CPT are not consistent with CMS' definition of add-on services as the costs of the add-on services exceed the costs of the imaging service with which they would be billed. Rather, CMS believes they are separate and distinct services that should be paid separately. For 2023, CMS proposes not to recognize the CPT add-on codes that describe SaaS procedures under the OPPS and instead establish C-codes to describe the add-on codes as standalone services. The new C-codes would be billed with the associated imaging service and be paid the same rate as the initial CPT code that provides data analysis using an existing image as both codes use the same technology. CMS lists the new C-codes and their descriptors in the proposed rule.

4. Comment Solicitation on Payment Policy for SaaS Procedures

The proposed rule describes SaaS procedures as a heterogenous group of services that are challenging to compare to existing medical services for purposes of determining clinical and resource similarity to make an APC assignment. To assist CMS with developing OPPS payment policy, CMS requests public comment on:

- How to identify services that should be separately recognized as an analysis distinct from both the underlying imaging test or the professional service paid under the PFS;
- How to identify costs associated with these kinds of services;
- How these services might be available and paid for in other settings (physician offices, for example); and

- How to consider payment strategies for these services across settings of care.

CMS suggests several alternatives for determining payment for SaaS-type technology services:

- Packaged Payment under a Single Code (G-code): Under this approach, the OPPS would not recognize either the standalone or the add-on codes describing SaaS procedures. Instead, all associated imaging and the SaaS would be described by a single HCPCS code, which could be assigned to a relevant clinical APC.
- Composite APCs: Providing a single payment for groups of services that are performed together, including the diagnostic imaging and SaaS procedure, during a single clinical encounter to result in the provision of a complete service.
- New Technology APCs: Use a HCPCS code (i.e., G- or C- codes) to describe both the diagnostic imaging and the SaaS procedure, and then assign the code that describes the combined services to New Technology APCs that would pay for both services.

The proposed rule also raises concerns about bias in software algorithms that have the potential to disparately affect the health of certain populations. CMS requests comments on how to prevent and mitigate bias in algorithms and predictive modeling.

H. Payment Adjustments: Domestic NIOSH-Approved Surgical N95 Respirator Masks

1. Introduction and Overview

CMS requested public comments on this issue in the FY 2023 IPPS proposed rule. Executive Order (E.O.) 13987 launched a whole-of-government approach to combat COVID-19 and prepare for future biological and pandemic threats. Pursuant to E.O. 13987, CMS is interested in ensuring the availability of domestically manufactured National Institute for Occupational Safety and Health (NIOSH) approved N95 surgical masks. The rule indicates that these masks are critical to controlling the spread of respiratory diseases like COVID-19 in current and future pandemics.

In the IPPS proposed rule, CMS indicated that it is considering IPPS and OPPS adjustments consistent with the policy goal of making sufficient supplies of NIOSH approved domestically manufactured N95 masks. CMS requested public comments on how to make such an adjustment—either through a per claim add-on payment or a biweekly interim lump-sum payment that would be reconciled at cost report settlement that accounts for the marginal difference in costs between NIOSH-approved surgical N95 respirators that were wholly domestically made and those that were not.

2. Public Comments and Proposal

Public comments on the IPPS rule supported an approach of CMS making biweekly interim lump-sum payments that would be reconciled at cost report settlement, although some commenters preferred a claims-based approach. Many commenters urged CMS to minimize the administrative burden on hospitals in the development of any N95 payment policy. MedPAC and

others stated that Medicare payment policy is not the most appropriate mechanism to support domestic manufacturing of medical supplies.

CMS proposes to make a payment adjustment under the OPPS and IPPS for the additional resource costs that hospitals face in procuring domestic NIOSH-approved surgical N95 respirators for cost reporting periods beginning on or after January 1, 2023. For the IPPS, the Secretary would make the adjustment under section 1886(d)(5)(I) of the Act, which specifically authorizes the Secretary to provide by regulation for such other exceptions and adjustments to the payment amounts under section 1886(d) of the Act as the Secretary deems appropriate. For the OPPS, the Secretary would make the adjustment under section 1833(t)(2)(E) of the Act, which authorizes the Secretary to establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments.

3. Proposed Definition of Domestic NIOSH-approved Surgical N95 Respirators

For purposes of this policy, CMS proposes to categorize all NIOSH-approved surgical N95 respirators purchased by hospitals into two categories: (1) Domestic NIOSH-approved surgical N95 respirators; and (2) Non-domestic NIOSH-approved surgical N95 respirators. CMS proposes to define "domestic NIOSH-approved surgical N95 respirators" as those where the respirator and all of its components are grown, reprocessed, reused, or produced in the United States. This definition is based on the Berry Amendment.[25] CMS proposes that a hospital may rely on a written statement from the manufacturer stating that the NIOSH-approved surgical N95 respirator the hospital purchased is domestic under the proposed definition. The rule provides a variety of options for who at the manufacturer could provide this certification and also that the certification could be on the product packaging or obtained through a group purchasing organization.

4. Proposed Payment Adjustment

CMS proposes to initially base the payment adjustments on the IPPS and OPPS shares of the estimated difference in the reasonable costs of a hospital to purchase domestic NIOSH-approved surgical N95 respirators compared to non-domestic NIOSH-approved surgical N95 respirators effective for cost reporting period beginning on or after January 1, 2023. These payments would be provided biweekly as interim lump-sum payments to the hospital and would be reconciled at cost report settlement.

In general, interim payments are determined by estimating the reimbursable amount for the year using Medicare principles of cost reimbursement and dividing it into twenty-six equal biweekly payments. The estimated amount is based on the most current cost data available, which will be reviewed and, if necessary, adjusted at least twice during the reporting period. (See CMS Pub 15-1 2405.2 for additional information.) The MACs would determine the interim lump-sum payments based on information that hospitals provide on a new supplemental cost reporting form. In future years, if finalized, the MACs would determine the interim biweekly lump-sum

[25] The Berry Amendment is a statutory requirement that restricts the Department of Defense (DoD) from using funds available to DoD for procurement of food, clothing, fabrics, fibers, yarns, other made-up textiles, and hand or measuring tools that are not grown, reprocessed, reused, or produced in the United States.

payments utilizing information from the prior year's surgical N95 supplemental cost reporting form, which may be adjusted based on the most current data available.

5. Proposed Calculation of the OPPS and IPPS Payment Adjustments on the Cost Report

In order to calculate the N95 payment adjustment for each eligible cost reporting period, CMS proposes to create a new supplemental cost reporting form. CMS indicates the estimated burden associated with the information collection requirements are based on recordkeeping requirements for the cost report at current 42 CFR § 413.20, which require providers of services to maintain sufficient financial records and statistical data for proper determination of costs payable by Medicare. The burden associated with this proposal would be the time and effort necessary to report the quantity and aggregate costs of domestic NIOSH-approved surgical N95 respirators and non-domestic NIOSH-approved surgical N95 respirators purchased by hospital for the period. CMS does not quantify the information collection requirement costs.

CMS proposes a five-step process for collecting information to determine the additional reasonable cost payment as summarized below:

1. Hospitals will separately report total quantity and aggregate cost for domestic NIOSH-approved respirators and non-domestic NIOSH-approved surgical N95 respirators.
2. Determine the differential costs between domestic NIOSH-approved and non-domestic NIOSH-approved surgical N95 respirators by first determining the hospital-specific unit cost (total cost divided by quantity). The cost difference equals the unit cost for domestic NIOSH-approved surgical N95 respirators less the unit costs for non-domestic NIOSH-approved surgical N95 respirators.
3. The aggregate differential costs is product of the unit cost difference and the quantity of NIOSH-approved surgical N95 respirators purchased.
4. Calculate IPPS and OPPS cost shares separately using information reported on other worksheets of the Medicare cost report as explained in more detail in the proposed rule.
5. Determine the IPPS and OPPS payment adjustment separately as the product of each's cost share and aggregate differential costs.

CMS provides a detailed hypothetical example of how this calculation would work in Table 50 of the proposed rule.

6. Budget Neutrality

To further support the strategic policy goal of maintaining the supply of NIOSH-approved surgical N95 respirators, CMS is not proposing to make the IPPS payment adjustment budget neutral. However, section 1833(t)(2)(E) of the Act that applies to OPPS payments provides that the Secretary shall establish adjustments necessary to ensure equitable payments in a budget neutral manner.

CMS indicates there is limited information available to determine a budget neutrality adjustment under the OPPS for the NIOSH-approved surgical N95 masks policy. To determine its estimate, CMS assumes that one surgical respirator mask is used per OPPS encounter or 103.4 million units for 2023. Based on available data, CMS estimates the difference in the average unit cost of domestic NIOSH-approved surgical N95 respirators and other masks is $0.20. CMS estimates that 40 percent of masks used will be domestic NIOSH-approved in the outpatient setting. Total OPPS costs are estimated at $8.3 million (103.4 million claims X $0.20 X 40 percent) requiring an adjustment of 0.9999 (-0.01 percent).

7. Future Policy

CMS may revisit its proposed approach to these payment adjustments as it gains more experience with the policy. Examples for future policy changes include basing the payment adjustment on a national differential in costs between the different types of surgical masks; making the interim payments as a claims-based add-on payment; establishing a national minimum average cost for non-domestic NIOSH-approved surgical N95 respirators if a hospital that only uses domestic NIOSH-approved surgical N95 respirators or has unusually low average costs for its non-domestic NIOSH-approved surgical respirators; and expanding the policy to include other protective supplies such as gowns and gloves.

I. Exempting Rural SCHs from Clinic Visit Office-Campus Payment Limitation

Since 2019, CMS has been paying a physician fee schedule (PFS) equivalent rate for a clinic visit provided in an off-campus provider-based department (PBD). The PFS equivalent rate was implemented over a 2-year transition period at 70 percent of the full OPPS rate in 2019 and 40 percent of the full OPPS rate in 2020. The reduction in payment applies to a clinic visit irrespective of whether the off-campus PBD is new after November 2, 2015 and subject to a PFS-equivalent rate for all of their services (a non-excepted off-campus PBD) or excepted from the reduction as a result of being in operation as November 2, 2015 (an excepted off-campus PBD).

CMS previously sought public comment on whether there should be exceptions from this policy for rural providers, such as those providers that are at risk of hospital closure or those providers that are rural SCHs. While commenters supported an exception for safety net hospitals and rural providers, CMS felt that the two-year phase in of the policy would help mitigate the financial concerns for these types of hospitals.

Since this policy was implemented, CMS has continued to assess how this policy has been implemented, and how it affects both the Medicare program itself and the beneficiaries it serves. This policy was designed to address an increase in total utilization as CMS observed a shift in utilization of clinic visits from physician offices to off-campus provider-based departments because of higher payments under the OPPS. Nonetheless, CMS recognizes that the volume of clinic visits furnished in off-campus PBDs of certain hospital types may primarily be driven by

factors other than higher payment, such as service shifts from the inpatient hospital to outpatient hospital setting and access issues.

CMS notes that there are a number of special payment provisions designed to maintain access to care in rural hospitals. Since 2006, rural SCHs have received a special 7.1 percent increase in payment for all services and procedures to compensate them for their higher costs relative to other hospitals paid under the OPPS. Rural SCHs have also been exempt from CMS' policy to adjust payment for drugs and biologicals acquired under the 340B program from ASP+6 percent to ASP-22.5 percent.

The proposed rule indicates that many rural providers, and rural SCHs in particular, are often the only source of care in their communities, which means beneficiaries and providers are not choosing between a higher paying off-campus PBD of a hospital and a lower paying physicians' office setting. The closure of inpatient departments of hospitals and the shortage of primary care providers in rural areas further drives utilization to off-campus PBDs in areas where rural SCHs are located. For these and other reasons, CMS believes that exempting rural SCHs from being paid a PFS-equivalent rate for a clinic visit in an off-campus PBD would help to maintain access to care in rural areas.

Accordingly, beginning in 2023, CMS proposes rural SCH will be excepted from being paid the PFS-equivalent rate in an excepted off-campus PBD. CMS is further soliciting comments on whether it would be appropriate to exempt other rural hospitals, such as those with under 100 beds from this policy. Excepting rural SCHs from this policy would result in an unadjusted payment for a clinic visit (G0463) in 2023 of approximately $131, with an approximate average copayment of $26 for the beneficiary. This compares to a proposed PFS-equivalent rate of $52, with an approximate average copayment of $10.

CMS estimates that exempting rural SCHs from this policy would increase OPPS spending by approximately $75 million in 2023.

XI. OPPS Payment Status and Comment Indicators

OPPS Payment Status Indicator Definitions

Each status indicator will identify whether a given code is payable under the OPPS or another payment system, and also the particular OPPS policies that apply to the code. The 2023 payment status indicator assignments for APCs and HCPCS codes are shown in Addenda A and B respectively. The complete list of proposed 2023 payment status indicators and their definitions are in Addendum D1.

For 2023, CMS proposes two changes to the status indicators:

- Revise the definition of status indicator "A" to include unclassified drugs and biologicals that are reportable under HCPCS code C9399 payable at 95 percent of AWP.
- Change the status indicator for hepatitis B vaccines from "F" to "L" so they are not subject to deductible and coinsurance.

Comment Indicator Definitions

For 2023, CMS is continuing to use the following comment indicators that are unchanged from 2022:

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

The definitions of the OPPS comment indicators for 2023 are listed in Addendum D2 of the proposed rule.

XII. Medicare Payment Advisory Commission (MedPAC) Recommendations

OPPS Update: In its March, 2022 "Report to Congress: Medicare Payment Policy," MedPAC recommended that Congress update Medicare OPPS payment rates in 2023 by the amount specified in current law. CMS is proposing to update OPPS rates consistent with current law.

ASC Update: MedPAC indicates that payments to ASCs are adequate and recommended no payment update. In 2019, CMS adopted a policy to use the hospital market basket to update ASC rates for five years in place of the CPI-U. Therefore, CMS is proposing to update ASC rates consistent with the its approach for updating hospital inpatient and outpatient services or at 2.7 percent (3.1 percent less 0.4 percent for TFP).

ASC Cost Data: MedPAC has recommended for many years that Congress require ASCs to report cost data to enable the Commission to examine the growth of ASCs' costs over time and analyze Medicare payments relative to the costs of efficient providers. While CMS acknowledges ASC cost data would be beneficial in establishing an ASC-specific market basket index for updating payment rates, CMS is not making any proposals at this time.

XIII. Ambulatory Surgical Center (ASC) Payment System

Summary of Selected Key Elements of ASC Payment Rates for 2023		
	ASCs reporting quality data	**ASCs not reporting quality data**
2022 ASC Conversion Factor	$49.916	
Wage index budget neutrality adjustment	1.0010	
2023 Update		
Hospital market basket update	3.1%	
Productivity adjustment	-0.4%	
Net MFP adjusted update	2.7%	
Penalty for not reporting quality data	0.0%	-2.0%
Net MFP and quality adjusted update	2.7%	0.7%
2023 Proposed ASC Conversion Factor	$51.315	$50.315

CMS estimates that under the proposed rule, total ASC Medicare payments for 2023 will be approximately $5.4 billion, an increase of $130 million compared with 2022 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-1772-p

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.

In the 2021 OPPS final rule, CMS significantly revised its policy for adding surgical procedures to the ASC Covered Procedures List (CPL) greatly expanding the number of surgical procedures that could be performed in the ASC setting. Specifically, CMS revised the ASC-CPL criteria

under 42 CFR 416.166, retaining the general standard criteria and eliminating five of the general exclusion criteria. In the 2022 OPPS final rule, CMS reinstated the general standards and exclusion criteria at §416.166 that were in place prior to 2021 and removed the added 2021 codes from the ASC CPL.

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

Comment and Finalization Timeframes for New and Revised HCPCS Codes				
ASC Quarterly Update CR	**Type of Code**	**Effective Date**	**Comments Sought**	**When Finalized**
April 2022	HCPCS (CPT and Level II codes)	April 1, 2022	2023 OPPS/ASC proposed rule	2023 OPPS/ASC final rule with comment period
July 2022	HCPCS (CPT and Level II codes)	July 1, 2022		
October 2022	HCPCS (CPT and Level II codes)	October 1, 2022	2023 OPPS/ASC final rule with comment period	2024 OPPS/ASC final rule with comment period
January 2023	CPT Codes	January 1, 2023	2023 OPPS/ASC proposed rule	2023 OPPS/ASC final rule with comment period
	Level II HCPCS Codes		2023 OPPS/ASC final rule with comment period	2024 OPPS/ASC final rule with comment period

April and July 2022 Codes - CMS Solicits Public Comments in this Proposed Rule

In the April 2022 ASC quarterly update, CMS states it made effective 19 new Level II HCPCS codes and no new CPT codes. Table 51 displays the codes and descriptors. In the July 2022 ASC quarterly update, CMS added 19 separately payable Level II HCPCS codes and 3 CPT codes to the list of covered surgical procedures and ancillary services. Tables 52 and 53 lists the codes and descriptors.

CMS notes that the proposed payment indicators, comments indicators, and 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 below. CMS does not display the proposed payment and comment indicators in the proposed rules referenced above as it has done in the past.

October 2022 and January 2023 HCPCS Codes - CMS Will Be Soliciting Public Comments in the 2023 Final Rule with Comment Period

CMS proposes to continue to assign comment indicator "NI" in Addendum BB to the 2023 OPPS/ASC final rule for those new and revised Level II HCPCS codes that are effective October 1, 2022. This indicates that CMS has assigned the codes an interim OPPS payment status for 2022. CMS will invite comments in the 2023 OPPS/ASC final rule with comment period on the interim payment indicators which will then be finalized in the 2024 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, 2023 that were received in time to be included in this proposed rule. They will be finalized in the 2023 OPPS/ASC final rule with comment period. Most Level II HCPCS codes are not released until sometime around November to be effective January 1. These Level II HCPCS codes will be released to the public through the 2023 OPPS/ASC final rule with comment period. These will be finalized in the 2024 OPPS/ASC final rule with comment period.

For the 2023 ASC update, the new and revised codes can be found in Addenda 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

Given its concerns with 2020 claims data as a result of the PHE, CMS did not assign permanent office-based designations for 2022 to any covered surgical procedure currently assigned a payment indicator of "G2". For this proposed rule, CMS proposes to resume its historical practice and review the most recent claims and utilization data (2021 claims in this case) for determining office-based assignments under the ASC payment system.

Based on its review of the 2021 volume and utilization data of covered surgical procedures, CMS identified 6 CPT/HCPCS codes that it proposes to permanently designate as office-based for 2023 (listed in Table 55 in the proposed rule). These procedures are performed more than 50 percent of the time in physicians' offices and CMS believes are of a level of complexity consistent with other procedures performed routinely in physicians' offices. Codes on this list include 0101T, 0446T, 15275, 21198, 31574, and 40830.

CMS proposes to continue to designate 8 procedures as temporarily office-based for 2023 (see Table 56 in proposed rule). Each of these procedures had less than 50 claims or no claims in its

data. For 2023, there are no new 2023 CPT codes for ASC covered surgical procedures that have been temporarily assigned office-based.

Proposed Device-Intensive ASC Covered Surgical Procedures

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.

For 2022 and subsequent years, CMS modified its approach to assigning device-intensive status to surgical procedures under the ASC payment system. First, it assigns device-intensive status to procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as
device-intensive procedures if their device offset percentage exceeds 30 percent under the ASC standard ratesetting methodology, even if the procedure is not designated as device-intensive under the OPPS. In addition, CMS also will assign device-intensive status under the ASC payment system with a default device offset percentage of 31 percent if a procedure is assigned device-intensive status under the OPPS, but has a device offset percentage below the device-intensive threshold under the standard ASC ratesetting methodology.

As discussed more below, CMS proposes to create a special payment policy under the ASC system whereby it would add 52 new C codes to the ASC CPL to provide a special payment for code combinations eligible for complexity adjustments. Under its proposal, the C code would retain the device-intensive status of the primary procedure as well as the device portion of the primary procedure and not the device offset percentage. The C-code device offset percentage would be established by dividing the device portion of the primary procedure by the OPPS complexity-adjusted APC payment rate based on the ASC standard ratesetting methodology.

The ASC covered surgical procedures that CMS proposes to designate as device-intensive, and therefore subject to the device-intensive procedure payment methodology for 2023, are assigned payment indicator "J8" and are included in ASC Addendum AA to the proposed rule. There are 491 codes in this proposed rule that are assigned the "J8" payment indicator. This includes its proposal to assign device-intensive status to 11 of the new C codes that it proposes to add to the ASC CPL as well as its methodology for determining the device portion for such procedures.

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 reduces the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device.

Proposed Additions to the List of ASC Covered Surgical Procedures for 2022

Under its regulations, covered surgical procedures furnished on or after January 1, 2022, are surgical procedures that meet the general standards (as specified at §416.166(b)) and do not meet the general exclusions (at §416.166(c)). These general standards and exclusion criteria are detailed below.

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.

Based on its review of procedures currently paid under the OPPS and not included on the ASC CPL, CMS proposes to update the ASC CPL by adding one lymphatic procedure to the list for 2023. Specifically, this procedure is CPT code 38531 – Biopsy or excision of lymph node(s); open, inguinofemoral node(s). CMS states that the procedure meets its general standard and exclusion criteria. CMS states that it will continue to gradually expand the ASC CPL as medical practice and technology continue to evolve and advance in future years. **CMS seeks comment on its proposed addition to the ASC CPL.**

Proposed Name Change and Start Date of Nominations Process

CMS explains that the terminology it used in the 2022 OPPS/ASC final rule with comment period and codified at §416.166(d) – "Nominations" – may have led to some confusion that this process is the primary or only pathway for interested parties to suggest procedures to be added to the ASC CPL. To eliminate this confusion, CMS proposes to change the name of the process finalized last year in the 2022 OPPS/ASC final rule with comment period from "Nominations" to the "Pre-Proposed Rule CPL Recommendation Process."

In addition, CMS notes that it is currently working on developing the technological infrastructure and Paperwork Reduction Act (PRA) package for the recommendations process. This is taking longer than anticipated. Thus, CMS proposes to revise the start date of the recommendation process in the regulatory text from January 1, 2023, to January 1, 2024, so that the text at §416.166(d) would specify that on or after January 1, 2024, an external party may recommend a surgical procedure by March 1 of a calendar year for the list of ASC covered surgical procedures for the following calendar year. CMS states that it continues to welcome all procedure submissions through the public comment process, as it has in previous years.

D. Payment Update: Covered Surgical Procedures and Ancillary Services List

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 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 2023 PFS non-facility practice expense payment amount, or the 2023 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 ASC Payment for Combinations of Primary and Add-On Procedures Eligible for Complexity Adjustments under the OPPS

In this section, CMS proposes a policy to provide increased payment under the ASC payment system for combinations of certain "J1" service codes and add-on procedure codes that are eligible for a complexity adjustment under the OPPS.

Background

CMS reviews how complexity adjustments are utilized to provide increased payment for certain comprehensive services under the OPPS. It applies a complexity adjustment by promoting qualifying paired "J1" service code combinations or paired code combinations of "J1" services and add-on codes from the originating C-APC. It packages payment for all add-on codes, but certain combinations of primary service codes and add-on codes may qualify for a complexity adjustment. CMS applies a complexity adjustment when the paired code combination represents a complex, costly form or version of the primary service when the frequency and cost thresholds are met. The frequency threshold is met when there are 25 or more claims reporting the code combination, and the cost threshold is met when there is a violation of the 2 times rule. CMS promotes these claims to the next higher cost C-APC within the clinical family unless the primary service is already assigned to the highest cost APC within the C-APC clinical family or assigned to the only C-APC in a clinical family. It does not create new C-APCs just to accommodate potential complexity adjustments.

CMS notes that comprehensive APCs cannot be adopted in the ASC payment system due to limitations of the ASC claims processing systems. There is not a process similar to the OPPS complexity adjustment policy in the ASC payment system to provide higher payment for more complex code combinations. In the ASC payment system, a 50-percent reduction for the lower-paying procedure is applied when multiple procedures are performed in a single operative session. Add-on procedure codes are not separately payable under the ASC payment system and are always packaged into the ASC payment rate for the procedure. Providers do not receive any additional payment when they perform a primary service with an add-on code in the ASC payment system.

For 2023 rulemaking, CMS evaluated the differences in payment in the OPPS and ASC settings for code pairs that included a primary procedure and add-on codes that were eligible for complexity adjustments under the OPPS and also performed in the ASC setting. Under the ASC payment system, it identified 26 packaged procedures (payment indicator = "N1") that combine with 42 primary procedures, which would be C-APCs (status indicator = "J1") under the OPPS, to produce 52 different complexity adjustment code combinations. It found that ASC services were paid approximately 55 percent of the OPPS rate for similar services in 2021, but for these code combinations it was only 25 to 35 percent of the OPPS rate.

CMS recognizes that this differential could potentially create financial disincentives for providers to offer these services in the ASC setting, which could negatively affect access to these services in ASC setting for Medicare beneficiaries.

Complexity Proposal

To address this issue, CMS proposes a new ASC payment policy that would apply to certain code combinations in the ASC payment system where CMS would pay for those code combinations at a higher payment rate to reflect that the code combination is a more complex and costlier version of the procedure performed. CMS proposes to add new §416.172(h) to codify this policy.

Specifically, CMS proposes that the ASC payment system code combinations eligible for additional payment under this proposed policy would consist of a separately payable surgical procedure code and one or more packaged add-on codes from the ASC CPL and ancillary services list. Add-on codes are assigned payment indicator "N1" (Packaged service/item; no separate payment made), as listed in the ASC addenda. It proposes that it would assign each eligible code combination a new C code that describes the primary and the add-on procedure(s) performed. C codes are unique temporary codes and are only valid for HOPD and ASC services and procedures. Under its proposal, CMS would add these C codes to the ASC CPL and the ancillary services list, and when billed, they would receive a higher payment rate that reflects that the code combination is a more complex and costlier version of the procedure performed.

CMS anticipates that the C codes eligible for this proposed payment policy would change slightly each year, as the complexity adjustment assignments change under the OPPS and CMS expects it would add new C codes each year accordingly. CMS proposes to add 52 new C codes to the ASC CPL. These proposed C codes for 2023 can be found in the ASC addenda (and are listed below). It proposes to add new §416.172(h)(1), titled Eligibility, to codify this policy.

Proposed C-Codes for 2023 – Combinations of Primary Procedure Code and Add-on Codes that are Eligible for a Complexity Adjustment

HCPCS Code	Short Descriptor	Proposed 2023 Payment Weight	Proposed 2023 Payment Rate
CXXX1	Deb bone 20 cm2 w/drug dev	20.2012	$1,036.62
CXXX2	Perc bx breast lesions stero	20.2012	$1,036.62
CXXX3	Perc bx breast lesions MR	20.2012	$1,036.62
CXXX4	Open exc cerv node(s) w/ id	45.5833	$2,339.11
CXXX5	Perq cvt&ls inj vert bodies	59.8164	$3,069.48
CXXX6	Perq ls&cvt inj vert bodies	59.8164	$3,069.48
CXXX7	Fusion of finger joints	59.8164	$3,069.48
CXXX8	Perq thor&lumb vert aug	122.7286	$6,297.82
CXXX9	Perq lumb&thor vert aug	122.7286	$6,297.82
CXX10	Dx bronch w/ navigation	27.0266	$1,386.87
CXX11	Bronch/lavag w/ navigation	27.0266	$1,386.87
CXX12	Bronch/bpsy(s) w/ navigation	27.0266	$1,386.87
CXX13	Bronch/bpsy(s) w/ ebus	27.0266	$1,386.87
CXX14	Cath/angio dialcir w/aplasty	27.5718	$1,414.85
CXX15	Cath/angio dial cir w/stents	27.5718	$1,414.85
CXX16	Cath/angio dial cir w/embol	27.5718	$1,414.85
CXX17	Cor angio w/ ivus or oct	44.4505	$2,280.98
CXX18	Cor angio w/ilic/fem angio	44.4505	$2,280.98
CXX19	Cor/gft angio w/ ivus or oct	44.4505	$2,280.98
CXX20	Cor/gft angio w/ flow resrv	44.4505	$2,280.98

HCPCS Code	Short Descriptor	Proposed 2023 Payment Weight	Proposed 2023 Payment Rate
CXX21	Cor/gft angio w/ilic/fem ang	44.4505	$2,280.98
CXX22	R hrt angio w/ ivus or oct	44.4505	$2,280.98
CXX23	R hrt angio w/flow resrv	44.4505	$2,280.98
CXX24	L hrt angio w/ ivus or oct	44.4505	$2,280.98
CXX25	L hrt angio w/flow resrv	44.4505	$2,280.98
CXX26	L hrt gft ang w/ ivus or oct	44.4505	$2,280.98
CXX27	L hrt gft ang w/flow resrv	44.4505	$2,280.98
CXX28	R&L hrt angio w/ ivus or oct	44.4505	$2,280.98
CXX29	R&L hrt angio w/flow resrv	44.4505	$2,280.98
CXX30	R&L hrt gft ang w/flow resrv	44.4505	$2,280.98
CXX31	Cath/aplasty dial cir w/stnt	87.2991	$4,479.75
CXX32	Angio fem/pop w/ us	105.9692	$5,437.81
CXX33	Angio w/ us non-coronary	102.0918	$5,238.84
CXX34	PTCA w/ plcmt brachytx dev	107.0005	$5,490.73
CXX35	Fem/pop revasc w/arthr & us	196.4272	$10,079.66
CXX36	Fem/pop revasc w/stent & us	194.6191	$9,986.88
CXX37	Opn/perq stents veins	183.5093	$9,416.78
CXX38	Insrt atril pm w/L vent lead	196.7288	$10,095.14
CXX39	Insrt vent pm w/L vent lead	197.2946	$10,124.17
CXX40	Insrt a & v pm w/L vent lead	200.9395	$10,311.21
CXX41	Rmv&rplc pm dul w/L vnt lead	197.3224	$10,125.60
CXX42	ERCP w/ pancreatoscopy	43.3515	$2,224.58
CXX43	ERCP w/bx & pancreatoscopy	43.3515	$2,224.58
CXX44	ERCP w/otomy, pancreatoscopy	43.3515	$2,224.58
CXX45	ERCP rmv calc pancreatoscopy	43.3515	$2,224.58
CXX46	Exch bil cath w/ rmv calculi	43.3515	$2,224.58
CXX47	Rep nph/urt cath w/dil stric	28.5996	$1,467.59
CXX48	Cnvrt neph cath w/ dil stric	33.4573	$1,716.86
CXX49	Exch neph cath w/ dil stric	28.5996	$1,467.59
CXX50	Chge urtr stent w/ dil stric	28.5996	$1,467.59
CXX51	Cysto w/ bx(s) w/ blue light	28.5996	$1,467.59
CXX52	Exc neuroma w/ implnt nv end	50.7074	$2,602.05

Payment Methodology for C Codes

CMS proposes the following payment methodology, which it would reflect in new §416.172(h)(2), titled "Calculation of Payment."

CMS proposes that the C codes would be subject to all ASC payment policies, including the standard ASC payment system ratesetting methodology. For example, the multiple procedure discounting rules would apply to the primary procedure in cases where the services corresponding to the C code are performed with another separately payable covered surgical procedure in the ASC setting. It proposes to use the OPPS complexity-adjusted C-APC rate to determine the ASC payment rate for qualifying code combinations (similar to how it uses OPPS APC relative weights in the standard ASC payment system ratesetting methodology).

CMS proposes to use the OPPS complexity-adjusted C-APC rate for each corresponding code combination to calculate the OPPS relative weight for each corresponding ASC payment system C code. For C codes that are not assigned device-intensive status (discussed below), it would multiply the OPPS relative weight by the ASC budget neutrality adjustment (or ASC weight scaler) to determine the ASC relative weight. It would then multiply the ASC relative weight by the ASC conversion factor to determine the ASC payment rate for each C code. In short, it would apply the standard ASC ratesetting process to the C codes. It proposes to add new §416.172(h)(2(i) to codify this policy.

For primary procedures assigned device-intensive status and that are a component of a C code created under this proposal, CMS believes it would be appropriate for the C code to retain the device-intensive status of the primary procedure as well as the device portion (or device offset amount) of the primary procedure and not the device offset percentage. For example, if the primary procedure had a device offset percentage of 31 percent (a proposed device offset percentage of greater than 30 percent would be needed to qualify for device intensive status) and a device portion (or device offset amount) of $3,000, C codes that included this primary procedure would be assigned device-intensive status and a device portion of $3,000 to be held constant with the OPPS. It would apply its standard ASC payment system ratesetting methodology to the non-device portion of the OPPS complexity-adjusted APC rate of the C codes. This may yield results where the device offset percentage is not greater than 30 percent of the OPPS complexity-adjusted APC payment rate. As is the case for all device-intensive procedures, it would apply the ASC standard ratesetting methodology to the OPPS relative weights of the non-device portion for any C code eligible for payment under this proposal. That is, CMS would multiply the OPPS relative weight by the ASC budget neutrality adjustment and the ASC conversion factor and sum that amount with the device portion to calculate the ASC payment rate. It proposes to add new §416.172(h)(2)(ii) to codify this policy.

For its budget neutrality calculations, CMS proposes to estimate the potential utilization for these C codes. It does not have claims data for packaged codes in the ASC setting because ASCs do not report packaged codes. Therefore, it proposes to estimate 2023 ASC utilization based upon how often these combinations are performed in the HOPD setting. Specifically, it would use the ratio of the primary procedure volume to add-on procedure volume from 2021 OPPS claims and apply that ratio against ASC primary procedure utilization to estimate the increased spending. It anticipates that it would continue this estimation process until it has sufficient claims data for the C codes that can be used to calculate code combination utilization more accurately in ASCs, likely for the 2025 rulemaking.

CMS welcomes comments on this proposal, including comments or suggestions regarding additional approaches that it should consider for this policy.

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

In the 2022 OPPS/ASC final rule, CMS adopted a universal low volume APC policy for 2022 and subsequent calendar years. Under its policy a clinical APC, brachytherapy APC, or new technology APC with fewer than 100 claims per year would be designated as a low volume APC. For those items and services, CMS will use up to 4 years of claims data to establish a payment rate for each item or service as it currently does for low volume services assigned to New Technology APCs. The payment rate for a low volume APC would be based on the highest of the median cost, arithmetic mean cost, or geometric mean cost calculated using multiple years of claims data.

Based on its analysis of claims data, CMS proposes to designate 4 brachytherapy APCs and 4 clinical APCs as Low Volume APCs under the ASC payment system. These meet its criteria and the APC cost metric would be based on the greater of the median cost, arithmetic mean cost, or geometric mean cost using up to 4 years of claims data. Table 58 in the proposed rule compares the cost statistics and indicates the proposed 2023 APC cost for these 8 APCs.

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 also proposes to continue to set the 2023 ASC payment rates and subsequent year payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for 2023 and subsequent year payment rates. For those covered ancillary services where the payment rate is the lower of the rate under the ASC standard rate setting methodology and the PFS proposed rates, the proposed payment indicators and rates are based on a comparison using the proposed PFS rates effective January 1, 2023.

CMS reminds readers of a proposal in the 2023 Physician Fee Schedule (PFS) proposed rule that has implications for HOPDs and ASCs. Section 90004 of the Infrastructure Investment and Jobs Act amended section 1847A of the Act and requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. Specifically, CMS proposes in the 2023 PFS proposed rule that the JW modifier would be used to determine the total number of billing units of the HCPCS code (that is, the identifiable quantity associated with a HCPCS code, as established by CMS) of a refundable single-dose container or single-use package drug, if any, that were discarded for dates of service during a relevant quarter for the purpose of calculating the refund amount. The 2023 PFS proposed rule also proposes to require HOPDs and ASCs to use a separate modifier, JZ, in cases where no billing units of such drugs were discarded and for which the JW modifier would be required if there were discarded amounts.

CMS notes that comments on these proposals should be done in response to the 2023 PFS proposed rule. Comments will be addressed in the 2023 PFS final rule.

Under a 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. For

2022, CMS finalized a policy to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under §416.174. CMS determined that four products were eligible for separate payment in the ASC setting under its final rule policy in 2022 (products listed in Table 59 in the rule).

Eligibility Criteria Technical Clarification and Proposed Regulation text Changes Regarding Pass-Through Status and Separately Payable Status

CMS clarifies and proposes regulation text changes regarding pass-through status and separately payable status with respect to non-opioid pain management drugs and biologicals that function as a supply. In the 2022 OPPS/ASC final rule with comment period, CMS finalized a policy that non-opioid pain management drugs and biologicals that function as supplies in surgical procedures that are already paid separately, including through transitional drug pass-through status under the OPPS, are not eligible for separate payment under §416.174. CMS notes that it established this policy but did not reflect it in regulation text.

CMS proposes now to clarify its policy by codifying the two additional criteria for separate payment for non-opioid pain management drugs and biologicals that function as surgical supplies in the regulatory text at §416.174 as a technical change. First, CMS proposes to provide at new §416.174(a)(3) that nonopioid pain management drugs or biologicals that function as a supply in a surgical procedure are eligible for separate payment if the drug or biological does not have transitional pass-through payment status under §419.64. If the transitional pass-through status expires during the calendar year, the drug or biological would qualify for separate payment on the first day of the next calendar year quarter after its pass-through status expires. Second, CMS proposes that new §416.174(a)(4) would reflect that the drug or biological must not already be separately payable in the OPPS or ASC payment system under a policy other than the one specified in §416.174.

Proposed 2023 Qualification Evaluation for Separate Payment of Non-Opioid Pain Management Drugs and Biologicals that Function as a Surgical Supply

As noted above, CMS finalized a policy to unpackage and pay separately at ASP+6 percent for non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting, are FDA approved, have an FDA-approved indication for pain management or as an analgesic, and have a per-day cost above the OPPS drug packaging threshold beginning on or after January 1, 2022. For 2023, the OPPS drug packaging threshold is proposed to be $135.

CMS discusses the evaluation of whether certain non-opioid alternatives meet the criteria established at §416.174. It re-evaluated the four non-opioid pain management drugs and biologicals that received separate payment in the ASC setting for 2022 to determine whether they continue to qualify for separate payment in 2023. Based on its evaluation CMS proposes that the drugs described by HCPCS codes C9290 (i.e., Exparel), J1097 (i.e., Omidria), and C9089 (i.e., Xaracoll) continue to meet the required criteria and should receive separate payment in the ASC setting. It proposes that the drug described by HCPCS code C9088 (i.e., Zynrelef) would not receive separate payment in the ASC setting under this policy as this drug will be separately

payable during 2023 under OPPS transitional pass-through status. More details on its evaluations can be found in the proposed rule.

CMS also evaluated drugs or biologicals that it believes may be newly eligible for separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply against the criteria described at §416.174(a). It evaluated whether Dextenza, described by HCPCS code J1096 (Dexamethasone, lacrimal ophthalmic insert, 0.1 mg), a drug with pass-through status expiring December 31, 2022, meets the criteria specified in §416.174. Based on its evaluation, CMS proposes that Dextenza receive separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply for 2023.

CMS welcomes stakeholder comment on its evaluations.

E. New Technology Intraocular Lenses (NTIOL)

CMS did not receive any requests for review to establish a new NTIOL class for 2023 by the annual deadline (March 1, 2022 due date, announced in last year's 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. Payment and Comment Indicators

Category I and III CPT codes that are new and revised for 2022 and any new and existing Level II HCPCS codes with substantial revisions were labeled with the proposed comment indicator "NP" to indicate that these codes are open for comment as part of the 2023 proposed rule.

Addenda DD1 and DD2 provide a complete list of the ASC payment and comment indicators for 2023.

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, the ASC conversion factor, and mix of services constant from 2021, CMS computes the ratio of:

- Total payments using the 2022 relative payment rates, to
- Total payments using the 2023 relative payment rates.

The 2023 total payments will also include spending and utilization related to the proposed new C codes for 52 primary procedures when performed with add-on packaged services. CMS estimates the additional spending to be approximately $5 million.

The resulting ratio, 0.8474, is the proposed weight scaler for 2023. 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). CMS proposes to use 2021 claims data to model its budget neutrality adjustment. 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 2021 and the 2023 national payment rates after application of the weight scaler, CMS computes the ratio of:

- ASC payments using the 2022 ASC wage indices, to
- ASC payments using the 2023 ASC wage indices.

The resulting ratio, 1.0010, is the proposed wage index budget neutrality adjustment to the conversion factor for 2022.

To update ASC rates, CMS would utilize the hospital market basket update of 3.1 percent minus the productivity adjustment of 0.4 percent. This yields an update of 2.7 percent for ASCs meeting quality reporting requirements. CMS would continue its policy of reducing the update by 2.0 percentage points for ASCs not meeting the quality reporting requirements, yielding an update of 0.7 percent for such ASCs. The resulting proposed 2022 ASC conversion factor is $51.315 for ASCs reporting quality data, and $50.315 for those that do not, computed as follows:

	ASCs reporting quality data	**ASCs not reporting quality data**
2022 ASC conversion factor	$49.916	
Wage adjustment for budget neutrality	x 1.0010	
Net MFP-adjusted update	x 1.027	x 1.007
2023 Proposed ASC conversion factor	$51.315	$50.315

Impact

CMS provides the estimated aggregate increases for the six specialty groups that account for the most ASC utilization and spending, assuming the same mix of services from the 2021 claims data. (Table 85 of the proposed rule and reproduced below.) The eye surgical specialty group remains the largest source of payments, with 1 percent increase in payments attributable to the changes proposed for 2023. The second largest group, nervous system, is estimated to see a 4 percent increase.

Table 85 – Estimated Impact of the Proposed 2023 Update to the ASC Payment System on Aggregate 2022 Medicare Program Payments by Surgical Specialty or Ancillary Items and Services Group		
Surgical Specialty Group	Estimated 2022 ASC Payments (in Millions)	Estimated 2023 Percent Change
Total	**$5,858**	**3%**
Eye	$1,789	1%
Nervous system	$1,200	4%
Musculoskeletal system	$999	6%
Gastrointestinal	$896	2%
Cardiovascular	$262	1%
Genitourinary system	$215	3%

CMS provides estimated increases for 30 selected procedures in Table 86 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 2 percent increase in payment. The second largest aggregate payment procedure, CPT code 63685, is expected to see a 3 percent increases. Total knee arthroplasty (new to the top 10 list) has $182 million in estimated 2022 ASC payments and is expected to increase by 4 percent.

Excerpt from Table 86: Estimated Impact of the 2023 Update to the ASC Payment System on Aggregate Payments for the Top 10 Procedures			
CPT/ HCPS Code	Short Descriptor	Estimated 2022 ASC Payments (in Millions)	Estimate 2023 Percent Change
66984	Xcapsl ctrc rmvl w/o ecp	$1,196	2
63685	Insrt/redo spine n generator	$300	3
45380	Colonoscopy and biopsy	$235	3
45385	Colonoscopy w/lesion removal	$191	3
27447	Total knee arthroplasty	$182	4
63650	Implant neuroelectrodes	$174	9
43239	Egd biopsy single/multiple	$160	1
64483	Njx aa&/strd tfrm epi 1/s 1	$106	2
66991	Xcapsl ctrc rmvl cplx insj 1+	$98	0
64590	Insrt/redo pn/gastr stimul	$95	7

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-1772-p. They include:

- AA – Proposed ASC Covered Surgical Procedures for 2023 (Including surgical procedures for which payment is packaged)
- BB – Proposed ASC Covered Ancillary Services Integral to Covered Surgical Procedures for 2023 (Including Ancillary Services for Which Payment is Packaged)
- DD1 – Proposed ASC Payment Indicators for 2023
- DD2 – Proposed ASC Comment Indicators for 2023

- EE – Surgical Procedures to be Excluded from Payment in ASCs for 2023
- FF – ASC Device Offset Percentages for 2023

XIV. Hospital Outpatient Quality Reporting (OQR) Program

CMS provides references to the legislative and regulatory histories of the OQR program. Section 1833(t)(17)(A) of the Act provides a 2.0 percentage point reduction in the annual Outpatient Department (OPD) fee schedule increase factor (Annual Payment Update, APU) for any subsection (d) hospital that does not submit data as required for the OQR program's measures.

CMS proposes to modify the reporting status of 1 measure, align the OQR program's encounter quarters for chart-abstracted measures to the calendar year, and add a targeting criterion for use in selecting hospitals for data validation. CMS generally seeks comment on all proposals. CMS also specifically requests comment on (1) the potential return of 1 procedural volume measure into the OQR program's measure set or adoption of a similar indicator for future use, and (2) measuring health care disparities through the OQR program.

No changes are proposed to previously finalized OQR program policies for measure selection, retention, and removal; data submission through the CMS web-based tool or the CDC National Healthcare Safety Network (NHSN) tool; data submission requirements for the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures (OP-37a-e); reporting and submission requirements for electronic clinical quality measures (eCQMs); population and sampling requirements; the review and corrections periods for chart-abstracted measures, eCQMs, and OAS-CAHPS; reconsideration and appeals procedures; public display of quality measures; processes for the maintenance of technical specifications for previously adopted OQR program measures; administrative requirements for participation in and withdrawal from the OQR program, and the ECE policy and process.

CMS posts lists of individual hospitals meeting or failing to meet OQR reporting requirements at https://qualitynet.cms.gov/outpatient/oqr/apu. For the CY 2022 payment determination, 3,268 of 3,298 hospitals (99%) met all reporting requirements including data submission, while 30 failed to do so. CAHs may choose but are not required to report OQR measures. For CY 2022, 1,291 of 1,354 (95%) CAHs reported data while 63 opted not to submit.

A table of the OQR program's measure set is provided later in this summary section. More information about the program can be found at https://qualitynet.cms.gov/outpatient and https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalOutpatientQualityReportingProgram.

A. OQR Program Quality Measures

1. Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31) (NQF #1536)

CMS proposes to change the reporting status of the measure *Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31) (NQF #1536)* from mandatory to voluntary beginning with the CY 2025 reporting period/CY 2027 payment determination and for subsequent years. The measure requires collection of visual function surveys from patients both preoperatively and postoperatively.

This measure has a lengthy and complex history and its reporting status has been changed multiple times as described by CMS in the rule. Most recently, during CY 2022 OPPS rulemaking, CMS finalized designating the measure as mandatory for reporting beginning with the CY 2025 reporting period/CY 2027 payment determination. Since that time, stakeholders have continued to voice concerns about the measure's reporting burden, particularly as the COVID-19 PHE continues. They cite medical staffing and supply shortages along with substantial fluctuations in patient case volumes as contributors to the perceived excessive reporting burden.

CMS acknowledges the concerns raised but also states its intention to revisit mandatory reporting of this measure after the PHE officially ends. CMS believes the OP-31 measure adds significant value to the OQR program's measure set by focusing on an area of care that is insufficiently addressed otherwise. The measure also is an outcome measure and isone that requires care coordination by practitioners across settings for satisfactory reporting, characteristics that CMS finds desirable. Finally, CMS notes that the measure has been consistently reported voluntarily up to the present time by some facilities and their data publicly displayed. CMS emphasizes that its status change proposal in this rule does not change the measure's voluntary status already finalized for CY 2023 and CY 2024 reporting.

CMS estimates a burden reduction of 97 hours and $4,519 per hospital if OP-31 is returned to voluntary reporting beginning with the CY 2025 reporting period/CY 2027 payment determination. CMS notes the decrease takes into account wage rate increases and a calculation error made during CY 2022 rulemaking. CMS estimates that no OQR burden changes or payment reduction impacts will occur as a result of the proposals to add a validation targeting criterion or alignment of patient encounter calendar quarters as described later in this summary.

2. Requests for Comment on Future Measures

a. Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures (OP-26)

CMS requests comments on the potential inclusion of a procedural volume measure in the Hospital OQR Program, to be accomplished either by (1) re-adopting the *Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP–26)* measure or (2) adopting another volume indicator. The agency also invites comments on what volume data hospitals currently collect and if it is feasible to submit those data to the OQR Program as an approach to

minimizing collection and reporting burden of a new volume measure. **CMS targets certain topic areas, listed below.**

- The usefulness of including a volume indicator in the Hospital OQR Program measure set and publicly reporting volume data.
- Input on the mechanism of volume data collection and submission, including anticipated barriers to data collection and submission and potential solutions.
- Considerations for designing a volume indicator to reduce collection burden and improve data accuracy.
- Potential reporting of volume by procedure type, instead of total surgical procedure volume data for select categories, and which procedures would benefit from volume reporting.
- The usefulness of Medicare versus non-Medicare reporting versus other or additional categories for reporting.

By way of background, CMS notes the continuing shift of a large number and wide range of procedur types whose performance has already shifted from the inpatient to outpatient setting (e.g., percutaneous coronary intervention, lower extremity total joint replacement). CMS believes that this trend supports the importance of tracking outpatient procedural volumes. CMS acknowledges that procedural volume may be associated with facility features that enhance outcomes (e.g., procedure-specific teams) and believes that such data would inform patients about a given facility's experience with various outpatient procedures. CMS further notes that an OQR program volume measure could generate useful data about the rapidly growing category of outpatient-based pain management procedures, which the agency is interested in tracking.

CMS describes the history of OP-26 in the OQR program; most recently the measure was removed during CY 2018 rulemaking due to lack of evidence linking better outcomes to this particular measure. If OP-26 were to be restored to the OQR program, the measure would need to go through the existing pre-rulemaking process as formal review by the Measure Applications Partnership (MAP) was not part of the required process for new measure adoption when OP-26 was first added to the OQR program's measure set. Any alternative to OP-26 would likewise be required to go through the process.

b. Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs

CMS notes its ongoing efforts to reduce inequity across its programs by reporting quality measure results stratified by demographic variables and patient social risk factors. CMS further notes having issued a lengthy and detailed RFI about employing measure stratification across its quality enterprise that describes key considerations potentially applicable to all of its quality programs, including the OQR program**. CMS requests that readers review the full RFI from section IX.B. of the FY 2023 IPPS/LTCH PPS final rule (87 FR 28479 through 28486) and submit feedback on potential applicability of the principles discussed therein to the OQR program. CMS directs that comments about OQR program applications be sent through the usual OPPS/ASC PPS formal comment process.**

The 5 key considerations described by CMS in the FY 2023 IPPS/LTCH proposed rule are listed below.

- Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification Across CMS Quality Reporting Programs
- Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting
- Principles for Social Risk Factor and Demographic Data Selection and Use
- Identification of Meaningful Performance Differences
- Guiding Principles for Reporting Disparity Measures

B. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

1. Aligning OQR Program Patient Encounter Quarters to the Calendar Year

CMS proposes to align the patient encounter quarters for the OQR program's chart-abstracted measures with the calendar year. All 4 quarters would be based on the calendar year that is 2 years prior to the applicable payment determination year. The current approach uses encounters occurring from Q2 that is 2 years prior to payment determination through Q1 that is 1 year prior to the payment determination (i.e., Q2 *t-2* through Q1 *t-1* where *t* is the applicable payment determination year). The changeover would begin with a transition year for CY 2025 payment determinations, for which only 3 quarters of data would be utilized: Q2, Q3, and Q4 of CY 2023. The changeover would be complete – using 4 quarters of data – beginning with CY 2026 payment determinations. In Tables 66 through 68 CMS provides the applicable dates for current and future years; these are consolidated into the table below, except that the clinical data submission deadlines below for CY 2024 are instead taken from Table 67 of the CY 2022 OPPS/ASC final rule (86 FR 63863). These finalized deadlines appear to have been incorrectly transferred into Table 66 in this proposed rule. The corrected deadlines are shown below in italic font.

OQR PATIENT ENCOUNTER QUARTERS AND DATA SUBMISSION DEADLINES	
Encounter Quarter	**Data Submission Deadline***
CY 2024 – Current Methodology – Previously Finalized	
Q2 2022 (April 1-June 30)	*11/1/2022*
Q3 2022 (July 1-September 30)	*2/1/2023*
Q4 2022 (October 1-December 31)	*5/1/2023*
Q1 2023 (January 1-March 31)	*8/1/2023*
CY 2025 – Transition Year Methodology -- Proposed	
Q2 2023 (April 1-June 30)	11/1/2023
Q3 2023 (July 1-September 30)	2/1/2024
Q4 2023 (October 1-December 31)	5/1/2024
CY 2026 – Subsequent Years Methodology -- Proposed (transition complete)	
Q1 2024 (January 1-March 31)	8/1/2024
Q2 2024 (April 1-June 30)	11/1/2024
Q3 2024 (July 1-September 30)	2/1/2025
Q4 2024 (October 1-December 31)	5/1/2025

OQR PATIENT ENCOUNTER QUARTERS AND DATA SUBMISSION DEADLINES	
Encounter Quarter	**Data Submission Deadline***
*All deadlines occurring on a Saturday, Sunday, or legal holiday, or any other day all or part of which is declared to be a nonwork day for Federal employees by statute or executive order would be extended to the first day thereafter.	

2. Hospital OQR Program Validation Requirements (§419.46(f))

CMS proposes to adopt an additional targeting criterion for use in hospital selection for OQR program data validation beginning with the CY 2023 reporting period/CY 2025 payment determination and for subsequent years:

- Any hospital with a two-tailed confidence interval that is less than 75 percent and that had less than 4 quarters of data due to having received an extraordinary circumstances exception (ECE) from OQR program data submission for one or more quarters.

CMS proposes to add this criterion because the hospital it describes would have less than 4 quarters of data available for validation and its validation results could be considered inconclusive for a payment determination. CMS clarifies that a hospital with less than 4 quarters of data but without having received an ECE for one or more quarters and that does not meet the 75 percent reliability threshold clearly is subject to both APU reduction and targeting for validation in the subsequent year. Similarly, a hospital that has 4 quarters of data subject to validation and does not meet the 75 percent threshold clearly is subject to both APU reduction and targeting for validation in the subsequent year.

Current criteria for targeted selection are: (1) having failed the previous year's validation, (2) having an outlier value for a measure, (3) not having been randomly selected for validation in any of the previous three years, and (4) having passed validation in the previous year with a two-tailed confidence interval that included 75 percent. The final criterion identifies hospitals whose accuracy falls within the statistical margin of error, and captures both passing and failing facilities.

C. Payment Reductions for Hospitals that Fail to Meet OQR Program Requirements

CMS proposes that existing policies with respect to computing and applying the payment reduction for hospitals that fail to meet the Hospital OQR Program requirements would be continued for the 2023 update factor. The resulting reduction ratio for hospitals that fail to meet OQR Program requirements, called the "reporting ratio", is 0.9805. It is calculated by dividing the proposed reduced conversion factor of $85.093 by the proposed full conversion factor of $86.785. Continuing previous policies, the reporting ratio would be applied to all services calculated using the OPPS conversion factor and applied to all HCPCS codes to which CMS has assigned status indicators J1, J2, P, Q1, Q2, Q3, R, S, T, V, or U, excluding services paid under the New Technology APCs to which CMS has assigned status indicators S and T.

The reporting ratio would continue to be applied to the national unadjusted payment rates and minimum unadjusted and national unadjusted copayment rates of all applicable services for hospitals that fail to meet the OQR program's reporting requirements. All other applicable standard adjustments to the OPPS national unadjusted payment rates also would continue to apply, and OPPS outlier eligibility and outlier payments also would be based on the reduced payment rates. Beneficiaries and secondary payers thus benefit from the payment reductions imposed on hospitals that fail quality reporting requirements.

CMS reports that for 2022 payment, 88 of 3,356 hospitals (2.6%) failed to meet the OQR Program requirements for a full update factor, compared to 77 of 3,163 hospitals (2.4%) failing in 2021. CMS does not anticipate that policies proposed for the OQR program for CY 2023 if finalized will impact the number of facilities that will receive payment reductions.

D. Summary Table: Hospital OQR Program Measures

Tables 61-63 in the rule list the previously finalized and proposed measure sets for CY 2024 through CY 2026 payment determinations and are consolidated into the table below.

Hospital OQR Program Measures by Payment Determination Year							
NQF	**Measure**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED arrival	X	X	X	X	Removed	
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention	X	X	X	X	Removed	
0289+	OP-5: Median Time to ECG	Removed					
0514+	OP-8: MRI Lumbar Spine for Low Back Pain	X	X	X	X	X	X
	OP-9: Mammography Follow-up Rates	Removed					
	OP-10: Abdomen CT – Use of Contrast Material	X	X	X	X	X	X
0513	OP-11: Thorax CT – Use of Contrast Material	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	Removed					
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery	X	X	X	X	X	X
	OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)	Removed					
0491+	OP-17: Tracking Clinical Results between Visits	Removed					
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients	X	X	X	X	X	X
0499+	OP-22: ED- Left Without Being Seen	X	X	X	X	X	X

Hospital OQR Program Measures by Payment Determination Year							
NQF	**Measure**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**
0661	OP-23: ED- Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival	X	X	X	X	X	X
0658	OP-29: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients	X	X	X	X	X	X
0659	OP-30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use	Removed					
1536	OP-31: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery[a]					*Remain Voluntary*	*Remain Voluntary*
2539	OP-32: Facility Seven Day Risk Standardized Hospital Visit Rate After Outpatient Colonoscopy	X	X	X	X	X	X
1822	OP-33: External Beam Radiotherapy for Bone Metastases	X	Removed				
	OP-35: Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	X	X	X	X	X	X
2687	OP-36: Hospital Visits After Hospital Outpatient Surgery	X	X	X	X	X	X
	OP-37a-e Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS-CAHPS) - 5 measures					*Voluntary*	X
	OP-38 COVID-19 Vaccination Coverage Health Care Personnel				X	X	X
	OP-39 Breast Cancer Screening Recall Rates			X	X	X	X
	OP-40 ST-Segment Elevation Myocardial Infarction (STEMI) eCQM					*Voluntary*	X

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

[a] Mandatory reporting of this measure was originally adopted for the CY 2016 payment determination. OP-31 was later excluded temporarily from the measure set beginning with the CY 2016 payment determination, but voluntary reporting was allowed beginning with the CY 2017 payment determination. Mandatory reporting beginning with the CY 2023 payment determination was proposed but in response to comments was finalized but delayed to begin with the CY 2025 reporting period/CY 2027 payment determination. In this rule, it is proposed to remain in voluntary status beginning with the CY 2025 reporting/CY 2027 payment determination and for subsequent years.

XV. Ambulatory Surgery Center Quality Reporting (ASCQR) Program

The Ambulatory Surgery Center Quality Reporting (ASCQR) Program is authorized under sections 1833(i)(2)(D)(iv) and (i)(7) of the Act. Payment determinations are linked to a quality reporting period that occurs two years in advance of the payment determination year (i.e., 2020 reporting is linked to 2022 payment). There is a 2.0 percentage point reduction to the update factor for ASCs that fail to meet all of the program's quality reporting requirements. An

exemption from program participation and payment reduction is given to an ASC that has fewer than 240 Medicare claims per year during an annual reporting period (the minimum case volume threshold).[26] CMS provides references to the legislative and regulatory histories of the ASCQR program.

CMS proposes to modify the reporting status of 1 measure and to continue its policies regarding determination and application of the payment reduction for ASCs that fail to satisfy the program's requirements. Most of this section of the rule is devoted to requests for comment about potential future actions: adoption of a procedural volume measure, approaches to restructuring the ASCQR program (e.g., specialty-centered approaches), and considerations for addressing interoperability and electronic health record (EHR) utilization in the program.

No changes are proposed to previously finalized ASCQR program policies regarding measure selection, retention, and removal; requirements and deadlines for data collection, submission, and processing for measures of all types and methods of submission (e.g., web-based, OAS CAHPS Survey); review and corrections periods for chart-abstracted measures; reconsideration and appeals procedures; public display of quality measures; processes for the maintenance of technical specifications for previously adopted ASCQR program measures; administrative requirements for participation in and withdrawal from the ASCQR program; and the ECE policy and process.

A summary table of the ASCQR program's measure set is provided below in section XV.A.2. More information about the program can be found at https://qualitynet.cms.gov/asc and https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ASC-Quality-Reporting.

A. ASCQR Program Quality Measures

1. Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (ASC-11)

CMS proposes to change the reporting status of the measure *Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (ASC-11)* from mandatory to voluntary beginning with the CY 2025 reporting period/CY 2027 payment determination and for subsequent years. The measure requires collection of visual function surveys from patients both preoperatively and postoperatively.

This measure has a lengthy and complex history and its reporting status has been changed multiple times as described by CMS in the rule. Most recently, during CY 2022 OPPS rulemaking, CMS finalized designating the measure as mandatory for reporting beginning with the CY 2025 reporting period/CY 2027 payment determination. Since that time, stakeholders have continued to voice concerns about the measure's reporting burden, particularly as the COVID-19 PHE continues. They cite medical staffing and supply shortages along with

[26] ASCs may also elect to withdraw from ASCQR program participation for a year but will be subject to the 2.0 percent payment reduction for that year.

substantial fluctuations in patient case volumes as contributors to the perceived excessive reporting burden.

CMS acknowledges the concerns raised but also states its intention to revisit mandatory reporting of this measure after the PHE officially ends. CMS believes the ASC-11 measure adds significant value to the ASCQR program's measure set by focusing on an area of care that is insufficiently addressed otherwise, by being an outcome measure, and by requiring care coordination by practitioners across settings for satisfactory reporting. CMS emphasizes that its status change proposal in this rule does not change the measure's voluntary status already finalized for CY 2023 and CY 2024 reporting. If a return to voluntary status for ASC-11 is finalized, CMS projects this change would produce a burden decrease of approximately 15.5 hours and $721 per facility. CMS does not anticipate any economic impact for the CY 2025 reporting period/CY 2027 payment determination from this change other than the burden decrease as described.

2. ASCQR Program Summary Measure Table

Tables 70-71 in the rule list the previously finalized and proposed measure sets for CY 2025-CY 2027 payment determinations and are consolidated into the table below.

ASCQR Program Measures by Payment Determination Year						
	2020	**2021**	**2022 & 2023**	**2024**	**2025**	**2026**
CMS WEB-BASED TOOL REPORTING						
ASC-1: Patient Burn (NQF #0263)+	*V**					
ASC-2: Patient Fall (NQF #0266) +						
ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267)+						
ASC-4: All-Cause Hospital Transfer/Admission (NQF #0265)+						
ASC-9: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658)	X	X	X	X	X	X
ASC-11: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536)+	*V***					
ASC-13: Normothermia Outcome	X	X	X	X	X	X
ASC-14: Unplanned Anterior Vitrectomy	X	X	X	X	X	X
CLAIMS-BASED REPORTING						
ASC-12: Facility 7-Day Risk Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539)	X	X	X	X	X	X
ASC-17: Hospital Visits After Orthopedic ASC Procedure (NQF #3470)			X	X	X	X
ASC-18: Hospitals Visits After Urology ASC Procedure (NQF #3366)			X	X	X	X

ASCQR Program Measures by Payment Determination Year						
	2020	**2021**	**2022 & 2023**	**2024**	**2025**	**2026**
ASC-19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at an ASC (NQF #3357)				X	X	X
OAS CAHPS SURVEY-BASED REPORTING						
ASC-15a-e Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS-CAHPS) - 5 measures	*V****					
CDC NHSN WEB REPORTING						
ASC-20: COVID-19 Vaccination Coverage Health Care Personnel				X	X	X
+ CMS notes that NQF endorsement for the measure has beenallowed to lapse by the measure steward. *V** Data collection suspended beginning with 2020 payment determination, resumed for 2024 reporting period with initial voluntary reporting followed by mandatory reporting beginning with 2025 reporting period/2027 payment determination. *V*** Voluntary reporting allowed through 2024 reporting period; finalized for mandatory reporting beginning with 2025 reporting period/2027 payment determination. However, measure is being proposed in this rule to instead return to voluntary status for the CY 2025 reporting period/CY 2027 payment determination and subsequent years. *V**** Mandatory reporting on a set of OAS CAHPS measures, scheduled to begin for the 2020 payment determination, was indefinitely delayed (82 FR 59450). Same set was finalized for voluntary reporting for the 2024 reporting period followed by mandatory reporting beginning with the 2025 reporting period/2027 payment determination. The measures are ASC-15a: About Facilities and Staff; ASC-15b: Communication About Procedure; ASC-15c: Preparation for Discharge and Recovery; ASC-15d: Overall Rating of Facility; and ASC-15e: Recommendation of Facility.						

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

No changes are proposed to the policies for determining the payment reduction for ASCs that fail to meet the ASCQR Program requirements. Statute requires that a 2.0 percentage point reduction to the ASC annual update be applied to ASCs that fail to meet the requirements. The reduction applies to services calculated using the ASC conversion factor with the payment indicators of A2, G2, P2, R2, Z2, and the service portion of device-intensive procedures identified by J8. The reduction does not apply to services that are assigned other status indicators for which payments are not calculated using the ASC 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. All other applicable adjustments to the ASC national unadjusted payment rates apply (e.g., wage index adjustment). When the update reduction is applied to a facility, beneficiary copayments are based on the reduced payment rate.

CMS states that of 5,386 ASCs eligible for the ASCQR program for CY 2022 payment determinations, 290 (5.4%) did not meet the requirements to receive the full annual payment update under the ASC fee schedule. CMS posts individual facility payment determination result lists on the QualityNet website https://qualitynet.cms.gov/asc/ascqr/apu#tab1. For the CY 2021 payment determination, all ASCs received the annual payment update because of nationwide data submission exceptions granted by CMS under the ASCQR program's ECE policy in response to the COVID-19 PHE.

C. Requests for Comment

1. Potential Future Specialty Centered Approach for the ASCQR Program

CMS seeks comment on future approaches by which ASCQR program participants could report using a customizable measure set that more accurately reflects care delivered in ASCs and accounts for services provided by individual facilities. As examples of approaches, CMS describes (1) a multispecialty set of measures from which ASC providers could choose a specified number that reflect the services (and related specialties) they perform, and (2) creation of specific specialized tracks that would standardize ASC quality measures within a given specialty area as performed by each facility.

CMS cites the structure and content of the Quality and Improvement Activities categories of the Merit-based Incentive Payment System (MIPS) track of the Quality Payment Program (QPP) for clinicians as a potential framework on which to build future ASCQR program reporting. CMS lists MIPS features that would be desirable for a future ASCQR program. The program should:

- Consist of limited, connected, and complementary sets of measures and related activities that are meaningful to clinicians;
- Include measures and activities resulting in comparative performance data that are valuable to patients and caregivers in evaluating clinician performance and making choices about their care;
- Promote subgroup reporting that comprehensively reflects the services provided by multispecialty groups; and
- Include measures selected using the Meaningful Measures 2.0 approach and, wherever possible, include the patient voice.

CMS poses multiple specific questions, listed below. The associated examples (Tables 73-75 in the rule) are also reproduced below (with reformatting for space considerations).

- Is the general concept of quality reporting by specialty feasible and desirable for ASCs participating in the ASCQR Program?
- Were CMS to adopt a specialty centered approach to quality measure reporting for the ASCQR Program, should CMS require that ASCs report a subset of quality measures that apply broadly to all ASCs? (An example of potential broadly applicable measures for ASCs based on CY 2022 performance year MIPS quality measures can be found in Table 73.)
- Were CMS to adopt a specialty centered approach for quality measure reporting for the ASCQR Program, what would be the appropriate number and type of measures that ASCs should be required to report? Are there minimum and maximum numbers of measures required for ASCs that provide meaningful information while not being overly burdensome? What is the preferred balance of required quality measures that apply broadly to all ASCs and quality measures that apply to a particular area of specialization?
- Were CMS to adopt a specialty centered approach for quality measure reporting for the ASCQR Program, which area(s) of specialization would benefit from such an approach and which would not?

- Were CMS to adopt a specialty centered approach for quality measure reporting for the ASCQR Program, should CMS define a set of measures for particular areas of specialization (for example, ophthalmology) or should measures be self-selected for individual facilities from selected categories, especially given that an ASC may be multi-specialty? (Examples of specialty centered measure sets for ASCs based on CY 2022 performance year MIPS quality measures can be found in Tables 74-75.)
- Were CMS to adopt a specialty centered approach for quality measure reporting under the ASCQR Program, should ASCs be required to report all measures in such a measure set, or should they be permitted to select a minimum number of measures from their selected measure set?
- Were CMS to adopt a specialty centered approach for quality measure reporting system under the ASCQR Program, what measures, if any, from the current ASCQR Program measure set should be retained and incorporated in such an approach?

MIPS Quality Measures With Potential Broad Applicability Within The ASCQR Program (From Table 73)	
MIPS Quality Measure Names	**MIPS Quality Measure Names**
Advance Care Plan	Anesthesiology Smoking Abstinence
CAHPS for MIPS Clinician/Group Survey	Closing Referral Loop: Specialist Report Receipt
Current Medication Medical Record Documentation	Multimodal Pain Management
Patient-Centered Surgical Risk Assessment and Communication	Perioperative Temperature Management*
Prevention Postoperative Nausea and Vomiting – Combination Therapy	Surgical Site Infection
Unplanned Hospital Readmission within 30 Days Postoperatively	Unplanned Reoperation within 30 Days Postoperatively
Use of High-Risk Medications in Older Adults	
*Equivalent Measure in Current ASCQR Measure Set: ASC-13 Normothermia	

Example Ophthalmology ASCQR Program MIPS Value Pathway (MVP) Measures (From Table 74)
MVP Quality Measure Names
Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the OR Within 90 Days of Surgery
Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery
Cataract Surgery: Difference Between Planned and Final Refraction
Cataracts: 20/40 or Better Visual Acuity Within 90 Days Following Cataract Surgery
Cataracts: Improvements in Patient's Visual Function Within 90 Days Following Cataract Surgery
Cataracts: Patient Satisfaction Within 90 Days Following Cataract Surgery*
*Based on OAS CAHPS Survey

Example Gastroenterology ASCQR Program MIPS Value Pathway (MVP) Measures (From Table 75)
MVP Quality Measure Names
Age Appropriate Screening Colonoscopy
Anastomotic Leak Intervention
Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients*

Example Gastroenterology ASCQR Program MIPS Value Pathway (MVP) Measures (From Table 75)
MVP Quality Measure Names
Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use
Photodocumentation of Cecal Intubation
*Similar Measure in Current ASCQR Measure Set: ASC-9

2. Potential Future Reimplementation of ASC Facility Volume Data on Selected ASC Surgical Procedures (ASC-7) Measure or Other Volume Indicator

CMS requests comments on the potential inclusion of a procedural volume measure in the ASCQR Program, to be accomplished either by (1) re-adopting the *ASC Facility Volume Data on Selected ASC Surgical Procedures (ASC-7)* measure or (2) adopting another volume indicator. The agency also invites comments on what volume data ASCs currently collect and if it is feasible to submit those data to the ASCQR Program as an approach to minimizing collection and reporting burden of a new volume measure. **CMS targets certain topic areas, listed below**.

- The usefulness of including a volume indicator in the ASCQR Program measure set and publicly reporting volume data.
- Input on the mechanism of volume data collection and submission, including anticipated barriers and solutions to data collection and submission.
- Considerations for designing a volume indicator to reduce collection burden and improve data accuracy.
- Potential reporting of volume by procedure type, instead of total surgical procedure volume data for select categories, and which procedures would benefit from volume reporting.
- The usefulness of Medicare versus non-Medicare reporting versus other or additional categories for reporting.

By way of background, CMS notes the continuing shift of a large number and wide range of procedure types for which performance has already shifted from the inpatient to outpatient setting, supporting the importance of procedural volume tracking. CMS also notes that Medicare-covered ASC services tend to be concentrated in a relatively small number of procedure codes and the prior ASC-7 measure tracked volumes for 6 procedural categories (Gastrointestinal, Eye, nervous System, Musculoskeletal, Skin, and Genitourinary). CMS acknowledges that procedural volume may be associated with facility features that enhance outcomes (e.g., procedure-specific teams) and believes that such data would inform patients about a given facility's experience with various outpatient procedures. CMS further notes that an OQR program volume measure could generate useful data about the rapidly growing category of outpatient-based pain management procedures, a category CMS wishes to further explore.

CMS describes the history of ASC-7 in the ASCQR program; most recently the measure was removed during CY 2018 rulemaking due to lack of evidence linking better outcomes to this particular measure. If ASC-7 were to be restored to the ASCQR program, the measure would need to go through the existing pre-rulemaking process as formal review by the Measure Applications Partnership (MAP) was not part of the required process for new measure adoption

when ASC-7 was first added to the ASCQR program's measure set. Any alternative to ASC-7 would likewise be required to go through the process.

3. Interoperability Initiatives in ASCs

CMS seeks comment to explore how ASCs are implementing tools in their facilities toward the goal of healthcare information exchange interoperability. In general terms, the agency requests input on (1) barriers to interoperability in the ASC setting; (2) the impact of health IT, including health IT certified under the ONC Health IT Certification Program, on the efficiency and quality of health care services furnished in ASCs; and (3) the ability of ASCs to participate in interoperability or EHR-based quality improvement activities, including the adoption of electronic clinical quality measures (eCQMs).

CMS highlights its interest in learning about capabilities of ASCs to report eCQMs. Although there currently are no eCQMs included in the ASCQR program's measure set, CMS indicates that a shift to such measures in the program is under consideration. CMS is also considering adopting selected measures from the hospital Promoting Interoperability program (PIP) and the Promoting Interoperability (PI) performance category of MIPS into the ASCQR program; the measures are listed in Table 76 of the rule (and listed below with reformatting for space considerations).

By way of background, CMS notes that ASCs were not eligible for the financial incentives to adopt and meaningfully use certified electronic health record technology (CEHRT) that were made available to hospitals and clinicians under the Health Information Technology for Economic and Clinical Health Act (HITECH Act, 2009). The hospital PIP and the clinician PI performance category were created as approaches to implementing the HITECH incentives. ASCs currently continue to have a lower adoption rate of CEHRT compared to hospitals and physician offices.

Specific questions posed by CMS are shown below, followed by a listing of examples taken from Table 76 of promoting interoperability measures from other CMS programs having potential applicability to ASCs.

- What do ASCs perceive as the benefits or risks of implementing interoperability initiatives in their facilities?
- What improvements might be possible with the implementation of interoperability initiatives in ASCs, including EHR utilization (reduced delays, efficiencies, ability to benchmark, etc.)?
- Do ASCs see interoperability initiatives as non-essential or detrimental to their business practices?

Example Promoting Interoperability Measures Applicable to the ASCQR Program (From Table 76)
PI Measure Names
Health Information Exchange: Bi-Directional Exchange
Provide Patients Electronic Access to Their Health Information
Query of the Prescription Drug Monitoring Program (PDMP)

Example Promoting Interoperability Measures Applicable to the ASCQR Program (From Table 76)
PI Measure Names
Safe Use of Opioids – Concurrent Prescribing eCQM
Security Risk Analysis
Support Electronic Referral Loops By Receiving and Reconciling Health Information
Support Electronic Referral Loops By Sending Health Information

XVI. Rural Emergency Hospital Quality Reporting (REHQR) Program

This section provides background and basic structural information about the REHQR program and proposes initial administrative requirements for hospitals seeking REH status. The majority of the section is devoted to discussing potential measures and has multiple embedded requests for comment. The discussion of potential measures is lengthy and detailed and readers are referred to section XVI.B. of the rule. Highlights of that discussion are provided later in this section.

A. Administrative Requirements

CMS proposes that REHs wanting to participate in the REHQR program must register for an account to use the agency's Hospital Quality Reporting (HQR) secure portal to submit data and must designate a Security Official (SO) for the account. Hospitals converting to REH status that already have HQR access may register by updating their profiles using their new REH CCNs. CMS is not requiring that the SO designation be maintained after the REH account is established and initial set-up completed.

B. Background and Considerations for Measure Selection

1. Background and Context

Section 1861(kkk)(7) of the Act, as added by Section 125 ofCAA 2021 establishes REHs as a new Medicare provider type that will furnish emergency department services and observation care. The REH must have a staffed emergency department 24 hours a day, 7 days a week and may elect to furnish other medical and health services on an outpatient basis. Providers that are CAHs and small rural hospitals (50 or fewer beds) as of December 27, 2020, may convert to REHs. Payments specific to REHs will begin on or after January 1, 2023.

Further, the Secretary must establish quality reporting requirements for REHs, require data submission at least quarterly, and publicly post performance data. In the 2022 OPPS PFS proposed rule, CMS solicited public comments to inform its policy making for REHs including quality measurement (86 FR 42288). A proposed rule issued June 30, 2022 – and open for comment through August 29, 2022 – addresses REH Conditions of Participation, but quality measure specifications and quality reporting requirements for REHs are deferred to future rulemaking (87 FR 40350).

2. Considerations for Measure Selection

CMS notes that the REHQR program measure set should consist of measures that are important, impactful, reliable, accurate and clinically relevant for REHs. Additionally, the measures should inform subsequent quality improvement efforts and consumer healthcare decision-making. CMS also notes that the number and characteristics of the hospitals that enroll as REHs will influence measure selection. Regardless of measures selected, measurement challenges are highly likely to occur due to the small number of hospitals as well as low service volumes overall and for specific services provided.

More specifically, CMS shares the following considerations for use in measure selection.

- Measure endorsement by the consensus-based entity (currently the NQF) is preferred, but in the absence of appropriate endorsed measures lack of endorsement will not preclude measure adoption.
- Measures should improve care, facilitate public transparency, and ensure accountability. CMS states that measures listed in Tables 76 and 77 meet these criteria and provide a starting point for measure consideration.
    - Table 76 presents OQR program data about 23 current and selected past measures being voluntarily and publicly reported by CAHs as of January 2022.
    - Table 77 includes 23 measures identified from data voluntarily and publicly reported by CAHs that are participating in the Medicare Beneficiary Quality Improvement Project (MBQIP) that is administered through HRSA's Rural Hospital Flexibility (Flex) program.
- Measures should not create unreasonable data collection and reporting burden, as REHs are likely to have very limited resources to devote to such efforts. Use of claims-based measures and eQCMs could limit burden.
- Measures must be relevant to the services provided by REHs and should target topics where variation in performance has been shown within this group of hospitals.
    - Measures addressing ED services should be emphasized since these services must be provided by all REHs.
    - Measures that have become topped out for larger, urban hospitals may remain relevant for REHs.
- Emphasis should be placed on measures for which technical specification or statistical adjustments can be made to compensate for low hospital numbers or service volumes.
- In support of CMS goals for advancing health equity through its quality enterprise, measures that address disparities and lend themselves to reporting stratified by demographic and social risk factor variables should be considered.

C. Requests for Comment on Potential REHQR Program Measures

For each specific measure reviewed, CMS provides additional information from sources such as Tables 76 and 77, MBQIP reports, OQR data analyses, and data published on Care Compare. The reader is referred to section XVI.B.2. for details; highlights are provided below. **CMS invites comment on all aspects of the measures and all topics reviewed in this section**.

1. Measures Recommended by the National Advisory Committee on Rural Health

a. OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival
OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention

These chart-abstracted measures are being replaced by a single eCQM in the OQR program but may be more accessible for REHs with more limited health IT capabilities than the eCQM. Many CAHs have experience with reporting one or both measures. They are directed at conditions for which patients frequently present to an ED: chest pain and acute coronary syndromes.

b. OP-4: Aspirin on Arrival

This chart-abstracted measure was removed from the OQR program in 2020 having become topped out. CMS presents information suggesting that sufficient variation remains among smaller, rural hospitals such that retention of this measure for REHs may be appropriate.

c. OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional
OP-22: Left Without Being Seen

These 3 measures are considered important metrics of timely delivery of emergency department care and have been successfully reported by many CAHs. OP-18 and OP-22 are currently included in the OQR program. OP-20 was removed as an OQR measure in 2018 rulemaking but support for its removal was far from unanimous.

d. Emergency Department Transfer Communications (EDTC)

This is a core measure under the MBQIP and many CAHs have experience with its use. Since REHs are expected to focus on triage and transfer, CMS believes this measure could have value.

2. Existing Claims-Based OQR Program Measures

a. OP-10: Abdomen Computed Tomography (CT) – Use of Contrast Material

Performance of an abdominal CT scan with contrast as well as without doubles the patient's radiation exposure. Rural facilities account for about a third of facilities reporting this measure but represent over 45 percent of outliers for the measure.

b. OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy

CMS suggests that this measure could add value to the REHQR program measure set for those REHs that opt to perform outpatient services such as gastrointestinal endoscopy. The results could be important to patients deciding whether to travel beyond their communities for recommended screening colonoscopies.

3. Additional Measurement Topics and Measures

CMS requests input on topics and measures derived from its review of comments received in response to the REH comment solicitation contained in the 2022 OPPS/ASC PPS proposed rule (86 FR 42288). Further, CMS invites comments on any other topics that would be applicable to an REH quality program. For all areas below, CMS asks for feedback about potential measures that address quality and equity when care is delivered by telehealth in rural settings and about ways in which REHs could utilize telehealth and telemedicine to bridge gaps in expertise and distance.

a. Telehealth

CMS suggests that telehealth may be an important contributor to ensuring quality of care at REHs by facilitating specialist evaluations and identifying patients for whom immediate transfer is critically important to achieving better outcomes.

b. Maternal Health

CMS describes the existence of "OB deserts" involving rural communities in many states and observes that REHs could provide emergency care and outpatient services that would improve maternal health-related care.

c. Mental Health

CMS cites evidence for disproportionately higher rates of mental health and substance abuse disorders in rural communities that is further amplified by lack of ready access to treatment. CMS states that REHs could provide both emergent and outpatient treatment services that would address this area of concern.

d. ED Services

CMS suggests that measures of ED service utilization would be important for the REHQR program since all hospitals will be delivering emergency services. CMS mentions an ED utilization measure already used in the MA program and a Medicaid measure under development. CMS notes that unscheduled returns to an ED after ED discharge ("bounce-back") is associated with many unwanted outcomes (e.g., ED overcrowding).

e. Equity

CMS states that rural populations face higher disease prevalence and risks along with greater access challenges for multiple medical conditions. CMS suggests potential adaption to REHs of the Hospital Commitment to Health Equity Measure proposed for addition to the IQR program. CMS also describes potential addition of a structural measure for which a hospital would attest to having a disparities impact statement or making an organizational pledge to equitable care.

4. Addressing Small Case Numbers

CMS states that measure reliability and validity often are contingent upon sufficient case numbers, and it anticipates having to deal routinely with such issues in the REHQR program. CMS mentions 2 recommendations made in a 2019 NQF report addressing this topic and invites feedback about their application to the REHQR program:

- "Borrow strength" by aggregating measure data over longer performance periods and emphasizing measures that are suitable for aggregation, and
- Reporting exceedance probabilities as an alternative to reporting absolute performance values – a technique used for event prediction.[27]

XVII. Organ Acquisition Payment Policy

A. Background of Organ Acquisition Payment Policies

Medicare pays for organ acquisition costs on a reasonable cost basis. In the FY 2022 IPPS proposed rule, CMS proposed to determine Medicare's share of reasonable costs using only organs transplanted into Medicare beneficiaries. CMS further proposed that Medicare would not share in the costs to procure organs used for research, except where explicitly required by law. These proposals were not finalized due to concerns expressed in the public comments.

B. Research Organs to Calculate Medicare's Share of Organ Acquisition Costs

In the FY 2022 IPPS proposed rule (86 FR 25668), CMS indicated that a "research organ" is an organ procured and used for research regardless of whether it is transplanted as part of clinical care.[28] The proposed rule indicated that research organs are not counted as Medicare usable organs in Medicare's share of organ acquisition costs but are counted as total usable organs. CMS finalized the first aspect of this proposal but not the second (although the proposed rule later says that transplant hospitals and hospital organ procurement organizations (HOPOs) are currently including research organs in the count of total usable organs).

CMS is now proposing to require that transplant hospitals (TH) and organ procurement organizations (OPO) exclude organs used for research from the numerator (Medicare usable organs) and the denominator (total usable organs) of the calculation used to determine Medicare's share of organ acquisition costs on the Medicare cost report. Under CMS' proposal, THs and OPOs would also be required to deduct the cost incurred in procuring an organ for research from their total organ acquisition costs.

This proposed rule would also specify that the determination of whether an organ is usable or not could be made by any surgeon, not just the excising surgeon which is current policy. If an organ is not usable, it is not counted as a Medicare usable organ or a total usable organ. CMS further

[27] National Quality Forum. Addressing Low Case-Volume in Healthcare Performance Measurement of Rural Providers: Recommendations from the MAP Rural Health Technical Expert Panel, Final Report 3 (March 2019).
[28] "Research organ" includes those intended for transplant but determined not to be usable for transplant and used for research.

clarifies that the costs to procure unusable organs are reasonable costs that may be reported on Medicare cost reports.

C. Costs of Certain Services Furnished to Potential Deceased Donors

Current CMS policy only allows costs incurred after the declaration of the donor's death and consent to donate as organ acquisition costs. However, there are donor costs that can only be performed prior to declaration of death, when death is imminent, to evaluate the organs for transplant viability and to prepare the donor for donation. Failure to provide these services to the potential donor may compromise the viability of organs and limit organ donation.

CMS proposes to allow a donor community hospital or TH to incur costs for hospital services attributable to a deceased donor or a donor whose death is imminent. Organ acquisition costs include hospital services authorized by the OPO when (1) there is consent to donate, (2) a declaration of death has been made or death is imminent and (3) these services must be furnished before the declaration of death. These costs must not be part of medical treatment that primarily offers a medical benefit to the patient as determined by the patient's healthcare team.

D. Clarification of Allocation of Administrative and General Costs

CMS indicates that some THs incorrectly report the "purchase cost" for acquiring an organ in an accumulated cost statistic that is used to allocate administrative and general (A&G) costs. The proposed rule clarifies that when a TH receives organs from an OPO or other TH, the receiving TH must exclude from its accumulated cost statistic the cost associated with these organs because these costs already include A&G costs. These longstanding Medicare cost finding principles are in accordance with 42 CFR § 413.24(d)(6), and specifically written in the Medicare cost report instructions.

E. Request for Information (RFI): Medicare's Share of Organ Acquisition Costs

In this section of the proposed rule, CMS is not making any proposals but is requesting information on an alternative methodology for counting organs for purposes of calculating Medicare's share of organ acquisition costs. While CMS will not be responding to comments submitted the final rule, it intends to use this input to inform future policy development.

1. Counting Organs for Medicare's Share of Organ Acquisition Costs

Medicare calculates its share of organ acquisition costs for THs/HOPOs by multiplying the allowable organ acquisition costs by the ratio of Medicare usable organs (the numerator) to total usable organs (the denominator) reported on the Medicare hospital cost report. In the FY 2022 IPPS proposed rule CMS explained why Medicare currently shares in the organ acquisition costs for some organs that are not actually transplanted into Medicare beneficiaries.

When Medicare added the ESRD benefit to Medicare coverage in 1972, Medicare presumed that most kidney transplant recipients would be Medicare beneficiaries receiving the ESRD benefit, and thus Medicare would pay a larger share of kidney acquisition costs. As Medicare added benefits for transplantation of non-renal organs and included the costs to procure non-renal

organs, Medicare cost reporting instructions incorporated the presumption that the ultimate transplant recipient was unknown but would likely be a Medicare beneficiary. Thus, some organs that are not ultimately transplanted into Medicare beneficiaries are currently being included in "Medicare usable organs" resulting in Medicare paying more than its share of organ acquisition costs.

In the FY 2022 IPPS proposed rule, CMS stated that Medicare does not intend to share in the cost of procuring organs that are not transplanted into Medicare beneficiaries (except those organs designated for transplant but subsequently determined to be unusable). CMS proposed to require that THs count the number of organs, and Independent Organ Procurement Organizations (IOPO) count the number of kidneys, actually transplanted into Medicare beneficiaries on their Medicare cost reports to more accurately calculate Medicare's share of organ acquisition costs.

Under CMS' proposal, THs and OPOs would have been required to track organs they furnish to other facilities and to determine and report on their Medicare cost reports, the number of those organs that were transplanted into Medicare beneficiaries. CMS did not finalize this proposal because of concerns expressed in the comments that THs and OPOs will not know whether an organ provided to another entity—an exported organ—is transplanted into a Medicare beneficiary. THs and OPOs also raised concerns about the potential reduction in Medicare revenue that may not be replaced by other parties under existing contractual arrangements.

In this RFI, CMS is seeking information on an alternative methodology for counting organs that will not require THs and OPOs to track exported organs but would require TH/OPOs to report only organs transplanted into Medicare beneficiaries for purposes of calculating Medicare's share of organ acquisition costs. CMS would exclude organs that a TH furnishes to other THs or OPOs from its Medicare share fraction, in both the numerator (Medicare usable organs) and denominator (total usable organs), and require revenue offsets against total organ acquisition costs for these organs. Such a methodology would result in an apportionment of costs and redistribution of reasonable organ acquisition costs to only organs transplanted into Medicare beneficiaries within the recipient TH, but it would not require TH/HOPOs to track organs they furnish to other THs and OPOs.

CMS requests comment on 13 specific questions that are intended to solicit information from THs and OPOs on the number and types of organs they acquire; age of the donors; insurance status of the potential recipients; income and revenue streams associated with organ acquisition; the financial impact of the alternative Medicare share calculation; whether other payers make payment for organ acquisition costs; implementation issues associated with the alternative Medicare share calculation; and other issues.

2. IOPO Kidney Standard Acquisition Charges

The discussion in this section of the rule parallels the previous section except it is limited to IOPOs and kidneys procured for transplant. In the case of IOPOs and kidney acquisition costs, the MAC establishes a standard acquisition charge (SAC) that the IOPO charges to acquire a kidney. Again, CMS expresses concern about the presumption that all organs transplanted are for Medicare patients and Medicare pays a higher share of the SACs of acquiring donor kidneys.

CMS is considering the same alternative organ counting methodology that was presented in the previous section. Such a methodology would result in IOPOs' SACs being reconciled and settled for all organ acquisition costs for organs actually transplanted into Medicare beneficiaries.

Additionally, for kidneys, such an alternative organ counting methodology would limit the kidney revenue IOPOs receive from THs and other OPOs to the kidney SAC amount. To ensure that an IOPO's kidney SAC appropriately covers its costs, CMS is considering a methodology under which IOPOs, rather than the Medicare contractor, would establish their kidney SACs, similar to how they establish their SACs for non-renal organs. This alternative methodology would place the fiscal responsibility on the IOPOs for kidneys, similar to non-renal organs.

The IOPO would estimate the reasonable and necessary costs it expects to incur for services furnished to procure deceased donor kidneys during its cost reporting period and divide that estimated amount by the projected number of deceased donor kidneys the IOPO expects to procure within its cost reporting period. CMS is considering a potential policy approach that would permit an IOPO to adjust its kidney SAC during the year, if necessary, to account for cost changes.

CMS requests information on 5 specific questions about any concerns IOPOs may have about the alternative methodology and setting their own SACs.

3. Reconciliation for All Organs for IOPOs

Currently, the contractor is required to review IOPOs' kidney acquisition costs and reconcile and settle those costs to ensure that Medicare pays its share on a reasonable cost basis. However, there is no similar requirement for the contractor to review, reconcile and settle IOPOs' non-renal organ acquisition costs. The lack of any process to reconcile costs for an IOPO's non-renal organ acquisition costs could result in an over or underpayment by Medicare. For these reasons, CMS is considering whether to have a revised and reconciliation process for IOPOs' non-renal organ acquisition costs.

Under this approach, Medicare-certified IOPOs would submit a Medicare cost report for review, reconciliation, and settlement of non-renal organ acquisition costs to determine Medicare's reasonable costs. This potential policy approach would mirror CMS' current approach for determining Medicare's reimbursement of IOPOs' kidney acquisition costs. CMS requested information on 5 specific questions regarding how the lack of a reconciliation process for non-renal organs affects IOPOs' costs and revenues and the incentives for procuring non-renal organs.

XVIII. REH Payment Policies and Other Issues

A. Payment Policies

1. Introduction

Section 125 of the Consolidated Appropriations Act (CAA), 2021 establishes REHs as a new Medicare provider type that will furnish emergency department services and observation care.

The REH must have a staffed emergency department 24 hours a day, 7 days a week. In addition, an REH may elect to furnish other medical and health services on an outpatient basis as the Secretary may specify through rulemaking. REHs may not provide acute inpatient services, with the exception of skilled nursing facility (SNF) services that are furnished in a distinct part unit.

An REH must have a transfer agreement in effect with a level I or level II trauma center and meet other conditions, including licensure, emergency department staffing, staff training and certification, and CoPs applicable to hospital emergency departments and CAHs for emergency services. REHs must have an annual per patient average length of stay of 24 hours or less.

Providers that are CAHs and small rural hospitals (50 or fewer beds) as of December 27, 2020, may convert to REHs. To be considered rural as of December 27, 2020, the hospital or CAH must have been either located in an area designated as rural by the Office of Management and Budget (OMB) or be treated as rural under the IPPS—e.g., located in an urban area but reclassified to a rural area for all IPPS purposes.

CMS solicited public comments through the 2022 OPPS rulemaking cycle on its implementation of the REH program and has taken all comments into consideration while drafting this proposed rule.

2. Covered Outpatient Department (OPD) services performed by REHs

Defining "REH Services". Section 1861(kkk)(1)(A) of the Act defines "REH services" as emergency department and observation services as well as, at the election of the REH, other medical and health services furnished on an outpatient basis as specified by the Secretary through rulemaking. CMS is proposing to define "REH services," as all covered outpatient department services that would be paid under the OPPS. This definition does not include services that may be provided in outpatient departments that are not paid under the OPPS such as laboratory services and outpatient rehabilitation therapy services.

Payment for REH Services. Section 1834(x)(1) of the Act states that payment for REH services "…shall be equal to the amount of payment that [would be paid under the OPPS] increased by 5 percent…". CMS proposes that payments for REH services will equal the applicable OPPS payment for the same service plus an additional 5 percent. CMS will update the OPPS claims processing logic to include an REH-specific payment flag to pay the OPPS payment rate plus 5 percent. Beneficiary coinsurance will be 20 percent of the OPPS payment without the additional 5 percent consistent with section 1834(x)(1) of the Act.

Services Performed by REHs that are not Specified REH Services. In order for a REH to meet the proposed CoPs, REHs must be capable of providing certain types of outpatient services that are not covered OPD services, such as basic laboratory services. Laboratory services and outpatient rehabilitation services are outside the scope of covered OPD services and do not meet the definition of a REH service that would be eligible for the 5 percent add-on payment. CMS proposes that any outpatient service furnished by an REH that does not meet the proposed definition of REH services would be paid at the same rate if performed in a hospital outpatient department and paid under a payment system other than the OPPS.

Consistent with section 1834(x)(3) of the Act, CMS proposes that an entity that is owned and operated by an REH that provides ambulance services will receive payment under the ambulance fee schedule. CMS is further proposing to modify the ambulance regulations to include an REH as a covered origin and destination for ambulance transport.

REHs are permitted under the law to have a distinct part unit (DPU) skilled nursing facility (SNF). Consistent with section 1834(x)(4), CMS proposes to pay for post-hospital extended care services provided by an REH in a SNF unit through the SNF prospective payment system.

Payment for an Off-Campus Provider-Based Department of an REH. The proposed rule includes a lengthy discussion and legal analysis of whether an off-campus PBD of an REH should be subject to a PFS-equivalent rate that applies to an off-campus PBD of a hospital that first began furnishing services after November 2, 2015. CMS proposes that an off-campus PBD of an REH would not be subject to the PFS-equivalent rate but requests comments on alternatives.

3. Monthly REH Facility Payment

Overview of the Monthly REH Facility Payment. Section 1834(x)(2) of the Act establishes an additional facility payment that is paid monthly to an REH. The additional facility payment is equal to:

$$\frac{((\text{Total CAH \$}_{2019} - \text{Total \$ (IPPS+OPPS+SNF PPS}_{2019}) \div \#\text{ of CAHs}_{2019})}{12}$$

That is, the additional facility payment will equal the difference between total payments to CAHs in 2019 less the total payments to CAHs had they been paid under the IPPS, OPPS and SNF PPS in 2019 divided by the number of CAHs in 2019 divided by 12 months. For 2024 and subsequent years, the monthly facility payment will be the amount of the monthly facility payment for the previous year increased by the hospital market basket percentage increase.

CMS will use the calendar year payments for the fiscal year payment systems (e.g., two different amounts will be used for 2019 depending upon whether the service was provided before October 1, or on or after October 1). The amounts will include beneficiary cost-sharing (which CMS notes is quite significant as beneficiary coinsurance according to a 2014 OIG Report was 47 percent of Medicare payments to CAHs in 2012).

Using detailed calculations provided in the proposed rule, CMS estimates that the combination of the estimated prospective payment for CAHs and the aggregate REH monthly facility payment would be close to the amount that REH would have received from Medicare if it had decided to stay as a CAH and not convert to an REH. CMS believes this result is consistent with the intent of enacting the REH statutory provision—to provide incentives for CAHs and small rural hospitals that might otherwise close to convert to REHs and continue to provide outpatient hospital care in rural communities.

Consistent with section 1834(x)(2)(D) of the Act, CMS proposes to require REHs to maintain

detailed information as to how the monthly facility payment has been used. REHs must make this information available upon request. CMS believes this requirement can be met using existing cost reporting requirements for outpatient hospital facilities that would include REHs.

Proposed Methodology to Estimate Medicare CAH Spending in 2019. CMS reviewed whether to use CAH claims data or cost reports to determine 2019 CAH spending. CMS proposes to use CAH claims data as the data shows higher expenditures and more CAHs and CMS believes it is more complete information than using CAH cost reports.

Proposed Methodology to Estimate Prospective Payments to CAH for 2019. Section 1834(x)(2)(C)(i)(II) of the Act directs CMS to use "the estimated total amount that the Secretary determines would have been paid under this title to such hospitals in 2019 if payment were made for inpatient hospital, outpatient hospital, and skilled nursing facility services under the applicable prospective payment systems for such services during such year." As this amount will be a subtraction from estimated 2019 spending for CAHs, the larger the figure, the less will be the additional monthly payment to REHs.

CMS views "under this title" as directing CMS to include payments that CAHs would have received for all services paid under Title XVIII of the Act, not just IPPS, OPPS and SNF services. Other services include inpatient rehabilitation facility (IRF) PPS, inpatient psychiatric facility (IPF) services and other fee-for-service payment systems had the CAH billed them as though they were a hospital or SNF. Other fee-for-service payments include clinical laboratory services; physician services; ambulance services; parenteral and enteral nutrition services; durable medical equipment, prosthetics/orthotics and supplies; vaccines and Medicare Part B drugs if those services and items are reported on an inpatient, outpatient or SNF claim.

CMS further proposes to impute supplemental payments that an IPPS hospital would have received had it been paid under the IPPS. Supplemental payments include new technology add-on, outliers, clotting factor, indirect medical education (IME), disproportionate-share (DSH) including uncompensated care, low-volume hospital, hospital value-based purchasing program (VBP) payments, hospital readmissions reduction program (HRRP), and hospital acquired conditions (HAC) adjustments.

Estimated new technology add-on payments, outlier payments, and clotting factor payments can be determined from the existing CAH claims data. For the low-volume adjustment, CMS will use the CAH's inpatient discharges to impute the adjustment had the CAH been an IPPS hospital. CMS proposes to estimate an aggregate amount of IME, DSH and uncompensated care spending that would have been paid to CAHs had they been IPPS hospitals in 2019 that uses the amounts paid to nearby hospitals. The proposed rule indicates that CMS has no feasible way of estimating VBP payments or HRRP, or HAC adjustments.

CMS provides a detailed methodology for how they calculated each of the types of payments listed above for a CAH had it been paid under the IPPS, OPPS or SNF PPS.

Proposal to determine the total number of CAHs in 2019. CMS proposes to use the number of unique CAH CCNs to determine the total number of CAHs in 2019 regardless of whether they

were open for a full or partial year.

Proposed Calculation of the Monthly REH Facility Payment for 2023. CMS uses the following steps to determine the monthly REH Facility Payment for 2023:

Step 1: The total amount of Medicare spending for CAHs in 2019 less estimated Medicare spending for CAHs in 2019 if inpatient hospital services, outpatient hospital services, and skilled nursing services had been paid on a prospective basis:

$12.08 billion – $7.68 billion = $4.40 billion

Step 2: Divide by the number of CAHs enrolled in Medicare in 2019 divided by 12 months:

($4,404,308,465/1,368) / 12 = $268,294

CMS proposes that the monthly facility payment for REHs for 2023 would be $268,294.[29] This amount would be increased in subsequent years by the hospital market basket.

4. Preclusion of Administrative or Judicial Review

The statute precludes administrative or judicial review of CMS' implementation of all of the REH program provisions including the condition of participation (and CMS' enforcement of them) and the determination of additional facility payments. CMS proposes to codify the preclusion of administrative and judicial review into the regulations.

5. Filing a Cost Report

CMS proposes to specify that an REH is required to file annual cost reports beginning on or after January 1, 2023, in a standardized electronic format.

B. Provider Enrollment

1. General Enrollment Provisions

Section 1861(kkk)(2)(A) requires REHs to be enrolled in Medicare. CMS indicates that the enrollment regulations would apply to an REH (just as they do to all other providers and suppliers) requiring:

- Completion and submission of the applicable enrollment application (Form CMS-855A: Medicare Enrollment Application: Institutional Providers).
- Submission of all required supporting documentation with the enrollment application.
- Completion of any applicable state surveys, certifications, and provider agreements.
- Reporting changes to any of the REH's enrollment information.
- Revalidation of enrollment.

[29] WOW!!!

- Undergoing risk-based screening.

As an REH will be a conversion from a CAH or a small rural hospital, CMS is proposing that an REH does not have to submit an initial enrollment application and can instead submit the Form CMS-855A change of enrollment form. Under CMS' proposal, the REH would not have to pay the application fee of $631. CMS' proposal is a deviation from its normal policy when a provider or supplier changes enrollment types. Normally, CMS would require the provider or supplier to terminate its existing enrollment and enroll as the new provider or supplier type.

CMS is adopting this special policy because of the close nexus between CAHs and small rural hospitals and use of the term "conversion" in the statute when referencing REHs reverting to CAH or small rural hospital status. Further, CMS believes there will be some efficiencies with a change of enrollment compared to an initial enrollment application that will facilitate the REH being enrolled timely by the January 1, 2023 effective date of the provision.

2. Screening Risk Levels

The enrollment regulations include three levels of CMS' assessment of the risk of fraud, waste, and abuse: limited; moderate; and high. Minimum screening functions that apply to all risk levels include:

- Verification that the provider or supplier meets all applicable Federal regulations and state requirements for their provider or supplier type.
- State license verifications.
- Database reviews on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider or supplier type.

CMS proposes to categorize REHs at a limited level of risk meaning that it would be subject to no additional screening requirements.

3. Effective Date of Billing Privileges

Based on existing regulations, the effective date of billing privileges for an REH will be the same date that the provider agreement or approval becomes effective. The provider agreement or approval is effective on the date the state agency, CMS, or the CMS contractor survey is completed (or on the effective date of the accreditation decision, as applicable) if, on that date, the provider or supplier meets all applicable Federal requirements.

C. Use of the Medicare Outpatient Observation Notice

Hospitals are required to provide the Medicare Outpatient Observation Notice (MOON) when a patient receives observation services for more than 24 hours. The notification explains the individual is an outpatient, not an inpatient, and the implications of that classification. REHs are not required by law to provide the MOON. While CMS is not proposing to require REHs to provide the MOON, it does believe there may be instances where the REH provides observation services for more than 24 hours and requests comment on whether the MOON should be

provided in those situations.

D. Physician Self-Referral Law Update.

1. Application of the Physician Self-Referral Law to Rural Emergency Hospitals

CMS concludes both that the physician self-referral law (Stark law) applies to REHs for the designate health services they furnish to Medicare beneficiaries and that the rural hospital exception and the whole hospital exception will not, in all cases, apply to REHs. Rural areas may change due to OMB designation updates, and an REH is not considered a hospital for purposes of the Stark law. The agency is concerned that, absent a broadly-applicable exception to the physician self-referral law (Stark law) referral and billing prohibitions for ownership or investment in REHs, access to medically necessary designated health services furnished by REHs that are owned or invested in by physicians (or their immediate family members)[30] could be inhibited.

Therefore, CMS would establish what it refers to as "the proposed REH exception." It would establish exceptions to the Stark law for financial relationships that do not pose a risk or program or patient abuse for ownership or investment interests in an REH for purposes of the designated health services furnished by the REH. However, CMS does not propose any new exceptions for specific designated health services or for compensation arrangements between REHs and physicians because it believes the existing exceptions in §§411.355 and 411.357 are sufficiently comprehensive to allow for nonabusive referrals and compensation arrangements between REHs and physicians. Some of the exceptions for compensation arrangements in §411.357 apply to hospitals and physicians. Because an REH is not considered a hospital, CMS proposes to permit an REH to use these exceptions when it would not pose a risk of program or patient abuse.

2. Proposed Exception for Rural Emergency Hospitals (§411.356(c)(4))

a. Scope and Structure

CMS proposes to add a definition of the term "rural emergency hospital" to §411.351; it would have the same meaning set forth in section 1861(kkk)(2) of the Act and §419.91. The proposed REH exception would apply to all referrals and billing for designated health services furnished by an REH if all the requirements of the exception are satisfied.

Program integrity requirements similar to those that apply to hospitals would apply to REHs; however, the focus would be on certain requirements in §411.362(b)(4) that relate to ensuring *bona fide* investment as they would apply to an REH. CMS does not believe that Congress intended the requirements for disclosure of conflicts of interest, prohibition on facility expansion, and prohibition on increasing aggregate physician ownership or investment levels to apply in the case of REHs. Similarly, it would not impose other requirements in section 1877(i) of the Act and §411.362, such as reporting and website disclosure requirements. CMS seeks comment on this approach.

The agency is considering whether to require REHs to submit annual reports containing a detailed description of the identity of each owner of or investor in the REH, as well as the nature and extent of all

30 Hereinafter in this section of the summary, any reference to a "physician" also includes a reference to the immediate family members of the physician.

ownership and investment interests in the REH. Comment is sought on whether REHs should disclose on any public website for the REH and in public advertising for the REH that it is owned or invested in by physicians, and whether REHs should require that each physician with an ownership or investment interest in the REH who is a member of the REH's medical staff agrees, as a condition of continued medical staff membership, to provide written disclosure of their ownership or investment interest in the REH to all patients whom the physician refers to the REH.

b. Entity Enrolled as an REH (§411.356(c)(4)(i))

CMS proposes that an entity that uses the proposed REH exception must be enrolled in Medicare as an REH. Facilities not enrolled as an REH could not use the proposed REH exception but may be able to use either the rural hospital or whole hospital exception.

c. Ownership in the Entire REH (§411.356(c)(4)(ii))

One condition of the proposed REH exception would be that the physician's ownership or investment interest must be in the entire REH and not merely in a distinct part or department of the REH. CMS believes that ownership or investment in only a distinct part or department of an REH (e.g., an imaging center) would be an incentive for self-referral; thus, the proposed condition would protect against overutilization and patient steering to less convenient, lower quality, or more expensive services and facilities. Comment is sought on this condition.

d. Conditioning Ownership or Investment on Making or Influencing Referrals or Generating Business for the REH (§411.356(c)(4)(iii))

Another requirement of the proposed REH exception would be that the REH does not directly or indirectly condition any ownership or investment interest held or to be held by a physician on the physician making or influencing referrals to the REH or otherwise generating business for the REH. This is essentially identical to the requirement that applies to hospitals using the rural provider and whole hospital exceptions; CMS would interpret the requirements applicable to REHs and hospitals in the same way.

The agency believes that an REH may fail to satisfy this requirement if it required a specified action or achievement with respect to referrals to or the generation of business for the REH before the purchase or receipt of the ownership or investment interest, or required divestiture of an ownership or investment interest after the occurrence or nonoccurrence of a specified action or achievement with respect to referrals to or the generation of business for the REH. Similarly, the REH could not condition the amount of an ownership or investment interest that a physician may purchase, receive, or maintain on the occurrence or nonoccurrence of a specified action or achievement. CMS seeks comment on what it means to condition an ownership or investment interest held or to be held by a physician on the physician making or influencing referrals to the REH or otherwise generating business for the REH.

CMS notes that this requirement prohibits policies and conduct that directly or indirectly condition ownership or investment interests held or to be held by a physician on the physician making or influencing referrals to the REH or otherwise generating business for the REH. It clarifies that an REH directly conditions ownership or investment interests by adopting policies that require a specific number, volume, or value of referrals to or other business for the REH during a particular time period. However, this may not

apply under circumstances where the REH directs the referrals of the physician under a *bona fide* employment relationship, personal service arrangement, or managed care contract between the REH and the physician that meets the other conditions of the proposed REH exception. Indirect conditioning may include, for example, adopting policies or standards of another person or organization to establish qualification criteria for purchasing or maintaining ownership or investment interests in the REH and those policies or standards required the physician to make or influence referrals to or generate business for the REH. Several examples are included in the preamble.

CMS states that its application and interpretation of the standards for "making or influencing referrals" and "otherwise generating business" and the definition of the term referral with respect to the proposed REH exception would be consistent with those standards and that definition as currently set forth in the exceptions (and the conditions for those exceptions) in regulation.
Comment is requested on this proposed requirement, including examples of directly and indirectly conditioning any ownership or investment interests held or to be held by a physician on the physician making or influencing referrals to the REH or otherwise generating business for the REH.

e. Offer of Ownership or Investment on More Favorable Terms (§411.356(c)(4)(iv))

To qualify for the proposed REH exception, the REH could not offer any ownership or investment interests to a physician on terms more favorable than the terms offered to a person that is not a physician. CMS notes that this condition is essentially identical to the requirement that applies to hospitals that use the rural provider and whole hospital exceptions. It seeks comment on this proposal as well as specific examples of conduct that would satisfy, or fail to satisfy, the proposed requirement.

f. Providing Loans or Financing for Ownership or Investment (§411.356(c)(4)(v))

CMS also proposes to prohibit an REH, and the owners of or investors in the REH, from directly or indirectly providing loans or financing for any investment in the REH by a physician. This condition is essentially identical to the requirement that applies to hospitals that use the rural provider and whole hospital exceptions. The preamble includes examples of both direct and indirect loan practices. Comment is sought on the proposal as well as specific examples of direct and indirect loans.

g. Guarantee, Make a Payment on, or Otherwise Subsidize a Loan (§411.356(c)(4)(vi))

Under the proposed REH exception, an REH, and the owners of or investors in the REH, could not directly or indirectly guarantee a loan, make a payment toward a loan, or otherwise subsidize a loan for a physician that is related to acquiring any ownership or investment interest in the REH. This condition is essentially identical to the requirement that applies to hospitals that use the rural provider and whole hospital exceptions. CMS notes that while the proposed requirement is worded in terms of an individual physician, the condition would also prohibit guaranteeing, making a payment toward, or otherwise subsidizing a loan for a group of physician owners or investors. The preamble incudes examples of each type of prohibited act, and comment is sought on the proposed requirement as well as on specific examples.

h. Proportional Distributions (§411.356(c)(4)(vii))

CMS proposes to require that ownership or investment returns are distributed to each owner of or investor in an REH in an amount that is directly proportional to the ownership or investment interest in the REH of such owner or investor. This condition is essentially identical to the requirement that applies to hospitals that use the rural provider and whole hospital exceptions. Thus, profit distributions, dividend payments, and other payouts on equity could only be tied to the number of shares owned by an investor, and not to their referrals or the other business the investor generates for the REH. The agency defines "proportional" to mean corresponding in size or amount. CMS believes that all owners and investors must be treated the same to ensure that the ownership or investment return to each owner of or investor in the REH is directly proportional to the particular owner's or investor's interest in the REH.

CMS seeks comment on its interpretation of the requirement; it requests specific examples of potentially nonabusive classifications of owners or investors that could justify the distribution of ownership or investment returns only to a subset of owners or investors in an REH or in an amount that is not directly proportional to the ownership or investment interest in the REH of each owner or investor.

i. Guaranteed Receipt of or Right to Purchase Other Business Interests (§411.356(c)(4)(viii))

Another condition to qualify for the proposed REH exception would be that any physician who has an ownership or investment interest in an REH may not directly or indirectly receive any guaranteed receipt of or right to purchase other business interests related to the REH; this would include the purchase or lease of any property under the control of any other owner of or investor in the REH or located near the premises of the REH. This condition is essentially identical to the requirement that applies to hospitals that use the rural provider and whole hospital exceptions.

CMS clarifies that other business interests related to the REH would include a wide array of investment opportunities, ventures, and interests, as well as the examples of the purchase and lease of property under the control of any other owner of or investor in the REH that are listed in the statutory and regulatory requirements applicable to hospitals that use the rural provider and whole hospital exceptions. Comment is sought on the proposed requirement as well as on specific examples of direct and indirect guaranteed receipt of other business interests, direct and indirect guaranteed rights to purchase business interests, and the types of business interests that should be considered related to an REH.

j. Offer to Purchase or Lease Other Property on More Favorable Terms (§411.356(c)(4)(ix))

The final condition of the proposed REH exception would prohibit an REH from offering a physician the opportunity to purchase or lease any property under the control of the REH or any other owner of or investor in the REH on more favorable terms than the terms offered to a person that is not a physician. This condition is essentially identical to the requirement that applies to hospitals that use the rural provider and whole hospital exceptions.

CMS explains the two main differences between the requirements at proposed §411.356(c)(4)(viii) [Guaranteed Receipt of or Right to Purchase Other Business Interests] and this condition. Under the condition for Guaranteed Receipt of or Right to Purchase Other Business Interests, the requirement applies to any business interests related to the REH and prohibits the guaranteed receipt of or right to purchase such other business interests. Under this condition [viz., Offer to Purchase or Lease Other Property on More Favorable Terms], the requirement applies only to property under the control of the REH, an owner of the

REH, or an investor in the REH, and prohibits the offering of the opportunity to purchase or lease such property on terms more favorable than the terms offered to a person that is not a physician.

3. Alternatives Considered

CMS considered whether to include an REH in the definition of hospital for purposes of the Stark law as it had done for critical access hospitals (CAHs). It decided not to do so because REHs are different from CAHs and other hospitals that offer inpatient hospital care and because an REH would have great difficulty meeting one of the existing exceptions for hospitals for ownership or investment interests under the Stark law. Certain REHs would presumptively be excluded from using the rural provider or whole hospital exceptions (i.e., REHs that had no physician owners or investors on March 23, 2010 or December 31, 2010, and REHs that did not have a Medicare provider agreement in effect on December 31, 2010). Additionally, even an REH that qualifies to use the rural provider or whole hospital exception could neither increase the amount of physician ownership or investment in the REH beyond the level of the original hospital on March 23, 2010 nor expand its aggregate number of operating rooms and procedure rooms. CMS was concerned that those limitations could adversely impact the services available to REH patients and the community in which it is located.

4. Applicability of Certain Exceptions in § 411.357 for Compensation Arrangements Involving REHs

CMS proposes to revise certain existing exceptions applicable to compensation arrangements involving specific types of providers to make them applicable to compensation arrangements to which an REH is a party. Specifically, the following exceptions would be modified to also permit an REH to provide remuneration to a physician if all requirements of the applicable exception are satisfied:

- Physician recruitment at §411.357(e),
- Obstetrical malpractice insurance subsidies at §411.357(r),
- Retention payments in underserved areas at §411.357(t),
- Electronic prescribing items and services at §411.357(v),
- Assistance to compensate a nonphysician practitioner at §411.357(x), and
- Timeshare arrangements at §411.357(y).

CMS notes that each of the existing exceptions noted above require that the compensation arrangement to which the exception applies be documented in a writing signed by the parties. The exception for retention payments in underserved areas also requires a written certification that the physician has a *bona fide* opportunity for future employment by a hospital, academic medical center, or physician organization that requires the physician to move the location of his or her medical practice at least 25 miles and outside the geographic area served by the hospital. The exception for assistance to compensate a nonphysician practitioner requires that records of the actual amount of remuneration provided by the hospital to the physician, and by the physician to the nonphysician practitioner, must be maintained for a period of at least 6 years. CMS does not propose any changes to the existing writing, signature, or record retention requirements.

5. Revised Cross-reference in Definition of "Rural Area" for Purposes of the Physician Self-referral Law (§411.351)

CMS notes that the definition of "rural area" as codified in §411.351 for purposes of the Stark law was never updated to reflect OMB's revised standards for defining MSAs. It proposes to modify the rural area definition" in §411.351 to reference §412.64(b) instead of §412.62(f) to mean an area that is not an urban area as defined at §412.64(b). CMS sees this as a technical change that will have no effect on the entities that qualify as "rural providers" under §411.356(c)(1); it welcomes comment on the proposal.

XIX. RFI on Use of CMS Data to Drive Competition in Healthcare

On July 9, 2021, President Biden issued an Executive Order on Promoting Competition in the American Economy (EO 14036), which identifies hospital consolidation as a major concern. The Fact Sheet that accompanied the Executive Order underscored that hospital mergers can be harmful to patients, encouraged the Justice Department and the Federal Trade Commission to review and revise their merger guidelines to ensure patients are not harmed by such mergers, and directed HHS to support existing hospital price transparency rules and to finish implementing legislation to address surprise hospital billing.

CMS highlighted prior MedPAC findings from literature reviews:

- By 2017, in most markets, a single hospital system had more than a 50 percent market share of discharges.
- Hospital consolidation leads to higher prices for commercially insured patients—primarily reflecting hospitals negotiating higher prices with insurers, rather than so-called cost shifting as a result of lower Medicare or Medicaid rates.
- The literature on the effect of mergers on quality of care is mixed and prevented a definitive conclusion.

CMS also cites research that higher prices are observed when physician practices merge.

CMS lists several of its activities to support competition, beginning as far back as 2001, including the following:

- Quality Initiatives, including publicly reporting quality measures for nursing homes, home health agencies, hospitals, and kidney dialysis facilities;
- Publicly available healthcare cost information—for example, through Medicare cost reports and payment information;
- Finalized regulations through CMS' Hospital Price Transparency and Transparency in Coverage initiatives; and
- Release of data outlining hospitals' and nursing facilities' mergers, acquisitions, consolidations, and changes in ownership in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS).

In response to the Executive Order, CMS seeks information from the public on how data that CMS collects could be used to promote competition across the health care system or protect the

public from the harmful effects of consolidation within healthcare. Specifically, CMS seeks comment on the following:

- What additional PECOS data would be helpful to release to help identify the impact of provider mergers, acquisitions, consolidations, and changes in ownership on the affordability and availability of medical care, and why?
- Should CMS release data on any mergers, acquisitions, consolidations, and changes in ownership that have taken place for any additional types of providers beyond nursing facilities and hospitals? If so, for which types of providers?
- What additional information collected by CMS would be useful for the public or researchers who are studying the impacts of mergers, acquisitions, consolidations, or changes in ownership?
- Would PECOS data for transactions occurring before the 2016 CMS revalidation effort be useful for the public or researchers, even if such data may be less complete?

XX. Prior Authorization

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, the process for adding new service categories using notice and comment rulemaking, the agency's discretion to exempt certain providers, and the agency's discretion to suspend the process generally or for a particular service. Table 80 in the proposed rule lists all the service categories and services to which prior authorization currently applies.[31]

B. Proposed Addition of Two New Service Categories

Effective for dates of services on or after March 1, 2023 CMS proposes to add the service category, Facet Join Interventions, to the prior authorization list. This new category would be added as new section §419.83(a)(3) and the existing paragraph (a)(3) would be moved to paragraph (b)(1) with other related changes.

The proposed Facet Joint Interventions service category would consist of facet joint injections, medial branch nerve blocks, and facet joint nerve destruction. Table 79 (reproduced below)

[31] Prior authorization must be obtained for service dates on or after July 1, 2020 for service categories which are: (i) Blepharoplasty, (ii) Botulinum Toxin Injections, (iii) Panniculectomy, (iv) Rhinoplasty, and (v) Vein Ablation. Prior authorization must be obtained for service dates on or after July 1, 2021 for service categories which are : (i) Cervical Fusion with Disc Removal and (ii) Implanted Spinal Neurostimulators.

identifies the CPT codes that CMS proposes would be included in the Facet Joint Interventions service category.

Table 79: 2023 Proposed List of Additional Outpatient Department Services That Require Prior Authorization	
Beginning for service dates on or after March 1, 2023	
Code	**Facet Joint Interventions**
64490	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; single level
64491	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; second level
64492	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; third and any additional level(s)
64493	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level
64494	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; second level
64495	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; third and any additional level(s)
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
64634	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint
64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint

CMS proposes March 1, 2023 as the effective date because the MACs, CMS, and OPD providers already have experience with the prior authorization process. In addition, CMS notes this new service category can be performed by some of the same provider types who furnish other services currently subject to the OPD prior authorization process.

CMS summarizes the analysis performed for utilization of the Facet Joint Interventions service category. It reviewed approximately 1 billion claims related to OPD services from 2012 through 2021 and determined that the overall rate of OPD claims increased each year by an average rate of 0.6 percent. This reflects a decrease from the 2.8 percent average rate the agency found for the 2021 OPPS/ASC proposed rule which evaluated claims from 2007 through 2018. CMS also found an average annual rate-of-increase in the Medicare allowed amount of 4.2 percent which is

also decrease when compared to the 7.8 percent rate identified in the 2021 OPPS/ASC proposed rule. CMS believes the decrease in the average annual increase in the claim volume and allowed amount from the increases reported in the 2021 OPPS/SDC proposed rule is likely due in part to the PHE. CMS found that the total Medicare allowed amount for the OPD services claims process in 2012 was approximately $48 billion and increased to $73 billion in 2021; during this same time period, the average annual increase in the number of Medicare beneficiaries per year was only 0.4 percent. CMS' analysis of the Integrated Data Repository[32] (IDR) shows similar results for the individual CPT codes for this service category. CMS believes the decrease in the average annual increase in the claim volume and allowed amount from the increases reported in the 2021 OPPS/SDC proposed rule is likely due in part to the PHE. Specifically, the claims data for 2020 showed a significance decrease in volume but the overall 9-year period demonstrates an increase for facet joint interventions increased.

In addition, the HHS Office of the Inspector General (OIG) has published multiple reports indicating questionable billing practices, improper Medicare payments, and questionable utilization of facet joint interventions.[33] In March 2022, the Department of Justice reported a $250 million fraud scheme involving physicians allegedly subjecting their patients to medically unnecessary facet joint injections in order to obtain illegal prescriptions for opioids.[34] CMS also 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.

C. Regulatory Impact

CMS estimates the year one administrative cost (10 months) for processing the prior authorization requests for the new service category as approximately $16 million. CMS estimated each review, including appeals, education and system changes, costs $50.

Based on other prior authorization programs, CMS estimates savings based on a 23 percent Savings and estimates that for the first ten months, there would be overall savings of $54.4 million. Annually, CMS estimates an overall gross savings of $65.3 million.

XXI. Overall Hospital Quality Star Rating

CMS believes that the Overall Star Rating provides consumers with a simple, easily understood overall rating for hospitals generated by combining multiple dimensions of quality into a single summary score for use during healthcare decision making. The rating system was first introduced and reported on Hospital Compare in July 2016 and now is accessible using Care Compare. The methodology was recently overhauled as finalized during 2021 rulemaking (85 FR 86182). Ratings have been refreshed periodically, and the next refresh is scheduled to occur during CY 2022.

---

[32] The IDR is a high-volume data warehouse integrating Medicare Parts A, B, C, and D and DME claims beneficiary and provider data sources. Additional information is available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/IDR/index.html.

[33] https://oig.hhs.gov/oas/reports/region9/92004004.asp and https://oig.hhs.gov/oas/reports/region9/92103002.asp.

[34] https://www.justice.gov/opa/pr/16-defendants-including-12-physicians-sentences-prison-distributing-66-million-opioid-pills.

In this rule, CMS proposes to revise regulation text at §412.190 for clarity and provides previously promised follow-up information about adding data from Veterans Health Administration (VHA) hospitals to the ratings. Finally, CMS also discusses the potential application of its measure suppression policy to ratings published in 2023 as needed to address COVID-19 PHE effects on the measure data underlying the ratings.

A. Regulation Text Amendment Regarding Frequency of Publication and Data Used

CMS proposes to clarify which data periods are used to refresh Overall Hospital Quality Star Ratings by referencing a quarter "within the prior 12 months" instead of a quarter "within the prior year". CMS believes the original language might have been construed to refer to a Care Compare refresh from the prior calendar year rather than the intended prior 12 months; the latter period could include months from two different calendar years. The revised language would appear at §412.190.

B. Adding Veterans Health Administration Hospitals to Hospital Quality Star Ratings

When finalizing a policy to include quality measure data from Veterans Health Administration (VHA) hospitals when calculating Overall Hospital Quality Star Ratings, CMS stated its intention to provide information about the impact of incorporating VHA data. In this rule, CMS describes an internal data analysis of 2021 Overall Hospital Quality Star Ratings for non-VHA hospitals before and after incorporation of VHA data into the ratings and ratings results for the VHA hospitals. Technical adjustments were made so that VHA and non-VHA measurement periods were harmonized for all measures.

Data were available for 3,474 hospitals -- 3,355 non-VHA and 119 VHA hospitals. Nearly 70 percent of all VHA facilities were included. CMS found:

- Nearly identical distributions of Star Ratings for the two hospital categories; and
- Some differences in peer group assignments between the two categories:
    - VHA: 12% Peer Group 3, 25% Peer Group 4, 63% Peer Group 5 and
    - Non-VHA: 10% Peer Group 3, 16% Peer Group 4, and 74% Peer Group 5.
- No change in ratings for 3,119 (93%) of non-VHA hospitals after VHA data were added:
    - 23 gained 1 star, 213 lost 1 star.

C. Potential Data Suppression for 2023 Overall Hospital Quality Star Ratings

CMS acknowledges concerns about publishing Overall Hospital Quality Star Ratings in the face of extenuating circumstances such as the COVID-19 PHE. Current policy allows for suppression of one or more measures used for Star Ratings when extenuating circumstances affect numerous hospitals (e.g., natural disasters), CMS makes calculation errors or has systemic issues (e.g., incorrect data processing), or a PHE substantially affects the underlying measure data.

CMS notes that data for nearly all measures used for the 2021 and 2022 Care Compare refreshes of Overall Hospital Quality Star Ratings were collected prior to the COVID-19 PHE declaration because CMS issued a blanket exception from quality data reporting for Q1 and Q2 2020

including all data sources. However, quality data collection resumed with Q3 2020 and has continued without further system-wide interruptions, and CMS has stated an intention to complete a refresh in 2023.

Additionally, CMS cites current policy under which a measure that is considered valid and reliable enough to be reported on Care Compare is thereby also considered to meet the criteria to be included in Overall Hospital Quality Star Ratings calculations. CMS states that this policy remains true even for measures that were suppressed in certain programs due to COVID-19 PHE impacts. Therefore, CMS currently anticipates including suppressed but publicly reported measures from the 3 hospital pay-for-performance programs in upcoming Overall Hospital Quality Star Ratings (e.g., 2023 refresh).[35]

CMS concludes by confirming its intention to refresh Overall Hospital Quality Star Ratings in 2023 on Care Compare, but also states that the agency may choose to exercise its suppression authority should analysis of the underlying measure data show it to have been substantially affected by the COVID-19 PHE.

[35] The 3 P4P programs are the Hospital Readmissions Reduction Program, Hospital Acquired Condition Reduction Program, and the Hospital Value-Based Purchasing Program.

TABLE 84—ESTIMATED IMPACT OF 2023 OPPS CHANGES

	(1)	(2)	(3)	(4)	(5)	(6)
	Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes & Market Basket**	**Rural SCH Off-Campus Policy**	**All Changes**
ALL PROVIDERS	3,502	0.0	0.1	2.9	0.1	2.9
ALL HOSPITALS (excludes hospitals held harmless and CMHCs)	3,411	0.1	0.2	2.9	0.1	3.0
URBAN HOSPITALS	2,686	0.1	0.2	3.0	0.0	2.9
LARGE URBAN >1 million	1,376	0.1	0.1	2.9	0.0	2.9
OTHER URBAN < 1 million	1,310	0.0	0.3	3.0	0.1	3.0
RURAL HOSPITALS	725	-0.1	0.0	2.6	0.7	3.2
SOLE COMMUNITY	374	-0.2	0.1	2.5	1.1	3.4
OTHER RURAL	351	0.0	-0.1	2.6	0.0	2.7
BEDS (URBAN)						
0 - 99 BEDS	887	0.6	0.2	3.5	0.0	3.4
100-199 BEDS	766	0.4	0.2	3.3	0.1	3.3
200-299 BEDS	415	0.2	0.1	3.0	0.1	3.0
300-499 BEDS	388	0.1	0.2	3.0	0.0	2.9
500 + BEDS	230	-0.3	0.2	2.6	0.0	2.6
BEDS (RURAL)						
0 - 49 BEDS	340	0.1	0.0	2.9	0.2	3.0
50- 100 BEDS	223	-0.1	0.3	2.9	0.6	3.2
101- 149 BEDS	85	-0.2	0.1	2.5	0.8	3.2
150- 199 BEDS	39	-0.2	-0.5	1.9	1.4	3.6
200 + BEDS	38	-0.3	-0.2	2.2	0.9	3.0
REGION (URBAN)						
NEW ENGLAND	129	-0.1	0.5	3.1	0.0	3.3
MIDDLE ATLANTIC	313	-0.1	-0.1	2.4	0.0	2.4
SOUTH ATLANTIC	449	0.2	0.0	2.9	0.0	3.0
EAST NORTH CENT.	418	0.0	-0.1	2.6	0.0	2.7
EAST SOUTH CENT.	159	0.1	-0.2	2.6	0.0	2.7
WEST NORTH CENT.	178	-0.2	1.2	3.7	0.1	2.9
WEST SOUTH CENT.	438	0.3	0.0	3.0	0.0	3.1
MOUNTAIN	200	0.4	0.4	3.5	0.1	3.3
PACIFIC	354	0.2	0.3	3.3	0.0	3.2

	(1)	(2)	(3)	(4)	(5)	(6)
	Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes & Market Basket**	**Rural SCH Off-Campus Policy**	**All Changes**
PUERTO RICO	48	0.3	-0.1	2.8	0.0	3.1
REGION (RURAL)						
NEW ENGLAND	20	-0.4	-0.5	1.8	1.9	3.6
MIDDLE ATLANTIC	47	-0.3	-0.5	1.8	1.7	3.9
SOUTH ATLANTIC	107	0.0	0.2	2.9	0.1	3.3
EAST NORTH CENT.	118	-0.1	-0.3	2.3	0.3	2.7
EAST SOUTH CENT.	139	-0.1	-0.3	2.3	0.4	3.0
WEST NORTH CENT.	88	-0.4	0.7	3.0	1.2	3.2
WEST SOUTH CENT.	138	0.3	-0.4	2.5	0.6	3.4
MOUNTAIN	45	0.0	1.7	4.5	0.3	2.9
PACIFIC	23	-0.3	-0.5	1.9	1.0	3.0
TEACHING STATUS						
NON- TEACHING	2,200	0.4	0.1	3.2	0.1	3.3
MINOR	813	0.1	0.1	3.0	0.1	3.0
MAJOR	398	-0.4	0.3	2.6	0.1	2.6
DSH PATIENT PERCENT						
0	4	1.1	0.6	4.4	0.0	4.5
GT 0 - 0.10	242	0.8	0.3	3.8	0.0	3.6
0.10 - 0.16	211	0.4	0.1	3.3	0.0	3.2
0.16 - 0.23	565	0.2	0.1	3.1	0.1	3.2
0.23 - 0.35	1,105	0.0	0.2	2.9	0.2	3.0
GE 0.35	873	-0.1	0.1	2.7	0.1	2.7
DSH NOT AVAILABLE **	411	-1.6	0.1	1.2	0.0	0.9
URBAN TEACHING/ DSH						
TEACHING & DSH	1,074	-0.1	0.2	2.8	0.0	2.8
NO TEACHING/DSH	1,215	0.5	0.1	3.3	0.0	3.3
NO TEACHING/NO DSH	4	1.1	0.6	4.4	0.0	4.5
DSH NOT AVAILABLE2	393	-1.6	0.1	1.1	0.0	0.9
TYPE OF OWNERSHIP						

	(1)	(2)	(3)	(4)	(5)	(6)
	Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes & Market Basket**	**Rural SCH Off-Campus Policy**	**All Changes**
VOLUNTARY	1,940	0.0	0.1	2.8	0.1	2.9
PROPRIETARY	1,033	0.7	0.0	3.5	0.0	3.5
GOVERNMENT	438	-0.2	0.3	2.8	0.1	2.8
CMHCs	25	-11.3	0.2	-8.7	0	-8.4
Column (2) includes all proposed CY 2023 OPPS policies and compares those to the CY 2022 OPPS.						
Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2023 hospital inpatient wage index. The proposed rural SCH adjustment would continue our current policy of 7.1 percent so the budget neutrality factor is 1. The proposed budget neutrality adjustment for the cancer hospital adjustment is 1.0000 because the proposed CY 2023 target payment-to-cost ratio is the same as the CY 2022 PCR target (0.89)						
Column (4) shows the impact of all budget neutrality adjustments and the addition of the 2.7 percent OPD fee schedule update factor (3.1 percent reduced by 0.4 percentage points for the productivity adjustment).						
Column (5) shows the differential impact of the proposed exception for rural sole community hospitals from clinic visits policy when furnished at off campus provider-based departments.						
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 3,502 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.						