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

The Centers for Medicare & Medicaid Services (CMS) released the calendar year 2023[1] final rule for Medicare's hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system (CMS-1772-FC) on November 1, 2022. Policies in the final rule will generally go into effect on January 1, 2023 unless otherwise specified.

The final rule will be published in the November 23, 2022 issue of the *Federal Register*. **The public comment period will end on January 3, 2023.** Public comments will be accepted on the codes listed in Addendum B of the final rule with a Comment Indicator (CI) of "NI" or "NP"—codes with either an interim or proposed Ambulatory Payment Classification (APC) where CMS has not previously sought comment.

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

The final rule also adopts additional policies to implement the Rural Emergency Hospitals (REH) program; a 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; and subsidizing the purchase of domestically produced National Institute of Occupational Safety and Health (NIOSH) approved N-95 masks, among other issues.

Addenda containing relative weights, payment rates, wage indices and other payment information are available on the CMS website at: CMS-1772-FC | CMS. (Scroll down to Downloads and Related Links to find addenda and other data used to set the 2023 OPPS rates). Unless otherwise noted, this weblink can be used to access any information specified as being available on the CMS website.

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

I. Overview

A. Estimated Impact on Hospitals

The increase in OPPS spending due only to changes in the 2023 OPPS final rule is estimated to be approximately $2.53 billion. Taking into account estimated changes in enrollment, utilization, and case-mix for 2023, CMS estimates that 2023 OPPS expenditures, including beneficiary cost-sharing, will be approximately $86.5 billion, an increase of $6.5 billion relative to 2022.

CMS estimates that the update to the conversion factor net of the total factor productivity (TFP) will increase payments 3.8 percent in 2023 (market basket of 4.1 percent less 0.3 percentage points for TFP). Including changes to the frontier wage index, reversal of a 340B budget neutrality adjustment, changes to outlier payments and a change to the payment adjustment for SCHs with off-campus provider-based departments, CMS estimates a 4.5 percent increase in payments between 2022 and 2023.

Hospitals that satisfactorily report quality data will qualify for the full update of 3.8 percent, while hospitals that do not will be subject to an update of 1.8 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 3,508 facilities (3,414 hospitals excluding CMHCs, cancer and children's hospitals held harmless to their pre-OPPS payment-to-cost ratios). Table 110 in the final rule (reproduced in the Appendix to this summary) includes the estimated impact of the final rule by provider type. It shows an estimated increase in expenditures of 4.5 percent for all providers. The following table shows components of the 4.5 percent total:

	% Change All Facilities
Fee schedule increase factor	3.8
Frontier Wage Index	0.1
Removal of the 340B Budget Neutrality Adjustment	0.8
Difference from 2022 outlier payments (1.26% vs. 1.0%)	-0.26
Change to Rural SCH Off-Campus Policy	0.1
All changes	4.5

The 3.8 percent fee schedule increase factor is explained above. CMS does not explicitly identify the frontier wage index as being responsible for a 0.1 percentage point increase in payments. However, column 3 of Table 110 now includes the frontier wage index which is not budget neutral while all other changes in that column are budget neutral. The only factor that can explain the 0.1 percentage point increase in payments is the frontier wage index.

Even though the removal of the 340B adjustment is intended to maintain budget neutrality for increases in payments for Part B drugs, the figure is a net positive because past year payments

were understated. CMS did not update the 340B adjustment for at least 3 prior years (2020 through 2022 and possibly 2019). If CMS had updated the 340B adjustment, payment would have been higher in prior years. The net increase in payments restores annual payments to the amount they otherwise would have been had CMS updated the 340B adjustment annually. In addition, CMS estimates that actual outlier payments in 2022 will represent 1.26 percent of total OPPS payments compared to the 1.0 percent set aside. As CMS estimates that outlier payments will be 1.0 percent for 2023, there is a -0.26 percentage point change in 2023 payments.

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 may have differential effects on individual facilities.

Although CMS projects an estimated increase of 4.5 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	4.7%
All Facilities (includes CMHCs and cancer and children's hospitals)	4.5%
Urban	4.9%
Large Urban	5.0%
Other Urban	4.8%
Rural	2.9%
Beds	
0-99 (Urban)	2.7%
0-49 (Rural)	2.3%
500+ (Urban)	6.9%
200+ (Rural)	3.0%
Major Teaching	2.8%
Type of ownership	
Voluntary	4.9%
Proprietary	1.3%
Government	5.9%

An increase or decrease larger than the average will be accounted for by the differing impact of the 340B budget neutrality adjustment. Those hospitals that were subject to the 340B policy will no longer be paid for separately payable drugs at average sales price (ASP)-22.5 percent and will instead be paid for these drugs at ASP+6 percent. For many (or most) hospitals eligible for 340B discounts, the increase in payments for separately payable drugs will more than offset any the budget neutrality adjustment applied to non-drug OPPS payments. The reverse will be true for hospitals ineligible for 340B drug discounts—they will receive no increase in payments for separately payable drugs and will only see a reduction in non-drug OPPS services due to this factor.

B. Estimated Impact on Beneficiaries

CMS estimates that the aggregate beneficiary coinsurance percentage will be 18.1 percent for all services paid under the OPPS in 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 ($1,600 in 2023) which accounts for the aggregate coinsurance percentage being less than 20 percent.

The inpatient hospital deductible limit is applied to the *actual* copayment 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.

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 June 30, 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 proposed to use cost report data from the June 2020 Hospital Cost Report Information System (HCRIS) data set, which only includes cost report data through 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 final rule payment rates, including the number of claims available at each stage of the process: https://www.cms.gov/files/document/2023-nfrm-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 final rule, CMS is bypassing the 174 HCPCS codes identified in Addendum N. There are seven new bypass codes 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. CMS received one comment asking it to revise the revenue code-to-cost center crosswalk consistent with National Uniform Billing Committee definitions to improve accuracy of OPPS rate setting with respect to chimeric antigen receptor therapy (CAR-T) administration services. CMS will analyze this recommendation and address in future rulemaking if warranted.

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 proposed 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. One comment wrote in support of CMS' proposal.

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 final rule. CMS received no comments on this issue.

Brachytherapy sources. The statute requires the Secretary to create APCs for brachytherapy consisting of a seed or seeds (or radioactive source)—i.e., "brachytherapy sources"—separately from other services or groups of services, in order to reflect the number, isotope, and radioactive intensity of the brachytherapy sources furnished. Since 2010, CMS has used the standard OPPS payment methodology for brachytherapy sources, with payment rates based on source-specific costs as required by statute. CMS proposed no changes to its brachytherapy policy for 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. For this reason, CMS will continue to use a rate of \$4.69 per mm^2 to set the 2023 rate 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 proposed to price four low volume brachytherapy APCs under this policy (excluding those that are priced using external data). CMS received one public comment in support of this policy.

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.

Table 1 of the final rule lists specific C-APC codes combinations where commenters requested complexity adjustments. Of the 12 code combinations listed in the table, CMS had already proposed one for a complexity adjustment that it is finalizing. It is adding one more brought to its attention by a public commenter. The remainder either did not qualify based on cost or frequency criteria or where ineligible because the secondary code is not an add-on and is not classified as a C-APC.

Other commenters requested CMS modify or eliminate the criteria that a combination have 25 or more claims and a violation of the 2 times rule that the mean cost for the highest cost procedure in the APC cannot be more than twice the mean cost of the lowest cost procedure in the originating C-APC to qualify for a complexity adjustment. Some commenters requested that clusters of procedures qualify for complexity adjustments. CMS declined to make these changes indicating that it continues to believe the established criteria are appropriate for applying a complexity adjustment.

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 proposed 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 also proposed 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).

CMS published an interim final rule with comment (IFC) on November 6, 2020 "Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (85

FR 71158-71160). This IFC excluded new COVID-19 treatments from being packaged into C-APCs on or after the effective date of the IFC until the end of the PHE, provided the treatment has an emergency use authorization from the FDA to treat COVID-19 and treatment is not limited to the inpatient setting. See section XXIII.C. for more details regarding this policy when the PHE ends.

As a result of its annual review of the services and APC assignments under the OPPS, CMS proposed to add one new C-APC in 2023: C-APC 5372 (Level 2 Urology and Related Services). Public commenters supported this change that CMS is finalizing.

There were other comments asking CMS to discontinue the C-APC policy for all brachytherapy insertion codes as the C-APC methodology "lacks the charge capture mechanisms to accurately reflect the costs of radiation oncology services." CMS responded that the commenters' calculations do not match how CMS calculates C-APC costs. There were also comments asking that specific brachytherapy codes be moved to higher paying C-APCs. CMS responded that these procedures did not qualify to be moved. No change is being made in response to these comments.

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 proposed to continue its prior composite APC policies for 2023. Several comments requested changes to status indicators for two neuropsychological testing codes to allow them to be paid separately. CMS declined to make this change indicating that it believes they continue to qualify to be paid under the composite APC for mental health services. CMS is finalizing its proposals without modification.

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 final 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 final relative weights respectively for each APC by its associated volume from 2021. It sums the 2022 and final 2023 relative weights respectively, and divides the 2023 final aggregate relative weights by the 2022 aggregate relative weights to determine the weight scaler. Using this process, CMS is adopting a weight scaler of 1.4122. The unscaled final 2023 relative payments are multiplied by 1.4122 to determine the final 2023 scaled relative weights that are shown in Addenda 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 final 2023 conversion factor is $85.5850[2] 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	1.0002	$86.1230	1.0002	$86.1230
Cap on Wage Index Reductions	0.9996	$86.0890	0.9996	$86.0890
Cancer Hospital Adjustment	1.0000	$86.0890	1.0000	$86.0890
Rural Hospital Adjustment	1.0000	$86.0890	1.0000	$86.0890
340B Adjustment	0.9691	$83.4290	0.9691	$83.4290
Update	1.0380	$86.5990	1.0180	$84.9310
Pass-Through/Outlier/N95 Adjustment	0.9883	$85.5860	0.9883	$83.9370
2023 Conversion Factor		$85.5860		$83.9370

CMS removes the prior year's pass-through and outlier adjustments (1.24 percent and 1.0 percent respectively) from the 2022 conversion factor which equals 1.0229 (1/(1-0.0124-0.01) or 2.29 percent). Wage index budget neutrality is 1.0002 (0.2 percent) for 2023. There is a cap on reductions to the wage index that requires a budget neutrality adjustment of 0.9996 (-0.04

[2] HPA calculates a slightly different conversion factor of $85.5860 using CMS' figures.

percent) for 2023. CMS indicates no additional budget neutrality adjustment is needed for the cancer and rural hospital adjustments.

The budget neutrality adjustment for ending the 340B policy equals 0.9691 (1/1.0319 or -3.09 percent). This means that due to ending of the 340B pricing policy and the resulting increase in hospital payments for 340B drugs, all other services are reduced by 3.09 percent.

The update of 1.038 (3.8 percent) equals the market basket of 4.1 percent less 0.3 percentage points for TFP for 2023.

CMS estimates that pass-through spending for drugs, biologicals and devices for 2023 will be $135.5 million, or 0.16 percent of OPPS spending, requiring a budget neutrality adjustment of 0.9984. 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 0.9883 (-1.17 percent).

The 2023 conversion factor for hospitals that submit quality data is $85.5850. The conversion factor for hospitals that do not submit quality data is subject to all of the same adjustments except the update is 1.018 (1.8 percent) instead of 1.038 (3.8 percent). In a different section of the rule, CMS indicates that the reduced conversion factor will be $83.9340.[3] 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 ($83.9340/$85.5850=0.9807).

As in CMS' IPPS rule (and other rules), public commenters argued that the market basket used to update OPPS rates is too low and not reflective the rate of inflation hospitals have been experiencing, particularly sharply rising labor cost and the increased use of higher cost contract nurses. Commenters suggested different sources for the market basket rate of increase or one-time adjustments to recognize sharply rising costs or inadequate increases from prior years. One commenter made a legal argument for why CMS could use its IPPS exceptions and adjustments authority to increase the OPPS market basket rate of increase. Similar to other rules, public commenters supported eliminating or reducing the productivity adjustment stating that economy-wide non-farm productivity overestimates what is achievable by hospitals.

While CMS did not accept the legal argument that the IPPS exceptions and adjustment authority could be applied to the OPPS payment update, it did indicate that if the adjustment were used for this purpose under the IPPS, the OPPS statute requires the same update that is applied under the IPPS. CMS did not specifically address the other comments but has addressed them in other rulemaking vehicles (such as the IPPS). The agency is not making any changes to the market basket in the OPPS final rule but notes that it is significantly higher than what was proposed (3.8 percent relative to 2.7 percent)

C. Wage Index Changes

CMS proposed to continue using a labor share of 60 percent and the fiscal year IPPS post-reclassified wage index for the OPPS in 2023. The final rule directs readers to the IPPS rule for

[3] HPA calculates a slightly different conversion factor for hospitals that do not submit quality data of $83.9370.

more details regarding specific policies affecting the 2023 wage index. In the FY 2023 IPPS rule, CMS is applying a 5 percent cap on reductions to a hospital wage index for any reason. CMS proposed to adopt this same policy under the OPPS for 2023. As noted in the prior section, CMS is making this change budget neutral, necessitating -0.04 percent budget neutrality adjustment to the conversion factor.

Public commenters generally supported the 5 percent cap on reductions to the wage index but asked that the policy not be applied budget neutral. One commenter opposed the cap as inconsistent with the purpose of the wage index which is to reflect geographic differentials in hospital labor costs. CMS responded that it is following the same policy that was adopted for the fiscal year 2023 IPPS final rule. Section 1833(t)(2)(D) of the Act further requires any changes to the wage index to be adopted budget neutral. In response to the commenter opposing the cap, CMS indicated that it will help hospitals more effectively budget and plan when there is predictability in the level of its wage index from year to year.

Other commenters supported or opposed specific wage index policies like the imputed floor or requested that Rural Emergency Hospitals (REHs) be permitted to reclassify to use another area's wage index. With regard to imputed floor, CMS responded that it implementing the statutory requirements as required. With regard to reclassification, CMS responded that reclassification only applies to IPPS hospitals. REHs are not IPPS hospitals.

For non-IPPS hospitals paid under the OPPS for 2023, CMS proposed to continue its past policies of assigning the wage index that would be applicable if the hospital were paid under the IPPS and allowing the hospital to qualify for the out-migration adjustment. For CMHCs, CMS proposed to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. CMS notes that, consistent with its current policy, the wage index that applies to CMHCs includes the rural floor adjustment but not the out-migration adjustment, which only applies to hospitals. CMS did not receive any public comments on these proposals that it is finalizing without change.

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

In cases where there are no data to calculate a hospital's CCR, CMS proposed to continue using the statewide average CCR to determine outlier payments, payments for pass-through devices, and other purposes. The statewide average is used for hospitals that are new, hospitals that have not accepted assignment of an existing hospital's provider agreement, and hospitals that have not yet submitted a cost report. CMS also proposed to use the statewide average default CCRs to determine payments for hospitals that appear to have a CCR falling outside the predetermined ceiling threshold for a valid CCR or for hospitals in which the most recent cost report reflects an all-inclusive rate status. Consistent with other policies to not use cost report data that span the COVID-19 PHE, CMS proposed 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. There were no public comments. CMS is finalizing its proposal.

E. Sole Community Hospital (SCH) Adjustment

For 2023, CMS proposed 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.

There were public comments asking the adjustment be applied to Medicare Dependent Hospitals, rural referral centers, urban sole community hospitals, and rural hospitals with fewer than 100 beds that do not qualify for SCH or critical access hospital status. CMS declined to adopt this suggestion stating that its study only showed significant cost differences in costs for rural SCHs.

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 proposed 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. CMS did not receive any comments on this proposal that it is finalizing without change.

Table 6 in the final rule shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals, with increases in OPPS payments for 2023 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. The final rule indicates that the estimated adjustments shown in Table 6 may be overstated as the cost reporting periods used for the estimates overlaps with costs and payments associated with each cancer hospital that may be impacted by the effects of the COVID-19 PHE.

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 proposed to continue setting aside 1.0 percent of the estimated aggregate total payments for OPPS outlier payments. It proposed calculating the fixed-dollar threshold using the same methodology that was used to set the threshold for 2022 and previous years. CMS proposed 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. All of these proposals are being finalized without change.

CMS proposed to set aside a portion of the 1.0 percent outlier pool, specifically an amount equal to less than 0.01 percent of outlier payments, for CMHCs for partial hospitalization program outlier payments. 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. This policy is also being finalized.

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 proposed to use 2021 Medicare claims data to set the 2023 outlier threshold. This proposal is being finalized without modification. To model hospital outlier payments and set the outlier threshold for the final rule, CMS applied a charge inflation factor of 1.13218 to approximate 2023 charges from 2021 claims.

CMS proposed to use hospital-specific overall ancillary CCRs from the April 2022 update to the Outpatient Provider-Specific File (OPSF) to determine the 2023 rule outlier threshold. However, CMS is using June 2020 cost report data for determining the 2023 OPPS relative weights. CMS explained that since the 2022 OPSF (July 2022 for the final rule) contains cost data primarily from 2021 and 2022 and is the basis for determining current 2022 OPPS outlier payments, CMS believes the 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 adjusted the July 2022 CCRs by 0.974495 to approximate 2023 CCRs.

For 2023, CMS is adopting a fixed dollar threshold of $8,625 (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.

Many commenters expressed concern about the large increase in the proposed 2023 fixed-dollar threshold. These commenters indicated that CMS proposed a large increase the IPPS fixed loss threshold but ultimately adopted a much lower figure after blending fixed loss amounts that were modeled with and without COVID inpatient admissions, implying CMS should adopt the same policy to calculate the OPPS fixed loss threshold.

CMS analyzed its methodology as well as the most up to date CCRs available in the July 2022 OPSF for determining 2023 estimated outlier payments. The agency believes it is reasonable to assume that there would continue to be some effects of the COVID-19 PHE on the outpatient

claims that are used for OPPS rate setting, similar to the 2021 claims data. As a result, CMS is not excluding cases for determining the CY 2023 fixed-dollar threshold.

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 status indicators, APC assignments, and payment rates can be found in Addendum B of this final rule.[4]

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

In the April 2022 OPPS quarterly update, CMS made effective 48 new Level II HCPCS codes and assigned them to interim OPPS status indicators and APCs (Table 7). CMS notes that several of the temporary HCPCS C-codes have been replaced with permanent J-codes, effective January 1, 2023; their replacement codes are listed in Table 7.

Comments and CMS' responses on proposed APC and SI assignments are addressed in their respective sections of this rule.

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 8); several of the temporary C-codes have been replaced with permanent J-codes.

Comments and CMS' responses on proposed APC and SI assignments are addressed in their respective sections of this rule.

3. October 2022 HCPCS Codes - CMS Solicits Public Comments

CMS proposes interim payment status indicators and APC assignments for HCPCS codes that will become effective October 1, 2022 in Addendum B to the 2023 final rule. These codes are flagged with comment indicator "NI" in Addendum B, indicating that CMS has assigned the codes an interim OPPS payment status for 2024. CMS proposes that these status indicators and APC assignments would be applicable in 2023. The status indicators and APC assignments for these codes will be finalized in the 2024 OPPS/ASC final rule.

The HCPCS codes are released to the public through the October 2022 OPPS Update CR and the CMS HCPCS website; the CPT codes will be released to the public through the AMA website.

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

4. January 2023 HCPCS Codes

a. New Level II HCPCS Codes – CMS Solicits Public Comments

CMS solicits comments on the new Level II HCPCS codes that will become effective January 1, 2023. 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 invites public comment** about the status indicators and APC assignments for these codes and this information will be finalized in the 2024 OPPS/ASC final rule.

b. CPT Codes - CMS Solicited Public Comments in the 2023 OPPS/ASC 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 the proposed rule (available in Addendum B of the proposed rule). CMS assigned a new comment indicator "NP" and requested comments on the proposed APC assignment and status indicators. NP indicates that the code is new for the next year or the code is an existing code with substantial revision to its code descriptor in the next year as compared to the current year, with a proposed APC assignment and that comments will be accepted on the proposed APC assignment and status indicator.

For the proposed rule, the CPT code descriptors in Addendum B were short descriptors and the long descriptors for the new and revised CPT codes were available in Addendum O. CMS noted that these new and revised CPT procedure codes had a placeholder for the fifth character. The final CPT code numbers are included in this final rule.

The final status indicators and APC assignments for the new CPT codes that are effective January 1, 2023 are listed in Addendum B to this rule.

Comments and CMS' responses on proposed APC and SI assignments are addressed in their respective sections of this rule.

Table 9 (reproduced below) summarizes the process used by CMS for updating codes.

Table 9: Comment and Finalization Timeframes 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

Table 9: Comment and Finalization Timeframes for New or Revised HCPCS codes				
OPPS Quarterly Update CR	**Type of Code**	**Effective Date**	**Comments Sought**	**Finalized**
July 2022	HCPCS (CPT and Level II Codes)	July 1, 2022	2023 OPPS/ASC proposed rule	2023 OPPS/ASC final rule with comment period
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 update are discussed in the relevant specific sections of this rule.

For 2023, CMS identified 23 APCs with violations of the 2 times rules and proposed changes to the procedure codes assigned to these APCs in Addendum B (identified with comment indicator "CH"). CMS noted that in many cases, the proposed procedure code reassignments and associated APC configurations for 2023 are related to changes in costs of services that were observed in the 2021 claims data.

2. APC Exceptions to the 2 Times Rule

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

- resource homogeneity;
- clinical homogeneity;
- hospital outpatient setting utilization;

- frequency of service (volume); and
- opportunity for upcoding and code fragments.

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

Table 10 (reproduced below) lists the 23 APCs that CMS finalizes 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. CMS notes it only identified APCs, including those with criteria-based costs, such as device-dependent CPT/HCPCS codes, with violations of the 2 times rule, where a 2 times rule violation is a relevant concept.

Table 10: Final 2023 APC Exceptions to the 2 Times Rule

2023 APC	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 2023 payment rates for these New Technology APCs are included in Addendum A.

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

CMS uses the following criteria for assigning a complete or comprehensive service to a New Technology APC:

1. the service must be truly new, meaning it cannot be appropriately reported by an existing HCPCS code assigned to a clinical APC and does not appropriately fit within an existing clinical APC;
2. the service is not eligible for transitional pass-through payment (however, a truly new comprehensive service could, on its own, qualify for assignment to a new technology APC even if it involves a device or drug that could, on its own, qualify for a pass-through payment); and
3. the service falls within the scope of Medicare benefits under section 1832(a) of the Act and is reasonable and necessary with section 1862(a)(1)(A) of the Act (66 FR 59898-59903).[5]

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

[5] Additional information is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospital/OutpatientPPS/passthrough_payment.

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 for 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 its 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. In 2022, CMS also finalized changes to the time period in which a service can be eligible for payment under a New Technology APC.

3. Procedures Assigned to New Technology APC Groups for 2023

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 finalizes its proposal 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 11.).

b. Administration of Subretinal Therapies Requiring Vitrectomy (APC 1562)
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 rate setting for HCPCS code C97770 and CMS finalizes its proposal to base the payment rate on claims data rather than on using a crosswalk to HCPCS code 67036. For 2023, CMS assigns HCPCS code C9770 to APC 1562 (Table 14).

c. Bronchoscopy with Transbronchial Ablation of Lesion(s) by Microwave Energy (APC 1562)
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 finalizes its proposal to continue to assign HCPCS code C9751 to APC 1562 (Table 11).

d. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies (APCs 1520, 1521, and 1523)
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 finalizes its proposal 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 finalizes reassigning CPT code 78431 from APC 1522 to APC 1523. CPT code 78432 had only 5 single frequency claims in 2021. CMS applies its universal low volume APC policy and finalizes reassigning CPT code 78432 from APC 1523 to APC 1520. CPT code 78433 had 954 single frequency claims in 2021. CMS finalizes reassigning CPT code 78433 from APC 1523 to APC 1521 (Table 15).

Multiple commenters supported the assignment of CPT code 78431 to APC 1523; these commenters also requested that CPT codes 78432 and 78433 be assigned to APC 1523. For CPT code 78433, CMS identified 1,034 separately payable claims which is well above the threshold for the low volume methodology. Using the geometric mean costs for the service described by CPT 78433, CMS calculated a cost of approximately $1,998 which is within the range for APC 1521 ($1,901-$2,000).

CMS notes there are only five separately payable claims for CPT code 78432. Using the new technology low volume policy to determine the appropriate APC assignment, CMS calculated the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data; CMS notes the only available claims data for 78432 is 2021. The arithmetic mean cost of approximately $1,900 was the highest cost for the service and CMS finalizes the APC assignment to APC 1520 ($1801-1900).

e. V-Wave Interatrial Shunt Procedure (APC 1590)
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 finalizes its proposal to continue to assign this procedure to APC 1590 (Table 16).

[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.

f. Corvia Medical Interatrial Shunt Procedure (APC 1592)
Corvia Medical's 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 finalizes its proposal to continue to assign this procedure to APC 1592 (Table 17).

g. Supervised Visits for Esketamine Self-Administration (APCs 1512 and 1516)
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 dissociation 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 the drug 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 proposed to use 2021 claims data to determine the payment rates for HCPCS codes G2082 and G2083. For 2023, CMS proposes to reassign HCPCS codes G2082 from APC 1508 to APC 151 and HCPCS code G2083 from APC 1511 to 1516 (Table 19). Commenters were generally in favor of this proposal.

CMS finalizes its proposal to assign HCPCS codes G0282 and G2083 to new technology APCs based on the codes' geometric mean costs. CMS notes, however, based on updated claims data available for this rule, the approximate geometric mean cost for HCPSC code G2082 is $1,056 and CMS finalizes assigning this code to APC 1512 (New Technology APC – Level 12 ($1001-$1100). The geometric mean cost for G2082 is $1,496 and CMS finalizes its proposal to assign G2083 to APC 1516 (New Technology-Level 16 ($1402-$1500) (Table 19).

h. DARI Motion Procedure (APC 1505)
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

[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.

was effective January 1, 2022. For 2022, CMS assigned CPT code 0693T to New Technology APC 1505.

For 2023, CMS finalizes its proposal to continue to assign CPT code 0693T to APC 1505 (Table 20).

i. Histotripsy Service (1575)
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 finalizes its proposal to continue to assign CPT code 0686T to APC 1575 (Table 21).

j. LiverMultiscan Service (1511)
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 finalizes its proposal to continue to assign CPT code 0648T to APC 1511 (Table 22).

In the 2022 OPPS final rule (86 FR 63542), CMS finalized that the service represented by CPT code 0649T was a packaged service per the OPPS packaging policy. In this final rule, CMS adopts a policy that Software as a Service (SaaS) add-on codes are not among the "certain services described by add-on codes" for which it packages payment with the related procedures or services (§419(b)(18)). Instead, SaaS CPT add-on codes will be assigned to identical APCs and have the same status indicator assignments as their standalone codes (discussed below in section X.G). CMS finalizes assigning CPT code 0649T to the same APC as CPT 0648T, New Technology APC 1511 (Table 22).

k. Minimally Invasive Glaucoma Surgery (MIGS) (APC 1563)
For 2022, two new Category I CPT codes were created for extracapsular cataract removal with insertion of intraocular lens prosthesis (66989 and 66991) and Category III code (0671T) for insertion of anterior segment aqueous drainage device was deleted. CMS assigned CPT codes 66989 and 6691 to New Technology APC 1526 and CPT code 0671T to APC 5491.

For 2023, CMS proposed to continue to assign CPT codes 66989 and 66991 to APC 1526. CMS notes it inadvertently misidentified the APC assignment as APC 1526, rather than 1563, in the preamble in the proposed rule. CMS finalizes the assignment of these codes to 1563 (Table 24).

l. Scalp Cooling (APC 1520)
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 sessions. CMS assigned CPT code 0662T to APC New Technology 1520.

For 2023, CMS finalizes its proposal to continue to assign CPT code 0662T to APC 1520 (Table 25).

m. Optellem Lung Cancer Prediction (LCP) (APC 1508)
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 finalizes its proposal to continue to assign CPT code 0721T to APC 1508. CMS agrees with a comment from the manufacturer of Optellum LCP to revise the description of the Optellum LCP proposed risk score. Consistent with its finalized policy for SaaS add-on codes (discussed below in section X.G.), CMS assigns CPT code 0722T to New Technology APC 1508 (Table 27).

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 finalizes its proposal to continue to assign CPT code 0723T to APC 1511. Consistent with its finalized policy for SaaS add-on codes (discussed below in section X.G.), CMS assigns CPT code 0724T to New Technology APC 1511 (Table 29).

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 finalizes its proposal to continue to assign HCPCS code C9782 to APC 1590 (Table 30).

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 proposed to apply this policy to four clinical APCs (5244, 5494, 5495, 5881) and four brachytherapy APCs (2632, 2635, 2636, 2647), all of which are low-volume for 2022. Table 31 of the final rule shows each APC's number of claims, geometric mean cost from 2021 claims, median cost, arithmetic mean cost and geometric mean cost using four years of data and the highest value among the alternatives.

Public comments supported CMS' proposal but requested that there be a 10 percent cap on the reduction in the APC's relative weight as the decline in value for APC 5495 was 32 percent under CMS' proposed rule methodology. CMS indicated that an additional procedure was assigned to APC 5495 in the final rule mooting the concern in the comment.

The proposal is being finalized without change. CMS notes it proposed to use the low volume methodology for one APC (5881 Ancillary Outpatient Services When Patient Dies) that now has more than 100 claims using final rule data. CMS is finalizing using the low volume methodology for this APC as public commenters would not have had an opportunity to comment on its value using the standard methodology in the proposed rule

E. APC-Specific Policies

This section discusses comments and CMS responses for **53 APC-specific proposals** (listed in the table below). The numbering in the table is consistent with the preamble format. Highlights of some of these proposals are summarized (indicated by an asterisk in the table). The reader is referred to the final rule for specific details.

	TOPIC*	APC	CMS Finalizes Proposed APC
1.	Abdominal Hernia Repair*	5341 & 5361	No
2.	Administration of Lacrimal Ophthalmic Insert into Lacrimal Canaliculus	5503	No
3.	Artificial Iris Insertion Procedure	5495	No

	TOPIC*	APC	CMS Finalizes Proposed APC
4.	Blood Product Not Otherwise Classified	9537	Yes
5.	Bone Density Tests/Bone Mass Measurement: BCT and DXR-BMD Analysis	NA	NA
6.	Calculus Aspiration with Lithotripsy Procedure	5376	Yes
7.	Cardiac Computed Tomography (CT)	5571	Yes
8.	Cardiac Contractility Modulation (CCM) Therapy	5232	Yes
9.	Cardiac Magnetic Resonance (CMR) Imaging	5572 & 5573	Yes
10.	ClariFix Procedure	5165	No
11.	Cleerly Labs	1511	Yes
12.	Coflex Interlaminar Implant Procedure	5116	Yes
13.	Colonic Lavage	5721	No
14.	CoverScan	5523	Yes
15.	COVID-19 Vaccine and Monoclonal Antibody Administration Services*	NA	NA
16.	Duplex Scan of Extracranial Arteries	5523	Yes
17.	Endoscopic Submucosal Dissection (ESD) Procedures	5303	No
18.	Endovenous Femoral-Popliteal Arterial Revascularization	5193	Yes
19.	External Electrocardiographic (ECG) Recording	5732	Yes
20.	Eye Procedures	5502 & 5503	Yes
21.	Eye-Movement Analysis Without Spatial Calibration	5734	Yes
22.	Fecal Microbiota Procedure	5301	Yes
23.	Fractional Flow Reserve Derived from Computed Tomography (FFRCT)	5724	Yes
24.	Gastrointestinal Motility	5722	No
25.	Gastrointestinal Myoelectrical Activity Study	5723	No
26.	Hemodialysis Arteriovenous Fistula Procedures	5194	Yes
27.	IB-Stim Application Service	5724	No
28.	IDx-DR: Artificial Intelligence System to Detect Diabetic Retinopathy	5733	Yes
29.	Insertion of Bioprosthetic Valve	5184	Yes
30.	InSpace Subacromial Tissue Spacer Procedure	5115	No
31.	Intervertebral Disc Allogenic Cellular and/or Tissue-Based Product Percutaneous Injection	5115	Yes
32.	Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS)	5463	Yes
33.	Medical Physics Dose	5723	No
34.	Minimally Invasive Glaucoma Surgery (MIGS)	5491	Yes
35.	Musculoskeletal Procedures	5111-5116	Yes
36.	Neurostimulator and Related Procedures*	5461-5465	No
37.	Optilune Cystourethroscopy	5374	Yes

	TOPIC*	APC	CMS Finalizes Proposed APC
38.	Pathology Services	5672	Yes
39.	Percutaneous Arthrodesis of the Sacroiliac Joint	5116	Yes
40.	Placement of Breast Localization Devices	5071 & 5072	Yes
41.	ProSense Cryoablation Procedures	5091	No
42.	Pulmonary Rehabilitation Services	5731	Yes
43.	Remote Physiologic Monitoring Services	NA	NA
44.	Repair of Nasal Valve Collapse	5165	No
45.	Single-Use Disposable Negative Pressure Wound Therapy (dNPWT)	5052	Yes
46.	Surfacer Inside-Out Access Catheter System	1534	Yes
47.	Total Ankle Replacement Procedure	5116	Yes
48.	Transcatheter Implantation of Coronary Sinus Reduction Device	5193 & 5194	No
49.	Transnasal Esophagogastroduodenoscopy (EGD)	5301 & 5302	No
50.	Unlisted Dental Procedures*	5871	No
51.	Urology and Related Services	5371-5378	No
52.	Waterjet Prostrate Ablation	5376	Yes
53.	Zoll uCor Heart Failure Management System (HFSM) Monitoring*	NA	NA
*Discussed in HPA Summary			

1. Abdominal Hernia Repair (APCs 5341 and 5361)

For 2023, the CPT Editorial Panel deleted 18 abdominal hernia repair codes and replaced them with 15 new codes. The predecessor/deleted codes were assigned to one of the following APCs for 2022: APC 5341 (Abdominal/Peritoneal/Biliary and Related Procedures), APC 5361 (Level 1 Laparoscopy and Related Services), and APC 5362 (Level 2 Laparoscopy and Related Procedures) (Table 33). CMS evaluated the new codes and because the predecessor codes were not a match to the new CPT codes, CMS proposed to assign eight of the new codes to APC 5341, six of the new codes to inpatient-only status, and one to packaged/bundled status because the code describes an add-on procedure (Table 34).

At the August 2022, HOP Panel Meeting, a presenter provided information on the proposed APC assignments; the Panel made no recommendations on the APC assignments for the new codes. Some commenters disagreed with the proposed assignments to APC 5341 for the eight separately payable codes and commenters provided a wide range of recommendations. CMS discusses five of these suggestions in the proposed rule.

Based on the various recommendations and input from the CMS medical advisors, CMS believes assigning the new codes to APCs 5341 and 5361 is the best option. CMS finalizes its proposal to assign CPT codes 49591, 49593, 49595, 49613, and 49614 to APC 5341 and assign CPT codes 49592, 49594, and 49614 to APC 5361. CMS finalizes its proposal to assign status indicator "C"

(designating "in-patient" only status) for CPT codes 49596, 49616-49618, 49621, 49622. In addition, CMS finalizes its proposal to assign status indicator "N" (packaged) to CPT code 49623. Table 35 summarizes the final 2023 status indicators, APC assignments, and payment for these codes.

15. 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 proposed 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. CMS also proposed 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.

CMS noted that the 2022 payment rates for COVID-19 vaccine administration services are site-neutral across most outpatient and ambulatory settings. In the 2023 PFS proposed rule, 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 such as the OPPS) using the annual increase to the Medicare Economic Index (MEI). CMS finalized this policy in the 2023 PFS final rule.[8]

Most of the commenters supported CMS' proposal. One commenter expressed concerns over site-neutral payment policies because it may make it more challenging for different settings to offer certain services when reimbursement does not adequately reflect the different costs for providing care. One commenter stated that adjustments to the payment rate for COVID-19 vaccine administration should be made consistent with the proposal in the 2023 PFS proposed rule and be adjusted based on MEI and GAF.

CMS continues to believe that the resources associated with COVID-19 vaccine administration do not vary across settings of care and are largely consistent across physician office and hospitals outpatient department settings. CMS agrees that for 2023, the payment rates should be consistent across settings of care and that a higher payment rate in the physician office could create financial incentives to furnish vaccines in that setting instead of the hospital setting. CMS will consider whether to implement permanent site-neutral payment rates in future rulemaking.

For 2023, CMS finalizes adoption of the PFS payment rates for COVID-19 vaccine administration using its equitable adjustment authority at section 1833(t)(2)(E) of the Act. CMS

[8] Available at https://public-inspection.federalregister.gov/2022-23873.pdf.

will continue this payment until the Emergency Use Authorization (EUA) declaration pursuant to section 564 of the Federal Food, Drug and Cosmetic (FD&C) Act covering these products ends.

- CMS finalizes payment rates for APCs 9397 and 9398 of $41.52 if the EUA declaration persists into 2023 and $31.14 if the EUA declaration is terminated in 2022. CMS notes it displays a payment rate of $41.52 in Addendum B of this rule and if needed, will update the APC payment rate to $31.14 through subregulatory guidance.
- CMS finalizes creating a new APC, APC 9399 (Covid-19 vaccine home administration), with a payment rate of $36.85 and reassign HCPCS code M0201.

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

Several commenters stated they supported a site-neutral payment policy for vaccines because in general the resource cost of administering a vaccine is consistent across settings of care but they believe the OPPS rate-setting is more acute that the PPS as the OPPS methodology is updated each year by new cost data which is a reliable source of current hospital costs. CMS acknowledges this input and will consider any changes to the payment methodology for preventive vaccines in future rulemaking.

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.[9]

For 2023, CMS finalizes its proposal to use its 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.

CMS noted 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

[9] 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.

rule[10], CMS clarified 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 under section 564 of the FD&C for drugs and biologics is terminated.

CMS finalizes its proposal 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 EUA declaration for drugs and biological products is terminated, so long as after the EUA is terminated these products have market authorization.

36. 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 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 the proposed rule, CMS believed that the five-level structure for this series remained appropriate. The proposed geometric mean cost for the Level 5 APC was $30,198.36 with the geometric means of codes with significant volume ranging from approximately $28,000 to $36,000. CMS noted 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 proposed to maintain the current 5-level structure. Given commenters' concerns about the current APC levels, CMS sought comments on the potential creation of a new Level 6 APC from the current Level 5 within the Neurostimulator and Related Procedures APC series. Several commenters supported the creation of a Level 6 Neurostimulator and Related Procedures APC but other commenters recommended maintaining the current 5 level APC structure. Several commenters requested that HCPCS code 0424T be temporarily assigned to New Technology APC 1581, which has a final OPPS payment rate of $55,000.50. Commenters believed that this temporary assignment would provide appropriate payment and support beneficiary access until sufficient claims data are available for rate-setting.

After reviewing the claims data for this final rule, CMS continues to believe the 5-level APC structure remains appropriate based on clinical and cost characteristics and finalizes its proposal to maintain the 5-level structure. CMS agrees with the request for reassignment of CPT code 0424T and reassigns the code to New Technology APC 1581 for 2023.

[10] 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.

50. 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 believed that APC 5161 was not the most clinically appropriate APC series for this code. For 2023, CMS proposed to reassign HCPCS code 41899 to clinical APC 5871, which is the only APC group that specifically describes dental procedures.

CMS received many comments expressing concern that patients with disabilities and children have limited access to dental care under general anesthesia in an operating room and explained why sedated dental care is important for vulnerable populations. Several comments from dentists described the difficulties reserving operating rooms to provide dental care to vulnerable patients requiring general anesthesia. A commenter recommended CMS create an oral rehabilitation code that would describe dental services under general anesthesia, including dental rehabilitation surgery, in a hospital or ASC. All commenters were supportive of the proposed reassignment of CPT code 41899 to APC 5871 and indicated that this increase in Medicare payment for covered dental procedures would potentially mitigate the reimbursement obstacles to access to operating rooms.

In response to comments, CMS notes there are statutory and regulatory limitations regarding Medicare coverage and payment for dental services. CMS also reiterates its longstanding policy of assigning unlisted codes, like CPT 41899, to the lowest level APC within the most appropriate clinically related APC group, without consideration of resource costs.

In response to comments referencing the dental proposals in the 2023 PFS proposed rule that will potentially expand the number of dental procedures covered by Medicare, CMS states that the assignment of a HCPCS code a payment rate under the OPPS does not mean the service is covered by the Medicare program but indicates only how the service may be paid if the MACs determine the service meets all program requirements for coverage. CMS notes it has not proposed to assign any additional codes describing specific dental services to an APC or to the ASC CPL list for 2023. CMS will address APC assignments for codes describing dental procedures that are described by the dental policy discussed in the 2023 PFS final rule in future rulemaking.[11]

Final Decision: After consideration of comments, CMS is not finalizing the proposed APC reassignment for CPT 41899 to APC 5871 (Dental Procedures). CMS states that the policies in this final rule only apply to hospital outpatient department services covered by Medicare Part B and paid under the OPPS. CMS finalizes:

- The continued assignment of CPT 41899 to APC 5161 (Level 1, ENT Procedures), the lowest-level, clinically appropriate APC.
    - The use of CPT 41899 should be limited to procedures that are not otherwise described by other, more specific dental codes. CMS states that unlisted CPT 41899 may be used more broadly to describe other dental or other dental-related

[11] Available at https://public-inspection.federalregister.gov/2022-23873.pdf.

procedures on teeth and gums, not otherwise described by other HCPCS codes assigned to APCs.

- The establishment of a new G-code, HCPCS G0330, which will be assigned to APC 5871.
    - G0330 describes facility services for dental rehabilitation procedures performed on patients who require monitored anesthesia (e.g., general, intravenous sedation (monitored anesthesia care)) and use of an operating room.
    - G0330 is not payable in the ASC setting; CMS will consider adding it to the ASC covered list in future rulemaking.
    - G0330 cannot be used to describe or bill the facility fee for non-covered dental professional services.
- Payment will be made for services identified with CPT code 41899 or G0330 when those services meet Medicare coverage requirements.

53. ZOLL Heart Failure Management System Service (HFSM) Monitoring

The HFMS is designed to help clinicians improve outcomes for heart failure patients with potential fluid management problems by providing monitoring for pulmonary fluid levels, an early indicator for heart failure decompensation. Effective July 1, 2023, the CPT Editorial Panel established CPT 0607T and 0608T to describe the HFSM. For 2023, CMS proposed to continue to assign CPT 0607T to status indicator "V" (clinic or ED visit) and APC 5012 (Clinic Visits and Related Services). CMS also proposed to continue to assign CPT 0608T to status indicator "S" (procedure or service, not discounted when multiple) and APC 5741 (Level 1 Electronic Analysis of Devices).

The manufacturer commented that these services are not performed in the HOPD setting and are exclusively IDTF services; the APC assignments has resulted in confusion that has impacted access of the HFMS to Medicare patients. The manufacturer requested that CMS revise the status indicators to either "A", "B", or "M" to indicate the services are not payable under the OPPS. The commenter also indicated that no hospital in the U.S. possesses the HFMS technology and the services are only provided through ZOLL's IDTFs.

CMS accepted the recommendation and finalizes status indicators for these codes to "A" to indicate that the services associated with CPT code 0607T and 0608T are contractor priced. CMS is also assigning these status indicator "A" to these codes under the PFS.

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 rate-setting. 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 proposed 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 rate-setting), CMS proposed 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 sought comments on how the circumstances for 2023 are similar to 2022, when it adopted the equitable authority to continue pass-through status.

Many commenters noted that the persistence of the PHE through 2021 and 2022 impacted beneficiary access to certain drugs, biologicals, and devices, and also disrupted product utilization which will be reflected in the 2021 claims data. Commenters believed the rationale for continuing separate payments for pass-through technologies impacted by the PHE remain just as pertinent for 2023 rate-setting as for the 2022 rate-setting.

CMS received many comments specific to providing additional quarters of separate payments for drugs and biologicals; a commenter was concerned about the continued major distortions in the claims data impacting numerous specialties. One commenter requested an extension of the pass-through period for all radiopharmaceuticals impacted by the ongoing PHE.

CMS appreciates these concerns but it does not agree that the circumstances for 2023 are similar to those in 2022 when it adopted the equitable adjustment to continue pass-through status for drugs, biologicals, and a device category with pass-through status that expired between December 31, 2021 and September 30, 2022. Based on CMS' decision 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 rate-setting) (discussed in section X.B), CMS finalizes its proposal 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.

CMS discusses a comment from Styker requesting the pass-through status for SpineJack® (C1062) continue through 2023 due to many reasons, including erroneous National Correct Coding Initiative (NCCI) claim edits and errors on commercial Medicare claims submission software edits. CMS responds that it will take these comments into consideration for the 2024 rulemaking.

CMS acknowledges it inadvertently stated that there were 11 device categories but omitted two devices from Table 30 in the proposed rule and inadvertently did not use the appropriate devices in the estimate of pass-through spending. Table 52, reproduced below, provides an updated list of 14 devices currently receiving device pass-through payment. CMS notes that three device

categories are finalized in this final rule with comment period. Based on the information in Table 52, eight device categories receive pass-through payments effective January 1, 2023.

Table 52: Devices with Pass-Through Status (or Adjusted Separate Payment) Expiring at the End of the Fourth Quarter of 2022, in 2023, or in 2024

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
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
C1831	Personalized, anterior and lateral interbody cage (implantable)	10/1/2021	9/30/3024
C1832	Autograft suspension, including cell processing and application, and all system components	1/1/22	12/31/2024
C1822	Monitor, cardiac, including intracardiac lead and all system components (implantable)	1/1/22	12/31/2024

*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.

Device pass-through applications are 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 eight 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 application was approved under the alternative pathway: the aprevo™ Intervertebral Body Fusion, effective October 1, 2021.

Detailed instructions on submission of a quarterly device pass-through application are included on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf.

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

- **Under the alternative pathway, CMS finalizes 2023 device pass-through payments for the VivoStim System and the continuation of the device pass-through payment status for the Aprevo Intervertebral Body Fusion Device.**
- **Under the traditional pathway, CMS finalizes 2023 device pass-through payments for the Evoke Spinal Cord Stimulation System and Ureterol.**

i. Alternative Pathway Device Pass-Through Applications

(1) aprevo™ Intervertebral Body Fusion Device[12]

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

CMS did not receive any comments about the newness criterion and concludes that Aprevo meets the newness criterion.

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

The applicant submitted a comment reiterating how aprevo meets the eligibility requirements. CMS agrees that Aprevo meets the eligibility criteria.

Establishing a New Device Category

(i) Existing payment category. CMS has not identified an existing pass-through payment category that describes aprevo. CMS did not receive any comments on this criterion and concludes that Aprevo meets the device category eligibility 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 aprevo meets all the cost criteria.

The applicant requested that CMS adjust the device offset amount associated with the use of the aprevo interbody device to reflect only the interbody device-related costs for the procedure. The applicant requested the analysis should be done with the applicable CPT code 22633 which

[12] 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.

describes a procedure requiring both the posterior interbody fusion and posterolateral fusion and that aprevo does not replace all existing technologies used in this procedure because the interbody device is not applicable to the posterolateral fusion. CMS appreciates the applicant's input and agrees that it should adjust the off-set amount associated with the use of the aprevo interbody device to $0. Addendum B of the final rule contains the APC payment rates for 2023.

Effective October 1, 2021, CMS finalizes the aprevo Intervertebral Body Fusion approval for pass-through payment.

CMS summarizes the applicant requests that CMS change the device descriptor for C1831 to include the posterior/transforaminal approach and to remove CPT code 22612 as an applicable code for billing devices described by C1831. CMS agrees with the applicant that the long descriptor for C1831 should be updated to include the posterior interbody implant device which is surgically placed through the posterior/transforaminal approach. CMS believes however, that the anterior and lateral implant devices should remain in the descriptor in the event that surgical procedures for their placement are removed from the IPO list in the future. Effective January 1, 2023 the long descriptor for C1831 will be "Interbody cage, anterior, lateral or posterior, personalized (implantable)."

CMS also agrees that CPT code 22612 was incorrectly included in the *October 2021 MLN Matters* article as an applicable code to bill devices described by C1831. CMS will provide updated instructions in the January 2023 MLN Matters article that removes CPT code 22612 and reflects the additional CPT codes 22632 and 22634 as applicable codes to bill devices described by C1831.

(2) MicroTransponder® Vivistim® Paired Vagus Nerve Stimulation (VNS) System (Vivistim® System)[13]

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.

The applicant reiterated that Vivistim System received FDA marketing authorization on August 27, 2021 but manufacturing delays prevented market availability of the device until April, 2022; the applicant requested the newness period begin on April 29, 2022. CMS replies that because it received the pass-through application on September1, 2021 which is within 3 years of the August 27, 2021 FDA premarketing approval it does not need to consider the date when the system was first marketed.

[13] 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.

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.

In the proposed rule, CMS noted 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 sought comments on whether Vivistim System meets this eligibility requirements.

In response to CMS' concerns, the applicant noted that the Vivistim System is similar to other implantable neurostimulator system that include implantable components and external components. The applicant stated the external components communicate remotely with the implantable pulse generator, are integral to the function of the system, and the implanted components cannot work as intended without the external paired stimulation control and vice versa. The applicant also asserted the FDA approval for the Vivistim System does not acknowledge a distinction between implanted and non-implanted components, which are collectively approved as a "device". The applicant noted that this is not unique to its system and is similar to other neurostimulator systems with reusable clinical interfaces for which a new device category was previously created (C1820, C1822, C1833 and C1825). The applicant also stated that the Vivistim System external paired stimulation controller is provided at no cost under a loaner agreement, where ownership of the device is retained by the manufacturer.

Based on the additional information provided by the applicant, CMS agrees that the components of the device are used for one patient only, come in contact with human tissue, and are surgically implanted or inserted. CMS notes that the eligibility criterion at §419.66(b)(3) differ from the criteria FDA utilizes to grant medical device approvals. CMS also agrees that the applicable components meet the eligibility requirement because they are not equipment, an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered and are not a supply or material furnished incident to a service (§419.66(b)(4)).

CMS concludes that the Vivistim System meets the eligibility criterion at §419.66(b)(3) and (4).

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 54 (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 54: 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

In the proposed rule, CMS noted 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 disagreed 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 believed 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 treatment at home. CMS believed the Vivistim System may be similar to devices currently described by C1767 and therefore appropriately described by C1767. CMS invited comment on whether the Vivistim system meets the device category criterion.

CMS summarizes the additional information provided by the applicant which clarified the distinction between the Vivistim system and VNS Therapy® System (C1767). The applicant described how the Vivistim system is unique because it is a neurostimulator that is actively paired with movement during rehabilitation by a skilled therapist who instructs the patient to perform upper limb rehabilitation exercises and delivers stimulation using a push-button feature of an external paired stimulation. The applicant clarified that the unique feature of the Vivistim System is the external paired stimulation controller, not the patient-engaged features of the device.

Based on this additional information, CMS concludes that Vivistim System meets the first eligibility criterion at §419.66(c)(1).

(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 System meets all the cost criteria. CMS did not receive any comments and concludes that Vivistim System meets the cost criteria.

Effective January 1, 2023, CMS finalizes approval for Vivistim System device pass-through payment.

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 uses 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. CMS did not receive any comments and concludes that the BrainScope TBI meets the newness criterion.

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 noted 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 questioned 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 invited comments on whether the BrainScope TBI meets the eligibility criteria.

CMS did not receive any comments and concludes that the BrainScope TBI des not meet the eligibility criteria to be considered a device for transitional pass-through payments. Because the device does not meet this criterion, CMS did not evaluate the product on the other criteria.

For 2023, CMS does not approve the BrainScope TBI for transitional device pass-through payment.

(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 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,[14] 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. CMS did not receive and comments and concludes that the Navigator meets the newness criterion.

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).

In response to CMS' concerns, the applicant stated that the Navigators are single use devices intended for one patient only, and that without the Navigators, real-time surgical navigation using the Elucent system cannot be performed. The applicant stated that the Navigator is inserted into the patient (generally into a surgical wound) as the surgeon uses the electrocautery tool to perform tissue excision. In addition, the applicant explained why the Navigators meet the eligibility requirements at §419.66(b)(4). Based on these comments and its review of the

[14] 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.

application, CMS determines that the Navigators meet the eligibility criteria at §419.66(b)(3) and (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. The applicant clarified the unique features of the Navigators. CMS concludes that the Navigator meets the device eligibility criterion at §419.66(c)(1).

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 summarized this information and discussed specific concerns with the submitted information. CMS noted that the abstract provided of an article appears to be a feasibility study for a potentially larger randomized control study; CMS also wondered if this article has been published or submitted to a peer-reviewed journal. CMS highlighted 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 noted 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.

All commenters addressing the substantial clinical improvement criterion offered support for approval of the application. Some commenters, including the applicant, discussed the lack of advances for breast conversation surgery and discussed the clinical and surgical benefits of using the Navigator and SmartClip soft tissue marker. A few commenters acknowledged the need for additional research and larger clinical trials to support the preliminary positive outcomes but believed that the approval of pass-through payment would improve patient access and additional studies.

The applicant submitted a comment that addressed CMS' concerns. After reviewing the comments, received CMS reiterates its concerns and continues to believe that additional information and evidence is needed from larger, multi-center published studies (including studies involving non-breast cancer related procedures) that provide comparative outcomes between the Navigators and existing technologies. CMS concludes it is not able to make a substantial clinical improvement determination. Because the device does not meet this criterion, CMS did not evaluate the product on the cost criterion.

For 2023, CMS does not approve the Navigators (NavSlim™ and NavPencil) for transitional device pass-through payment.

(3) SmartClip™ Soft Tissue Marker. NO

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 stated the impacts of the PHE limited breast cancer surgery. CMS noted 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 sought comments about whether SmartClip meets the newness criterion.

The applicant reasserted that because the global COVID-19 pandemic the newness criterion should be determined by the date of market availability for the EnViso Navigation System (March 22, 2019). CMS does not agree that the pandemic created a basis for claiming a verifiable delay in the U.S. market availability for the SmartClip. CMS states it assesses compliance with the newness criterion by measuring the amount of time from the date of market availability, not available time on the market. CMS determines that the SmartClip does not 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 invited comments on whether the SmartClip meet the eligibility criteria at §419.66(b).

The applicant asserted that the SmartClip meets the eligibility requirements of §419.66(b)(4). CMS determines that the SmartClip meets the eligibility criteria at §419.66(b)(3) and (4).

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. The applicant also asserted that the SmartClip was closely

related to the SmartPill used in CPT code 91112. CMS noted 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.[15] 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.[16] CMS invited comments on whether the SmartClip meets the device category criterion.

Two commenters, including the applicant, discussed how the SmartClip can be differentiated from other tissue markers because it is an electromagnetically activated, single-use, sterile soft tissue marker used for anatomical surgical guidance. Another commenter disagreed with the applicant's statement that these procedures would be reported with CPT code 91112 which is used with the SmartClip device because the SmartPill is an endoluminal capsule used in the diagnosis of GI devices and these devices are not related devices and are not used for similar purposes.

CMS agrees that the SmartClip can be differentiated from the passive tissue markers identified with HCPCS code A4648. It also agrees with the commenter that the SmartClip and Smart Pill are not functionally related devices and have vastly different indication. CMS notes it is unlikely that a surgical procedure to place a fiducial marker in soft tissue using the SmartClip device would be reported with CPT code 91112. CMS concludes that the SmartClip meets the device eligibility criterion at §419.66(c)(1).

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 summarized this information and discussed specific concerns with the submitted information, which incorporate several of the concerns previously discussed with the Navigators application. CMS reiterated 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 reiterated 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.

All commenters offered support for approval of the SmartClip application and discussed the limited advances that have been made in breast conservation surgery. Several commenters discussed the difficulties associated with wire localization techniques and described the clinical and surgical benefits of using the Navigator and SmartClip. The applicant submitted a comment that addressed CMS' concerns. CMS appreciates the applicant's responses as well as the other

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

comments received. After reviewing the comments received, CMS reiterates its concerns and continues to believe that additional information and evidence is needed from larger, multi-center published studies (including studies involving non-breast cancer related procedures) that provide comparative outcomes between the Navigators and existing technologies. CMS concludes it is not able to make a substantial clinical improvement determination. Because the device does not meet this criterion, CMS did not evaluate the product on the cost criterion.

For 2023, CMS does not approve the SmartClip for transitional device pass-through payment.

(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 stated 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. CMS concludes the Evoke SCS System meets the newness criterion.

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

The applicant asserted that the Evoke SCS System meets the eligibility requirements of §419.66(b)(4). CMS determines that the Evoke SCS System meets the eligibility criteria at §419.66(b)(3) and (4).

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 55) 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.

The applicant and many other commenters agreed with CMS' assessment. A competitor asserted that the Evoke SCS System is described by an existing category and described how the AdaptiveStim, first commercially introduced by Medtronic in 2011, is also a closed-loop SCS device. The commenter also stated that, even if CMS asserts that codes C1820 and C1822 are only for open-loop neurostimulators as suggested in the proposed rule, the codes still apply to Evoke because the product can deliver both open-loop and closed-loop stimulation modes. The commenter concludes that since the existing closed-loop Adaptive Stim system has been accurately described by C1820, the Evoke also meets the description of the existing code C1820 and therefor would not meet the newness criterion at §419.66(c)(1).

CMS appreciates the comments received. Because the Evoke SCS System measures and uses the evoked compound action potentials to instantaneously adjust subsequent stimulation output on every stimulation pulse, CMS believes it is a unique true closed-loop system. CMS concludes that the device meets the newness criterion at §419.66(c)(1).

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 summarized this information and discussed specific concerns. CMS noted that none of the studies provided compared the Evoke SCS System to other currently available technologies, specifically open-loop SCS products. CMS acknowledged 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 asserted 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 requested additional details about how these results would be generalizable to the U.S. population. CMS also invited comment on whether there are existing technologies which may be appropriate comparators to the Evoke SCS System.

The applicant submitted a comment that addressed CMS' concerns. Many commenters also provided additional information about the Evoke study and the Avalon Australian study. Based on these comments, CMS agrees that the Evoke SCS System open-loop stimulation mode is largely equivalent to other commercially available SCS systems and thus served as an appropriate comparator for closed loop versus open-loop spinal cord stimulation. CMS also concurs with commenters that the results of the Avalon study are generalizable to the U.S. population

A competitor agreed with CMS' concerns regarding the use of the Evoke device in both arms of the RCT and stated there is no comparative data regarding the relative clinical benefit of the Evoke closed loop system. The commentor notes that the RCT for the Senza SCS system included a comparison to a completely different commercially available device programmed to use low-frequency, open-loop stimulation. In addition, the commentor compares some of the results of the Evoke RCT and the Senza SCS system RCT. In response to these comments, CMS states it does not believe the Senza SCS System RCT is equivalent to the situation of the Evoke SCS System RCT and thus does not provide a sufficient counterfactual. CMS also notes that the comparison of the results is not accurate as CMS believes the Evoke RCT demonstrated statistically significant improvements in both leg pain and overall, back and leg pain combined.

After consideration of the application and comments, CMS concludes that the Evoke SCS System represents a substantial clinical improvement over existing technology.

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.

The applicant explained that their request for a new device category would only apply to the generator and charger components of the Evoke SCS System and provided clarification regarding the cost breakdown of the eligible ($32,000) versus ineligible components ($5,000). CMS recalculated the formulas for the three cost significant requirements and determined that the Evoke SCS System meets the cost criteria.

Effective January 1, 2023, CMS finalizes approval for the Evoke SCS System for transitional device pass-through payment.

(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. CMS concludes the Pathfinder meets the newness criterion.

Eligibility. According to the applicant, the Pathfinder meets all the eligibility requirements. CMS concludes 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. CMS agrees that the Pathfinder meets the criterion at §419.66(c)(1).

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 summarized this information and discussed specific concerns. CMS noted 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 was also concerned that the articles related to endoscopists' workload is limited to the same study center with only two participating endoscopists. CMS believed it is difficult to make comparisons with these limited studies. CMS sought comments on whether the Pathfinder shows superiority over existing devices or existing methods used in cases of endoscopic looping and abnormal anatomy.

No comments were submitted regarding whether the Pathfinder meets the substantial clinical improvement criterion. CMS reiterates its concerns and concludes that the Pathfinder does not represent a substantial clinical improvement relative to existing technologies currently available. Because the device does not meet this criterion, CMS did not evaluate the product on the cost criterion.

For 2023, CMS does not approve the Pathfinder for transitional device pass-through payment.

(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. CMS concludes that the Ureterol meets the newness criterion.

Eligibility. The applicant states the Ureterol meets all the eligibility criteria. CMS concludes that the Ureterol meets the eligibility criteria (§419.66(b)(3) and (4)).

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. CMS concludes that the Ureterol meets the eligibility criterion at §419.66(c)(1).

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 summarized this information and discussed specific concerns. CMS noted that most of the evidence provided supports the need to follow established reprocessing guidelines for reusable devices. In addition, none of the studies referenced another disposable device as a comparator. CMS requested additional evidence demonstrating a comparison of the Ureterol's performance against other similarly disposable devices.

The applicant provided source articles that demonstrated the increased risks associated with using reusable devices, bud did not provide clinical studies that reference another disposable device as a comparator. CMS still believes it would be helpful to see comparative studies but agrees that the evidence demonstrating improved patient outcomes and reduced patient risk associated with the single-use Ureterol device in comparison with reusable devices represents substantial clinical improvement.

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

Effective January 1, 2023, CMS finalizes approval for the Ureterol for transitional device pass-through payment.

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. 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 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]

[17] This policy will also streamline the effort required from anyone summarizing these applications.

CMS finalizes its proposal to publicly post OPPS device pass-through application online, including the completed application forms and certain related materials (as described below), and any additional updated application information submitted subsequent to the initial application submission (except information identified by the applicant as confidential), at the time the proposed rule is issued. With the exception of information included in a confidential information section of the application, and materials identified by the applicant as copyrighted and/or not otherwise releasable to the public, the contents of the application and related materials may be posted publicly. CMS finalizes the proposed alternative implementation date of March 1, 2024; public posting of all OPPS device-pass-through applications will begin with the 2025 proposed and final rules.

Beginning with applications submitted on or after March 1, 2024, CMS finalizes its proposal to post online the completed application forms and certain related materials (e.g., attachments and uploaded supportive materials) it receives from applicants. CMS will also post information acquired subsequent to the application submission. CMS will publicly post all completed application forms and related materials at the same time the proposed rule is issued. CMS notes it is continuing 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 finalizes its proposal that on the application form, the applicant will 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 finalizes 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 the public posting of applications will 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 fundamentally changing 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 will 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 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 will continue to provide discussion of concerns or issues for applications submitted and in the final rule, CMS will continue to provide an explanation of CMS' determination.

CMS received several comments regarding this proposal. Some commenters were fully supportive of the efforts toward greater transparency and public input. Some commenters urged CMS not to adopt the proposal for a variety of reasons including the need to protect proprietary and trade-sensitive information and a few commenters were concerned the public posting would negatively impact product innovation. CMS responds that it will have a mechanism for applicants to submit confidential information, including proprietary and trade secret information, CMS notes that it believes applicants generally have limited need to submit confidential information given a device must have FDA clearance or approval prior to the date of the application.

CMS did not receive any comments regarding the implementation date. After further consideration, it finalizes the alternative implementation date of March 1, 2023 instead of January 1, 2023. This will allow public posting to begin with the 2025 OPPS proposed rule.

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.

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.[18] 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 finalized proposal to use 2021 claims for 2023 OPPS/ASC rate-setting purposes, CMS finalizes using 2021 claims information for determining device offset percentages and assigning device-intensive status.

The full listing of 2023 device-intensive procedures provided in Addendum P.[19] CMS notes that its claims accounting narrative for this final rule can be found under supporting documentation for the 2023 OPPS/ASC final rule on the CMS website.

CMS does not accept commenter's recommendation to use invoices as an alternative data source for determining device-intensive status for procedures that do not have a device offset percentage that exceeds the 30 percent device-intensive threshold for the following procedures: HCPCS

[18] 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.
[19] Addendum P is available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.

code C9757 and CPT codes 55880, 58674, 65426, and 65778. CMS also does not agree with a commenters recommendation that it assign the device offset percentage of CPT code 0627T to 0629T. CMS notes it does not have any claims data for CPT code 0629T to determine a device offset percentage. In response to a comment, CMS confirms that HCPCS code C2596 is categorized as a device and the costs associated with this device are reflected in the device offset percentage of CPT code 0421T. CMS also clarifies that HCPCS code C1889 may be billed with a procedure that does not have device-intensive procedure. CMS notes the April 22 update of the OPPS, CMS revised Chapter 4, section 61.1 of the Medicare Claims Processing Manual to clarify that hospitals should report HCPCS code C1889 for the use of devices that are not described by a specific HCPCS code.

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.

Some commenters continued to request that CMS restore the device-to-procedure and procedure-to-device edits. CMS continues to believe that the elimination of these edits is appropriate because hospitals know how experience in coding and reporting these claims completely.

For 2023, CMS is not making 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 making 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.

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

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

Section 1833(t)(6) of the Act provides for temporary additional payments or "transitional pass-through payments" for certain drugs and biologicals. For pass-through payment purposes, radiopharmaceuticals are "drugs." As required by statute, transitional pass-through payments for a drug or biological can be made for at least 2 years, but not more than 3 years, after the payment was first made under the OPPS. Pass-through drugs and biologicals for 2023 and their designated APCs are assigned status indicator "G" in Addenda A and B of the final rule. For 2023, CMS proposed to continue using ASP+6 percent as payment for pass-through drugs and biologicals. CMS also proposed 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 57 of the final rule lists 32 drugs and biologicals where CMS will expire pass-through payment at the end of 2022. Table 58 lists 43 drugs and biologicals where CMS proposed 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 59 of the final rule lists 49 drugs where CMS proposed to continue pass-through payment for all 2023.

Some of the products listed in Table 57 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 to continue using 2019 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 used for rate-setting. As CMS is now using 2021 data to set the APC relative weights for 2023, these data will reflect the costs of the products that received more than three years of pass-through payment. CMS no longer sees a need to continue the special extended period of pass-through payments. CMS received many comments requesting additional quarters of pass-through payments. Responses to these comments were addressed in section IV. as the same issue relates to pass-through devices as it does to pass-through drugs.

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 60 of the final rule lists the APCs where CMS will apply an offset for policy packaged drugs paid on pass-through.

CMS directs readers to the following link for a file of APC offset amounts used to evaluate cost significance for candidate pass-through device categories and drugs and biologicals and for establishing any appropriate APC offset amounts: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files. The file was not available for the proposed rule. One commenter requested CMS release a copy of this file with the proposed rule but CMS disagrees "that it is necessary to release a copy of the APC offset file with the proposed rule."

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 proposed 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 (PPI) 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).

Commenters generally opposed raising the packaging threshold. One commenter requested CMS reduce the threshold stating that the increase has significantly outpaced the OPPS update in

recent years. CMS responded that the packaging threshold is specifically linked to an index that accounts for the increase in drug pricing. It is unrelated to the OPPS update. The proposal is being finalized without modification.

CMS proposed 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 June 30, 2022,[20] 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 final rule, CMS uses ASP+6 percent for each HCPCS code with manufacturer-submitted ASP data from the 2nd quarter of 2022 (data that will be used to pay for drugs and biologicals in physicians' offices effective October 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 proposed 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.

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 proposed 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 proposed 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:

[20] The final 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 June 30, 2022 consistent with past practice. HPA has queried CMS about the accuracy of this sentence.

- 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.

Public comments reiterated concerns expressed in prior rulemaking regarding policy packaging. For instance, there was a comment that recommended separate payment for drugs that are administered at the time of ophthalmic surgery and have an FDA-approved indication to treat or prevent postoperative issues. Other comments suggested separately paying for diagnostic radiopharmaceuticals subject to the same or a higher packaging threshold. There were comments asking CMS to institute edits that require nuclear medicine procedures to be billed with a radio-labeled product edit to ensure the full costs associated with the procedure are included in the APC determination.

CMS reiterated its principles for policy packaging—e.g., that in each of these instances, the product is functioning as a supply to another procedure that is treating the patient's condition. If cost of the supply is correctly billed to Medicare by the hospital, the cost of the procedure will appropriately include all of its costs and separate payment will be unnecessary.

In response to reinstating radiolabeled product edits to nuclear medicine procedures, CMS indicates these edits were in place between 2008 and 2014. The edits assisted hospitals in reporting codes and charges so their claims fully and appropriately reflected the costs of radiolabeled products. Once there was sufficient experience with reporting codes and charges, CMS retired the edits as it expects hospitals to code and report their costs appropriately, regardless of whether there are claims processing edits in place.

CMS is making no changes in response to these comments. All of its policies above are being finalized without modification.

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

For 2023, CMS proposed 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 61 of the final rule.

2. Payment for Drugs and Biologicals without Pass-Through Status that are not Packaged

As indicated above, CMS proposed 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

reflected that CMS will continue to pay ASP-22.5 percent. However, CMS indicated 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 intended 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) at wholesale acquisition cost (WAC)+3 percent when ASP pricing data are not yet available from the manufacturer. 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 final 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 final rule for which there was no ASP information available for the 2nd quarter of 2022 (used for payment in physician's offices for the 4th 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.

There were public comments asking CMS to make the add-on higher than 6 percent of ASP; maintain the status indicator assignment for two drugs (HCPCS codes Q2041 and J7402) to allow them to be paid separately rather than packaged; and raise the add-on to WAC from 3 percent to 6 percent for radiopharmaceuticals in their initial marketing period because these products have higher preparation and storage costs.

In response to these comments, CMS indicated that the statutory default pricing in the absence of a survey of acquisition costs is generally ASP+6 percent for drugs and biologicals. CMS is changing the status indicator of HCPCS code Q2041 to allow for separate payment consistent with a commenter's request—the change to packaged payment in the proposed rule was made in error.

For HCPCS J7402, CMS referred the commenter to its policy stated in a prior section for what occurs when a policy packaged drug is no longer paid on a pass-through basis. With respect to the add-on for radiopharmaceuticals, CMS indicates that WAC is higher than ASP as it does not

include discounts and rebates. As such, CMS believes a 3 percent add-on for new radiopharmaceuticals with WAC based pricing is sufficient.

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 payment 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 proposed to continue all of its biosimilar policies unchanged for 2023. There were no public comments and CMS is finalizing all comments as proposed.

On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117-169) was signed into law. Section 1847A(b)(8) of the Act, as amended by section 11403 of the IRA, requires an increase in the add-on payment for qualifying biosimilar biological products from 6 percent to 8 percent of the ASP of the reference biological for a 5-year period. To be eligible for the increase, the ASP of the biosimilar cannot be more than the ASP of the reference biological. The 5-year period begins October 1, 2022 for existing biosimilars and the first day of the calendar quarter in which payment is first made for new biosimilars. Additional details will be in subsequent rulemaking.

3. Payment Policy for Therapeutic Radiopharmaceuticals

For 2023, CMS proposed to continue paying for therapeutic radiopharmaceuticals at ASP+6 percent. For therapeutic radiopharmaceuticals for which ASP data are unavailable, CMS proposed to determine 2023 payment rates based on 2021 geometric mean unit cost. Public comments supported CMS' proposal. One public comment asked CMS to change the status indicator for HCPCS code A9699 (Radiopharmaceutical, therapeutic, not otherwise classified) to allow it to be paid separately rather than packaged. CMS declined to make the change indicating that the longstanding indicator for this code has required it to be packaged. CMS is finalizing all of its proposals without modification.

4. Payment for Blood Clotting Factors

For 2023, CMS proposed 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 will not 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/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/ClotFactorFurnishFee. One public comment supported CMS proposal. CMS is finalizing the proposal without modification.

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

CMS proposed 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' 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. There were no public comments on this proposal that CMS is finalizing without modification.

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 (GAO) 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. The policy continued while CMS pursued its appeal.
- 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 indicated 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 anticipated 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 also accepted 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. Even though the Supreme Court decision does not apply to any year after 2019, CMS made clear in the proposed rule that it intended to reverse its 340B policy retroactively to also apply to 2020 through 2022. In the

proposed rule, CMS indicated that it was still evaluating how to apply the Supreme Court's decision to prior cost years and solicited public comments on the best way to craft any proposed, potential remedies affecting calendar years 2018-2022.

One further development on the 340B litigation occurred on September 28, 2022. On that date, the district court vacated the CMS' 340B reimbursement rate for the remainder of 2022 without requiring any offset for budget neutrality. The final rule indicates that CMS has since taken the necessary steps to implement the district court's order.[21]

CMS established two modifiers (modifiers JG and TB) in 2018 to track when hospitals acquired drugs under the 340B program. Modifier "JG" is used by hospitals subject to CMS' 340B payment policy of ASP-22.5 percent. Modifier "TB" is used by children's hospitals, IPPS-exempt cancer hospitals and rural SCHs that are not subject to the CMS' 340B payment policy. If modifier "JG" is on the claim, the adjustment was applied. The adjustment is not applied when modifier "TB" is on a claim but the modifier allows CMS to know that the drug was acquired under the 340B program.

In the proposed rule, CMS indicated that it would apply a negative budget neutrality adjustment in 2023 for the increase in payment for 340B drugs—essentially reversing the positive budget neutrality adjustment CMS applied in 2018. The original budget neutrality applied in 2018 was +3.19 percent to offset approximately $1.6 billion in reduced drug payments. As CMS' estimate of the required budget neutrality adjustment was made in 2017 before it had information on billing using the "JG" modifier, the estimate was made in the absence of precise information on when the adjustment would be applied. CMS indicated in the rulemaking at that time that it would revise the budget neutrality adjustment once it had information on application of the 340B policy using the "JG" modifier (82 FR 59483). However, CMS never revised the initial budget neutrality adjustment for 2018 or any subsequent year.

To reverse the adjustment, CMS indicated that 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, CMS proposed to apply a budget neutrality adjustment of 0.9596 (-4.04 percent) to offset this additional $1.96 billion in payments. CMS solicited public comments on the budget neutrality adjustment.

Comments/Responses: Public comments were the following categories:

[21] The district court's order to apply ASP+6 percent to drugs acquired under the 340B drug discount program applies prospectively from September 28, 2022. However, Medicare Administrative Contractors (MACs) are allowing ASP+6 percent to be paid for drugs acquired under the 340B program for the entire year. For example, see https://medicare.fcso.com/Processing_Issues/0499495.asp and https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00003428. HPA has verified that a system's edit—potentially one that would apply nationally—has been adopted to allow payment at the higher ASP rate for drugs acquired under the 340B program with dates of service in 2022 before September 28, 2022. This information is inconsistent with CMS' website (https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps) although CMS did validate that the MAC's message was correct in response to an inquiry.

Remedy for Prior Years: A majority of commenters requested that CMS promptly pay hospitals the additional amounts owed for 340B drug payments from 2018 to 2022 including interest. There were commenters concerned that hospitals not be required to collect higher coinsurance from beneficiaries in response to increased payments. The majority of commenters also requested that CMS not recoup higher payments made as a result of the budget neutrality adjustment applied to offset the lower drug payments. These commenters argued a retrospective payment adjustment would have a significant financial impact and would penalize hospitals for a policy that CMS adopted that has been deemed unlawful by the Supreme Court.

MedPAC and a few other commenters stated that any changes in response to the Supreme Court's decision should be made budget-neutral arguing that it would be fiscally imprudent to increase Medicare spending by approximately $2 billion in each year that CMS applied the overturned 340B policy (2018 through 2022) without making a corresponding budget neutrality adjustment. Several commenters suggested CMS should adopt a budget neutral, prospective-only solution to address payments from 2018 through 2022.

CMS acknowledged the comments and will take them into account as it formulates a remedy to address reduced payment amounts to 340B hospitals for 2018 through 2022. The response also acknowledges that there is a motion pending before the district court on this same issue. CMS plans to issue a separate proposed rule detailing a remedy for 2018 to 2022 in advance of the 2024 OPPS/ASC proposed rule.

Reverting to ASP+6 Percent for Drugs Acquired under the 340B Program: The vast majority of commenters supported paying for all drugs at ASP+6 percent. Some commenters opposed reverting to ASP+6 percent for 340B acquired drugs and requested CMS undertake new drug cost survey to inform the payment rate for 2024 that more closely approximates the costs incurred by 340B providers. One commenter made a legal argument that CMS' policy to revert back to ASP+6 percent is arbitrary and capricious under the Administrative Procedures Act.

CMS responded that it will take commenters' feedback regarding undertaking a new drug cost survey into consideration for potential future rulemaking. In response to the legal argument, CMS indicated that its policy is consistent with the Supreme Court's decision.

Collecting the "JG" and" TB" Modifiers: Many commenters opposed continuing to require hospitals to use the "JG" and "TB" claims modifiers. Other commenters supported continuing to require these modifiers. CMS responded that it remains important to continue collecting the "JG" and "TB" modifiers to track the utilization of 340B acquired drugs and biologicals under the OPPS.

Budget Neutrality Adjustment for 2023 and Prior Years: Many commenters opposed applying any budget neutrality adjustment at all for the end of CMS' 340B policy, or, in the alternative, requested that CMS phase in the adjustment over several years. Other commenters indicated the adjustment should offset the +3.19 percent increase in payments that CMS originally applied in 2018 in place of the -4.04 percent that CMS proposed. These commenters argued that CMS never updated the original +3.19 percent adjustment so it would be unfair to remove more money from the system than CMS ever added.

CMS declined not applying a budget neutrality adjustment at all or phasing it in over multiple years as being inconsistent with its statutory obligations to maintain annual budget neutrality. In response to adopting a lower budget neutrality offset, CMS agreed "that under these specific circumstances it is appropriate to decrease payments for non-drug items and services by a percentage that would offset the percentage by which they were increased when CMS implemented the 340B policy in CY 2018."

Other comments indicated that CMS' failure to update the 340B budget neutrality adjustment resulted in payments for non-drug OPPS services being too low for 2020 through 2022. The commenters suggested that CMS could apply a one-time budget neutrality adjustment for 2023 to increase non-drug OPPS payments to account for what commenters believed were underpayments for non-drug items and services in these prior years. CMS responded that it will take this suggestion into account as it prepares a separate proposed rule to address the remedy for 2018 to 2022

Rural Hospitals: There were public comments indicating that reversal of the 340B policy will adversely affect rural hospitals. CMS acknowledges that rural hospitals are disproportionately affected by the reversal of its 340B policy with the budget neutrality adjustment. However, the budget neutrality adjustment is required by law.

Final Decision: To offset the additional costs of ending the 340B policy of ASP-22.5 percent, CMS is applying a budget neutrality adjustment of -3.09 percent (0.9691) or 1/1.0319 for 2023—e.g., reversing the adjustment it originally applied for 2018 but did not update. As CMS applied a budget neutrality adjustment of 1.0319 in 2018, reversing the policy requires dividing by the same figure. CMS indicates the adjustment to the conversion factor is appropriate in these circumstances because it removes the effect of the 340B policy as originally adopted in 2018 ensuring the conversion factor is equivalent to the one that would be in place if the 340B drug payment policy had never been implemented (e.g., 2023 spending will increase relative to 2022 but the increase is appropriate in "these circumstances" as the budget neutrality adjustment was not updated in prior years and payments would have been higher).

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

CMS' Packaging Policy: 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 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

APC	HCPCS	2022 Geometric Mean Cost
5055 (Level 5 Skin Procedures)	15273	$3,326.39

For 2023, CMS proposed to determine the high-cost/low-cost status for each skin substitute product based on either the product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold. CMS is using 2019 data for this purpose.[22]

The 2023 MUC threshold is $47 per cm^2 rounded to the nearest $1, and the 2023 PDC threshold is $837 rounded to the nearest $1. CMS will 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 will continue assigning it to the high-cost group in 2023. Otherwise, CMS will assign the skin substitute to the low-cost group.

For 2023, CMS is continuing the following policies:

- Skin substitutes with pass-through payment status will be assigned to the high-cost category.
- Skin substitutes with pricing information but without claims data will be assigned to either the high- or low-cost categories based on the product's ASP+6 percent payment rate (WAC+3 percent if ASP is unavailable, 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.

CMS noted that it proposed to treat all skin substitute products consistently across healthcare settings as incident-to supplies rather than as biologicals in the 2023 PFS proposed rule. Under this proposal, manufacturers would not have reported ASPs for skin substitute products starting in 2023. CMS' plan for the OPPS was to determine whether a product should 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. However, the proposed policy in the PFS rule was not finalized, mooting several of the comments made on the 2023 OPPS/ASC proposed rule. Manufacturers will continue to report ASP for skin substitutes in 2023. Table 62 of the final rule lists the high/low-cost group assignment for each skin substitute.

Comments/Responses: Comments from the Hospital Outpatient Payment (HOP) Panel and others reiterated prior comments that CMS eliminate the packaging of the graft skin substitute add-on codes (CPT codes 15272, 15274, 15276, and 15278; HCPCS codes C5272, C5274, C5276, and C5278). These comments argue CMS' policy eliminates the variation in payment for wound care treatments based on the size of the wound discouraging treatment of larger and more costly wounds. Other commenters requested that CMS eliminate packaging of skin substitutes altogether.

[22] As CMS is using 2021 data for most other purposes for calculating proposed 2023 OPPS rates and policies, it is unclear (and unexplained) why CMS is using 2019 data here. This may be a typographical error in the final rule.

CMS reiterates its prior responses that packaging is intended to promote efficiencies based on a system of averages. While some cases may be more costly to treat, other cases will be less costly to treat. Overall, payment based on an average should adequately compensate hospitals.

There were also comments from the HOP Panel and others that CMS should not be differentiating payment based on the part of the body where the skin graft occurs. Commenters claim that the cost to apply graft skin substitute products does not depend on the location of the wound. The same amount of product and the same clinical resources are used to treat the wound independent of its location.

CMS' response indicates that the CPT codes themselves differentiate the part of the body where the skin graft is applied and many of these codes are assigned to the same APC so payment is not differentiated. In circumstances where payment is differentiated because the graft application procedures are assigned to different APCs, CMS indicates that the cost data for the codes justify the distinction.

One commenter requested that powdered substitute products be assigned to either the high- or low-cost skin substitute group as is currently done for graft skin substitutes. CMS disagreed and said a powder is not a graft even if the product forms a sheet scaffolding similar to a graft skin substitute product as the commenter asserted.

There were public comments asking that CMS always use ASP+6 percent, WAC+3 percent, or 95 percent of AWP to assign a skin substitute to the high- or low-cost group. Other comments questioned CMS' assignment of a particular skin substitute (A2001) to the low-cost group as it had been assigned to the high-cost group in 2022 and CMS' policy is to retain that assignment for 2023 even if the product no longer exceeds the MUC or PDC threshold.

CMS disagreed with the first comment, indicating that OPPS claims data is a better estimate of costs than ASP, WAC or AWP pricing. CMS agreed with the second comment and Table 62 of the final rule will reflect the assignment of A2001 to the high-cost group for 2023.

Final Decision: CMS is finalizing all of the above skin substitute policies without modification. Table 62 includes the final 2023 cost category assignment for each skin substitute.

Deletion of HCPCS Code C1849: CMS proposed 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 proposed to assign this code to the low-cost group.

Public comments support all of these proposals. CMS is finalizing all of these proposals without change. Consistent with its proposed and final rule policies, all A codes are assigned to the high-cost group with the exception of the A code for an unclassified skin substitute product. All of these decisions are reflected in Table 62.

Consistent Treatment of Skin Substitutes. In the proposed rule, CMS noted 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 led 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 indicated its intention to reform its skin substitute policies over the next one to five years with the following objectives:

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

Consistent with these goals, CMS proposed to treat skin substitutes as medical supplies in the 2023 PFS. The proposal would have retired all Q codes for skin substitutes by January 1, 2024 requiring manufacturers of these products to apply for a medical supplies A codes during the intervening period. Effective January 1, 2024, these products would have been contractor-priced in physician offices. CMS indicated its intent 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 did not finalize these proposals and will instead hold a Town Hall meeting in early 2023 to engage interested stakeholders in establishing future policy related to skin substitutes.

CMS also proposed to use the term "wound care management products" in place of "skin substitutes." The proposed rule indicated 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 indicated that the terms "care management" or "management" are not intended to 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.

Most commenters disagreed with CMS' proposal to use "wound care management product" in place of "skin substitutes." A number of comments suggested specific alternatives. CMS decided not to finalize a change in terminology.

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

Beginning in 2013, CMS finalized a policy to provide an additional payment of $10 for the marginal cost for radioisotopes produced by non-HEU sources (77 FR 68323). 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 indicated 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 proposed to continue the additional $10 payment for diagnostic radiopharmaceuticals containing Tc-99m through December 31, 2024.

Public comments both supported and opposed CMS' proposal to end the additional $10 payment for radioisotopes sourced from non-HEU source on or after December 31, 2024. Opponents of the proposal urged CMS to continue the additional payment of $10 either permanently or until a majority of radiopharmaceutical claims for Tc-99m reported HCPCS code Q9969 clearly show

that the radiopharmaceutical is sourced with non-HEU material. These commenters requested an increase in the $10 payment to the amount it would be if indexed to the hospital market basket since 2013; require claims edits to identify whether the Tc-99m radiopharmaceutical is sourced from non-HEU or HEU reactors; and eliminate coinsurance because of the administrative burden associated collecting such a small amount of revenue.

CMS declined to do any of these suggestions stating that by 2023 all radiopharmaceuticals will be sourced from non-HEU sources and the incentive payment to use these products will no longer be needed.

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' policy 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 proposed 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 advised interested parties to direct their comments on this issue to the 2023 physician fee schedule proposed rule.

D. Inflation Reduction Act – Beneficiary Coinsurance

Section 11101 of the IRA requires a drug manufacturer to pay a rebate to Medicare if the ASP of their drug product rises at a rate that is faster than inflation. Effective April 1, 2023, OPPS and ASC coinsurance will be based on the inflation adjusted Part B drug price for a Part B subject to this provision that is not packaged when the drug's price is less than ASP+6 percent. Medicare's payment will be ASP+6 percent amount less the beneficiary coinsurance. Additional details will be in subsequent rulemaking.

VI. Estimate of Transitional Pass-Through Spending

For the proposed rule, CMS estimated 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 was a large difference in estimated pass-through payments from these two policy options for drugs and biologicals.

For the final rule, CMS is adopting a policy to pay ASP+6 percent for all drugs and biologicals including drugs acquired under the 340B program that are not on pass-through. Therefore, a drug or biological acquired under the 340B program, whether paid on pass-through or not, will be paid ASP+6 percent. As a result, pass-through will make no difference in payment for a separately payable drug.

Pass-through will only make a difference in payment for policy packaged drugs as pass-through will allow these drugs to be paid separately at ASP+6 percent rather than packaged into the APC payment. CMS estimates total pass-through spending in 2023 of $135.6 million (0.16 percent of total OPPS spending)—$82.1 million for devices and $53.5 million drugs and biologicals.

A. Devices

CMS estimates pass-through spending of $82.1 million in 2023 for devices—$21 million for those recently eligible for pass-through payments that will continue for 2023 and $61.1 million for those CMS knows or projects could be approved for pass-through status in 2023.

B. Drugs and Biologicals

CMS estimates pass-through spending of $53.5 million in 2023 for drugs and biologicals—$33.5 million for those recently eligible for pass-through payments that will continue for 2023 and $20 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 solicited comments but did not propose any changes for 2023 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. One commenter requested CMS provide a set of national guidelines for selecting the level of emergency department visit to bill. CMS believes it is unlikely that one set of straightforward national guidelines could apply to the reporting of all emergency department visits.

For off-campus provider-based departments being paid a physician fee schedule equivalent rate, CMS proposed to continue paying 40 percent of the full OPPS rates. This policy is being finalized without change. Beginning in 2023, CMS proposed to exempt rural SCH from being paid the physician fee schedule equivalent rate. This policy is 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 rate-setting 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 proposed 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 proposed 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 proposed 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.

Most commenters expressed concern about the proposed decrease in PHP per diem rates. They noted that the 2023 payment rates were below the calculated geometric mean per diem costs, which they believe would have severe impacts on access to PHP services. In response to assertions that the agency applied a different methodology to determine the payment rates for PHP services furnished in 2023, CMS says it used the same methodology it has used in the past and applies the same modifications in developing the 2023 rates as it did for the 2022 rates.

In the final rule, citing its authority under section 1833(t)(2)(E) of the Act, CMS applies an equitable adjustment to finalize a 2023 CMHC PHP APC payment rate of $142.70, which is the same payment rate in effect for 2022. The final hospital-based PHP geometric mean per diem cost is $275.83.

CMS continues to use CMHC APC 5853 (Partial Hospitalization (3 or more services per day)) and hospital-based PHP APC 5863 (Partial Hospitalization (3 or more services per day)) 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 final 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 rate-setting 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 uses 2021 PHP claims for 2023 rate-setting. However, as CMS did for 2022, it uses cost report data from the June 2020 HCRIS data set (which only includes cost report data through 2019).

CMS finalizes its proposal to exclude data from nonstandard cost centers reported on lines that do not correspond to the cost center number in its 2023 PHP rate-setting; one example of this is hospital reporting of Psychiatric/Psychological Services. It found that including this additional data could potentially decrease the geometric mean cost of APC 5863 (Partial Hospitalizations (3 or more services) for hospital-based PHPs) by 12 percent. No comments were received on this proposal.

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 final 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.

Before any trims or exclusions were applied, there were 28 CMHCs in the PHP claims data file. CMS excludes data from three CMHCs with geometric mean costs per day of more than ±2 standard deviations from the geometric mean cost per day for all CMHCs (two higher and one lower). No CMHC is excluded for missing wage index data, and one provider is excluded from rate-setting because it had no days containing 3 or more units of PHP-allowable services. CMS adjusts the CCR for 8 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 7 CMHCs were missing CCR information.

Twenty-four CMHCs were included in the 2023 calculation. CMS removed 483 CMHC claims which left 3,732 CMHC claims for the 2023 rate-setting. The 2023 geometric mean per diem

cost for all CMHCs for providing 3 or more services per day is $135.68 (an increase from $129.93 calculated for 2022).

Even though the final 2023 CMHC PHP geometric mean cost of $135.68 is nearly the same as the final 2022 geometric mean cost floor of $136.14, the calculated payment rates for the two years are substantially different. The 2022 final payment rate is $142.70 and the proposed and final calculated payment rates for 2023 are $130.54 and $131.94, respectively. Additionally, the final 2023 CMHC PHP geometric mean per diem costs is $135.68, which is higher than the calculated 2023 CMHC PHP APC payment rate of $131.94. Using the OPPS standard methodology, including the effect of budget neutralizing all other OPPS policy changes unique to 2023, resulted in the final calculated CMHC PHP APC payment rate being unexpectedly lower than the CY 2022 final CMHC PHP APC rate. Thus, in the final rule, CMS makes an equitable adjustment to finalize $142.70 as the 2023 CMHC PHP APC payment rate; this adjustment applies only for 2023 and not for subsequent years.

2. Hospital-based PHP Providers

CMS continues 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 provider 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 $275.83 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	Final PHP APC Geometric Mean Per Diem Costs*	Final Payment Rates**
5853	Partial Hospitalization (3 or more services per day) for CMHCs	$135.68	$142.70
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	$275.83	$268.22

* Table 63 of the final rule shows the 2023 PHP APC geometric mean per diem costs.
** The 2023 final payment rates are from Addendum A to the final 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 notes 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 using 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.

These interim policies under the April 30, 2020 interim final rule with comment are confirmed as final in this rule for the duration of the COVID-19 PHE; see the summary of section XXII.B.4 below for a description of comments received and agency responses.

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 final rule (described below), CMS designates 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. CMS does not recognize these 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. Physicians are 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 a PHP patient who typically receives PHP services at a CMHC may also receive non-PHP remote mental health services from a hospital outpatient department.

Many commenters supported the proposal of making remote behavioral health services available to patients in PHPs; they noted that small rural hospitals have used virtual care to meet a surging demand of behavioral health needs in rural communities, which improves continuity of care and removes barriers to access mental health care in isolated and underserved communities. Under the proposed clarification, remote behavioral health services would not be recognized as PHP services; some commenters encouraged CMS to carefully monitor whether clinicians believe that these remote services may count toward the required care for PHP patients. They also urged CMS to provide more specific instructions about the documentation requirement to update the patient's PHP plan of care to appropriately reflect any change to the type, amount, duration, or frequency of the therapeutic services planned for that patient in circumstances when a PHP patient receives non-PHP remote mental health services from a hospital outpatient department.

In response, CMS clarifies that non-PHP remote mental health services furnished to a beneficiary in a PHP will not be counted as PHP services in the determination of payment for a PHP day. Further, OPPS policy limits the aggregate payment for specified "less resource-intensive mental health services" furnished on the same date to the payment for a day of partial hospitalization services provided by a hospital.

Although CMS does not recognize remote mental health services as PHP services, it acknowledges that there will be circumstances when a patient under a PHP plan of care may need to temporarily receive remote mental health services. Thus, it clarifies that remote mental health services that are included in a PHP patient's plan of care will not limit a patient's eligibility for continued participation in a PHP if all other program requirements are met. Specifically, for a patient who needs at least 20 hours per week of PHP services, CMS will consider remote mental health services that are included in the patient's plan of care to be consistent with the regulation at §410.43(c)(1), which states that PHPs are intended for patients that require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care. Thus, if a PHP patient receives non-PHP mental health services remote services, the plan of care should reflect those services, and the inclusion of those services in the plan of care would not limit the patient's eligibility for continued participation in a PHP to the extent that other patient eligibility requirements are met.

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 asked for 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?

Commenters praised the flexibility of remote mental health services for PHP patients during the COVID-19 PHE, which have allowed providers of PHP services to maintain continuity of care for patients and expand their programs to individuals otherwise outside of the provider's service area. Commenters explained remote PHP services have most often been used when patients are in quarantine due to contracting COVID-19, when patients do not have transportation to attend in-person services, and to reach individuals living in an area without accessible PHP services. The comments may inform future rulemaking.

D. Outlier Policy for CMHCs

For 2023, CMS continues to calculate the CMHC outlier percentage, cutoff point and percentage payment amount, outlier reconciliation, outlier payment cap, and fixed-dollar threshold pursuant to established policies. 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 0.01 percent of total hospital outpatient payments in 2023 (excluding outlier payments), and it designates less than 0.01 percent of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs for PHP outliers.

CMS continues 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 also continues 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 applies an equitable adjustment to the CY 2023 CMHC APC payment rate by maintaining the CY 2022 CMHC APC payment rate; thus, the estimates impact on CMHCs is 0.0 percent.

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 proposed 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 proposed 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 multiple	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.

Comments/Responses: Public commenters generally supported CMS' proposed changes to the IPO list. There was one comment opposed to removing all of the procedures CMS proposed to remove from the IPO list and one comment that specifically opposed removing CPT code 16036 from the IPO list.

The commenter opposed to removing all proposed procedures from the IPO list indicated that the services cannot be safely performed in an outpatient setting because they require care and services available only in the inpatient setting. The commenter opposed to removing CPT code 16036 from the IPO list stated that the procedure is not widely performed in the hospital outpatient department setting although it may be performed on an emergency basis and would never be performed in an ASC. The outpatient claims likely represent patients who received emergency treatment and then were sent to an outpatient burn center after stabilization.

CMS agrees that CPT code 16036, should not be removed from the IPO list but disagrees with the comment opposed to removing all of proposed procedures from the IPO list. CMS reiterates prior statements made many times that just because a procedure is removed from the IPO list, it may be still be performed on an inpatient basis. The physician will make a clinical determination as to the appropriate setting where to perform a procedure.

There were three comments requesting that CPT code 47550 be removed from the IPO list as it is an add-on code related to primary services that may already be performed outpatient. One commenter requested that CMS also remove CPT codes 21188, 21255, 21343, 21344, 21348, 21423, and 21436 from the IPO list as these procedures are similar to the CPT codes CMS is proposing to remove from the IPO list.

CMS agreed CPT code 47550 meets the criteria to be removed from the IPO list (criterion #3 listed above) as does CPT code 21255 (criterion #2 and #3). As CPT 47550 is an add-on code, it will not receive separate payment under the OPPS. Payment will be packaged into payment for its primary procedure. CPT code 21255 will be made a C-APC—APC 5165 for Level 5 ENT procedures. CMS will maintain the IPO list status for the other codes commenters requested be removed from the IPO list.

Two commenters asked CMS to reverse its decision to reinstate the IPO list after it had been eliminated for 2020. CMS does not plan to revisit the decision to reestablish the IPO list. CMS believes the IPO list is a valuable tool for ensuring that the Medicare only pays for services under the OPPS that can safely be performed in the hospital outpatient setting.

Other commenters urged CMS to develop guidance on which patients are appropriate candidates for receiving services in the inpatient setting versus the outpatient setting to mitigate payer denials. CMS did not respond directly to the request from these commenters. It reiterated prior responses that CMS' policy in this area balances between:

- Section 1801 of the Act's prohibition on CMS interfering with the practice of medicine,
- The need to provide clear information about CMS billing and payment rules that ensure hospitals, physicians, and other stakeholders can understand and operate within them, and
- Specific decisions about the most appropriate care setting for a given surgical procedure are complex medical judgments made by the physician based on the beneficiary's individual clinical needs and preferences and on the general coverage rules requiring that any procedure be reasonable and necessary (86 FR 63675).

CMS added that it contracts with Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs) to review a sample of short stay hospital inpatient claims for compliance with the 2-midnight rule—CMS' guidance for when a procedure is appropriately performed inpatient.

Procedures removed from the IPO list are exempt from denials based on site-of-service during a 2-year period after being removed from the IPO list. During this period, the BFCC-QIO may conduct medical reviews for educational purposes but will not deny claims or make referrals to recovery audit contractors for noncompliance with the 2-midnight rule.

CMS also plans to use experience gained through BFCC-QIO reviews to engage with stakeholders for determining if developing additional materials for services that are newly removed from the IPO list would be helpful.

Final Decision: CMS is finalizing its proposals with the modification that CPT code 16036 will not be removed from the IPO list and CPT codes 47550 and 21255 will be removed from the IPO list. Table 65 contains all of the changes to the IPO list for 2023 including CPT code status indicators and APC assignments.

X. Nonrecurring Policy Changes

A. Mental Health Services Furnished to Patients in their Homes

1. 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 regulations will remain waived 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 requiring in-person mental health care 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 proposed 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 proposed 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 proposed 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 in the hospital or CAH.

CMS proposed to create code C7900[23] 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 C7901 would be for 30 to 60 minutes of service and code C7902 would be for each additional 15 minutes service beyond 60 minutes. CMS proposed to use 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 C7900 and C79901 to APCs.

As these codes pay approximately $60 and $20 respectively, CMS proposed assigning codes C7900 and C7901 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 C7902 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.

Comments/Responses: Commenters generally supported CMS' proposal although some asked CMS expand the proposal to other services. There were comments that using C-codes will be confusing because existing CPT codes describe similar services.

CMS responded that it will consider expansions of the policy in future rulemaking. C-codes are necessary because CPT codes could also be billed by the hospital to account for the costs hospitals incurred when there is an associated professional service—which is not permitted under this policy.

Many commenters stated that the proposed rates did not accurately capture all of the costs to the hospital of providing these services. These commenters suggested CPT codes 90832 (Psychotherapy, 30 minutes with patient) through 90838 (Psychotherapy, 60 minutes with patient when performed with an evaluation and management service) as the comparators for pricing the OPPS codes.

CMS acknowledged that there are likely costs to the hospital other than the time of the hospital staff providing these services but believes these costs are likely minimal given that the beneficiary is in their home and not in the hospital. CMS rejected using the alternative comparators suggested by the commenters as these psychotherapy codes are not provided remotely.

Most commenters recommended that CMS revise the requirements that a service must be provided "in" the hospital in order to qualify as payment for an outpatient service. One commenter requested clarification as to whether the supervising physician would have to be physically located at the hospital to meet general supervision requirements.

CMS is amending the regulations to add "or through the use of communication technology for mental health services" to make clear the patient does not need to be "in the hospital" for the service to be a hospital outpatient service. In response to the request for clarification of the

[23] In the proposed rule, the final code numbers for C7900, C7901 and C7902 were not yet available so CMS used placeholder codes.

physician supervision requirement, CMS indicates a general level of supervision is required—the service must be furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the service).

A few commenters requested that CMS clarify that when these services are furnished by hospitals that are owned or operated by the Indian Health Service (IHS), Indian Tribes, or Tribal Organizations, they are paid at the all-inclusive rate (AIR) applicable to IHS and Tribal hospitals. CMS clarified that these services will be paid to IHS and Tribal Hospitals at the AIR.

Final Decision: CMS is finalizing the policy as proposed with the modification to the regulations that the service may be furnished remotely through the use of communication technology in addition to "in the hospital" to qualify for payment as an outpatient hospital service.

2. 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 also 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 proposed 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 PFS and for an RHC 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 proposed the same delay for in-person visit requirements for remote outpatient mental health services provided by hospitals and CAHs.

Comments/Responses: Commenters object to the requirement for an in-person visit within 6 months prior to or after the first telehealth service. However, this is a requirement of statute for telehealth services billed under the PFS. CMS believes parallel policies should apply to analogous mental health services under the OPPS. In response to comments, CMS clarifies if a patient begins receiving telehealth or OPPS mental health services during the pandemic or the 151 days after the end of the PHE, the 6-month requirement is waived. It only applies to patients that begin receiving telehealth mental health services under the PFS or OPPS mental health services more than 151 days after the end of the PHE unless an exception applies.

Final Decision: CMS is finalizing its proposal without modification.

3. 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 PFS 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 proposed a similar policy for mental health services furnished remotely by hospital clinical staff to beneficiaries in their homes through communications technology. Specifically, CMS proposed 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.

Public comments were supportive of CMS' policy although there were some comments that objected to hospitals being required to have the capacity to furnish services via two-way, audio/video in rural areas or areas without access to reliable broadband. As these services are intended to be analogous to an in-person service, CMS believes the requirement upon the hospital is appropriate. The policy is being finalized without change.

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 focused 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. An intensive outpatient

treatment program (IOP) 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 requested comment in the proposed rule 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 expressed specific interest 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 offered, practitioners that furnish services, and any other relevant information to the extent it would inform CMS' ability to ensure that Medicare beneficiaries have access to this care.

Commenters were generally supportive of CMS providing payment for IOP services. Some commenters stated that existing HCPCS coding was adequate to describe IOP services, while other commenters stated that it was necessary for the OPPS to create Medicare specific coding to describe these services. CMS will consider these comments for future rulemaking.

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 PFS 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 a health care setting and a rural area to be paid via telehealth under the PFS until December 31, 2023. After that time, CR, ICR and PR services cannot be provided via telehealth.

During the PHE, CR, ICR and PR may be provided under the OPPS with direct physician supervision via a virtual presence to a patient in the hospital or at home. The virtual supervision policy will end with the conclusion the COVID-19 PHE as will the ability for the patient to receive CR, ICR and PR from their homes as an OPPS service. After that time, the physician must be immediately available to meet the direct supervision requirement for the hospital to be paid for CR, ICR and PR and the patient must be in the hospital to receive these services. CMS proposed to allow for virtual physician direct supervision physician through the end of 2023 comparable to the PFS.

Public comments supported CMS' proposal, further asking that these flexibilities continue beyond December 31, 2023. CMS responded that it does not have the flexibility to allow the patient's home to be provider based to the hospital after the PHE ends. This means CR, ICR and PR will have to be provided in the hospital and will no longer be able to originate from the patient's home and paid under the OPPS. However, CMS will retain the policy to allow the direct supervision requirement to be met by the presence of the supervising practitioner through two-way, audio/video when the beneficiary is physically located in the hospital until December 31, 2023.

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 believes that 2019 data, as the most recent complete calendar year of data prior to the COVID-19 PHE, is 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 proposed 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 the 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 proposed to exclude claims for C9803 to determine payment for APC 5731 for 2023.

For cost reports, CMS proposed to use the same ones originally used to set rates for 2021—which in most cases include 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 a 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 and 2022 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 made 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.

Comments/Responses: Most commenters supported CMS' proposal. Three commenters suggested alternatives such as reverting to the latest available full set of cost reports; using the December 2020 extract of electronic Medicare cost reports; using partial year 2022 utilization data and applying growth estimates and cost inflation factors to the data.

CMS rejected these ideas reiterating its concerns that using its standard process or a later set of cost reports would include data that overlaps the pandemic and would distort 2023 OPPS rates compared to using data from 2021 utilization data that is likely to be more typical of what will occur in 2023 or cost reports preceding initiation of the pandemic in 2020. Use of partial year utilization data from 2022 would result in CMS having substantially fewer claims to set rates while applying a growth factor would either have no impact if applied uniformly across all services or potentially distort the accuracy of the relative weights if applied differentially to specific services.

One commenter requested that CMS continue to allow use of HCPCS code C9803 after the end of the PHE and that some portion of claims for this service be used for rate setting purposes. Another commenter indicated that CMS proposed to exclude HCPCS code C9803 from OPPS rate-setting but that its data files indicate otherwise. CMS rejected the first comment stating that once the PHE ends, specimen collection for COVID-19 will be a packaged service just as it is for specimen collection for all other laboratory services. For the second comment, CMS corrected the oversight and has excluded HCPCS code C9803 from rate-setting used to determine the APC relative weight APC 5731.

Final Decision: CMS is finalizing its proposal without modification and revised the rate-setting calculation to exclude the claims and cost data associated with HCPCS code C9803 for APC 5731.

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 PFS final rule made the changes permanent.

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

In the 2023 PFS proposed rule, CMS 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 PFS. 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 proposed 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 NPPs are authorized to do so under their scope of practice and applicable state law.

Comments/Responses: The majority of commenters supported CMS' proposal. Some commenters objected to the term "nonphysician practitioner" requesting that each place this term appears that it be replaced with the relevant professional title of the practitioner being referenced, or, in the alternative suggested by one commenter, "advanced practice providers." Another commenter asked CMS to include "or other supervising practitioner" in the definition of direct supervision.

CMS indicates that the relevant regulations specifically list the professional titles that are included in the term "nonphysician practitioner" for the purpose of each regulation. It is therefore unnecessary and would be impractical to replace all instances of "nonphysician practitioner" throughout each regulation with a list of each practitioner's professional title. As the regulations already specify the individual professional titles that apply to specified services, CMS does not believe adding "or other supervising practitioner" adds any clarity to the regulations.

There were commenters opposing the change arguing that physician and NPP skill sets are not interchangeable. CMS acknowledges that physicians have a higher level of education and more rigorous and training than NPPs. However, CMS does not agree that this makes NPPs unqualified to supervise diagnostic tests. CMS further indicates that NPPs are only permitted to supervise diagnostic tests to the extent permitted under the NPPs scope of practice and state law.

Final Decision: CMS is finalizing its policy as proposed. The final rule also indicates that CMS is extending a temporary provision that allows outpatient diagnostic tests to be supervised through the use of audio/video real-time communications technology (excluding audio-only) from the end of the PHE to the end of the calendar year in which the PHE ends, paralleling requirements that apply to telehealth services and other services under the PFS.

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 a Category A investigational device exemption (IDE) device 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 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 proposed 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 policy 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.

Public commenters supported the policy. CMS is finalizing the proposal without modification. CMS anticipates that that manufacturers will notify CMS of a need for a unique code to preserve the scientific integrity of a Category B IDE trial. Billing instructions for Category B IDE device trials provided in the Medicare Claims Processing Manual (Pub. 100-04) Chapter 68, Section 2 will be updated to include changes in policy made by this final rule.

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 tradename 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 magnetic resonance images (MRI). 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 service—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 date 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 stated 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 proposed 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 listed the new C-codes and their descriptors in the proposed rule.

Comments/Responses: Most public commenters supported CMS' proposal to pay separately for SaaS procedures although they disagreed that separate HCPCS codes are necessary to implement the policy. Commenters suggested that CMS just make the CPT codes separately payable to avoid the need for duplicative codes. Allowing payment for the CPT codes under the OPPS will also facilitate payment from private payers and other non-Medicare payers.

CMS agrees and will not be finalizing its proposal to create C codes for SaaS procedures. Rather, CMS will recognize the CPT codes for separate payment under the OPPS. The add-on code will be assigned to the same APC as its standalone code where the imaging and SaaS procedure are billed under a single code such that payment for the SaaS code is comparable under both scenarios.

MedPAC and several other comments oppose separate payment for expensive services that do not necessarily provide a substantial clinical improvement. Paying separately undermines the integrity of PPS payment bundles and can limit the competitive forces that generate price reductions among like services, lead to overuse (to the extent clinically possible), and shift financial pressure from providers to Medicare, according to MedPAC. Other commenters encouraged CMS to seek ways to increase packaging and the extent to which services can be bundled with related services based on encounters or episodes of care.

CMS responded that it provides payment for SaaS technologies that have been approved by the FDA and that have received a CPT code from the AMA, lessening concerns about the quality of these services. While CMS agrees that packaging encourages efficiency and is an essential component of the OPPS, the services described by CPT add-on codes 0649T, 0722T, and 0724T are not consistent with CMS' definition of add-on services for the purposes of its packaging policy. As the costs associated with the add-on codes exceed the costs of the imaging service with which it would be billed, CMS believes equitable payment for SaaS procedures represented by add-on codes can be achieved by setting their payment rates commensurate with the SaaS procedures represented by standalone codes.

Final Decision: CMS will recognize the SaaS CPT add-on codes and pay them separately. The SaaS CPT add-on codes will be assigned to identical APCs and have the same status indicator assignments as their standalone codes. Table 69 lists SaaS CPT codes and their APC and status indicator assignments.

4. Comment Solicitation on Payment Policy for SaaS Procedures

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

Comments/Responses: Several commenters stated that SaaS technology represents a heterogenous group of technologies. CMS' characterization of SaaS technology is overly inclusive. Commenters had a variety of suggestions for how to develop consistent terminology to accurately describe SaaS technology. Some commenters argued that CMS should not establish a single policy that would apply to all SaaS-type technology but instead separately evaluate each new technology to determine appropriate HCPCS coding, including whether or not a potential CPT code can be used to support payment for the separate and distinct service under the OPPS.

There were a number of comments on payment policy approaches to recognizing SaaS technologies that were similar to those on CMS' specific proposal to create C-codes in place of add-on codes to allow for separate payment. As with CMS' specific proposal, commenters both supported and opposed creating C or G codes for SaaS technologies. There was support for assigning SaaS technologies to new technology APCs and a comment opposed to create composite APCs for SaaS technologies. With respect to bias in software algorithms, the general sentiment in the comments was that this issue is one for FDA rather than CMS.

Final Decision: CMS thanked the commenters for their input but did not respond to any comments.

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 Policy

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 proposed 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.

Comments/Responses: While many public comments supported the proposal, MedPAC and others opposed it. MedPAC said the proposal would undermine the prospective, bundled nature of Medicare's hospital payments by paying hospitals more as their costs increase. Other commenters were doubtful the policy would be effective as the subsidy would not be large enough to shift hospital purchasing decisions.

Others commenters stated the policy would lead to unintended consequences like higher costs for domestically produced surgical N95 respirators as subsidies would increase prices. One commenter suggested an alternative where CMS would provide a payment adjustment to providers who attest to purchasing domestically manufactured surgical N95s through contracts that include terms related to the manufacturer having on-hand inventory. Such a policy would incent domestic manufacturers to have more inventory on-hand in the event of another spike in future demand and the market would not have to rely increased manufacturing that was problematic during the early days of the pandemic. There were also comments asking CMS to expand the policy to include other medical supplies.

CMS agreed with MedPAC generally on its bundling comments. However, the subsidy in this instance is intended to further the public policy goal ensuring that quality PPE is available to health care personnel when needed—e.g., there is a larger public policy goal served by this policy. With respect to whether the subsidy will influence purchasing decisions, CMS believes making the marginal cost of domestically produced N-95 masks lower will encourage the purchase of larger quantities of domestic surgical N95 respirators and thereby help to provide sustained support for the production and availability of these respirators over the long term.

With respect to the alternative proposal suggested by one commenter and others asking the policy be expanded to other medical supplies, CMS will consider these ideas in the future as it makes changes to the policy based on further experience. CMS further notes that this policy would be one among others to maintain an adequate inventory of medical supplies to meet future public health emergencies: See "Public Health Supply Chain and Industrial Base One-Year Report" available on the HHS website at https://aspr.hhs.gov/MCM/IBx/2022Report/Pages/default.aspx for more information.

Final Determination: CMS is finalizing proposed payment adjustments under the OPPS and IPPS for the additional resource costs that hospitals face in procuring domestic NIOSH-approved surgical N95 respirators.

3. Definition of Domestic NIOSH-approved Surgical N95 Respirators

For purposes of this policy, CMS proposed 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 proposed 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 proposed 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.

[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.

Comments/Responses: There were public commenters supporting use of the Berry Amendment for the definition of domestically NIOSH-approved surgical N95 respirators as it is a familiar standard for the manufacturing industry. Others were concerned hospitals will not be familiar with the Berry Amendment and instead suggested that any product with a "Made in USA" designation be considered compliant with the policy. One commenter concerned about the availability of domestic raw materials suggested using content threshold requirements outlined in the Federal Acquisition Regulations that implement the Buy American Act, which require 60 percent of the value of a product's components to be manufactured in the U.S.

CMS continues to believe that it should use the Berry amendment for its definition of domestic NIOSH-approved surgical N95 respirator. The Berry Amendment is a familiar contracting standard for the manufacturing industry. The "Made in USA" designation is not a contracting standard. With respect to the comment suggesting CMS modify the proposed definition of a domestic surgical N95 respirator to include respirators in which at least 60 percent of the value of a product's components were manufactured in the U.S., CMS believes manufacturers already have significant capacity to produce surgical N95 respirators that meet the proposed definition without adding additional requirements.

Many commenters were concerned about the burden associated with this policy. Burdensome aspects of this policy noted by the commenters include differentiating costs for domestically produced respirators from non-domestically produced respirators including the need for hospitals to obtain a written statement from the manufacturer stating that the surgical N95 respirators the hospital purchased are domestic. Some commenters suggested that CMS should require manufacturers to meet new labeling and reporting requirements to reduce burden. Another commenter suggested CMS maintain a list of manufacturers whose products meet the proposed definition of domestic and make this information available to the public.

CMS disagrees that it will be highly burdensome to attest that a surgical N-95 mask meets the domestically produced requirement. For the final rule, CMS estimates that the total burden associated with this policy for each hospital would be 0.50 hours per year at a cost of $25.43. The proposed rule states it would be in manufacturers' interest to provide written attestations that a surgical N-95 mask meets the requirements to be domestically produced given hospitals comprise a significant portion of their customer base. This interest on the part of the manufacturer will significantly reduce the burden on hospital of this policy. CMS further adds that it is not requiring the written manufacturer statements to cover a specific order or lot of domestic respirators purchased by a hospital as long as all of the domestic respirators purchased by the hospital are covered by associated written manufacturer statements.

Final Decision: CMS is finalizing its proposal without modification.

4. Payment Adjustment

CMS proposed 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 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. 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 proposed 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 did not quantify the information collection requirement costs in the proposed rule.

CMS proposed 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 are the 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 70 of the final rule.

Several comments expressed concern with basing the subsidy on Medicare utilization only. These commenters indicated that such a policy would favor high Medicare utilization hospitals relative to low Medicare utilization hospitals and would make the policy less likely to achieve its goal. CMS reiterated an earlier response that this policy is not being adopted in isolation. See "Public Health Supply Chain and Industrial Base One-Year Report" available on the HHS website at: https://aspr.hhs.gov/MCM/IBx/2022Report/Pages/default.aspx for further information.

MedPAC, while not supportive of the proposed payment adjustment, stated that CMS should set the unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators at a national level (rather than on a hospital-by-hospital basis) to reduce burden on hospitals, encourage hospitals to purchase the most economical domestically made product, and reduce the ability of hospitals to increase their payments by artificially inflating reported N95 costs. One comment stated that using a national unit cost differential would lead to underpayments for hospitals that utilize a higher number of surgical N95 respirators. CMS will consider MedPAC's and the other comments as it gains more experience with this policy.

6. Budget Neutrality

To further support the strategic policy goal of maintaining the supply of NIOSH-approved surgical N95 respirators, CMS did not propose 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.

In the proposed rule, CMS indicated 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 assumed that one surgical respirator mask is used per OPPS encounter or 109.3 million units for 2023 using final rule data. Based on available data, CMS estimated the difference in the average unit cost of domestic NIOSH-approved surgical N95 respirators and other masks is $0.20. CMS estimated that 40 percent of masks used will be domestic NIOSH-approved in the outpatient setting. Total OPPS costs are estimated at $8.7 million (109.3 million claims X $0.20 X 40 percent) requiring an adjustment of 0.9999 (-0.01 percent).

Commenters opposed the budget neutrality adjustment under the OPPS stating it would be counter to CMS' public policy goal and would result in hospital's not purchasing domestically produced N95 masks. Others expressed concern about the impact of the budget neutrality adjustment on safety net or smaller hospitals which may be less able to absorb the higher costs of acquiring domestically produced medical supplies. CMS acknowledged these comments but indicated that that authority under which this policy is being adopted—section 1833(t)(2)(E) of

the Act—requires budget neutrality. There were no public comments on this estimation methodology.

CMS is finalizing the budget neutrality adjustment, as updated based on data for the final rule.

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

Since 2017, CMS has been paying a PFS equivalent rate for services provided in a an off-campus hospital outpatient provider-based department (PBD) that opened on or after November 2, 2015.[26] Since 2019, CMS has been paying the PFS equivalent rate for a clinic visit (G0463) irrespective of whether the off-campus PBD is new on or after November 2, 2015. CMS implemented this policy over a 2-year period paying 70 percent of the OPPS rate for G0453 in 2019 and 40 percent of the rate in 2020 and subsequent years.

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 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 be primarily 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 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

[26] This date is when the Bipartisan Budget Act of 2015 (Pub. L. 114-74) was enacted.

paid a PFS-equivalent rate for a clinic visit (G0463) in an off-campus PBD would help to maintain access to care in rural areas.

Accordingly, beginning in 2023, CMS proposed to except rural SCHs from being paid the PFS-equivalent rate for a clinic visit (G0463) in an excepted off-campus PBD. CMS further solicited 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 $121, with an approximate average copayment of $24 for the beneficiary based on final rule data. This compares to a final PFS-equivalent rate of $48, with an approximate average copayment of $10. The average cost of this policy to a beneficiary would be $14 per visit. CMS estimates that exempting rural SCHs from this policy would increase OPPS spending by approximately $71 million in 2023.

Comments/Responses: The majority of commenters supported CMS' proposal while many argued for expanding it to other types of hospitals such as: urban SCHs; hospitals that provide a disproportionate share of the nation's uncompensated care, and serve high proportions of Medicaid, Medicare, and uninsured patients; hospitals located in primary care health professional shortage areas (PC-HPSA) or treat a certain percentage of patients that reside in a PC-HPSA; Medicare Dependent Hospitals; rural hospitals with fewer than 100 beds; rural referral centers; and Medicaid disproportionate share hospitals. Public commenters argued that the same logic that applies to rural SCHs being exempt from this policy would also apply to these types of hospitals.

CMS' general response to comments requesting an expansion of this policy to other types of hospitals rested on its foundational argument for why rural SCHs receive a 7.1 percent adjustment to their OPPS rates. In each of these cases—unlike rural SCHs—Congress did not determine that any of these hospital types required additional payments for outpatient services. In the case of the rural SCHs, section 1833(t)(13)(B) authorizes an appropriate adjustment for hospitals located in rural areas where the Secretary determines, based on a study, that the costs incurred by these hospitals by APC group exceed costs incurred by hospitals in urban areas.

In the 2006 OPPS final rule (70 FR 68556 through 68561), CMS presented the results of its study showing rural SCHs were the only rural hospital type that had higher resource costs for covered outpatient department services. CMS found no significant difference in cost between small rural hospitals with 100 or fewer beds and urban hospitals. Only rural SCHs are being excepted from this policy, because CMS continues to believe that the underlying principles of the clinic visit policy continue to justify application of the volume control method for clinic visits to the remaining hospital types, including most rural and safety-net providers.

One commenter—although supportive of the exemption for rural SCHs—requested that CMS monitor the effects of exempting these locations from site neutral payments. CMS agreed and

will continue to monitor the effects of exempting rural SCHs from the clinic visit policy. CMS may revisit this policy in future rulemaking as necessary.

Final Decision: CMS is finalizing the policy as proposed.

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 2023 payment status indicators and their definitions are in Addendum D1.

For 2023, CMS proposed 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.

Public commenters supported these proposed changes. CMS is finalizing the proposed changes without modification.

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. CMS requests comments in the proposed rule. Comments will not be accepted in the final rule.
"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 are accepted on the proposed APC assignment for the new code in the final rule.

The definitions of the OPPS comment indicators for 2023 are listed in Addendum D2. There were no public comments on the comment indicator definitions.

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 adopting an OPPS rate update 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 updating ASC rates consistent with its approach for updating hospital inpatient and outpatient services, which is 3.8 percent (4.1 percent less 0.3 percentage points 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 has not made any proposals to do so because of the burden such reporting would impose on ASCs.

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	1.0008	
2023 Update		
Hospital market basket update	4.1%	
Productivity adjustment	-0.3%	
Net MFP adjusted update	3.8%	
Penalty for not reporting quality data	0.0%	-2.0%
Net MFP and quality adjusted update	3.8%	1.8%
2023 ASC Conversion Factor	$51.854	$50.855

CMS estimates that under the final rule, total ASC Medicare payments for 2023 will be approximately $5.3 billion, an increase of $230 million compared with 2022 levels inclusive of changes in enrollment, utilization, and case mix changes.

As with the rest of the OPPS final rule and other CMS rules, addenda related to the ASC section (and referenced in this summary) are available only on the CMS website, at https://www.cms.gov/medicaremedicare-fee-service-paymentascpaymentasc-regulations-and-notices/cms-1772-fc

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 the proposed rule; and
- New codes for which it will be seeking comments in the final rule with comment period.

Table 74 in the final 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

Comment and Finalization Timeframes for New and Revised HCPCS Codes				
ASC Quarterly Update CR	**Type of Code**	**Effective Date**	**Comments Sought**	**When Finalized**
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 Solicited Public Comments in the 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 71 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 72 and 73 list the codes and descriptors.

CMS notes that the 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 did not receive any comments on the proposed ASC payment indicator assignments for the new Level II HCPCS codes and is finalizing the proposed ASC payment indicator assignments for these codes.

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

CMS assigned 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 invites comments in this final rule on the interim payment indicators which would be finalized in the 2024 OPPS/ASC final rule with comment period.**

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

CMS sought comment on proposed new and revised CPT codes effective January 1, 2023 that were received in time to be included in the proposed rule. CMS did not receive any comments on

the proposed ASC payment indicators for the new CPT codes effective January 1, 2023, so CMS is finalizing these codes as proposed.

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 the proposed rule, CMS resumed its historical practice and reviewed 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 finalized to permanently designate as office-based for 2023 (listed in Table 76 in the final 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 also finalized its proposal, with a modification, to designate 8 procedures as temporarily office-based for 2023 (see Table 78 in final rule). It finalized the addition of a new CPT code 0581T (Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral) to the ASC list of covered surgical procedures. 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.

Some commenters did not support its proposal to assign a permanent office-based designation to CPT 15275 as they argued that an insufficient ASC payment rate has contributed to a low claims volume and a site of service shift away from the ASC setting. CMS disagrees and responds that it assigns procedures to be permanently designated as office-based based on physician claims that report the procedure across all settings of care, both inpatient and outpatient. If the office-based utilization exceeds 50% of total utilization across all settings of care and total utilization exceeds 50 claims, CMS then proposes such procedures be permanently designated as office-based. Based on its review of CY 2021 claims and utilization data for this final rule with comment period, for CPT code 15725, there were a reported 90,211 claim lines in the physician office setting and a reported 154,108 claim lines across all settings of care.

CMS finalizing its proposal, without modification, to permanently designate the procedures in Table 76 as office-based procedures. It also finalizes its proposal, with a modification to include CPT code 0581T, to designate the procedure as temporarily office-based for 2023.

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 rate-setting 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 rate-setting methodology.

As discussed more below, CMS finalizes a special payment policy under the ASC system whereby it will add 55 new C codes to the ASC CPL to provide a special payment for code combinations eligible for complexity adjustments. Under its policy, the C code will 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 will be established by dividing the device portion of the primary procedure by the OPPS complexity-adjusted APC payment rate based on the ASC standard rate-setting methodology.

The ASC covered surgical procedures that CMS designates 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 final rule. There are 490 codes in this final rule that are assigned the "J8" payment indicator. This includes its policy to assign device-intensive status to 10 of the new C codes that it added to the ASC CPL as well as its methodology for determining the device portion for such procedures.

Many commenters requested that CMS use invoice or cost data submitted by manufacturers to determine the device portion for the ASC payment rate in lieu of the proposed default device offset percentage of 31 percent. Other commenters requested that CMS use invoice data or a subset of claims data to determine device-intensive status for certain procedures where hospitals have inaccurately coded devices as surgical supplies; therefore, the device offset percentage calculated from the claims statistics does not reflect the true cost of the device.

CMS does not accept the commenter's recommendations to use invoice data in lieu of claims data or a subset of its cost data to determine the device portion of the ASC payment rate. It reviews its general approach that it may temporarily assign a higher offset percentage if warranted by additional information in certain rare instances. For new procedures that do not have claims data CMS may assign a device offset percentage from a predecessor code or from a clinically similar procedure code that uses the same device. It also notes that hospitals are expected to adhere to the guidelines of correct coding and append the correct device code to the claim when applicable; CMS believes its claims database represents the most accurate source of device cost information available. It does not believe it would be appropriate to exclude in whole or in part the available claims data that it has for rate-setting and for determining device offset percentages.

CMS did accept certain recommendations to assign device offset percentage to certain codes based on comments. This includes the following:

- CPT code 0629T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; first level)
- CPT code 0671T (Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more);
- HCPCS code C9764 (Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed); and
- HCPCS code C9766 (Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed).

It also removed device-intensive status from CPT code 0428T (Removal of neurostimulator system for treatment of central sleep apnea; pulse generator only) based on a comment.

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.

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 finalizes its proposal to update the ASC CPL by adding a 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. Several specialty groups expressed broad support for expanding the ASC CPL and adding the lymph node procedure.

Multiple commenters recommended specific codes that they believed met the criteria to be added to the ASC CPL, including cardiovascular and cardiac ablation codes, thyroid-related procedures, and electroconvulsive therapy. Several orthopedic providers requested that total shoulder arthroplasty, total ankle arthroplasty and lumbar spine fusion procedures be added to the CPL. It received 64 procedure recommendations in total (listed in Table 81 in the final rule).

CMS stated that it individually assessed each of the 64 procedures evaluating clinical data on these procedures from multiple sites of services, reviewing the literature and experiential data provided in public comments, and examining claims volume to determine whether these procedures meet each of the regulatory criteria at 42 CFR 416.166. Based on its review, CMS CPL, it believes that four procedures (CPT codes 19307, 37193, 38531, and 43774) out of the 64 procedure recommendations it received can be safely performed for the typical beneficiary in the ASC setting and meet the general standards and exclusion criteria for the ASC CPL as set forth in 42 CFR 416.166(b) and (c), respectively.

These procedures, listed in Table 80 below, are:

- CPT 19307 (Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle)
- CPT 37193 (Retrieval (removal) of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural road mapping, and imaging guidance (ultrasound and fluoroscopy), when performed)
- CPT 38531 (Biopsy or excision of lymph node(s); open, inguinofemoral node(s))
- CPT 43774 (Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components)

Due to patient safety concerns, CMS believe the remaining 60 procedures should not be added to the ASC CPL. CMS provides a detailed rationale organized by anatomical category in the final rule.

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 finalizes its proposal 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 finalizes its proposal 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) specifies 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.

Commenters were generally supportive of the clarification of the future pre-proposed rule recommendation process. CMS finalizes its proposal.

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

ASC Payment for Covered Surgical Procedures

CMS continues its policy to update payments for office-based procedures and device-intensive procedures using its established methodology and 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.

ASC Payment for Combinations of Primary and Add-On Procedures Eligible for Complexity Adjustments under the OPPS

In this section, CMS finalizes 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 the ASC setting for Medicare beneficiaries.

Complexity Finalized Policy

To address this issue, CMS finalized a new ASC payment policy that will apply to certain code combinations in the ASC payment system where CMS will 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 adds new §416.172(h) to codify this policy.

Specifically, CMS finalizes that the ASC payment system code combinations eligible for additional payment under this policy will 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 will 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 policy, CMS will add these C codes to the ASC CPL and the ancillary services list, and when billed, they will 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 payment policy will change slightly each year, as the complexity adjustment assignments change under the OPPS and CMS expects it will add new C codes each year accordingly. CMS adds 55 new C codes to the ASC CPL in 2023. These C codes for 2023 can be found in the ASC addenda (and are listed below). It adds new §416.172(h)(1), titled Eligibility, to codify this policy.

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

HCPCS Code	Short Descriptor	Final CY 2023 Payment Weight	Final CY 2023 Payment Rate
C7500	Deb bone 20 cm2 w/drug dev	20.6832	$1,072.51
C7501	Perc bx breast lesions stero	20.6832	$1,072.51
C7502	Perc bx breast lesions MR	20.6832	$1,072.51

HCPCS Code	Short Descriptor	Final CY 2023 Payment Weight	Final CY 2023 Payment Rate
C7503	Open exc cerv node(s) w/ id	46.4624	$2,409.26
C7504	Perq cvt&ls inj vert bodies	60.5171	$3,138.05
C7505	Perq ls&cvt inj vert bodies	60.5171	$3,138.05
C7506	Fusion of finger joints	60.5171	$3,138.05
C7507	Perq thor&lumb vert aug	124.0889	$6,434.51
C7508	Perq lumb&thor vert aug	124.0889	$6,434.51
C7509	Dx bronch w/ navigation	27.2566	$1,413.36
C7510	Bronch/lavag w/ navigation	27.2566	$1,413.36
C7511	Bronch/bpsy(s) w/ navigation	27.2566	$1,413.36
C7512	Bronch/bpsy(s) w/ ebus	27.2566	$1,413.36
C7513	Cath/angio dialcir w/aplasty	27.8465	$1,443.95
C7514	Cath/angio dial cir w/stents	27.8465	$1,443.95
C7515	Cath/angio dial cir w/embol	27.8465	$1,443.95
C7516	Cor angio w/ ivus or oct	44.8773	$2,327.07
C7517	Cor angio w/ilic/fem angio	44.8773	$2,327.07
C7518	Cor/gft angio w/ ivus or oct	44.8773	$2,327.07
C7519	Cor/gft angio w/ flow resrv	44.8773	$2,327.07
C7520	Cor/gft angio w/ilic/fem ang	44.8773	$2,327.07
C7521	R hrt angio w/ ivus or oct	44.8773	$2,327.07
C7522	R hrt angio w/flow resrv	44.8773	$2,327.07
C7523	L hrt angio w/ ivus or oct	44.8773	$2,327.07
C7524	L hrt angio w/flow resrv	44.8773	$2,327.07
C7525	L hrt gft ang w/ ivus or oct	44.8773	$2,327.07
C7526	L hrt gft ang w/flow resrv	44.8773	$2,327.07
C7527	R&L hrt angio w/ ivus or oct	44.8773	$2,327.07
C7528	R&L hrt angio w/flow resrv	44.8773	$2,327.07
C7529	R&L hrt gft ang w/flow resrv	44.8773	$2,327.07
C7530	Cath/aplasty dial cir w/stnt	88.3120	$4,579.33
C7531	Angio fem/pop w/ us	105.7203	$5,482.02
C7532	Angio w/ us non-coronary	102.0024	$5,289.23
C7533	PTCA w/ plcmt brachytx dev	106.5754	$5,526.36
C7534	Fem/pop revasc w/arthr & us	194.5291	$10,087.11
C7535	Fem/pop revasc w/stent & us	192.8382	$9,999.43
C7537	Insrt atril pm w/L vent lead	194.7346	$10,097.77
C7538	Insrt vent pm w/L vent lead	194.1979	$10,069.94
C7539	Insrt a & v pm w/L vent lead	197.9109	$10,262.47

HCPCS Code	Short Descriptor	Final CY 2023 Payment Weight	Final CY 2023 Payment Rate
C7540	Rmv&rplc pm dul w/L vnt lead	194.5441	$10,087.89
C7541	ERCP w/ pancreatoscopy	43.8422	$2,273.39
C7542	ERCP w/bx & pancreatoscopy	43.8422	$2,273.39
C7543	ERCP w/otomy, pancreatoscopy	43.8422	$2,273.39
C7544	ERCP rmv calc pancreatoscopy	43.8422	$2,273.39
C7545	Exch bil cath w/ rmv calculi	43.8422	$2,273.39
C7546	Rep nph/urt cath w/dil stric	28.8611	$1,496.56
C7547	Cnvrt neph cath w/ dil stric	33.4466	$1,734.34
C7548	Exch neph cath w/ dil stric	28.8611	$1,496.56
C7549	Chge urtr stent w/ dil stric	28.8611	$1,496.56
C7550	Cysto w/ bx(s) w/ blue light	28.8611	$1,496.56
C7551	Exc neuroma w/ implnt nv end	50.7505	$2,631.62
C7552	R hrt art/grft ang hrt flow	44.8773	$2,327.07
C7553	R&l hrt art/vent ang drg ad	44.8773	$2,327.07
C7554	Cystureth blu li cyst fl img	16.3541	$848.03
C7555	Rmvl thyrd w/autotran parath	82.5413	$4,280.10

Payment Methodology for C Codes

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

The C codes are subject to all ASC payment policies, including the standard ASC payment system rate-setting methodology. For example, the multiple procedure discounting rules will 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. CMS will 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 rate-setting methodology).

CMS will 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), CMS will multiply the OPPS relative weight by the ASC budget neutrality adjustment (or ASC weight scaler) to determine the ASC relative weight. It will 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 rate-setting process to the C codes. It adds 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 policy, the C code will 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 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, then the 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. CMS would apply its standard ASC payment system rate-setting 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, CMS would apply the ASC standard rate-setting 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 adds new §416.172(h)(2)(ii) to codify this policy.

For its budget neutrality calculations, CMS estimates 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, CMS will estimate 2023 ASC utilization based upon how often these combinations are performed in the HOPD setting. Specifically, it will 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 will 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.

All of the commenters who responded to this policy were supportive of providing a complexity adjustment for complex procedures in the ASC setting and urged CMS to finalize the ASC special payment policy for OPPS complexity adjusted C-APCs, as proposed. They believed this approach would result in more appropriate payments for those ASC procedures that require greater resources than the individual primary service and align with other site neutral payment policies. CMS finalizes the ASC special payment policy for OPPS complexity-adjusted C-APCs, as proposed. The final C codes for CY 2023 can be found in ASC addendum AA.

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 finalizes its proposal 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 will 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 82 in the final rule compares the cost statistics and indicates the 2023 APC cost for these 8 APCs.

CMS did not receive any comments on its proposal and based on claims data available for the final rule it finalizes its proposal.

Payment for Covered Ancillary Services

CMS finalizes its policy 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 will 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 rates, the payment indicators and rates are based on a comparison using the PFS rates effective January 1, 2023.

Requirement in the Physician Fee Schedule CY 2023 Proposed and Final Rule for HOPDs and ASCs to Report Discarded Amounts of Certain Single-dose or Single-use Package Drugs

CMS reminds readers of a policy in the 2023 Physician Fee Schedule (PFS) final 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 finalizes in the 2023 PFS final rule that the JW modifier will 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 final rule also requires 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.

Comments on this issue are addressed in the 2023 PFS final rule.

Inflation Reduction Act – Section 11101 Regarding Beneficiary Coinsurance

On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117-169) was signed into law. Section 11101 of the IRA requires drug manufacturers to pay a rebate if the ASP of their drug product rises at a rate that is faster than the rate of inflation. Section 1833(i)(9) requires that under the ASC payment system beneficiary coinsurance for a Part B rebatable drug that is not packaged to be calculated using the inflation-adjusted amount when that amount is less than the otherwise applicable payment amount for the drug furnished on or after April 1, 2023.

The coinsurance computation amount is equal to 20 percent of the inflation-adjusted payment amount for a Part B rebatable drug. The payment to the provider or ASC (as described in section 1833(a)(1)(EE)) will be paid the difference between the beneficiary coinsurance of the inflation-adjusted amount and the ASP plus 6 percent. This statutory change begins April 1, 2023.

ASC Payment System Policy for Non-Opioid Pain Management Drugs and Biologicals that Function as Surgical Supplies

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 percent. 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 83 in the final rule).

Final 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 $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 proposed 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 proposed 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 and final rules.

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 proposed that Dextenza receive separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply for 2023.

There was overall general support for CMS' proposal to pay separately in the ASC setting for the four drugs. Commenters expressed concerns with CMS no longer paying for Zynrelef under the policy at §416.174 as they believed this drug is beneficial for patients in managing their pain. CMS finalizes its proposal to pay separately for Exparel, Omidria, Xaracoll, and Dextenza as non-opioid pain management drugs that functions as a supply in a surgical procedure under the ASC payment system for CY 2023. CMS states that Zynrelef is not eligible for separate payment in the ASC setting as a non-opioid pain management drug that functions as a supply in a surgical procedure, because it is already separately payable as a pass-through drug.

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

CMS clarifies and finalizes 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 now clarifies 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 provides 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 finalizes 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.

CMS received several comments acknowledging the technical changes. CMS finalizes, as proposed, the modifications to §416.174 to reflect its current policy.

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. ASC 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 comment indicator "NP" to

indicate that these codes were 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 continues to update relative weights using the national OPPS relative weights and the PFS non-facility PE RVU-based amounts when applicable. CMS scales the relative weights as under prior policy. Holding ASC use, 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 new C codes for 55 primary procedures when performed with add-on packaged services. CMS estimates the additional spending to be approximately $5 million.

The resulting ratio of 0.8594 is the weight scaler for 2023. The scaler applies 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 does 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 uses 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, 1.0008, is the wage index budget neutrality adjustment to the conversion factor for 2023.

To update ASC rates, CMS would utilize the hospital market basket update of 4.1 percent minus the productivity adjustment of 0.3 percent. This yields an update of 3.8 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 1.8 percent for such ASCs. The resulting 2023 ASC conversion factor is $51.854 for ASCs reporting quality data, and $50.855 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 1.0008	
Net MFP-adjusted update	x 1.038	x 1.018
2023 ASC conversion factor	$51.854	$50.855

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 111 of the final rule and reproduced below). The eye surgical specialty group remains the largest source of payments and will see a 3 percent increase in payments attributable to the changes for 2023. The second largest group, nervous system, is estimated to see a 4 percent increase.

Table 111 – Estimated Impact of the 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	**$5,859**	**4%**
Eye	$1,789	3%
Nervous system	$1,200	4%
Musculoskeletal system	$999	7%
Gastrointestinal	$896	5%
Cardiovascular	$262	2%
Genitourinary system	$215	4%

CMS provides estimated increases for 30 selected procedures in Table 112 in the final rule; the top 10 procedures in terms of total Medicare ASC payments 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 4 percent increase in payment. The second largest aggregate payment procedure, CPT code 63685, is expected to see a 1 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 112: 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	4

Excerpt from Table 112: 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
63685	Insrt/redo spine n generator	$300	1
45380	Colonoscopy and biopsy	$235	5
45385	Colonoscopy w/lesion removal	$191	5
27447	Total knee arthroplasty	$182	4
63650	Implant neuroelectrodes	$174	8
43239	Egd biopsy single/multiple	$160	3
64483	Njx aa&/strd tfrm epi 1/s 1	$106	4
66991	Xcapsl ctrc rmvl cplx insj 1+	$98	1
64590	Insrt/redo pn/gastr stimul	$95	5

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-fc. They include:

- AA – ASC Covered Surgical Procedures for 2023 (Including surgical procedures for which payment is packaged)
- BB – ASC Covered Ancillary Services Integral to Covered Surgical Procedures for 2023 (Including Ancillary Services for Which Payment is Packaged)
- DD1 – ASC Payment Indicators for 2023
- DD2 – 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 Hospital Outpatient Department (HOPD) 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 finalizes as proposed 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 discusses responses received to requests for comment on (1) incorporating a procedural volume measure into the OQR program's measure set and (2) measuring health care disparities through the OQR program.

No changes were 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; or the extraordinary circumstances exception(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 3,356 eligible hospitals (97%) met all reporting requirements including data submission, while 88 failed to do so.

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. Hospital OQR Program Quality Measures

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

CMS finalizes as proposed 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.

Most commenters strongly supported reporting, citing the substantial burden associated with OP-31 and the ongoing COVID-19 PHE. Successful reporting of this measure requires cooperation among physicians and facilities for collection of visual function surveys from patients both preoperatively and postoperatively. Some further suggested that the measure should never be made mandatory.

CMS acknowledges the burden concerns raised by commenters. However, CMS believes that OP-31 is a high-value measure for the OQR program as it captures a patient-reported outcome after one of Medicare's most commonly performed procedures and plans to revisit making the measure mandatory through future rulemaking. CMS notes that a subset of hospitals have been able to consistently report this measure voluntarily. Additional resource information is being added to the OQR Program Specifications Manual and CMS is engaged in polling successful measure reporters to identify best practices; these actions are intended to facilitate successful reporting by all facilities.

2. Requests for Comment on Future Measures

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

CMS requested 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 invited 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.

OP-26 collected volume data for 9 procedure categories: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, Skin, and Other. It was dropped from the OQR program during CY 2018 rulemaking because nonspecific procedure volume data were viewed as providing little actionable or relevant information with clear links to better outcomes. At that time, commenters supported measure removal. CMS observes that subsequently a large number and wide range of procedures have shifted to the outpatient setting. Some evidence has emerged that procedural volume may be associated with facility features that enhance outcomes (e.g., procedure-specific teams), so that volume data could be informative for patients and families.

Commenters variously supported (1) restoration of OP-26 to the OQR program measure set; (2) adoption of a volume measure other than OP-26 (to be determined); and (3) not adopting any volume measure. Several noted that CMS can track HOPD procedure volumes through hospital claims data. Others stated that any volume measure proposed should first be endorsed by the National Quality Forum (NQF).

CMS reiterates its current belief that volume measures are informative and valuable for beneficiaries, citing the inverse correlation of volume to complication rates after total hip arthroplasties. CMS notes that OP-26 required all-payer data submission (i.e., not just Medicare) and believes such data to be more informative than Medicare-only data that would be generated via claims-based measurement. A reinstated OP-26 measure or a new volume measure each would be required to go through the current standard pre-rulemaking process for CMS measures with review by the Measure Applications Partnership (MAP) and consideration of submission for NQF endorsement. CMS expresses appreciation to all respondents and indicates their comments will be considered during future rulemaking.

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

As part of its enterprise-wide focus on advancing health equity, in the proposed rule CMS asked readers to review an RFI issued in 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 identified the following key considerations as a framework for feedback:

- 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, and
- Guiding Principles for Reporting Disparity Measures.

Comments were numerous. CMS summarizes them and confines its responses to expressions of appreciation; it also indicates that the feedback will be used to inform future policy proposals. The full discussion is available in section XIV.B.6.b. of the rule; highlights are provided below.

- Commenters supported cautiously approaching health equity issues through quality measurement and results stratification as CMS has begun to do in some of its quality programs (e.g., Hospital Readmission Reduction Program).
- Stratification contributes to identifying disparities but does not inherently provide resources to resolve them; stratification is one component of overall strategy to advance health equity.
- Stratification for multiple factors could lead to small sample sizes and reduce utility of stratified measurement.
- Considerable support was received for use of area-based indicators to stratify measures.
- Measure selection for stratified analyses must take into account which factors are controllable and actionable by providers. Not all measures are suitable for stratification.
- Many commenters urged CMS to prioritize use of existing measures, data collection tools, and large datasets as part of equity-related quality measurement.
- Harmonization and alignment across programs whenever possible will reduce newly added burden for providers and add to overall strategic cohesion.
- Support was expressed for both of the CMS Disparities Methods (Within-Facility and Across-Facility) as conceptual analytic approaches but most believed that the Within-Facility method was better suited to stratified equity analyses.
- Support varied across methods for identifying meaningful performance differences (e.g., benchmarking, peer grouping, rank ordering) and no consensus emerged.
- CMS should establish a timeline with goals and milestones for data standardization, data collection, measure development, and implementation. A phased approach for setting goals and expectations to address disparities should be adopted by CMS as facility readiness varies considerably.
- Self-reported data remain the gold standard for demographic and social risk factor data collection but robust privacy safeguards are essential.
- Data definitions and collection processes must be standardized and emphasize interoperability.
- Numerous variables were suggested for collection and stratified analyses.
- Confidential results reporting to providers was strongly supported with later consideration of public reporting.
- Data should be validated before public reporting and prior to use for making payment adjustments.

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 finalizes as proposed to align the patient encounter quarters for the OQR program's chart-abstracted measures with the calendar year. All 4 quarters will be based on the calendar year that is 2 years prior to the applicable payment determination year.[27]

The change will be phased in and begin with a transition year for CY 2025 payment determinations during which only 3 quarters of data will be utilized (Q2, Q3, and Q4 of CY 2023). Changeover will be complete—using 4 quarters of data—beginning with CY 2026 payment determinations. In Tables 88 through 90 CMS provides the applicable dates for current and future years and corrects errors from the corresponding tables of the proposed rule. The finalized tables are consolidated into the single table below.

Comments received were supportive.

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 – Finalized	
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 -- Finalized (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
*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 finalizes as proposed 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:

[27] 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).

- 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.

Commenters were supportive. A hospital meeting the new criterion would have less than 4 quarters of data available for validation and previously its validation results could have been considered inconclusive for a payment determination.[28]

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 is subject to both APU reduction and targeting for validation in the subsequent year. Similarly, a hospital that has 4 quarters of data and does not meet the 75 percent threshold is subject to both APU reduction and targeting for validation in the subsequent year.

3. Electronic Clinical Quality Measure (eCQM) Reporting and Data Submission Requirements

CMS reminds readers that during CY 2022 rulemaking the first eCQM was adopted into the OQR program measure set beginning with voluntary reporting for the CY 2023 reporting period/CY 2025 payment determination: OP-40 ST-Segment Elevation Myocardial Infarction (STEMI). Mandatory reporting will be phased in over several years as shown in Table 93 of the rule and reproduced below for informational purposes.

TABLE 93: Progressive Increase in eCQM Reporting Beginning with the CY 2023 Reporting Period/CY 2025 Payment Determination and for Subsequent Years

Calendar Year Period	Reporting Quarters	Reporting Status
CY 2023 Reporting/CY 2025 Payment	Any quarter	Voluntary
CY 2024 Reporting/CY 2026 Payment	One self-selected quarter	Mandatory
CY 2025 Reporting/CY 2027 Payment	Two self-selected quarters	Mandatory
CY 2026 Reporting/CY 2028 Payment	Three self-selected quarters	Mandatory
CY 2027 Reporting/CY 2029 Payment and Subsequent Years	Four self-selected quarters (1 full CY)	Mandatory

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

CMS finalizes as proposed that existing policies with respect to computing and applying the payment reduction for hospitals that fail to meet the Hospital OQR Program requirements will be continued using the 2023 update factor. The resulting reduction ratio for hospitals that fail to meet OQR Program requirements, called the "reporting ratio," is 0.9807. It is calculated by dividing the proposed reduced conversion factor of $83.934 by the proposed full conversion factor of $85.585. Continuing previous policies, the reporting ratio will be applied to all services calculated using the OPPS conversion factor and applied to all HCPCS codes to which CMS has

[28] Other 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.

assigned status indicators J1, J2, P, Q1, Q2, Q3, R, S, T, U or V, excluding services paid under the New Technology APCs to which CMS has assigned status indicators S and T.

The reporting ratio will continue to be applied to the national unadjusted payment rates and minimum unadjusted and national unadjusted copayment rates of all applicable services for hospitals that fail to meet the OQR program's reporting requirements. All other applicable standard adjustments to the OPPS national unadjusted payment rates also will continue to apply, and OPPS outlier eligibility and outlier payments also will 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 eligible 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.

D. Summary Table of Hospital OQR Program Measures

Tables 85-87 in the rule list the finalized 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					

Hospital OQR Program Measures by Payment Determination Year							
NQF	**Measure**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**
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
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[a]	OP-31: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery					*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 finalized 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).[29] CMS provides references to the legislative and regulatory histories of the ASCQR program.

CMS finalizes as proposed 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. CMS also discusses responses received to requests for comment on 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 were 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 later in this summary section. 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 finalizes as proposed to change the reporting status of the measure *Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (ASC-11) (NQF #1536)* from mandatory to voluntary beginning with the CY 2025 reporting period/CY 2027 payment determination and for subsequent years.

Most commenters strongly supported voluntary reporting, citing the substantial burden associated with ASC-11 since successful reporting of this measure requires cooperation among physicians and facilities for collection of visual function surveys from patients both preoperatively and postoperatively. Some further suggested that the measure should never be made mandatory.

[29] 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.

Some commenters noted that ASC-11 was originally developed as a clinician-level not facility-level measure and is therefore inappropriate for inclusion in a facility quality measure set (i.e., the ASCQR program). Others asserted that ASC-11 post-procedure survey data collection violates CMS regulations (42 CFR 416.2) that prohibit ASCs from postoperatively offering anything beyond integral ancillary services furnished immediately after a surgical procedure.

CMS responds that development of a clinician-level measure does not inherently preclude its use in a facility-level program. Further, CMS states that facilities and clinicians are equally responsible for the quality of care furnished in ASCs. The agency notes that ASCs are responsible for determining which clinicians are allowed to furnish services in their ASCs. Additionally, CMS views the postoperative data collection for ASC-11 to be permissible as part of satisfying the post-surgical assessment and discharge planning requirements found in 42 CFR 416.52.

CMS acknowledges the burden concerns voiced. However, the agency also reiterates its view that ASC-11 is a high-value measure for the ASCQR program as it captures a patient-reported outcome after one of Medicare's most commonly performed outpatient procedures, and no other ASCQR program measure serves this purpose. CMS states plans to revisit making the measure mandatory through future rulemaking after the COVID-19 PHE ends. CMS notes that a subset of facilities have been able to consistently report this measure voluntarily and anticipates that all facilities ultimately could do so. Additional resource information is being added to the ASCQR Program Specifications Manual and CMS is engaged in polling successful measure reporters to identify best practices to be shared across the ASC community; these actions are intended to facilitate successful reporting by all facilities.

2. ASCQR Program Summary Measure Table

Tables 94-95 in the rule list the previously finalized measure sets and newly finalized changes for CY 2026-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

ASCQR Program Measures by Payment Determination Year						
	2020	**2021**	**2022 & 2023**	**2024**	**2025**	**2026**
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: Hospital Visits After Urology ASC Procedure (NQF #3366)			X	X	X	X
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 been allowed 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, was finalized for mandatory reporting beginning with 2025 reporting period/2027 payment determination but in this rule is finalized for 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 payment indicators of A2, G2, P2, R2, or Z2, and to 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.

For CY 2023 the ASC conversion factor for facilities that successfully meet all quality reporting requirements will be $51.854 and $49.916 for those failing to meet quality reporting requirements. Calculation details are provided earlier in the rule (section XIII.H.2.b.).

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 estimates 4,646 facilities will submit data for the CY 2023 payment determination. CMS posts individual facility payment determination result lists on the QualityNet website https://qualitynet.cms.gov/asc/ascqr/apu#tab1.

C. Requests for Comment

1. Potential Future Specialty Centered Approach for the ASCQR Program

CMS requested 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. Two examples of approaches were described: (1) a multispecialty set of measures from which ASC providers could choose a specified number that reflect the services they perform (and their related specialties), and (2) a set of specialized tracks that would standardize ASC quality measures within a given specialty area reflecting procedures performed by each facility.

CMS posed multiple questions and provided tables illustrating the two example approaches (multispecialty set in Table 96 versus specialized tracks Tables 97 and 98) along with potentially applicable measures. The measures are drawn from the Merit-based Incentive Payment System (MIPS) quality measure inventory. The reader is referred to section XV.B.5.b. for the full set of questions, tables, and extensive background material presented by CMS to frame discussion of this topic. Excerpts from the tables and of comments received are provided below along with responses from CMS.

MIPS Quality Measures with Potential Broad Applicability Within the ASCQR Program (From Table 96)	
Measure Name	**Measure Name**
Advance Care Plan	Surgical Site Infection
CAHPS for MIPS Clinician/Group Survey	Unplanned Reoperation within 30 Days
Prevention Postoperative Nausea and Vomiting – Combination Therapy	Multimodal Pain Management

Example Ophthalmology ASCQR Program (From Table 97)
MVP Quality Measure Names
Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery
Cataracts: 20/40 or Better Visual Acuity Within 90 Days Following Cataract Surgery

Example Gastroenterology ASCQR Program (From Table 98)
MVP Quality Measure Names
Age Appropriate Screening Colonoscopy

Example Gastroenterology ASCQR Program (From Table 98)
MVP Quality Measure Names
Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients

Commenters expressed interest in a specialty-centered future approach for the ASCQR program, and many specific measures were suggested for inclusion. CMS agrees with commenters that this approach could lead to data reporting that is more meaningful for facilities, clinicians, and patients. Concerns were voiced about reporting burden and measure redundancy. CMS asserts that responsibility for ASC quality of care is shared by facilities and the physicians working within them and that the approaches under consideration would provide important data that are not currently available through the ASCQR program. No consensus was reached by commenters about the ideal balance between broadly applicable and specialty-specific measures in a revised ASCQR program and whether measures should be mandated or self-selected. Both chart-abstracted and digital measure formats received support. Commenters recommended that extensive changes should be phased-in, about which CMS is noncommittal. CMS emphasizes several times that no proposals for revamping the ASCQR program are being made at this time.

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

CMS requested comments on the potential inclusion of a procedure 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 invited 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.

ASC-7 required volume data collection for 7 procedure categories: Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin. It was dropped from the ASCQR program during CY 2018 rulemaking because nonspecific procedure volume data were viewed as less useful than procedure-specific data. At that time, some but not all commenters supported measure removal. CMS observes that subsequently a large number and wide range of procedures have shifted to the outpatient setting. Some evidence has emerged that procedural volume may be associated with facility features that enhance outcomes (e.g., procedure-specific teams), so that volume data could be informative for patients and families.

Scant support was expressed for restoration of ASC-7 to the ASCQR program measure set. Support for any volume measure was divided. Suggestions for a new measure or a revised ASC-7 included increasing granularity by adding more procedure categories to those in ASC-7 or by adopting procedure-specific measures (e.g., for total knee arthroplasty outcomes). Several commenters noted that CMS can track ASC procedure volumes through Medicare claims data. Others stated that any volume measure proposed should first be endorsed by the National Quality Forum (NQF).

CMS reiterates its current belief that volume measures are informative and valuable for beneficiaries, citing the inverse correlation of volume to complication rates after total hip

arthroplasties. CMS notes that ASC-7 required all-payer data submission (i.e., not just Medicare) and believes such data to be more informative than Medicare-only data that would be generated via claims-based measurement. A reinstated ASC-7 measure or a new volume measure each would be required to go through the current standard pre-rulemaking process for CMS measures with review by the Measure Applications Partnership (MAP) and consideration of submission for NQF endorsement. CMS expresses appreciation to all respondents and indicates their comments will be considered during future rulemaking.

3. Interoperability Initiatives in ASCs

CMS requested comments about how ASCs are implementing tools in their facilities that support the goal of healthcare information exchange interoperability. In general terms, the agency requested 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). Measures from the Promoting Interoperability Program (for hospitals) and the MIPS Promoting Interoperability performance category (for clinicians) potentially adaptable to the ASC setting were presented by CMS for consideration (shown in this final rule as Table 99 and from which an excerpt is provided below).

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). ASCs have a lower adoption rate of CEHRT compared to hospitals and physician offices.

Examples of Promoting Interoperability (PI) Measures Potentially Applicable to the ASCQR Program (From Table 99)
PI Measure Names
Provide Patients Electronic Access to Their Health Information
Query of Prescription Drug Monitoring Program (PDMP)
Support Electronic Referral Loops By Receiving and Reconciling Health Information

Some commenters were supportive of moving ASCs towards health information exchange interoperability. Suggestions were made for EHR infrastructure funding by CMS (similar to HITECH funding), an environmental scan of current ASC health IT capabilities, and that ASC participation in interoperability initiatives be voluntary (i.e., unassociated with any payment penalties), at least for a transition period. Confidential results reporting to facilities was recommended. Substantial concerns were voiced about administrative burden and costs. CMS responds that reporting burden would be minimized through electronic quality measures though acknowledges the significant upfront costs to ASCs of EHRs and their associated health IT infrastructure. CMS also states that interoperable electronic quality measures would facilitate measure alignment across quality programs, including the ASCQR program. CMS indicates feedback received will be considered during future rulemaking.

XVI. Rural Emergency Hospital Quality Reporting (REHQR) Program

A. Administrative Requirements

CMS finalizes as proposed that REHQR program participants each 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.

No comments were received on the proposed administrative requirements. CMS indicates that hospitals converting to REH status that already have HQR access may register by updating their profiles using their new REH CCNs. Further, CMS is not requiring that the SO designation be maintained after the REH account is established and initial set-up completed, but highly recommends that the SO activity be maintained.

B. Background and Considerations for Measure Selection

1. Background and Context

Section 1861(kkk)(7) of the Act, as added by Section 125 of 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 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.

2. Considerations for Measure Selection: General Principles

CMS provides general principles for the agency's use during REHQR program measure selection. No associated proposals were made and no stakeholder feedback is reported.

- 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. Some hospital OQR program measures already being reported by CAHs and some from the Medicare Beneficiary Quality Improvement Project (MBQIP) meet these criteria.[30]
- 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.

[30] The MBQIP is administered through the Health Resources and Services Administration's Rural Hospital Flexibility (Flex) program.

    - 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

1. Comments about Measures

CMS discusses comments received on the specific measures listed below.

Measures Recommended by the National Advisory Committee on Rural Health and Human Services

OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival
OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
OP-4: Aspirin on Arrival
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
Emergency Department Transfer Communications (EDTC)[31]

Existing Claims-Based OQR Program Measures Identified by CMS

OP-10: Abdomen Computed Tomography (CT) – Use of Contrast Material
OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy

Commenters uniformly supported efforts underway by CMS to identify measures appropriate for adoption into the REHQR program measure set through future rulemaking. However, there was little consensus among commenters about specific measures or ideal measure types (e.g., digital). All of the measures listed above received both support and opposition. Suggested additions for consideration were OP-5: Median Time to ECG and OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Interpretation Within 45 Minutes of ED Arrival, as these measures were believed to assess access to and timeliness of care. Commenters disagreed as to whether digital or chart-abstracted measures would reduce or increase burden. Some supported claims-based measures as minimally burdensome. Many supported a small initial measure set and a pay-for-reporting structure with gradual measure expansion over time and stated that technical assistance from CMS to REHs would be necessary.

[31] This measure is part of the MBQIP measure inventory.

2. Comments about Measurement Topics

CMS reviews comments received on the following measurement topics identified in the proposed rule as potentially applicable to REHs: telehealth, maternal health, behavioral health, ED services, and equity.

Substantial support was received for incorporating all of these measure topics into the REHQR program. The NQF's Rural Health Advisory Group 2022 Key Rural Measures were recommended as an additional source of measurement topics and measures, as they were designed to maximize rural relevance and to be resilient to low volume challenges. Many voiced concerns about the adequacy of REH infrastructure capabilities, especially in regards to electronic health records, digital quality measure reporting and the use of telehealth.

Telehealth was supported as an enabler of specialty access to maternal and behavioral health services. The NQF's Rural Telehealth and Healthcare System Readiness Measurement Framework was recommended as a measure source. Adoption of measures of screening for behavioral health conditions was suggested along with structural measures of maternal health and health equity. Measure stratification by demographics or social risk factors was advocated by some to advance equity while others suggested delaying measures of equity until the REHQR program is further developed and related measures are validated in other CMS quality programs.

Many emphasized the importance of ED services metrics given the focus of REHs on emergency care, tirage, and prompt transfers to higher levels of care. The MBQIP measure *Emergency Department Transfer Communications (EDTC)* received specific support along with the *ED CAHPS* patient experience-of-care survey.

3. Comments Addressing the Challenges of Small Case Numbers

CMS acknowledges comments received on the measurement challenges presented by small case numbers that are likely to occur at REHs for any given measure.

Many commenters shared their concerns about the impacts of small case numbers on reliability and validity, particularly if data were to be publicly reported. Suggested approaches to the case number challenge included aggregating measure data over longer time periods, avoiding setting minimum case thresholds, and using statistical methodology that adjusts for low volumes.

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

The following definitions will be helpful to understand this section:

- Transplant Hospital (TH) – A hospital certified by Medicare as a transplant hospital.
- Hospital Organ Procurement Organization (HOPO) – A hospital-based organ procurement organization (OPO). Organ acquisition costs for a HOPO are reported on the hospital cost report.
- Independent Organ Procurement Organization (IOPO) – An independent organ procurement organization that is not hospital-based and submits its own cost report to be paid for organ acquisition costs.

For purposes of this section, an organ procurement organization (OPO) will include both HOPOs and IOPOs. HOPO will refer only to hospital OPOs and IOPO will refer only to independent OPOs.

"Reasonable costs" refers to a payment methodology where allowable costs are reported on a cost report and Medicare pays its share of the hospital's allowable or reasonable costs. As organ acquisition costs are paid on a reasonable cost basis, THs and OPOs report their reasonable costs on the Medicare cost report. The ratio of Medicare usable organs to total usable organs is applied to reasonable cost to determine Medicare's payment or its share of the hospital's reasonable 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. 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.

In the FY 2022 IPPS/LTCH PPS final rule with comment period, CMS finalized its proposal to require that organs used for research be excluded from Medicare usable organs in Medicare's share of organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a)), and kidneys used for research be excluded from Medicare usable kidneys in Medicare's share of kidney acquisition costs under § 413.412(c).

Due to the number and nature of the comments received, CMS did not finalize its proposal that would have required OPOs and THs to include organs designated for research activities prior to the time the donor entered the hospital's operating room for surgical removal of the organs in the count of total usable organs or its proposal to exclude organs intended for transplant but subsequently determined to be unusable and donated to research from Medicare usable organs or total usable organs.

In the 2023 OPPS rule, CMS proposed to require that THs and OPOs exclude organs used for research from the denominator (total usable organs) in the ratio used to determine Medicare's share of organ acquisition costs on the Medicare cost report. Research organs include any organ (with the exception of certain pancreata as set forth in § 413.406(a)) used for research, regardless of whether the organ was intended for research or intended for

transplant but subsequently determined unsuitable for transplant and instead furnished for research.

When a research organ is included as a total usable organ, this results in assignment of a full standard acquisition charge (SAC) to each research organ. CMS' proposal would exclude research organs from being included in the count of total usable organs, and as a result would not assign a full SAC on the Medicare cost report for each research organ procured. However, when an organ identified as a research organ is transplanted into a patient, the organ is counted as a total usable organ and a full SAC is assigned.

The proposed rule also specified that the determination of whether an organ is usable or not could be made by any surgeon, not just the excising surgeon. CMS further clarified that the costs to procure unusable organs intended for transplant are reasonable costs that may be reported on Medicare cost reports.

Comments/Responses: The majority of commenters opposed CMS' proposal based on a misunderstanding of the policy. This issue is extremely complex and the misunderstandings were in two categories: Ratio of Medicare Usable Organs to Total Usable Organs and the Cost Finding. There were comments on other issues listed below as well.

Ratio of Medicare Usable Organs to Total Usable Organs or Medicare Cost Allocation: As stated above, this ratio is applied to total allowable costs to determine Medicare's share of the reasonable costs of THs, HOPOs and IOPOs. This process is known as the cost allocation.

Medicare's cost reporting instructions currently advise HOPOs and THs to include organs intended for transplant but ultimately used for research as total usable organs in the ratio of Medicare usable organs to total usable organs. However, IOPOs are instructed to exclude these organs from both the numerator and denominator of the ratio.

Many commenters mistakenly believed that Medicare would no longer share in the acquisition costs for organs that are *intended* for transplant but subsequently determined unsuitable for transplant and instead furnished for research. Based on some of the public comments, CMS believes the confusion may have been caused by the following statement: "For the purpose of determining Medicare's share of organ acquisition costs, we intend a 'research organ' to be an organ used for research…regardless of whether the organ was intended for research, or intended for transplant…instead used for research" (87 FR 44767).

Many commenters mistakenly believed that under CMS' proposal Medicare would no longer pay for organs initially intended for transplant if those organs were later used for research. CMS did not mean to imply that Medicare would not continue to share in the acquisition costs of organs that are intended for transplant but subsequently determined unsuitable for transplant and instead furnished for research. Its intention was to rectify the inconsistency in the cost reporting instructions between IOPOs, HOPOs and THs regarding application of the policy.

To address commenters' concerns, CMS is clarifying that the acquisition costs of organs that are initially intended for transplant, but subsequently determined unsuitable for transplant and

instead furnished for research, are allowable organ acquisition costs. This is similar to the organ acquisition costs for organs that are initially intended for transplant, but subsequently determined unsuitable for transplant and *discarded*, which are also allowable organ acquisition costs. These same policies will apply to THs, HOPOs and IOPOs for all organs. Under CMS' final rule policy, THs, HOPOs and OPOs will exclude organs intended for transplant but ultimately used for research or discarded from both the numerator and denominator of the ratio used in the Medicare cost allocation.

There will be no change to Medicare's policy with respect to acquisition costs of organs that were initially intended for research. These costs will be considered non-allowable (except pancreata for islet cell transplants as specified in § 413.406(a)). Under § 413.90, costs incurred for research purposes, over and above usual patient care, are also not allowable costs.

Cost Finding: The cost finding relates to how reasonable costs are determined on the Medicare cost report before the cost allocation is applied. CMS Ruling 1543-R specifies how the cost finding is done when an organ procurement organization seeks to procure multiple organs from a deceased donor.

Several commenters also understood CMS' proposal to change how OPOs do the cost finding by no longer following the principles of CMS Ruling 1543-R with respect to reporting costs for organs intended for transplant but ultimately used for research. Those commenters were not supportive of CMS' proposal and requested CMS require OPOs to continue following the guidance set forth in CMS-Ruling 1543-R on this issue.

CMS responded that its proposal was not intended to affect the cost finding. The final rule affirms that OPOs should continue to follow the guidance set forth in CMS Ruling 1543-R, "Allocation of Donor Acquisition Costs Incurred by Organ Procurement Organizations."

Reducing Allowable Cost for Costs Associated with Research: There were a number of comments that indicated that costs associated with procuring organs used for research are only included in total organ acquisition costs in circumstances where the organs were considered viable for potential transplant at the time the donor entered the operating room, but the organs were subsequently deemed unsuitable for clinical reasons. Organ acquisition costs are nominal for these organs, typically reimbursed either by the TH or the research institution, and OPOs account for any revenues received for research organs through an offset to the costs they report on their cost report. These commenters stated that to the extent costs incurred for organs intended for transplant but determined unsuitable for transplant and instead furnished for research exceed revenues received for such organs, those costs should be included in total acquisition costs. CMS agreed with these commenters' analysis for reporting costs. Any costs for organs intended for transplant but used for research would be offset by revenues received for those organs. Any costs for organs always intended for research will be reported in a non-reimbursable cost center.

Rehabilitated Organs: A few commenters indicated that they found the proposed rule to be unclear on whether organs that are rehabilitated under a research protocol and subsequently transplanted into a Medicare beneficiary may be counted as Medicare organs. Others believe

CMS proposed to exclude Medicare coverage for organs transplanted in conjunction with a qualified clinical trial inconsistent with its policies on coverage of routine costs in a clinical trial.

CMS responded that when an organ is transplanted into a patient, the organ is counted as a total usable organ and a full standard acquisition charge is assigned. This includes organs "rehabilitated under a research protocol" that are subsequently transplanted into a patient, as well as organs transplanted under the Medicare clinical trials policy. The transplanted organ would be counted as a Medicare usable organ if transplanted into a Medicare beneficiary.

Determination of Whether an Organ is Usable: CMS proposed that the decision as to whether an organ is usable or not can be made by any surgeon, not just the excising surgeon. Several commenters suggested that "surgeon" be replaced with "physician" or "any physician" as intensivists, cardiologists and pulmonologists may make organ feasibility decisions. CMS agreed with this comment and is modifying the regulation as suggested.

Final Decision: CMS is finalizing its proposal with numerous modifications to the regulations to address the confusion many commenters had with the proposal related to the Medicare cost allocation for organs used in research. In addition, Medicare is changing "surgeon" to "physician" with respect to the determination of whether an organ is usable for transplant. For clarity, Medicare's final policies on three major issues where public commenters had confusion are:

Cost Allocation: Organs intended for transplant but ultimately used for research are excluded from the ratio of Medicare usable organs to total usable organs (excluded from both the numerator and the denominator for THs and all OPOs including HOPOs and IOPOs).

Cost Finding: CMS is making no changes to the cost finding principles in CMS 1543-R. The instructions in CMS 1543-R will continue to be applicable.

Reporting Research Costs: Costs associated with organs intended for transplant but ultimately used for research will continue to be allowable costs. Costs for these organs are generally nominal and are often offset by revenue received for procuring these organs. To the extent a TH or OPO has costs that exceed revenues for these organs, they remain allowable costs.

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 proposed 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.

Comments/Responses: Commenters universally supported CMS' proposal but raised specific clarifying questions. In response to these questions, CMS indicated:

- All organ acquisition costs, including those that may be incurred prior to the donor's death but when death is imminent, must be authorized by the OPO before the TH or a donor community hospital can begin incurring costs.
- Donor community hospitals and THs that bill OPOs a negotiated rate may renegotiate those rates to account for added costs associated with organ acquisition costs that are incurred prior to the donor's death when death is imminent.
- The donor community hospital or TH must bill the OPO the lesser of:
    - Its customary charges that are reduced to cost by applying its most recently available hospital specific inpatient operating CCR for the period in which the service was rendered, or
    - A negotiated rate.
- Donor community hospitals or THs may incur allowable costs for hospital services attributed to a deceased donor or a donor whose death is imminent irrespective of whether that death is cardiac or brain death.
- The effective date of the policy being adopted in the rule is for cost reporting periods beginning on or after January 1, 2023. Prior guidance applies to earlier cost reporting periods.

Final Decision: CMS is finalizing the proposed policy effective for cost reporting periods beginning on or after January 1, 2023 with a modification that the OPO must authorize the TH or donor community hospital to initiate organ procurement before it can begin incurring costs.

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 clarified 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, according to the proposed rule.

Public commenters strongly disagreed with CMS' proposal arguing that the costs for organ acquisition incurred by a TH would be no different than any other costs it incurs with respect to whether it would receive a portion of allocated A&G costs. Public commenters argued that A&G costs for the TH would be independent and different costs than those incurred by the OPO.

While CMS agrees that THs and OPOs would have independent A&G costs, it still disagrees with the public commenters that its proposal was inconsistent with Medicare reasonable cost principles. Nevertheless, CMS is withdrawing the proposal, indicating that appropriate allocation

of A&G for THs' purchase costs from OPOs will require additional analysis, evaluation and provider education. CMS may revisit the clarification of this issue in future rulemaking.

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

In this section of the proposed rule, CMS did not make any proposals but requested information on an alternative methodology for counting organs for purposes of calculating Medicare's share of organ acquisition costs. CMS did not repeat the proposed rule request for comments and neither summarized nor responded to comments. Public comments will be used to inform future policy development.

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 (DPU).

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.

Effective January 1, 2023, REHs will receive 105 percent of payment for OPPS services and a monthly facility payment of $272,866 as described in more detail below. CMS solicited public comments through the 2022 OPPS rulemaking cycle on its implementation of the REH program. Those comments were considered for the 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 proposed 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.
Public commenters supported CMS' proposal. One commenter expressed concern about a health system referring its outpatients to a member REH to obtain higher payments. CMS responded that it would monitor REH utilization for this issue.

Method II CAHs are those CAHs whose physicians have reassigned their billing right to the CAH and the CAH can bill for those physicians' services and receive payment at 115 percent of the PFS. There were comments asking that CMS allow a CAH converting to REH status be allowed to continue Method II billing. CMS responded that Method II billing is only available to CAHs under the statute, not REHs. REHs will be ineligible for Method II billing.
CMS is finalizing its proposal without modification.

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 proposed 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.

CMS received several out-of-scope comments (e.g., allow IHS and Tribal Hospitals to convert to REH status and receive the 5 percent bonus on the higher all-inclusive rate that applies to these facilities; ensure that REHs are eligible for the 340B drug discount program; and designate REHs as eligible facilities to receive graduate medical payments). As these comments are out-of-scope to the proposed rule, CMS is not taking any action in response to them. CMS is finalizing all policies as proposed.

Services Performed by REHs that are not Specified REH Services. In order for an 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 proposed 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 proposed that an entity that is owned and operated by an REH that provides ambulance services will receive payment under the ambulance fee schedule. CMS further proposed 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 DPU SNF. Consistent with section 1834(x)(4), CMS proposed to pay for post-hospital extended care services provided by an REH in a SNF unit through the SNF prospective payment system (PPS).

Several comments asked CMS to pay the 5 percent bonus on all REH services, not just those that would be covered OPD services. CMS responded that it does have authority under the statute to pay a 5 percent bonus on REH services that are not covered OPD services.

One commenter requested clarification whether the CMS packaging of laboratory services will apply to REH services. CMS confirmed that the same packaging rules will apply to REH services that apply to covered OPD services.

One commenter asked that an REH with a SNF be allowed to transition from CMS' prior SNF payment system to the Patient Driven Payment Model system. CMS indicated that the statute requires an REH DPU SNF to be paid through the currently applicable SNF PPS.

CMS is finalizing its proposals without modification.

Payment for an Off-Campus Provider-Based Department of an REH. The proposed rule included 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 proposed that an off-campus PBD of an REH would not be subject to the PFS-equivalent rate but requested comment on the issue.

Public comments supported CMS' proposal. Several commenters asked whether a rural health clinic (RHC) that is provider based to a hospital or CAH that is under 50 beds could retain the benefits of having this special status. These RHCs have a higher payment limit per visit than other RHCs. CMS indicates that when an RHC is provider-based to a hospital or CAH that converts to an RHC, the provider-based RHC may retain that status.

CMS is finalizing its proposal without modification.

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 proposed to 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). Public comments supported this proposal. CMS also proposed to include beneficiary cost-sharing in the calculation (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).[32]
Using detailed calculations provided in the proposed rule, CMS estimated 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 proposed to require REHs to maintain detailed information as to how the monthly facility payment has been used. REHs must make this information available to CMS upon request. CMS believes this requirement can be met using existing cost reporting requirements for outpatient hospital facilities that would include REHs.

Comments/Responses: Most commenters supported including beneficiary coinsurance in the calculation of the REH monthly payment. MedPAC stated that the REH monthly facility payment should be calculated by removing coinsurance from the both the total amount of CAH spending in 2019 and the estimated prospective payment for CAHs in 2019. Doing so would reduce the annual additional payment from $3.2 million to $1.5 million providing "sufficient financial stability for REHs while also demonstrating that Medicare is a prudent payer of program funds."

CMS disagrees. It believes the intent of the REH legislation was to provide financial assistance to support existing outpatient hospital and emergency department care in rural areas when it may not be feasible in the future for CAHs or small rural hospitals to maintain an inpatient hospital capacity. CMS believes the intent of the monthly facility payment is to address the gap in outpatient payment a CAH would experience in converting from reasonable costs to prospective payment.

There were comments concerned about the adequacy of the hospital market basket for updating the REH monthly facility payment as well as concerns that the monthly facility payment is calculated from 2019 data but will include no market basket update for the intervening years before payment is made beginning in 2023. CMS responded that sections 1834(x)(2)(B)(i) and (C)(i) of the Act specify that the monthly facility payment for 2023 should be based on 2019 payment data and includes no provision for adjusting the payment amount to account for payment increases that CAHs and OPPS hospitals have received in the intervening years. CMS will monitor the adequacy of the market basket for updating the REH monthly payment amount. Several commenters requested CMS develop a cost report for REH providers based on the cost reporting structure for CAHs. CMS responded that it will allow REH providers to continue to use their current cost reporting formats. If REH-specific cost reporting is determined to be necessary,

[32] While beneficiary coinsurance is the standard Part B coinsurance of 20 percent for outpatient services in CAHs, beneficiaries pay 20 percent of CAH charges which are higher than 101 percent of reasonable costs—Medicare's payment allowance to the CAH. As a result, beneficiary coinsurance is higher than the 20 percent of Medicare's payment allowance. Meanwhile, Medicare pays 80 percent of its allowance for Part B outpatient services. Including the beneficiary's coinsurance results in CAHs being paid more than 100 percent of reasonable costs.

CMS address this issue in future rulemaking.

CMS is finalizing all of the above proposals without modification.

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 proposed 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. Public commenters supported CMS' proposal that it is finalizing without modification.

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; and vaccines and Medicare Part B drugs if those services and items are reported on an inpatient, outpatient or SNF claim.
CMS proposed 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 proposed 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 indicated that CMS has no feasible way of estimating value-based purchasing payments, hospital readmissions reduction, or hospital acquired condition adjustments.

CMS provided 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.

Comments/Responses: Public commenters were in the following categories:

Part B Services and Medicare Advantage Payments. Commenters asked whether spending for clinical laboratory, physician services, ambulance services, parenteral and enteral nutrition, durable medical equipment, prosthetics/orthotics, and supplies, and vaccines and Medicare Part B drugs were included in the reported amount for CAH Medicare spending for CY 2019. Other commenters asked about whether CMS included Medicare Advantage (MA) payments in the calculation. There were also comments asking about how CMS treated billing for Method II CAHs that receive payment for physicians' services at 115 percent of the PFS. CMS responded that inclusion of these payments does not affect the calculation as they are paid to CAHs in the same way as if CAHs were paid under prospective payment systems (e.g., under a fee schedule, a methodology specified in statute or through contractual arrangements in the case of MA).

Adjustments for Coding. IPPS hospitals have strong incentives to comprehensively code diagnoses on the claim in order to receive payment in the highest paying DRG. CAHs do not have the same incentive as they are paid 101 percent of reasonable cost irrespective of how they code diagnoses. In the proposed rule, CMS indicated that they would not make any adjustment to CAH claims for potential under-coding of diagnoses on CAH claims as CAHs are not paid under the IPPS where more comprehensive coding can result in higher payments. Commenters supported this proposal.

3-Day Payment Window. Commenters raised questions about CMS' application of the "3-day payment window."[33] Under the 3-day payment rule, all diagnostic services and related therapeutic services provided on the calendar day of an inpatient admission and the prior 3 calendar days are bundled into the IPPS payment when provided by an entity wholly owned or operated by the hospital. The 3-day payment window applies to IPPS hospitals but not CAHs. This means that CAHs will be paid separately for outpatient services that may be bundled into CMS' IPPS payment as a result of the 3-day payment window. The commenters are concerned that CMS overstates the amount that CAH would be paid if they were paid under the IPPS by not bundling the services that would be subject to the 3-day payment window. CMS acknowledges this issue but indicates that it has no reliable way to make an adjustment to bundle payment for services into the CAH's payment if it were paid under the IPPS.

Inpatient Quality Reporting and Promoting Interoperability Programs. There were also comments concerned that CMS overstates what CAHs would be paid by assuming they would all meet the requirements of the Inpatient Quality Reporting and the Promoting Interoperability Programs. Hospitals that do not meet the requirements of these programs are subject to a reduced update for not reporting quality data or being a meaningful user of electronic health records. The public commenters believe CMS overstates what a CAH's IPPS payments would be by assuming that CAHs would receive the full update under these programs. CMS responded that a very high proportion of hospitals qualify for the full update under these programs and it would not be reasonable to believe that CAHs would have a lower compliance rate if they were paid under the IPPS.

[33] Both the commenters and CMS incorrectly refer to a "72-hour rule." The reference should be to the "3-day payment window." CMS neither labels the rule correctly nor describes its application accurately. This summary will refer accurately to the 3-day payment window and describe its correct application in the context of the public comments and responses.

Low-Volume Adjustment. Commenters stated that the low-volume adjustment should not apply to CAHs that are within 15 miles of another provider, regardless of whether that facility is presently a CAH or an IPPS hospital. They encouraged CMS to identify the CAHs that do not meet the criteria and eliminate the low-volume adjustment applied to those CAHs. CMS agreed and revised its methodology. The revision will increase the REH monthly payment by $4,573.

Disproportionate Share (DSH) and Uncompensated Care Payments. Commenters objected to CMS' methodology for projecting DSH and uncompensated care payments CAHs would have received if paid prospectively. They recommend excluding the amount of DSH and uncompensated care add-on payments from estimated prospective payment amounts since there is not a reliable method to make projections. CMS considered this issue and described an alternative approach from Acumen that would predict a hospital's DSH and uncompensated care from its IPPS payment using:

- A hospital's rural/urban indicator based on actual geographic location;
- The percentage of population below the poverty line of the hospital's zip code area; and
- The percentage of the hospital's dually eligible Medicare/Medicaid beneficiaries.

Both methodologies produced similar results. CMS is retaining its methodology used in the proposed rule to predict a CAH's DSH and uncompensated care payments.

Indirect Medical Education (IME). Commenters stated that no IME add-on payments should be included for any CAH that did not have a residency program in 2019. CMS responded that projected IME add-on payment already factors in this concern by treating most CAHs as if they do not receive IME payment.

SNF Payment. CMS proposed not to require CAHs submit additional information in order to project payments for SNF and swing bed services. Public commenters supported this proposal. Final Decision: CMS is implementing most of its proposals without modification. As described above, it modified its determination of the low-volume hospital payment adjustment to exclude any CAH within 15 road miles of another CAH or IPPS hospital.

Determining the total number of CAHs in 2019. CMS proposed 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. Commenters requested that CMS adjust the count of CAHs for those that opened or closed during 2019. CMS rejected that comment indicating that the plain language of the statute requires CMS to use the total number of CAHs that were operating in 2019 irrespective of whether they were open for a full year.

Calculation of the Monthly REH Facility Payment for 2023. CMS used the following steps to determine the monthly REH facility payment for 2023 in the final rule (including the revision to the low volume adjustment):

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 – $7.60 billion = $4.48 billion

Step 2: Divide by the number of CAHs enrolled in Medicare in 2019 divided by 12 months:
($4,479,370,835/1,368) / 12 = $272,866

CMS is adopting a monthly facility payment for REHs for 2023 of $272,866. This amount will be increased in subsequent years by the hospital market basket.

There were public comments out of scope to the proposed rule that asked the monthly facility payment be exempt from sequestration or varied by the size of the facility, neither of which is permitted under the statute. CMS is finalizing the above calculation as modified based on public comments.

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 conditions of participation, CMS' enforcement of them, and the determination of additional facility payments. CMS proposed to codify the preclusion of administrative and judicial review into the regulations. Some commenters requested CMS not codify into regulations the preclusion on judicial review. CMS is finalizing this provision without change as it is a requirement of law.

5. Filing a Cost Report

CMS proposed to specify that an REH is required to file annual cost reports beginning on or after January 1, 2023, in a standardized electronic format. (In a prior section of the rule, CMS was asked to develop an REH specific cost report. CMS responded that it will allow REH providers to continue to use their current cost reporting formats. The implication of this response is that a CAH would continue to submit a CAH cost report as an REH and a hospital would continue to submit a hospital cost report as an REH).

6. Ambulance Services

Consistent with the statute, CMS will allow REHs to provide ambulance services. Ambulance services will be paid under the ambulance fee schedule. CMS has also modified its regulations to allow REHs to be an allowable origin and destination site for ambulance transport. Public commenters supported these changes.

B. Conditions of Participation

1. Introduction

CMS proposed CoPs for REHs that are modeled closely after the CoPs for CAHs. In some instances, CMS proposed requirements that are similar to the CoPs for hospitals and conditions

for coverage (CfC) for ASCs. The below lists the CoPs that CMS proposed REHs must meet. To the extent relevant, this summary may either refer to an existing CoP (or CfC as applicable) without providing additional detail on the requirement or provide additional detail beyond just a reference to an existing CoP or CfC if there are new requirements being proposed.

2. Definition

CMS proposed to define an REH as an entity that operates for the purpose of providing emergency department services, observation care, and other outpatient medical and health services specified by the Secretary in which the annual per patient average length of stay does not exceed 24 hours. The REH may not provide inpatient services, except those furnished in a DPU licensed as a SNF to furnish post-hospital extended care services.[34]
Comments/Responses: Public commenters raised a variety of clinical situations where they believe the patient would require longer than a 24 hour stay. They asked CMS to exercise enforcement discretion to permit longer lengths of stay than 24 hours. CMS responded that the 24-hour annual per patient average length of stay is a statutory requirement and cannot be modified. However, as the 24-hour limit on length of stay is an average, CMS recognizes that some patients will receive services for longer periods of time, while others will receive services for a shorter amount of time.

CMS recommends that facilities maintain documentation of instances in which a patient is unable to be transferred timely or when there are specific situations in which the patient's stay may exceed 24 hours. If the services being provided by the REH are appropriate for this provider type (such as outpatient low-risk labor and delivery and outpatient behavioral health services), the REH should not routinely exceed the length of stay. If more complex patients present to the REH, they would be expected to be transferred to a facility that is able to provide a higher level of care.

The time calculation for determining the length of stay of a patient receiving services at the REH is similar to the approach used in ASCs and begins with the registration, check-in or triage of the patient (whichever occurs first) and ends with the discharge of the patient from the REH.
Final Decision: CMS is finalizing its proposal without modification.

3. Basic Requirements

Participating REHs would be limited to those facilities that meet the definition of an REH and have in effect a Medicare provider agreement. The final rule adds REHs to the list of providers required to obtain a provider agreement.

[34] CMS' proposed rule appears to be suggesting than an REH's DPU SNF may provide Medicare covered post-REH SNF services. However, REH services by definition are not inpatient services and are limited to an average of 24 hours per patient that would make it impossible for an REH patient to meet the 3-day prior inpatient hospitalization required to receive Medicare covered post-hospital SNF services. The REH could, however, provide SNF services to a patient meeting the 3-day prior inpatient hospitalization requirement referred from a general acute care hospital. CMS confirmed this conclusion for the proposed rule CoPs but appears not to have corrected this text in the final rule.

4. Designation and Certification

CMS proposed that an REH must have been a CAH or an IPPS hospital with not more than 50 beds either located in a county (or equivalent unit of local government) considered rural (as defined by OMB) or treated as rural for IPPS purposes as of December 27, 2020.
In response to public comments, CMS confirmed that if a CAH or rural IPPS hospital with no more than 50 beds was open on December 27, 2020 and then closed on or after that date, it could reopen and enroll as an REH if it meets the REH CoPs. Bed count will be determined by calculating the number of available bed days during the most recent cost reporting period divided by the number of days in the most recent cost reporting period. Although not stated in the final rule, this is the same methodology for determining bed count for indirect medical education and Medicare Dependent Hospitals (see 42 CFR §412.105).

5. Compliance with Federal, State, and Local Laws and Regulations

CMS proposed to require the REH to be in compliance with applicable Federal laws, state, and local laws and regulations. Consistent with the law, the REH must be located in a state that provides for the licensing of such hospitals under state or applicable local law and be licensed in the state as an REH or be approved as meeting standards for licensing by the agency in the state or locality responsible for licensing hospitals. There were no public comments on this proposal. CMS is finalizing the proposal without change.

6. Governing Body and Organizational Structure

CMS proposed to require the REH to have an effective governing body, or responsible individual or individuals, that is legally responsible for the conduct of the REH. This requirement is consistent with the hospital and CAH CoPs. With respect to services delivered via telemedicine, CMS proposed to require the governing body of the REH (or responsible individual(s)) ensure that the distant-site telemedicine entity furnishes its services in a manner that enables the REH to comply with all applicable CoPs and standards.

Commenters supported these provisions. Several commenters suggested that local physicians and/or physicians with rural emergency care experience serve on the governing board of the REH. Other commenters suggested that a physician with board certification in emergency medicine oversee the care and services provided by the REH given their primary function of providing emergency care. CMS responded that it is not adopting these suggestions as requirements as it would like to promote a high degree of flexibility in how REHs handle staffing decisions, including the board or responsible individual(s).

Some commenters wanted to ensure that CMS would not obstruct the ability for REHs to provide services via telemedicine, while other commenters suggested that CMS take steps to ensure that telemedicine was not used in a wasteful or inappropriate manner to substitute for visitation with a local physician. CMS responded that the proposed requirements mirror the CAH and hospital requirements regarding telemedicine by requiring a written agreement regarding the provision of services via telemedicine.

CMS is finalizing these provisions as proposed.

7. Provision of Services

CMS proposed to require that the REH's health care services must be furnished in accordance with appropriate written policies that are the same as in the CAH CoPs. CMS is finalizing these provisions as proposed.

8. Emergency Services

Consistent with the hospital and CAH CoPs, CMS proposed the REH must provide the emergency care necessary to meet the needs of its patients in accordance with acceptable standards of practice. The REH must have emergency services that are organized under the direction of a qualified member of the medical staff and are integrated with other departments of the REH. CMS proposed that there must be adequate medical and nursing personnel qualified in emergency care to meet the needs of the facility but is not requiring a physician or non-physician practitioner to be on site at the facility at all times.

Public comments made recommendations for specific minimum staffing requirements to be maintained by the REH including the credentials those staff must have. CMS responded it expects REHs to have staff that meet the needs of the community they serve. The individual who fulfills the requirement that the REH must be staffed at all times must be competent in the skills needed to address emergency medical care. This individual must be able to receive patients and activate the appropriate medical resources to meet the care needed by the patient.

One commenter asked that CMS waive provisions of the Emergency Medical Treatment and Labor Act (EMTALA) to allow REHs to divert patients to a higher-level facility if the clinical staff at the REH does not believe the facility can provide the appropriate level of care and the patient is stable enough to transport. CMS responded that REHs are subject to EMTALA and CMS cannot waive that requirement. REHs must provide a medical screening examination to any individual who comes to the emergency department and requests such an examination, and prohibits hospitals with emergency departments from refusing to examine or treat individuals with an emergency medical condition. REHs converted from CAHs or small rural hospitals with emergency departments will be familiar with EMTALA's requirements.
CMS is finalizing this provision as proposed.

9. Laboratory Services

CMS proposed the same CoP to REHs that applies to hospitals at 42 CFR § 482.27 and to provide the same laboratory services identified in the CAH CoPs. REH laboratory services must be performed in a facility certified in accordance with the Clinical Laboratory Improvement Act. Public commenters generally supported CMS' proposal with some suggesting CMS should not require REHs to provide more laboratory services than CAHs. Others suggested specific laboratory services that an REH must provide. CMS responded that the proposed standard for laboratory services for REHs requires the REH to provide basic laboratory services essential to the immediate diagnosis and treatment of the patient consistent with nationally recognized

standards of care for emergency services. CMS believes that REHs should have the flexibility to determine the laboratory services that are appropriate for their scope of services and patient population.

CMS is finalizing this provision as proposed with minor change to the regulatory language.

10. Radiologic Services

CMS proposed REH radiologic requirements consistent with the hospital and CAH radiologic requirements found at 42 CFR § 482.26 and at 42 CFR § 485.635(b)(3) respectively and the interpretative guidelines for CAHs in Appendix W of the State Operations Manual (SOM). Public commenters supported these proposals. One commenter said radiology requirements should not be separate from the Provisions of Services CoP. CMS responded that separate radiology requirements are consistent with the hospital and CAH CoPs. The requirement is being finalized as proposed.

11. Pharmaceutical Services

CMS does not have a separate pharmaceutical services CAH CoP. Hospitals do have a separate pharmaceuticals CoP. However, the conditions for CAHs include a number of standards throughout for the oversight, storage and administration of drugs and biologicals. There are additional guidelines for pharmaceutical services in the interpretive guidelines. Consistent with the hospital CoPs, CMS proposed a separate REH CoP for pharmaceutical services. Commenters supported CMS' proposal. Some commenters stated that the proposed CoP is based on the hospital CoP for pharmaceutical services and requested only provisions of the CAH CoPs be applicable. CMS responded that small hospitals and CAHs that transition to the REH provider-type would currently be complying with the proposed REH requirements to support the delivery of pharmaceutical services when they change provider-type. The requirements CMS is finalizing will not create additional compliance burden for REHs. CMS is finalizing its policy as proposed.

12. Additional Outpatient Medical and Health Services

CMS proposed that REHs be allowed to provide additional medical and health outpatient services and apply the same standards to additional services provided by REHs that apply to hospitals at 42 CFR § 482.54(c). Given that the REH does not provide inpatient services, patients requiring a higher level of care would be required to be transferred to an acute care hospital or CAH. CMS also requested comments on whether REHs should provide maternal health services that include prenatal care, low-risk labor and delivery, and postnatal care.

Commenters supported CMS' proposal including REHs providing prenatal care, low-risk labor and delivery services, and any outpatient surgical procedures associated with labor and delivery, as appropriate, with the necessary staff, equipment and medications to ensure that the patient can be treated or stabilized and transferred if necessary. Other commenters stated that providing low-risk deliveries and a surgical team to handle these cases would put a financial burden on REHs.

Some comments requested that REHs be allowed to establish distinct part inpatient psychiatric and/or inpatient rehabilitation units to treat patients requiring these services. CMS responded that the statute does not permit distinct part units other than SNFs.

There were over 3,000 comments opposing the proposal that CRNAs be supervised by an operating practitioner. CMS responded that the proposed CRNA supervision requirement is consistent with the hospital and CAH CoPs and ASC CfCs. States may opt out of this requirement. The rule provides instructions on how to apply for the opt-out.
CMS is finalizing the provision as proposed.

13. Infection Prevention and Control; Antibiotic Stewardship

CMS proposed a CoP for infection prevention and control and antibiotic stewardship programs consistent with hospital and CAH CoPs. Public commenters supported CMS' proposal although there were comments asking CMS to delay implementation to allow time for training of staff. CMS responded that these provisions will be familiar to a CAH or hospital converting to REH status, making a delay in implementation unnecessary. The proposal is being finalized without modification.

14. Staffing and Staff Responsibilities

CAA, 2021 requires that the emergency department of the REH be staffed 24 hours a day, 7 days a week. CMS believes that REHs should have the flexibility to determine how to staff the emergency department with the expectation that the individual(s) staffing the emergency department is competent to receive patients and activate appropriate medical resources for the treatment of the patient. CMS proposed that REHs meet the applicable CAH requirements at 42 CFR § 485.631 for staffing and staff responsibilities.

CMS proposed the REH standards align with the CAH emergency services CoP at 42 CFR § 485.618 requiring that there be a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care, on call and immediately available by telephone or radio contact, and available on site within specified timeframes.

While CMS did not propose to require that REHs have a board-certified emergency physician serve as the medical director, it encourages REHs to have such a physician serve in the capacity of medical director if possible.

While some commenters agreed with CMS' proposal, others believe a clinician should be on-site at all times and that an EMT or a nurse would not provide sufficient staffing to meet the requirement that an REH be staffed 24 hours a day, 7 days a week. These commenters felt that that this role should be filled by a physician, nurse practitioner, clinical nurse specialist, or physician assistant with training or experience in emergency care. As the statute did not have a requirement on the qualifications of the staff needing to be onsite 24 hours a day, 7 days a week,

CMS believes REHs should have the flexibility to determine who is best to fill this role based on the scope of services provided by the REH and the population served.

CMS is finalizing its proposal with modification that the individual staffing the REH onsite must have the ability to effectively communicate information regarding the condition of patients presenting to the emergency department for treatment to the physician or other practitioner notified of the patient's arrival.

15. Nursing Services

As REHs only provide outpatient services, CMS does not believe that all of the nursing services requirements for hospitals and CAHs would be appropriate for REHs. Consistent with the hospital requirements, CMS proposed to require that REHs have an organized nursing service that is available to provide 24-hour nursing services for the provision of patient care. Public commenters supported this proposal. One commenter suggested an RN always be available onsite at the REH. As REHs are required to provide emergency services and observation care, CMS believes it is appropriate for them to have a registered nurse, clinical nurse specialist, or licensed practical nurse on duty whenever the REH is providing these services. CMS is finalizing the provision as proposed.

16. Discharge Planning

CMS proposed to closely align the discharge planning requirements for REHs with the requirements for hospitals and CAHs. In addition, in order to encourage patient engagement and understanding of their discharge plan or instructions, CMS recommended that providers follow the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care.[35]

Public commenters supported the proposal. One commenter suggested that CMS require REHs to comply with the hospital discharge planning standard which requires the hospital, as part of the discharge planning process, inform the patient or the patient's representative of their freedom to choose among participating Medicare providers and suppliers of post-discharge services and must, when possible, respect the patient's or the patient's representative's goals of care and treatment preferences, as well as other preferences they express. CMS indicates this standard applies to hospitals only—but under its proposal, REHs would subject to a similar standard. CMS is finalizing the provision without change.

17. Patient's Rights

CMS proposed to establish the patient's rights CoP for REHs based on the patient's rights CoP for hospitals at 42 CFR § 482.13. CMS proposed to add these same patient's rights to the CAH CoPs as well (as explained in the next section). Some of these requirements are currently in the State Operations Manual for CAHs while some are not explicitly required. The patient's rights CoPs for REHs and CAHs are less prescriptive than those for hospitals based on the scope of services they provide and patient populations that they serve. CMS' proposal included:

[35] Culturally and Linguistically Appropriate Services - Think Cultural Health (hhs.gov)

- Notice of Rights. CMS proposed that an REH must inform each patient—or when appropriate, the patient's representative (as allowed under state law)—of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible. This includes requiring the REH to establish a process for the oversight and prompt resolution of patient grievances and for informing each patient whom to contact to file a grievance.
- Exercise of Rights. CMS proposed to specify those rights a patient has regarding their medical care, which includes the right to make informed decisions including the right to request or refuse treatment (but not demand inappropriate or unnecessary treatment).
- Privacy, Safety, and Confidentiality of Patient Records. CMS proposed that the patient has the right to personal privacy, confidentiality of records, receive care in a safe setting, be provided access to medical records and be free from all forms of abuse or harassment.
- Use of Restraints and Seclusion. CMS proposed requirements that are less burdensome than those for hospitals because the need for REHs to utilize restraints and seclusion should be low and patients in need of restraint and seclusion should be transferred to a higher level of care. CMS explicitly requested comments on the potential need to require standards that are more stringent to address patient protections, and the feasibility of implementing such requirements in rural communities.
- Staff Training Requirements for the Use of Restraints or Seclusion. The same proposed training requirements would apply to REHs and CAHs.
- Death Reporting Requirements. These requirements are similar to those for hospitals at 42 CFR § 482.13 when reporting deaths associated with the use of seclusion or restraint.
- Patient Visitation Rights. CMS proposed to establish requirements related to a patient's visitation rights consistent with the current hospital and CAH regulations.

Public commenters supported these provisions that CMS is finalizing without change.

18. Quality Assessment and Performance Improvement (QAPI) Program

CMS proposed to require that every REH develop, implement and maintain an effective, ongoing, REH-wide, data-driven QAPI program. The REH would be required to measure, analyze and track quality indicators. Similar to the program activities standard for hospitals at 42 CFR § 482.21(c), CMS proposed to require the REH to set priorities for its performance improvement activities and that these activities are focused on high-risk, high-volume, or problem-prone areas. Consistent with a new CoP being proposed for CAHs and one already in existence for hospitals, CMS proposed to allow REHs that are part of a multi-facility system consisting of multiple separately certified hospitals, CAHs, and/or REHs to elect to have a unified and integrated QAPI program.

Public commenters generally supported CMS' proposals, specifically allowing REHs that are part of a multi-facility system to elect to have a unified and integrated QAPI program. Other commenters noted that REHs may not have the resources to gather and analyze data to inform a QAPI program. CMS responded to this comment by stating hospitals who may convert to an REH currently adhere to these standards.

Two commenters requested that CMS use the CAH standard for Executive Responsibilities rather than the hospital one. CMS chose not to mirror the CAH standard for Governance and Leadership because it references a requirement that the CAH's governing body be ultimately responsible for addressing outcome indicators related to readmissions, which is not relevant for REHs because they do not provide inpatient services.

CMS is finalizing its proposal. To address the concern raised earlier about staffing and staff responsibilities, CMS is incorporating staffing into the REH's QAPI program by requiring the REH to measure, analyze and track staffing as a quality indicator to assesses processes of care, REH service and operations.

19. Transfer Agreements

By law, REHs must have a transfer agreement with a level I or level II trauma center. CMS proposed to require that REHs must have in effect an agreement with at least one Medicare-certified hospital that is a level I or level II trauma center for the referral and transfer of patients requiring emergency medical care beyond the capabilities of the REH. While CMS expects REHs to have a transfer agreement in place with a level I or II trauma center, REHs may also have a transfer agreement with a hospital that is not designated as a level I or II trauma center. As the law subjects REHs to EMTALA requirements, CMS modified the EMTALA regulations to include their application to REHs.

Public comments supported the proposal but requested that CMS allow the requirement to have an agreement with level I or level II trauma center be met by an agreement with a closer facility if the nearest level I or level II trauma center was more than 50 miles away. CMS responded that a facility must have a transfer agreement with a level I or level II trauma center to meet the statutory requirement. It is not a requirement that CMS can waive.

Other commenters requested CMS establish specific requirements for the transfer agreements (e.g., the trauma center must be able to take psychiatric inpatients or offer pediatric trauma care). CMS believes that REHs should have the flexibility to determine the content of the agreements with a level I or level II trauma center based on what will best meet the needs of the patients in their communities.

CMS is finalizing the provision as proposed.

20. Medical Records

CMS proposed the same requirements for REHs that apply to CAHs at 42 CFR § 485.638. Commenters supported CMS' proposal. One commenter asked whether a physician or other health professional would be required to sign the medical record for patients receiving observation services. CMS responded that the REH is required to maintain records that are signed and dated by a qualified health professional for each patient receiving health services including observation services. CMS is finalizing this provision as proposed.

21. Emergency Preparedness

CMS proposed emergency preparedness requirements consistent with those for CAHs. The emergency preparedness requirements for all Medicare-participating providers and suppliers are consistent, with some differences based on the provider type (such as inpatient versus outpatient). Public commenters supported CMS' proposal. The proposal is being finalized without modification.

22. Physical Environment

All Medicare and Medicaid participating providers and suppliers are currently subject to the 2012 edition Health Care Facilities portion of the Life Safety Code (LSC), a compilation of fire safety requirements for new and existing buildings that is updated and published every 3 years by the National Fire Protection Association. Chapters 7, 8, 12, and 13 would not apply to REHs. The provisions of the LSC would not apply in a state if CMS finds that a fire and safety code imposed by state law adequately protects patients. CMS proposed to allow for waivers of these provisions under the same conditions and procedures that it currently uses for waivers of applicable provisions of the LSC to other health care providers.

Public commenters supported CMS' proposal. Some commenters asked whether CMS was planning to use a later edition of the LSC. CMS responded to these comments stating that it reviews the LSC every 3 years and has not adopted the more recent standards because there have not been significant revisions. The next revision to the LSC will be in 2024. CMS will consider adopting that 2024 version of the LSC in future rulemaking after it completes its review.

CMS proposed to use the LSC requirements that are applicable to ASCs rather than hospitals or CAHs. Some commenters requested CMS apply the LSC requirements applicable to hospitals and CAHs. CMS believes the ASC LSC requirements are more appropriate for REHs than those for hospitals and CAHs as, like ASCs, REHs do not provide inpatient services.
CMS is finalizing its proposals without modification.

23. SNF Distinct Part Unit

CMS proposed that a DPU SNF must be in an area that is separately licensed and certified to provide SNF services at all times. A DPU SNF must be physically distinguishable from the REH and must be fiscally separate for cost reporting purposes. The beds in the certified DPU SNF of an REH must meet the requirements applicable to DPU SNFs at 42 CFR part 483, subpart B. A DPU SNF of an REH is not subject to the REH's length of stay limits of less than an annual per patient average of 24 hours.

Commenters were supportive of this proposal. CMS made clear in response to comments that the same 3-day prior inpatient hospital stay requirement will apply to an REH's SNF DPU as any other SNF. However, as the REH can cannot provide inpatient hospital services, the 3-day prior inpatient hospitalization must happen somewhere else.

CMS is finalizing the provision with a modification to add clarifying language that the DPU SNF

must be separately licensed and certified, in addition to complying with the requirements of participation for long-term care facilities.

C. Critical Access Hospital (CAH) Conditions of Participation

1. Status and Location

To meet the CAH location requirements, a CAH must be (1) located more than a 35-mile drive from a hospital or another CAH (or 15 miles in the case of mountainous terrain or areas with only secondary roads available); or (2) certified before January 1, 2006, by the state as being a necessary provider of health care services to residents in the area. A secondary road is a road that is not a primary road.

Presently, primary roads are defined as any U.S. highway, including any road (1) in the National Highway System, as codified at 23 U.S.C. section 103(b); (2) in the Interstate System, as defined at 23 U.S.C. section 103(c); or (3) which is a U.S.-Numbered Highway (also called "US Routes" or "US Highways") as designated by the American Association of the State Highway and Transportation Officials regardless of whether it is also part of the National Highway System.

This definition exists in sub-regulatory guidance only.
CMS proposed to revise 42 CFR § 485.610(c) to clarify that a "primary road" is a numbered Federal highway, including interstates, intra-states, expressways or any other numbered Federal highway; or a numbered state highway with two or more lanes each way. In the proposed rule, CMS specifically solicited comments on whether numbered Federal highway should exclude include only those with two or more lanes in each direction, similar to the description of numbered state highways.

The proposed rule indicated CMS plans to enforce the revised location requirements using a centralized, data-driven review procedure that focuses on hospitals being certified in proximity to a CAH, rather road classifications. CMS would review all hospitals and CAHs within a 50-mile radius of the CAH during each review of eligibility, and then subsequently on a 3-year cycle.

Following the initial review of distance and location, further investigations would focus primarily on expanded healthcare capacity and access to care within the 35-mile radius of the CAH. Those CAHs with no new hospitals within 50 miles would be immediately recertified. Those CAHs with new hospitals within 50 miles will receive additional review based on the distance from the new hospital and the definitions for primary roads and mountainous terrain. To facilitate this review, CMS will utilize the geocoding of hospitals to identify those CAHs that are located within 50 miles of another certified hospital. Those CAHs that do not meet the regulatory distance and location requirements at the time of review would be identified as non-compliant and may face enforcement actions.

Comments/Responses: Many commenters supported refining the current definition of "primary roads" and codifying the definition in regulation. Commenters also stated the definition of

"primary roads" should only include numbered Federal highways with two or more lanes each way consistent with the requirements for state highways. Including numbered Federal highways with only one lane in each direction would result in decertification of many CAHs. CMS agrees with the commenters and is finalizing the definition of "primary roads" to include numbered Federal highways with two or more lanes each way, similar to the description of numbered state highways. CMS does not see a need to define a secondary road as some commenters requested as a secondary road is any road that is not a primary road.

Several comments requested clarification regarding whether the establishment of an REH could prevent an existing or potential CAH from meeting the CAH distance requirements, given that a CAH must be located more than a 35-mile drive (or more than a 15-mile drive on in areas with only secondary roads available or in mountainous terrain) from a hospital or another CAH. CMS responded that an REH within a 35-mile drive (or 15 miles in the case of mountainous terrain or areas with only secondary roads available) will not affect a CAH's eligibility.
Similarly, some commenters requested that CMS codify sub-regulatory guidance that proximity of IHS or Tribal Hospitals are not considered when determining whether a CAH meets the location requirements. CMS declined to adopt this comment as it was out-of-scope to the proposed rule but this issue has been clarified elsewhere in rulemaking.

Some commenters requested that CMS allow existing CAHs to be exempt from the proposed primary roads definition and instead "grandfather in" the CAH designation of existing CAHs based on meeting the distance requirements with the current definition of primary roads. CMS responded that except for necessary provider CAHs, the statute requires the CAH distance requirements to be continually met in order for the hospital to maintain its status as a CAH. The statute exempts necessary provider CAHs from the distance requirements.

Final Decision: CMS is finalizing its proposal with a modification to specify a primary road of travel for determining the driving distance of a CAH and its proximity to other providers is a numbered Federal highway, including interstates, intra-states, expressways or any other numbered Federal highway with two or more lanes each way; or a numbered State highway with two or more lanes each way.

2. Patient's Rights

CAHs do not currently have any patient's rights CoPs in the CFR—only in sub-regulatory guidance (the State Operations Manual). CMS proposed to establish patient's rights CoPs that are similar to those for hospitals although less prescriptive. The proposed rule would allow CAHs to develop policies and procedures based on the scope of services they provide and patient populations they serve. The proposed patient's rights provisions of CAHs are the same as those being proposed for REHs described earlier (i.e., less stringent than hospital requirements as a CAH would not be expected to encounter patient situations where restraint and seclusion are required and if those are encountered, those patients would be referred to a better equipped facility).

CMS specifically solicited comments on the appropriateness of the patient's rights requirements proposed for restraint and seclusion, the potential need to require standards that are more

stringent to address patient protections, and the feasibility of implementing such requirements in rural communities.

Most commenters supported the new proposed patient's rights CoP for CAHs. One commenter requested CMS delay the effective date to give facilities the time to establish processes and train staff. CMS responded that the revisions to the CAH CoPs will be effective 60 days from publication of the final rule. Commenters did state that some CAHs have already incorporated patient rights into their daily practices. CMS is finalizing the provisions as proposed.

3. Unified and Integrated Medical Staff: Multi-Facility System

CMS proposed requirements for a unified and integrated medical staff in multi-facility CAH systems that are in alignment the current standards for hospitals. These same standards would apply to REHs and would require CAHs to:

- Allow for either a unique medical staff for each facility or for a unified and integrated medical staff shared by multiple hospitals, CAHs, and REHs within a health care system.
- Hold a CAH or REH responsible for showing that it actively addresses its use of a system unified and integrated medical staff model.
- Require that the medical staff members holding privileges at each separately certified CAH or REH in the system have voted either to participate in a unified and integrated medical staff structure or to opt out of such a structure, and to maintain a CAH or REH-specific separate and distinct medical staff for their respective CAH/REH.
- Require that the unified and integrated medical staff has bylaws, rules, and requirements that describe its processes for self-governance, appointment, credentialing, privileging, and oversight, as well as its peer review policies and due process rights guarantees, which include a process for the members of the medical staff of each separately certified CAH/REH (that is, all medical staff members who hold specific privileges to practice at that CAH/REH) to be advised of their rights to opt out of the unified and integrated medical staff structure after a majority vote by the members to maintain a separate and distinct medical staff for their CAH/REH.
- The unified and integrated medical staff must be established in a manner that takes into account each CAH/REH's unique circumstances, and any significant differences in patient populations and services offered in each CAH/REH.
- The unified and integrated medical staff give due consideration to the needs and concerns of members of the medical staff, regardless of practice or location, and the CAH/REH has mechanisms in place to ensure that issues localized to particular CAHs/REHs are duly considered and addressed.

Public commenters supported these proposals. CMS is finalizing them without change.

4. Unified and Integrated Infection Prevention and Control and Antibiotic Stewardship: Multi-Facility System

CMS proposed to establish the same CoP for infection prevention and control in CAHs and REHs as hospitals in multi-facility systems. The governing body for a multi-facility system could elect to have unified and integrated infection prevention and control and antibiotic stewardship

programs for all of its member facilities, including any CAHs/REHs, after determining that such a decision is in accordance with all applicable state and local laws. The system's single governing body would be responsible for ensuring that each of its separately certified CAHs/REHs meet all of the requirements.

Commenters suggested that CMS work with Congress to implement support/funding for electronic surveillance systems in infection control. CMS responded this comment is outside of the scope of proposed rulemaking. CMS is finalizing the provision as proposed.

5. Unified and Integrated QAPI Program: Multi-Facility System

CMS proposed to allow CAHs/REHs that are part of a multi-facility system consisting of multiple separately certified hospitals, CAHs, and/or REHs to elect to have a unified and integrated QAPI program after determining that such a decision is in accordance with all applicable state and local laws. Once again, the system's governing body is responsible and accountable for ensuring that each of its separately certified CAHs/REHs meets the proposed QAPI program requirements. CMS did not receive any comments on this proposal that it is finalizing without modification.

D. 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.
- Undergoing risk-based screening.

As an REH will be a conversion from a CAH or a small rural hospital, CMS proposed 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 proposed to deviate 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 proposed 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.

Public commenters supported CMS' proposals. Several commenters asked whether an REH could convert back to a CAH or an IPPS hospital via a Form CMS-855A change of information application. CMS responded that once a CAH or IPPS hospital has converted to an REH, any subsequent change to a different provider or supplier type would require an initial enrollment application.
CMS further adds it did not intend to imply that an initial enrollment application would not be required when an REH converts back to a CAH or IPPS hospital when it stated in the proposed rule that "[the statute] references a 'conversion' from an REH back to a CAH or an [IPPS hospital] (rather than termination as an REH and initial enrollment as a CAH or [IPPS hospital]" (87 FR 44788). The remainder of the response makes clear a change of enrollment rather than a new enrollment is only applicable to a CAH or IPPS hospital that converts to an REH, not the reverse. CMS further clarifies that once a CAH or IPPS hospital is enrolled as an REH, its status as a CAH or IPPS hospital is terminated. It cannot be two different provider types enrolled in Medicare simultaneously.

One commenter asked whether a CAH or IPPS hospital that closed after December 27, 2020 but is otherwise eligible to convert to an REH can submit a Form CMS-855A change of information rather than an initial application. CMS responded that such a facility may submit a Form CMS-855A change of information instead of an initial enrollment and will modify the regulatory language to clarify this point.

CMS is finalizing its policies as proposed with minor changes to the regulatory language for clarity. CMS will post information on its website and issue detailed guidance to the MACs

regarding the processing of REH enrollment applications. CMS will also issue a Medicare Learning Network® Matters article explaining: (1) the enrollment process to prospective REHs; and (2) where REHs can direct any questions they have concerning this process.

E. 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 for the patient's rights. 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. CMS did not receive any comments on this issue. No further action is being taken

F. Physician Self-Referral Law Updates

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 designated 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. In the proposed rule, the agency was 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)[36] could be inhibited.

CMS proposed to establish a "proposed REH exception," which would have established 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. CMS did 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 non-abusive 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 proposed 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))

CMS does not finalize its proposal to create a new exception for ownership or investment in an REH. Noting strong objections to the proposed exception from some commenters, it believes the REH exception as proposed would not protect against the specific types of patients and program abuse that the physician self-referral law is intended to deter, including overutilization, mis-utilization, and patient steering to lower

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

quality, higher cost, or less convenient services. Some commenters disagreed with the agency's rationale for not applying some of the program integrity requirements imposed on hospitals that use the whole hospital and rural provider exceptions; they believe that the proposed exception would have imposed less of a burden on REHs than the whole hospital and rural provider exceptions pose for physician ownership or investment in hospitals. Specifically, the view was that any REH-specific exception for physician ownership or investment should include all requirements applicable to physician ownership or investment in hospitals under the whole hospital and rural provider exceptions, including prohibitions on facility expansion, transparency requirements, and patient safety requirements. However, commenters did not object to the proposed treatment of REHs as hospitals for purposes of the Stark law.

CMS is persuaded by commenters that the proposed REH exception did not provide sufficient protections against patient or program abuse. It agrees that the potential for cherry-picking and lemon-dropping, as well as other practices the Stark law is designed to deter, may persist in the REH context, especially for those REHs with service areas that include a mix of rural and urban areas. CMS was also concerned that its proposed REH exception could provide incentives for CAHs and small rural hospitals that are economically capable of sustaining inpatient beds to convert to REHs and avoid the physician self-referral law's more stringent requirements for hospitals.

CMS did not agree with suggestions to apply the same existing requirements for physician-owned hospitals in any final REH exception because it found some of those requirements, such as the limitation on the aggregate number of operating rooms, procedure rooms, and beds, are not suitable for REHs. However, CMS concludes that REHs may use the rural provider exception codified at §411.356(c)(1), without application of the additional requirements for hospitals in §411.362. The one substantive requirement of the rural provider exception is that the entity must furnish substantially all (not less than 75 percent) of the designated health services it provides to residents of rural areas; the substantially all rule does not apply to services that are not designated health services. CMS acknowledges that monitoring the residence of beneficiaries receiving designated health services could be burdensome for REHs; however, it believes the monitoring burden for REHs under the rural provider exception would be limited to those REHs located in rural areas but that have service areas that encompass urban areas.

CMS does finalize its proposal to define the term "rural emergency hospital" in §411.351. A rural emergency hospital has the same meaning set forth in section 1861(kkk)(2) of the Act and §419.91.

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

CMS finalizes without modification its proposals 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 are 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 emphasizes that it did not propose, nor is it making, any changes to the existing writing, signature, or record retention requirements.

4. 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 finalizes its proposal 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).

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

In the proposed rule, CMS sought 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. In its request for information (RFI), CMS cited President Biden's Executive Order on Promoting Competition in the American Economy (EO 14036, July 9, 2021), which identifies hospital consolidation as a major concern. CMS also cited MedPAC literature reviews and other research findings.

CMS said it received 21 responses to the Competition RFI questions, as well as 180 submissions (176 of which were form letters) related to CMS' hospital price transparency efforts and its role in driving competition. CMS thanked those who commented and will take comments into consideration in the future.

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 outpatient services. Regulations for the prior authorization process are found at 42 CFR §§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.

B. Addition of New Service Category

Effective for dates of services on or after March 1, 2023, CMS proposed to add the service category Facet Joint Interventions to the prior authorization list. This new category would be added as new section 42 CFR § 419.83(a)(3) and the existing paragraph (a)(3) would be moved to paragraph (b)(1) with other related changes.

The Facet Joint Interventions service category would consist of facet joint injections, medial branch nerve blocks, and facet joint nerve destruction. Table 103 of the final rule includes the full list of services that are subject to prior authorization including the below codes for Facet Joint Interventions.

List of Codes Requiring Prior Authorization Effective 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 proposed 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.

In the proposed rule, CMS presented analysis showing that claims volume for CPT codes 64490-64495 and 64633-64636 increased by 47 percent between 2012 and 2021, reflecting a 4 percent average annual increase, which is higher than the 0.6 percent annual increase for all OPD services. For the facet joint injection and medial branch block services, CPT codes 64490-64495, CMS observed an increase of 27 percent between 2012 and 2021, reflecting a 2.5 percent average annual increase. For nerve destruction services, CPT codes 64633 through 64636, CMS observed an increase in volume of 102 percent between 2012 and 2021, which was an average annual increase of 7 percent.

CMS further noted that Office of the Inspector General (OIG) published a report in 2020 identifying $748,555 in improper payments out of $3.3 million in paid Medicare claims for facet joint injections with an audit period from January 1, 2017, through May 31, 2019. In 2021, the OIG published a report on facet denervation procedures. During the audit period from January 2019 through 2020, the OIG reported that Medicare improperly paid physicians $9.5 million for selected facet joint denervation procedures. In March 2022, the Department of Justice reported on a $250 million healthcare fraud scheme that took place from 2007 to 2018 involving physicians from multiple states who allegedly subjected their patients to medically unnecessary facet joint injections in order to obtain illegal prescriptions for opioids.

The proposed rule indicated that comparing the utilization rate for the particular service category to the overall rate of growth for Medicare OPD services generally is an appropriate method for identifying unnecessary increases in volume, particularly where there are no legitimate clinical or coding reasons for the changes. CMS did not find any possible causes for the increases in volume that would indicate the growth rates for these services was necessary. CMS believes prior authorization for these services will be an effective method for controlling unnecessary increases in the volume of these services and expects that it will reduce the instances in which Medicare pays for services that are determined not to be medically necessary.

Comments/Responses: Public commenters raised a variety of concerns about this policy as categorized below:

Provider Burden: Commenters conveyed that prior authorization processes can add burden and costs, unnecessary delays or denials of appropriate care, and directly impact the patient's access to timely proper medical care. CMS responded that it has established timeframes for contractors to render decisions on prior authorization requests, as well as an expedited review process when the regular review timeframe could seriously jeopardize the beneficiary's health, which enables hospitals to receive timely provisional affirmations. The prior authorization policy requires hospitals to submit the same documents needed to support claim payments, just earlier in the process.

Effective Date: Several comments recommended extending the March 1, 2023 implementation date until at least July 1, 2023, consistent with the timeline CMS has used when implementing prior authorization for other service categories. CMS believes that hospitals and Medicare's contractors have sufficient prior experience with prior authorization to accommodate an earlier implementation data than in the past. Nevertheless, CMS is finalizing an implementation date for prior authorization for the facet joint interventions of July 1, 2023, which is consistent with previous July 1 implementation dates for current service categories.

Opioid Concerns: Some commenters specifically said that prior authorization of the facet joint interventions service category could cause delays in appropriate care and lead patients toward alternative pain relief options like opioids. CMS acknowledges the benefits that facet joint intervention services offer for chronic pain. However, it believes these are non-emergency procedures that require the beneficiary to undergo at least 3 months of conservative treatment prior to the procedure. The implication is that CMS does not believe prior authorization will result in delays that lead to use of opioids to control pain.

Burden Estimates: Commenters believe CMS understates the burden estimate by only considering the time required by the surgeon's clerical staff to respond to the prior authorization requirement. CMS responded that it used a clerical staff rate because the documentation being submitted is the same documentation that should be regularly maintained in support of claims submitted for payment. There are no new documentation requirements for payment.

Methodology Concerns: Some commenters indicated that a higher rate of increase in utilization than the national average is not indicative of an unnecessary increase in volume. There could be many reasons for the increase in their utilization. Some commenters also asked CMS to release the MACs' prior authorization data, such as how many outpatient departments are exempt from prior authorization due to having over a 90 percent approval rate, average processing timeframes for initial and resubmission requests, and whether there are any changes in the volume of utilization for the services that are required prior authorization.

CMS continues to believe that comparing the utilization rate for services in the proposed service category to the baseline growth rate for all Medicare hospital outpatient services is an appropriate method for identifying unnecessary increases in volume—particularly for services like facet joint injections where there have been findings of questionable billing practices.

The response further indicates that the number of exempt providers varies among MAC jurisdictions. Among all MACs, the average volume of exempt OPD providers is 16.7 percent, with one MAC having as many as 35 percent of OPD providers exempt. The average initial review timeframe on a prior authorization request is 4.4 days, and the average resubmission review timeframe is 4.3 days—considerably shorter than the 10-day upper limit to make a determination. CMS will consider sharing data regarding the changes in the volume of utilization of the HOPD services that require prior authorization.

Process to Remove Services from Prior Authorization: In response to comments, CMS indicates that it may suspend the prior authorization process requirements generally or for a particular

service at any time by issuing a notification on the CMS website. The response details when specific procedure codes have been removed from prior authorization.

Use of Local Coverage Determinations (LCD): Some commenters suggested use of LCDs and contractor articles to inform providers of coverage criteria and appropriate utilization in place of prior authorization. CMS indicates LCDs and other contractor communications indicate whether a particular item or service is covered on a contractor-wide basis. Among other methods, prior authorization, prepayment, and post-payment reviews are used to verify compliance with these policies.

Legal Basis for Prior Authorization: Some commenters continue to question whether section 1833(t)(2)(F) of the Act authorizes CMS to establish a prior authorization process. This issue was addressed in the 2020 OPPS/ASC and 2021 OPPS/ASC final rules.

Contractor Denials after Receiving Prior Authorization: A commenter expressed difficulty dealing with third-party auditors, such as Recovery Auditors, retrospectively denying payment for procedures that were granted prior authorization. CMS responded that claims receiving a provisional affirmation decision should generally not be subject to additional medical reviews, including by Recovery Auditors (although other types of auditors may select these claims for review). CMS encouraged hospitals to contact it with specific examples of post-payment reviews of claims with a provisional prior authorization affirmation decision, so it can investigate further.

Performing Services Different Than Originally Submitted for Prior Authorization: CMS recognizes that sometimes a procedure's necessity could not be anticipated before it was furnished. Providers may submit prior authorization requests for multiple potential procedures if they believe that this could be a possibility.

Becoming an Exempt Provider: To become an exempt provider, a provider must have an approval rate of 90 percent or greater on prior authorization requests. Medicare contractors will calculate the compliance rate by dividing the total number of initial requests with provisional affirmations by the total number of initial requests for all eight service categories subject to prior authorization and notify providers with a compliance rate of 90 percent or greater.

Associated Anesthesia: The associated claim for anesthesia care would follow standard claim review guidelines and does not require prior authorization. However, the service should not take place if prior authorization is denied. A service receiving provisional prior authorization may be later denied based on either of the following: (1) Technical requirements that can only be evaluated after the claim has been submitted for formal processing; or (2) Information not available at the time of a prior authorization request. CMS or its contractor may deny claims for services related to services on the list of hospital outpatient department services for which the provider has received a denial. This may affect payment for the associated anesthesia and other services.

Qualified Reviewers and Electronic Review: One commenter requested that facet joint intervention reviews be conducted by board-certified pain medicine specialists. CMS responded that it requires MACs to use registered nurses when reviewing medical documentation with

oversight of a Medical Director and additional clinician engagement if necessary. Medical Directors are physicians from different medical specialties, including anesthesiology and pain management.

Some commenters suggested that CMS should explore requiring electronic approvals across all payers, thereby increasing the speed of the prior authorization process and curtailing unnecessary delays in care provision. CMS supports a variety of electronic mechanisms used by providers in submitting prior authorization requests, including individual MAC portals and CMS' electronic submission of medical documentation (esMD) system.

CMS is finalizing its proposal to add facet joint interventions to the list of hospital outpatient department services requiring prior authorization with the modification that the requirements for prior authorization will begin July 1, 2023.

C. Regulatory Impact

Administrative Costs: The overall economic cost impact of adding Facet Joint Interventions to the OPD prior authorization list is approximately $13.3 million in the first year based on 6 months of prior authorization for the new service category. The 5-year impact is approximately $118.7 million, and the 10-year impact is approximately $250.4 million. The 5- and 10-year impacts account for year one, including only 6 months. Additional administrative paperwork costs to private sector providers and an increase in Medicare spending to conduct reviews combine to create the financial impact; however, this impact is offset by Medicare savings.

Medicare Savings: CMS estimates an overall Medicare savings of $65.3 million.

XXI. Overall Hospital Quality Star Rating

CMS believes that the Overall Star Ratings provide consumers with a simple, easily understood overall rating for hospitals. The Overall Star Ratings are 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 most recent refresh occurred in July 2022.

A. Frequency of Publication and Data Used

CMS finalizes revising regulation text at §412.190 to clarify the data periods that may be used to refresh Overall Hospital Quality Star Ratings. The revised language states that the Overall Star Ratings are published once annually using data publicly reported on Hospital Compare or its successor website (now Care Compare) from a quarter within the previous 12 months. Previously, the data were required to come from a quarter within the prior year. CMS interprets "the previous 12 months" to mean Care Compare refreshes occurring in either the first or last month of that 12-month period and any time in between (e.g., a 2023 Star Ratings release

potentially includes data refreshes from quarters beginning in July and October 2022 and January, April, and July 2023).

Commenters were generally supportive of the revised language. Some stated that Star Ratings should be released in the same months each year for predictability and consistency; hospitals and the public should be notified of an upcoming release as far in advance as possible; and that a Star Ratings release should not include data that had been refreshed during the same month as the ratings were released.

CMS notes it must balance using recent data with providing adequate notice to hospitals and the public; typically, the ratings are released roughly 6 months after the Care Compare refresh from which data were used for ratings calculations. Star Ratings releases also are impacted by the heterogeneous measurement periods and refresh cycles of the component measures aggregated into the ratings and by extraordinary circumstances that compromise data utility (e.g., COVID-19 PHE).

B. Veterans Health Administration (VHA) Hospitals

In the proposed rule, CMS provided findings from its internal analysis of the impact of incorporating VHA data into Overall Hospital Quality Star Ratings, scheduled to begin with the 2023 ratings. Data were available for 3,474 hospitals—3,355 non-VHA and 119 VHA hospitals. Nearly 70 percent of all VHA facilities were included. Key findings included the following:

- Nearly identical distributions of Star Ratings for the two hospital categories.
- 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.[37]

CMS made no new proposals about VHA data use but in this final rule shares comments received. Support for including VHA data was divided. Differences in hospital case mix and services provided were viewed as confounding factors along with the considerable overlap between the VHA and Medicare beneficiary populations. Alternative approaches to hospital peer grouping were described. Options for tailoring by consumers of the publicly displayed results were suggested, such as the ability to separately generate Star Ratings only for VHA or non-VHA hospitals. A suggestion was made for a totally separate VHA Star Ratings system.

CMS notes that fully 50 percent of VHA-enrolled veterans are also eligible for Medicare. CMS further notes that a VHA rating system was discontinued in 2020 as part of an initiative to facilitate access by veterans to care outside of the VHA system. The agency indicates that the peer grouping approach used for Star Ratings determinations is the product of several stakeholder workgroups and a Technical Expert Panel. CMS states that providing customization options for consumers (e.g., non-VHA hospital ratings only) is not feasible operationally and is

[37] Methodology and results of the analysis are discussed extensively in section XXI.B. of the final rule.

not compatible with some of the statistical methods used to construct Star Ratings (e.g., clustering algorithm). CMS indicates that ongoing monitoring of VHA and non-VHA measure performance and ratings results will be performed and any related changes to the Overall Hospital Star Ratings program would be proposed through future rulemaking.

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

In the proposed rule, CMS discussed potential issues associated with the 2023 Overall Hospital Quality Star Ratings refresh due to the inclusion of data collected during the COVID-19 PHE. CMS reprised its policy for Star Ratings suppression, which includes allowing for suppression when the underlying measure data are substantially affected by a PHE. CMS noted that measures suppressed for use in pay-for-performance program adjustments may still meet criteria for display on Care Compare and for use in Star Ratings calculations. CMS did not make any proposals concerning Star Ratings suppression.

In this final rule, CMS shares stakeholder feedback received related to potential Star Ratings suppression. Multiple commenters expressed appreciation for the proposed rule's suppression discussion and strongly encouraged continued transparency by CMS about this topic. Many also recommended ongoing data analysis to inform a decision whether or not to suppress 2023 Star Ratings.

CMS responds with continued commitments to ongoing measure performance monitoring and decision-making transparency. CMS notes that during Overall Star Ratings determinations, CMS does not perform adjustments for patient or hospital-level factors beyond those already incorporated into the component measures of the Star Ratings. CMS states that while rationales for any suppression decisions will be shared publicly (e.g., via rulemaking), it does not plan to provide detailed analytic results on Care Compare. CMS also states that the suppression status of measures in pay-for performance quality programs (e.g., Hospital Value-Based Purchasing Program) is not relevant to Overall Star Ratings as the latter are designed to serve as a consumer-friendly informational tool rather than for payment policy.

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.

XXII. Finalization of Certain COVID-19 Interim Final Rules

A. Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (CMS-1744-IFC)

CMS responds to public comments and states final policies for certain provisions in the April 6, 2020 IFC entitled "Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (CMS-1744-IFC).

1. Inpatient Hospital Services Furnished Under Arrangements Outside the Hospital During the Public Health Emergency (PHE) for the COVID-19 Pandemic

In the April 6, 2020 IFC, CMS changed its "under arrangements" policy during the COVID-19 PHE for beginning March 1, 2020, so that hospitals could have greater flexibility to furnish inpatient services, including routine services outside the hospital's campus or premises. CMS expected that during the COVID-19 PHE, hospitals would be treating patients in locations outside the hospital for a variety of reasons, including limited beds and/or limited specialized equipment such as ventilators, and for a limited time period, and that during this time hospitals would not be treating patients outside the hospital for gaming reasons. However, CMS emphasized that it was not changing its policy that a hospital must exercise sufficient control and responsibility over the use of hospital resources in treating patients.

Commenters supported the modification of CMS' policy concerning routine services provided under arrangements outside the hospital during the COVID-19 PHE, and many recommended that it extend that modification for a reasonable period (e.g., one year) after the end of the PHE. CMS declines to extend the policy after the end of the COVID-19 PHE though it notes that if a future PHE calls for such flexibility, it would address the issue at that time.

CMS finalizes without modification its policy that, effective for services provided for discharges for patients admitted to the hospital during the PHE for COVID-19 beginning March 1, 2020 until the end of the PHE, if routine services are provided under arrangements outside the hospital to its inpatients, these services are considered as being provided by the hospital. When the COVID-19 PHE ends, and consistent with prior policy (adopted in the FY 2012 IPPS/LTCH PPS rulemaking), for purposes of Medicare payment, only the therapeutic and diagnostic items and services described in section 1861(b)(3) of the Act may be furnished under arrangements outside the hospital. If routine services are provided in the hospital to its inpatients, these services will be considered as being provided by the hospital. However, if these services are provided to patients outside the hospital, the services will be considered as being provided under arrangement, and not by the hospital.

2. Counting Resident Time During the PHE for the COVID-19 Pandemic

Under the April 6, 2020 IFC and for the duration of the COVID-19 PHE, CMS permitted a hospital to claim a resident for indirect medical education (IME) or direct graduate medical education (DGME) if the resident is performing patient care activities within the scope of their approved program via telecommunications, in their own home, or in a patient's home. CMS finalizes these provisions of the April 6, 2020 IFC without modification. When the COVID-19 PHE ends, a hospital may not count a resident for purposes of Medicare IME or DGME payments if the resident is performing activities with the scope of their approved program in their own home, or a patient's home.

3. Modification of the Inpatient Rehabilitation Facility (IRF) Face-to-Face Requirement for the PHE During the COVID-19 Pandemic

Under the April 6, 2020 IFC (85 FR 19252), the face-to-face visit requirements at §§412.622(a)(3)(iv) and 412.29(e) were allowed to be conducted via telehealth to safeguard the health and safety of Medicare beneficiaries and the rehabilitation physicians (or, in accordance with the 2021 revised regulations, the nonphysician practitioners) treating them during the COVID-19 PHE. Commenters were supportive, and the policy is finalized without modification for use only during the COVID–19 PHE. When the COVID–19 PHE ends, rehabilitation physicians or nonphysician practitioners will be required to visit IRF patients face-to-face at least three times per week.

4. Direct Supervision by Interactive Telecommunications Technology

In the April 6, 2020 IFC and for the duration of the COVID-19 PHE, CMS modified the definition of direct supervision (at §§410.32(b)(3)(ii) and 410.28(e)) to state that the necessary presence of the physician includes virtual presence through audio/video real-time communications technology when use of such technology was indicated to reduce exposure risks for the beneficiary or health care provider. The definition of direct supervision of pulmonary, cardiac and intensive rehabilitation (at §410.27(a)(1)(iv)(D)) was similarly modified to state that the necessary presence of the physician includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider. These modifications were extended until the later of December 31st, 2021, or the end of the calendar year in which the PHE ends, in the 2021 final rules for the PFS and the OPPS.

CMS sought comment in the 2023 OPPS proposed rule whether it should extend the duration of the altered definition of direct supervision of pulmonary, cardiac and intensive rehabilitation through the end of 2023. As noted above in the summary of section X.C of this final rule, CMS extends the duration of the modified definition of direct supervision of pulmonary, cardiac and intensive rehabilitation until the later of December 31st, 2023, or the end of the calendar year in which the PHE ends.

Some commenters encourage CMS to make these modifications permanent while others expressed safety concerns for allowing virtual supervision of home infusion therapy services. CMS finalizes revisions to the definition of direct supervision for purposes of §§410.32(b)(3)(ii), 410.28(e), and 410.27(a)(1)(iv)(D) to permit virtual direct supervision until December 31st of the calendar year in which the PHE ends.

B. Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program (CMS-5531-IFC)

CMS responds to public comments and states final policies for certain provisions in the May 8, 2020 IFC entitled “Medicare and Medicaid Programs, Basic Health Program, and Exchanges;

Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program" (CMS-5531-IFC).

1. Medical Education Payments

a. Indirect Medical Education

In the May 8, 2020 IFC, several policies were implemented on an interim final basis to hold hospitals harmless from reductions in IME payments due to increases in bed counts during the COVID-19 PHE. Similarly, inpatient rehabilitation facilities (IRFs) and inpatient psychiatric facilities (IPFs) were held harmless from reductions to teaching status adjustment payments due to COVID–19.

CMS finalizes without modification the policy under the May 8, 2020 IFC that allows a hospital, for the duration of the COVID-19 PHE to maintain the same available bed count as it was on the day before the COVID-19 PHE was declared. When the COVID-19 PHE ends, any added beds will be considered in determining the hospital's IME payments.

To ensure that teaching IRFs or teaching IPFs could address bed capacity issues by taking patients from inpatient acute care hospitals without being penalized by lower teaching status adjustments, CMS adopted an interim final policy to freeze the IRFs' or IPFs' teaching status adjustment payments at their values prior to the COVID–19 PHE. The policy is confirmed as final for the duration of the COVID-19 PHE.

CMS notes that it did not establish a transition policy to support hospitals as they prepare for future potential surges or adapt to more regular practices. It believes hospitals have had sufficient time to adapt their business practices for the end of the PHE. The agency will clarify in the cost reporting instructions that for cost reporting periods ending on or after March 1, 2020 and beginning before the end of the COVID-19 Public Health Emergency, if an IRF's or IPF's calculated teaching adjustment factor is below the teaching adjustment factor that was applicable on February 29, 2020, then the IRF's or IPF's teaching adjustment factor is equal to the teaching adjustment factor that was applicable on February 29, 2020.

b. Time Spent by Residents at Another Hospital During the PHE

Several policies were implemented on an interim final basis related to time spent by residents at another hospital during the COVID-19 PHE (see 85 FR 27568 for an overview). Unanimous support was expressed for allowing teaching hospitals during the COVID-19 PHE to claim the time spent by residents training at other hospitals for purposes of IME and DGME payments. Some suggested the policy should be made permanent, but CMS notes the statute would preclude such a policy outside the context of a PHE. CMS confirms that, for the duration of the COVID-19 PHE, both the sending and receiving hospital agree that the sending hospital will claim the time and new teaching hospitals can accept residents as a receiving hospital from a sending hospital without having to include them on its cost report. The agency disagrees with a comment

that sated the requirement for the resident to be at the sending hospital before going to the receiving hospital and return to the sending hospital at the end of PHE is unnecessary.

CMS finalizes without modification the provisions of the May 8, 2020 IFC that allow teaching hospitals during the COVID-19 PHE to claim payments the time spent by residents training at other hospitals during the COVID-19 PHE for purposes of IME and DGME. CMS notes that when the COVID-19 PHE ends, the presence of residents in non-teaching hospitals will trigger establishment of IME and/or DGME FTE resident caps at those non-teaching hospitals (and for DGME will trigger establishment of per resident amounts (PRAs) at those non-teaching hospitals).

2. CARES Act Waiver of the "3-Hour Rule"

Section 3711(a) of the CARES Act requires the Secretary to waive during the COVID-10 PHE the requirement (under §412.622(a)(3)(ii)) that an intensive rehabilitation therapy program generally consists of at least 3 hours of therapy (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics therapy) per day at least 5 days per week (the 3-hour rule). The CARES Act waiver is available without regard to whether the patient was admitted for standard IRF care or to relieve acute care hospital capacity; thus, it is available to all patients and all IRFs.

CMS finalizes the waiver of the 3-hour rule during the COVID-19 PHE. The waiver will be terminated for all IRF admissions occurring after the end of the COVID-19 PHE; patients who are admitted to IRFs during the PHE will remain under the waiver until they are discharged from the IRFs.

3. Modification of IRF Coverage and Classification Requirements for Freestanding IRF Hospitals for the PHE During the COVID–19 Pandemic

The May 8, 2020 IFC provided an exception to the IRF coverage requirements at §§412.29(d), (e), (h), and (i) and 412.622(a)(3), (4), and (5) for care furnished to patients admitted to freestanding IRF hospitals solely to relieve acute care hospital capacity during the COVID-19 PHE. This was done in recognition of the institutional differences between freestanding IRF hospitals and IRF distinct part units of hospitals. CMS believes that freestanding IRF hospitals have needed the flexibility during the COVID-19 PHE to determine the best care for each patient who is admitted solely to provide surge capacity for acute care hospitals in the state (or region, as applicable). The flexibilities for freestanding IRF hospitals apply only to the extent a state (or region, as applicable) has not moved beyond Phase 1 of reopening under the "Guidelines for Opening Up America Again." These limitations apply only to the provisions stated in the IFC and not to any blanket waivers issued, and freestanding IRF hospitals must document the particular phase for the state when admitting the patient and exercising the flexibilities. CMS expects that these facilities would provide standard IRF-level care for those beneficiaries who would benefit from IRF-level care and would otherwise receive such care in the absence of the COVID-19 PHE.

Commenters supported the flexibilities though some objected to the limitation of their use only before or during Phase 1 of reopening. CMS believes the limitation is appropriate. CMS also provides additional guidance for this waiver through its Technical Direction Letter #200515 to contractors and additional information on its COVID-19 flexibilities and waivers website at https://www.cms.gov/coronavirus-waivers.

CMS finalizes its waiver without modification during the COVID-19 PHE. Patients admitted to IRFs during the PHE will remain under these waivers until they are discharged from the IRFs. The waivers will no longer apply to patients who are admitted to IRFs after the end of COVID-19 PHE. CMS makes a number of conforming changes to its regulations, including the addition of a definition of state (or region, as applicable) that are experiencing a surge to §412.622(c).

4. Furnishing Outpatient Services in Temporary Expansion Locations of a Hospital or a Community Mental Health Center (CMHC) (Including the Patient's Home)

In the May 8, 2020 IFC, CMS included a blanket waiver for hospitals and CMHCs providing Partial Hospitalization Program (PHP) services to treat a temporary expansion location where a beneficiary may be located, including the beneficiary's home, as a provider-based department (PBD) of the hospital or as a temporary extension of the CMHC. This was intended to support the goals of infection control as well as ensuring access to PHP services. Under the waiver, providers could furnish certain PHP services remotely to patients in a temporary expansion location of the hospital or CMHC, which could include the patient's home if it was made provider-based to the hospital or an extension of the CMHC.

PHP services furnished using telecommunications technology were expected to involve both audio and video. However, because some beneficiaries might not have access to video communication technology, under the waiver, PHP services may be furnished using only audio where both audio and video are not possible. CMS also clarified that services that required drug administration could not be furnished using telecommunications technology. With the exception of the authority to provide PHP services remotely, all other requirements for coverage of and payment for such services remain in effect. These requirements include that all services furnished under the PHP still required an order by a physician, had to be supervised and certified by a physician, and had to be furnished in accordance with coding requirements by a clinical staff member working within his or her scope of practice.

Commenters were supportive; some asked for a transition policy after the end of the COVID-19 PHE. CMS declines to provide a transition policy and notes that after the end of the PHE, the statute limits payment for PHP services furnished to beneficiaries in a home or residential setting.

5. Furnishing Hospital Outpatient Services Remotely for Services Other Than Mental Health
CMS finalizes all the provisions of section II.F. of the May 8, 2020 IFC (*Furnishing Hospital Outpatient Services in Temporary Expansion Locations of a Hospital or a Community Mental Health Center (Including the Patient's Home)* 85 FR 27562 through 27566) without modification during the COVID-19 PHE. These provisions include that when a hospital's clinical staff are furnishing hospital outpatient services (such as drug administration, education, and training

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 requirements of §410.27(a)(1)[38] to be met. This policy is sometimes referred to as the Hospitals Without Walls policy. CMS also finalizes its policy that when a patient is receiving a professional Medicare telehealth service in a location that is considered a hospital PBD, and the patient is a registered outpatient of the hospital, the hospital in which the patient is registered may bill the originating site facility fee for the service. It also finalizes its clarification of the applicability of section 603 of the BBA 2015 to hospitals furnishing care in the beneficiaries' homes (or other temporary expansion locations). These flexibilities will end once the COVID-19 PHE terminates.

6. Treatment of New and Certain Relocating Provider-Based Departments During the PHE

In May 8, 2020 IFC, the Secretary waived Medicare's provider-based rules in §413.65 for the duration of the PHE. However, the waiver did not address whether a PBD is excepted or non-excepted from the payment policies under section 603 of the BBA 2015. In response, in order to improve access to care for patients during this time, CMS permitted on and off-campus departments to use the extraordinary circumstances policy to seek approval to relocate a PBD on or after March 1, 2020 through the remainder of the PHE and continue to be paid under the OPPS. The hospital's purpose must be to address the COVID-19 pandemic, and the relocation must be consistent with the state's emergency preparedness or pandemic plan. The agency created a streamlined extraordinary circumstances policy for this purpose.

Once the PHE is over, these PBDs must either return to their prior location or be paid for outpatient services at 40 percent of OPPS rates. While relocated PBDs can apply under the extraordinary circumstances policy using the regular process to continue being paid full OPPS rates after the PHE, the COVID-19 PHE will not be a justification for permitting an off-campus PBD to continue being paid under the OPPS.

CMS finalizes all these policies without modification and notes that the flexibilities will end when the PHE terminates.

C. OPPS Separate Payment for New COVID–19 Treatments Policy for the Remainder of the PHE (CMS-9912-IFC)

CMS responds to public comments and states final policies for certain provisions in the November 6, 2020 IFC entitled "Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (CMS-9912-IFC), relating to separate payment under the OPPS for new COVID-19 treatments for the remainder of the PHE (85 FR 71158 through 71160)).

For services furnished on or after the effective date of the November 9, 2020 IFC and until the end of the PHE for COVID-19, CMS created an exception to its OPPS C-APC policy to ensure new COVID–19 treatments that meet two criteria would, for the remainder of the COVID-19

[38] Section 410.27(a)(1) relates to requirements for Part B payment for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service.

PHE, always be separately paid and not packaged into a C-APC when they appear on the same claim as the primary C-APC service. First, the treatment must be a drug or biological product authorized to treat COVID-19. This could be shown either as indicated in section "I. Criteria for Issuance of Authorization" of the letter of authorization for the drug or biological product, or the drug or biological product is FDA approved to treat COVID-19. The second criterion is that the emergency use authorization for the drug or biological product must authorize the use of the product in the outpatient setting or not limit its use to the inpatient setting, or the product must be approved by the FDA to treat COVID-19 disease and not limit its use to the inpatient setting.

Commenters supported the policy though some argued that qualifying COVID-19 therapies should be excluded from the OPPS 340B payment adjustment, that co-insurance for the therapies be waived, and that the exemption should be permanent. CMS notes that the 340B payment adjustment would not apply in 2023. It also notes that it lacks the statutory authority to waive co-insurance in this instance, and CMS believes its standard policy of packaging adjunctive items and services into payment for primary C-APC services is appropriate for COVID-19 treatments outside the context of the COVID-19 PHE.

CMS finalizes this policy as implemented in the November 6, 2020 IFC and notes that the policy will end with the termination of the PHE.

TABLE 110: 2023 OPPS Impact Table

	(1)	(2)	(3)	(4)	(5)	(6)	(7)
	Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adj.**	**340B Adj.**	**All Budget Neutral Changes & Update**	**Rural SCH Visits Policy**	**All Changes**
ALL PROVIDERS*	3,508	0.0	0.1	0.8	4.8	0.1	4.5
ALL HOSPITALS (excludes hold harmless and CMHCs)	3,414	0.0	0.2	0.9	5.0	0.1	4.7
URBAN HOSPITALS	2,707	0.1	0.2	1.2	5.3	0.0	4.9
LARGE URBAN	1,388	0.1	0.1	1.3	5.4	0.0	5.0
(GT 1 MILL.)							
OTHER URBAN	1,319	0.0	0.3	1.0	5.2	0.1	4.8
(LE 1 MILL.)							
RURAL HOSPITALS	707	-0.1	0.0	-1.0	2.7	0.7	2.9
SOLE COMMUNITY	375	-0.2	0.0	-1.8	1.7	1.1	2.3
OTHER RURAL	332	0.0	-0.1	0.6	4.3	0.0	4.0
BEDS (URBAN)							
0 - 99 BEDS	907	0.5	0.1	-1.3	3.1	0.0	2.7
100-199 BEDS	764	0.3	0.2	-0.6	3.7	0.0	3.4
200-299 BEDS	417	0.1	0.2	0.2	4.4	0.1	4.0
300-499 BEDS	391	0.1	0.2	1.0	5.1	0.0	4.6
500 + BEDS	228	-0.2	0.2	3.4	7.3	0.0	6.9
BEDS (RURAL)							
0 - 49 BEDS	327	0.2	0.0	-1.3	2.5	0.2	2.3
50- 100 BEDS	222	-0.1	0.3	-1.3	2.6	0.6	2.5
101- 149 BEDS	81	-0.2	0.1	-0.3	3.3	0.8	3.6
150- 199 BEDS	40	-0.2	-0.6	-0.4	2.6	1.3	3.9
200 + BEDS	37	-0.4	-0.2	-0.9	2.3	0.9	2.8
REGION (URBAN)							
NEW ENGLAND	129	-0.1	0.0	1.2	5.0	0.0	4.9
MIDDLE ATLANTIC	314	-0.1	-0.1	1.5	5.2	0.0	4.8
SOUTH ATLANTIC	451	0.2	-0.1	1.1	5.1	0.0	4.8
EAST NORTH CENT.	420	-0.1	-0.1	1.2	4.9	0.0	4.7
EAST SOUTH CENT.	161	0.2	-0.2	2.3	6.2	0.0	5.9
WEST NORTH CENT.	182	-0.1	1.2	1.4	6.3	0.1	5.2
WEST SOUTH CENT.	446	0.2	0.1	0.1	4.1	0.0	3.9

	(1)	(2)	(3)	(4)	(5)	(6)	(7)
	Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adj.**	**340B Adj.**	**All Budget Neutral Changes & Update**	**Rural SCH Visits Policy**	**All Changes**
MOUNTAIN	202	0.4	1.3	0.6	6.2	0.1	5.6
PACIFIC	354	0.2	0.2	1.3	5.6	0.0	5.1
PUERTO RICO	48	1.1	-0.2	-2.6	2.0	0.0	2.0
REGION (RURAL)							
NEW ENGLAND	19	-0.4	-0.7	-1.3	1.3	1.9	2.9
MIDDLE ATLANTIC	47	-0.2	-0.4	-0.7	2.4	1.7	4.1
SOUTH ATLANTIC	107	0.0	0.0	-0.4	3.4	0.1	3.4
EAST NORTH CENT.	112	-0.2	-0.4	-1.2	2.0	0.3	2.1
EAST SOUTH CENT.	136	0.0	-0.2	0.5	4.1	0.4	4.4
WEST NORTH CENT.	86	-0.3	0.7	-2.2	1.9	1.1	1.7
WEST SOUTH CENT.	132	0.3	-0.5	-2.0	1.5	0.6	2.0
MOUNTAIN	45	0.1	2.1	-0.9	5.0	0.3	3.1
PACIFIC	23	-0.2	-0.7	0.1	3.0	0.9	3.6
TEACHING STATUS							
NON-TEACHING	2,180	0.3	0.1	-0.8	3.4	0.1	3.1
MINOR	825	0.1	0.1	0.5	4.6	0.1	4.2
MAJOR	409	-0.3	0.2	3.3	7.2	0.1	6.8
DSH PATIENT PERCENT							
0	3	0.8	-0.4	-3.1	1.0	0.0	0.8
GT 0 - 0.10	224	0.5	0.5	-2.6	2.1	0.0	1.7
0.10 - 0.16	240	0.3	0.1	-2.5	1.6	0.0	1.1
0.16 - 0.23	562	0.2	0.0	-2.5	1.5	0.1	1.3
0.23 - 0.35	1,107	0.0	0.2	1.1	5.1	0.2	4.8
GE 0.35	864	-0.1	0.1	3.9	8.0	0.1	7.6
DSH NOT AVAILABLE **	414	-1.1	0.1	-2.6	0.1	0.0	-0.4
URBAN TEACHING/ DSH							
TEACHING & DSH	1,092	-0.1	0.2	2.0	6.0	0.0	5.6
NO TEACHING/DSH	1,198	0.4	0.1	-0.7	3.6	0.0	3.3
NO TEACHING/NO DSH	3	0.8	-0.4	-3.1	1.0	0.0	0.8
DSH NOT AVAILABLE2	414	-1.1	0.1	-2.6	0.1	0.0	-0.4
TYPE OF OWNERSHIP							
VOLUNTARY	1,935	0.0	0.1	1.2	5.2	0.1	4.9

	(1)	(2)	(3)	(4)	(5)	(6)	(7)
	Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adj.**	**340B Adj.**	**All Budget Neutral Changes & Update**	**Rural SCH Visits Policy**	**All Changes**
PROPRIETARY	1,042	0.5	0.1	-2.7	1.6	0.0	1.3
GOVERNMENT	437	-0.1	0.3	2.2	6.3	0.0	5.9
CMHCs	27	-9.1	0.0	-3.1	-8.6	0.0	0.0
Column (1) shows total hospitals and/or CMHCs.							
Column (2) includes all final 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 final FY 2023 hospital inpatient wage index. The final rural SCH adjustment would continue our current policy of 7.1 percent so the budget neutrality factor is 1. The final budget neutrality adjustment for the cancer hospital adjustment is 1.0000 because the final CY 2023 target payment-to-cost ratio is the same as the CY 2022 PCR target (0.89)							
Column (4) shows the impact of paying for 340B-acquired drugs at ASP+6 percent and making the adjustment to remove the 3.19 percent CY 2018 OPPS budget neutrality adjustment from payment for non-drug services.							
Column (5) shows the impact of all budget neutrality adjustments and the addition of the 3.8 percent OPD fee schedule update factor (4.1 percent reduced by 0.3 percentage points for the productivity adjustment).							
Column (6) shows the differential impact of the proposed exception for rural sole community hospitals from the clinic visits policy when furnished at off campus provider-based departments.							
Column (7) shows the additional adjustments to the conversion factor, including the change to except rural sole community hospitals from the clinic visit policy when provided at excepted off campus provider-based departments and 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 3,508 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.							