Medicare Program: 2024 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs Proposed Rule Summary

The Centers for Medicare & Medicaid Services (CMS) released the calendar year 2024[1] proposed rule for Medicare's hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system (CMS-1786-P) on July 13, 2023. Policies in the proposed rule will generally go into effect on January 1, 2024 unless otherwise specified. The proposed rule will be published in the July 31, 2023 issue of the *Federal Register*. **The public comment period will end on September 11, 2023.**

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

The 2024 OPPS proposed rule also includes a number of other provisions such as the implementation of an intensive outpatient program (IOP), changes to the hospital price transparency program, Medicare payment for dental services, and others. CMS also requests public comment on providing payment incentives for hospitals to maintain a buffer stock of essential medicines. Based on the public comments received on this topic, CMS may adopt provisions in the final rule to go into effect as soon as cost reporting periods beginning on or after January 1, 2024, even though CMS has not made any formal proposals.

Addenda containing relative weights, payment rates, wage indices and other payment information are available on the CMS website at: https://www.cms.gov/medicare/medicare-fee-service-payment/hospitaloutpatientpps/hospital-outpatient-regulations-and/cms-1786-p.

TABLE OF CONTENTS

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

I. Overview

A. Estimated Impact on Hospitals

The increase in spending due only to changes in the 2024 OPPS proposed rule is estimated to be approximately $1.92 billion. Taking into account estimated changes in enrollment, utilization, and case-mix for 2024, CMS estimates that OPPS expenditures, including beneficiary cost-sharing, will be approximately $88.6 billion, which is approximately $6.0 billion higher than estimated expenditures in 2023.

CMS estimates that the update to the conversion factor net of the total factor productivity (TFP) will increase payments 2.8 percent in 2024 (market basket of 3.0 percent less 0.2 percentage points for TFP). Including changes to outlier payments, pass-through payment and the application of the frontier state wage adjustment, CMS estimates a 2.9 percent increase in payments between 2023 and 2024.

Hospitals that satisfactorily report quality data will qualify for the full update of 2.8 percent, while hospitals that do not will be subject to an update of 0.8 percent (a statutory reduction of 2.0 percentage points). All other adjustments are the same for the two sets of hospitals. Of the approximately 3,097 hospitals that meet eligibility requirements to report quality data, CMS determined that 77 hospitals will not receive the full OPPS increase factor.

Medicare makes payments under the OPPS to approximately 3,567 facilities (3,472 hospitals excluding CMHCs, cancer and children's hospitals held harmless to their pre-OPPS payment to cost ratios). Table 100 in the proposed rule (reproduced in the Appendix to this summary) includes the estimated impact of the proposed rule by provider type. It shows an estimated increase in expenditures of 2.9 percent for all facilities and hospitals. The following table shows components of the 2.9 percent total:

	% Change All Facilities
Fee schedule increase factor	2.8
Difference in pass through estimates for 2023 and 2024	-0.10
Difference from 2023 outlier payments (0.78% vs. 1.0%)	0.22
All changes	2.9

For 2023, CMS estimates pass-through spending would be 0.16 percent of OPPS spending. For 2024, CMS estimates that pass-through spending for drugs, biologicals and devices will be $234.1 million, or 0.26 percent of OPPS spending. The difference between these figures (0.16 – 0.26 = -0.10 percentage point) is the required adjustment to ensure that pass-through spending remains budget neutral from one year to the next. In addition, CMS estimates that actual outlier payments in 2023 will represent 0.78 percent of total OPPS payments compared to the 1.0 percent set aside for 2024, a 0.22 percentage point change in 2024 payments. Taken together, these factors product the total increase in 2024 OPPS payments of 2.9 percent.

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

Although CMS projects an estimated increase of 2.9 percent for all facilities, the rule's impacts vary depending on the type of facility. Impacts will differ for each hospital category based on the mix of services provided, location and other factors. Impacts for selected categories of hospitals are shown in the table below:

Facility Type	2024 Impact
All Hospitals	3.0%
All Facilities (includes CMHCs and cancer and children's hospitals)	2.9%
Urban	2.8%
Large Urban	2.8%
Other Urban	2.8%
Rural	4.4%
Beds	
0-99 (Urban)	3.2%
0-49 (Rural)	4.6%
500+ (Urban)	2.1%
200+ (Rural)	3.7%
Major Teaching	2.4%
Type of ownership	
Voluntary	3.0%
Proprietary	3.4%
Government	2.8%

The payment impacts are largely consistent between the different categories of hospitals. Generally, an increase or decrease larger than the average will be accounted for by recalibration of APC weights or changes to the wage index. The higher increase for rural hospitals is accounted for by recalibration of the relative weights and the wage index. Similarly, recalibration of the relative weights appears to also benefit smaller hospitals on average. Proprietary hospitals also appear to benefit in 2024 from APC recalibration.

B. Estimated Impact on Beneficiaries

CMS estimates that the aggregate beneficiary coinsurance percentage will be 18.0 percent for all services paid under the OPPS in 2024. 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.

II. Updates Affecting OPPS Payments

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

1. Database Construction

a. Database Source and Methodology

For 2024, CMS is using 2022 hospital final action claims for services furnished from January 1, 2022 through December 31, 2023 processed through the Common Working File as of December 31, 2022 (approximately 93 million claims). CMS is using 2021 Medicare cost reports in most cases to develop the cost-to-charge ratios (CCR) that are used to convert hospital charges to cost.

In a separate document available on the CMS website, CMS provides a detailed description of the claims preparation process and an accounting of claims used in the development of the proposed rule payment rates, including the number of claims available at each stage of the process: https://www.cms.gov/files/document/2024-nprm-opps-claims-accounting.pdf.

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

For the 2024 proposed rule, CMS is bypassing the 187 HCPCS codes identified in Addendum N. There are 13 new bypass codes identified with an asterisk in column D. CMS indicates that the list of bypass codes may include codes that were reported on claims in 2022 but were deleted for 2023.

b. Calculation and Use of 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 2024, 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.

For 2024, CMS is proposing to update crosswalk for chimeric antigen receptor therapy (CAR-T) administration services consistent with public comments on the 2023 proposed rule and changes made by the National Uniform Billing Committee. CMS proposes:

- Revising revenue codes 0870 (Cell/Gene Therapy General Classification) and 0871 (Cell Collection) to be mapped to a primary cost center of 9000 (Clinic);
- Revising revenue codes 0872 (Specialized Biologic Processing and Storage - Prior to Transport) and 0873 (Storage and Processing After Receipt of Cells from Manufacturer) to be mapped to a primary cost center of 3350 (Hematology);
- Revising revenue codes 0874 (Infusion of Modified Cells) and 0875 (Injection of Modified Cells) to be mapped to a primary cost center of 6400 (Intravenous Therapy); and
- Revising revenue codes 0891 (Special Processed Drugs - FDA Approved Cell Therapy) and 0892 (Special Processed Drugs - FDA Approved Gene Therapy) to be mapped to a primary cost center of 7300 (Drugs Charged to Patients).

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. CMS does not use nonstandard cost centers on cost report lines that do not correspond to the cost center number because of concerns about the accuracy of data reported in these cost centers.

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

In past years, to determine each APC's relative weight, CMS takes single procedure claims and adjusts charges to costs for each procedure within an APC and then calculates the APC's geometric mean cost. The relative weight is the geometric mean cost of the APC divided by the geometric mean cost across all APCs. CMS standardizes the relative weights to the APC for G0463, an outpatient hospital visit—the most commonly furnished service billed under the OPPS. CMS is continuing to follow this basic process for 2024. The 2022 claims data that CMS is using for 2024 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.

(i) Blood and blood products

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

(ii) Brachytherapy sources

The statute requires the Secretary to create APCs for brachytherapy consisting of a seed or seeds (or radioactive source)—i.e., "brachytherapy sources"—separately from other services or groups of services, in order to reflect the number, isotope, and radioactive intensity of the brachytherapy sources furnished. Since 2010, CMS has used the standard OPPS payment methodology for brachytherapy sources, with payment rates based on source-specific costs as required by statute. CMS proposes no changes to its brachytherapy policy for 2024.

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 2023, 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 three claims for HCPCS code C2645 in the 2022 utilization data. The geometric mean cost is $168.67. The proposed rule indicates that CMS is unable to use these claims for ratesetting purposes given the reporting of only one unit per claim and the high geometric mean cost. For this reason, CMS proposes to use its equitable adjustment authority under section 1833(t)(2)(E) to continue the rate of $4.69 per mm^2 for 2024 for HCPCS code C2645.

Beginning in 2022, CMS adopted a low volume APC policy to use up to four years of claims data for APCs with fewer than 100 single procedure claims in a year that can be used for rate-setting. For these APCs, CMS will determine the relative weight based on the higher of the arithmetic mean cost, median cost, or geometric mean cost. CMS proposes to price four low volume brachytherapy APCs under this policy (excluding those that are priced using external data). For 2024, CMS proposes to designate five low volume APCs where the special methodology will be used to determine the relative weight.

Recommendations for HCPCS codes that describe new brachytherapy sources should be directed to: outpatientpps@cms.hhs.gov or 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.

Beginning in 2019, CMS excluded procedures assigned to new technology APCs from packaging into C-APCs because of a concern that packaging payment reduces the number of 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.

Beginning in 2023, CMS adopted a new policy to exclude HCPCS Code C9399 (Unclassified drugs or biologicals) from being packaged into a C-APC. 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 the new drug or biological. Since the implementation of the C-APC policy in 2015, payment for 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 added a new definition to status indicator "A" to include unclassified drugs and biologicals that are reportable with HCPCS code C9399.

As a result of its annual review of the services and APC assignments under the OPPS, CMS is not proposing to convert any existing APCs to C-APCs. However, CMS is proposing to create two new APCs that it will designate as C-APCs—APC 5496 (Level 6 Intraocular Procedures) and APC 5342 (Level 2 Abdominal/Peritoneal/Biliary and Related Procedures).

The full list of C-APCs, the data CMS used to evaluate creating a C-APC, and C-APC complexity adjustments are found in Addendum J. C-APCs with a status indicator of "J1" or "J2" (only for the Comprehensive Observation Services C-APC) can be found in other Addenda as well.

c. Calculation of Composite APC Criteria-Based Costs

Since 2008, CMS has used composite APCs to make a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. At this time, CMS' composite APC policy applies only for mental health services and multiple imaging services. CMS is not proposing any changes to its composite APC policies for 2024.

For the mental health composite APC 8010, CMS caps the payment to be no more than APC 5863 for partial hospitalization (3 services furnished in a day). Partial hospitalization is the most intensive of the outpatient mental health services. CMS does not believe the mental health composite APC payment should be higher than the highest partial hospitalization payment. APC 5863 had been the highest paid partial hospitalization APC until the creation of APC 5864, which is for 4 or more partial hospitalization services per day.

CMS requests comment on whether the payment for composite APC 8010 should be capped at the payment for APC 5864. In the proposed rule, CMS indicates a preference for maintaining the current policy as it believes a patient needing more than 3 outpatient mental health services per day would potentially require an inpatient admission.

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, the proposed rule indicates that section 4135(a) and (b) of the Consolidated Appropriations Act (CAA), 2023 prohibit packaged payment and require separate payment for non-opioid pain relief treatments effective January 1, 2025 through December 31, 2027. CMS will include proposals to implement this CAA provision in the 2025 OPPS rule. Section XIII.F describes this provision in more detail. While CMS expects this policy to operate similarly in the ASC and hospital outpatient department (HOPD) settings, CMS welcomes comment on whether there are any HOPD specific payment issues it should take into consideration when planning to implement this provision for 2025.

4. Comment Solicitation on OPPS Packaging for Diagnostic Radiopharmaceuticals

CMS reviews the history of its packaging policy for diagnostic radiopharmaceuticals as well as how it has responded to public comments on these issues over the years. CMS specifically requests comment on how OPPS packaging policy for diagnostic radiopharmaceuticals has impacted beneficiary access, including whether there are specific patient populations or clinical disease states for whom this issue is especially critical. It is particularly interested in clinical scenarios where the packaging policy discourages use of higher cost radiopharmaceuticals that may be indicated based on the patient's clinical needs for the product.

Some payment approaches that CMS would consider adopting include:

1. Paying separately for diagnostic radiopharmaceuticals with per-day costs above the OPPS drug packaging threshold of $140;
2. Establishing a specific per-day cost threshold that may be greater or less than the OPPS drug packaging threshold;
3. Restructuring APCs, including by adding nuclear medicine APCs for services that utilize high-cost diagnostic radiopharmaceuticals;
4. Creating specific payment policies for diagnostic radiopharmaceuticals used in clinical trials; and
5. Adopting codes that incorporate the disease state being diagnosed or a diagnostic indication of a particular class of diagnostic radiopharmaceuticals.

The first option would no longer require diagnostic radiopharmaceuticals to be policy packaged. They could be paid separately like any other drug or biological if their per day costs exceed the packaging threshold. However, CMS' longstanding belief is that diagnostic radiopharmaceuticals should have their payment packaged as they function as supplies during a diagnostic test or procedure.

The second option would be similar to the first one except there would be a unique packaging threshold that applies only to diagnostic radiopharmaceuticals. CMS solicits comments on the rationale for creating a threshold that would be different from the OPPS drug packaging threshold.

The third option has been suggested by some public commenters. CMS seeks comment on how to operationalize this approach and what advantage this approach would have for beneficiaries, hospitals, and CMS.

CMS suggested the fourth option because it recently became aware that some interested parties believe that CMS packaging policies could influence participation of beneficiaries and testing sites in clinical trials. CMS believes there could be a multitude of reasons recruiting study sites and beneficiaries for clinical trials is difficult. Nevertheless, CMS is interested in public comments on how such a policy would work, whether it would result in more clinical trial participation and which clinical trials should be targeted.

Public commenters suggest the fifth option to reflect the higher cost of more expensive radiopharmaceuticals in the APC payment when a specific product is indicated for the patient. Alternatively, if there is a specific clinical indication in which a wide variety of diagnostic radiopharmaceuticals can be used, all with varying costs, CMS' payments would not incent a higher-cost diagnostic radiopharmaceutical when there is a lower-cost, but clinically similar, diagnostic radiopharmaceutical alternative.

Although CMS has not proposed a specific policy, it is seeking public comments on potential modifications to its packaging policy for diagnostic radiopharmaceuticals that it may adopt for 2024.

5. 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 (2022) to determine budget neutrality for changes in the OPPS relative weights for the proposed rule year (2024). Holding all other variables constant, CMS multiplies the 2023 final relative weights and the 2024 proposed relative weights respectively for each APC by its associated volume from 2022. It sums the 2023 and proposed 2024 relative weights respectively, and divides the 2024 proposed aggregate relative weights by the 2023 aggregate relative weights to determine the weight scaler. Using this process, CMS is adopting a weight scaler of 1.4152. The unscaled proposed 2023 relative payments are multiplied by 1.4529 to determine the proposed 2024 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 2023 and 2024 do not increase or decrease expenditures. However, SCODs are not affected by the budget neutrality adjustment.

B. Conversion Factor Update

The proposed 2024 conversion factor is $87.4880 for hospitals receiving the full update for outpatient quality reporting. The components of the update are shown below:

	Full Update		Reduced Update	
2023 Conversion Factor (CF)	**$85.5850**	**Resulting CF**		**Resulting CF**
Remove pass-through & outliers from prior year CF	1.0117	$86.5890	1.0117	$86.5890
Wage Index Budget Neutrality	0.9974	$86.3640	0.9974	$86.3640
Cap on Wage Index Reductions	0.9975	$86.1480	0.9975	$86.1480
Cancer Hospital Adjustment	1.0005	$86.1910	1.0005	$86.1910
Rural Hospital Adjustment	1.0000	$86.1910	1.0000	$86.1910
Update	1.0280	$88.6050	1.0080	Not Provided
Pass-Through/Outlier	0.9874	$87.4880	0.9874	Not Provided
2024 Conversion Factor	**87.4880**	**$87.4880**		**$85.7820**

Note: This table is HPA's creation. CMS does not provide the step-by-step calculation for the reduced update. Consequently, the resulting conversion factor after the update is not provided in the rule.

CMS removes the prior year's pass-through (0.0016) and outlier adjustment (0.0100) from the 2023 conversion factor which equals 1.0117 (1.17 percent).[2] Wage index budget neutrality is 0.9974 (-0.26 percent) for 2024. The cap on reductions to the wage index requires a budget neutrality adjustment of 0.9975 (-0.25 percent) for 2024. The cancer hospital adjustment is 1.0005 (0.05 percent). The rural sole community hospital adjustment is 1.0000 (0.0 percent) for 2024.

The update of 1.028 (2.8 percent) equals the market basket of 3.0 percent less 0.2 percentage points for TFP for 2024. This update is the same as was proposed in the FY 2024 IPPS proposed rule and is based on the IHS Global Insight (IGI) fourth quarter 2022 forecast of the FY 2024 hospital market basket with historical data through the third quarter of 2022. The final rule market basket will be based on the IGI second quarter 2023 forecast of the FY 2024 hospital market basket used for the IPPS update. The TFP estimates are from the same period.

CMS estimates that pass-through spending for drugs, biologicals and devices for 2024 will be $234.1 million, or 0.26 percent of OPPS spending. The outlier adjustment is 0.99 (-1.0 percent). The combined adjustment for pass-through and outliers is 0.9874 (-1.26 percent).

The proposed 2024 conversion factor for hospitals that submit quality data is $87.4880. The conversion factor for hospitals that do not submit quality data is subject to all of the same adjustments except the update is 1.0080 (0.8 percent) instead of 1.0280 (2.8 percent). The proposed

[2] Removing the budget neutrality adjustment from the prior year requires division so the factor equals 1.0/(1-0.01-0.0016) or 1.17.

conversion factor for hospitals that do not submit quality data is $85.7820 according to CMS. (HPA calculates a slightly higher conversion factor of $85.7860.)

C. Wage Index Changes

CMS is proposing to continue using a labor share of 60 percent and the fiscal year IPPS post-reclassified wage index for the OPPS in 2024. The propose rule directs readers to the IPPS rule for more details regarding specific policies affecting the proposed 2024 wage index. In the FY 2023 IPPS rule, CMS adopted a policy to apply a 5 percent cap on reductions to a hospital wage index for any reason. This same policy will apply under the OPPS for 2024. As noted in the prior section, CMS proposes to make this change budget neutral, necessitating a -0.25 percent budget neutrality adjustment to the conversion factor.

For non-IPPS hospitals paid under the OPPS for 2024, CMS is proposing to continue its past policies of assigning the wage index that would be applicable if the hospital were paid under the IPPS and allowing the hospital to qualify for the out-migration adjustment—an adjustment that a hospital may qualify for if a high proportion of its workers commute to adjacent higher wage areas. For CMHCs, CMS proposes to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the Core-Based Statistical Area (CBSA) where the CMHC is located. CMS notes that, consistent with its current policy, the wage index that applies to CMHCs includes the rural floor adjustment but not the out-migration adjustment, which only applies to hospitals.

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

In cases where there are no data to calculate a hospital's CCR, CMS proposes to continue using the statewide average CCR to determine outlier payments, payments for pass-through devices, and other purposes. The statewide average is used for hospitals that are new, hospitals that have not accepted assignment of an existing hospital's provider agreement, and hospitals that have not yet submitted a cost report. CMS also proposes to use the statewide average default CCRs to determine payments for hospitals that appear to have a CCR falling outside the predetermined ceiling threshold for a valid CCR or for hospitals in which the most recent cost report reflects an all-inclusive rate status. The table of statewide average CCRs can be found at: https://www.cms.gov/medicare/medicare-fee-service-payment/hospitaloutpatientpps/annual-policy-files/2024.

E. Sole Community Hospital (SCH) Adjustment

For 2024, CMS proposes to continue applying a 7.1 percent payment adjustment under section 1833(t)(13)(B) of the Act for rural SCHs, including essential access community hospitals, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs. The adjustment is budget neutral and is applied before calculating outliers and copayments.

F. Cancer Hospital Adjustment

Eleven cancer hospitals meeting specific statutory classification criteria are exempt from the IPPS. Medicare pays these hospitals under the OPPS for covered outpatient hospital services. The Affordable Care Act requires an adjustment to cancer hospitals' outpatient payments sufficient to bring each hospital's payment-to-cost ratio (PCR) up to the level of the PCR for all other hospitals—the target PCR. The change in these additional payments from year to year is budget neutral. The 21st Century Cures Act reduced the target PCR by 1.0 percentage point and excludes the reduction from OPPS budget neutrality. The cancer hospital adjustment is applied at cost report settlement rather than on a claim-by-claim basis.

To calculate the proposed 2024 target PCR, CMS uses the same extract of cost report data from the Hospital Cost Report Information System used to estimate costs to determine the 2024 OPPS relative weights which, in most cases, would be the most recently available hospital cost reports. The cost reporting periods were predominantly from fiscal years ending in 2021 and 2022. CMS estimates a proposed target PCR of 0.86 or 86 percent. After reducing this PCR by 1.0 percentage point, the target will be 0.85 or 85 percent.

The target PCR has ranged from 0.88 to 0.92 from 2012 through 2023. CMS believes the lower target PCR of 0.85 proposed for 2023 may be a result of the lingering effects of the COVID-19 PHE on hospital payments and costs. However, CMS continues to believe the target PCR for cancer hospitals should be based on the latest available data. Nevertheless, CMS remains concerned about instability in cancer hospital adjustment payments and potential volatility in the PCR from transitioning to post-COVID-19 PHE costs. As result, CMS proposes to limit the reduction in the target PCR to 1.0 percentage point annually. As the 2023 target PCR was 0.89, CMS' proposal would result in a target PCR of 0.88.

Table 5 in the proposed rule shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals, with increases in OPPS payments for 2024 ranging from 11.6 percent to 56.9 percent. CMS indicates that the reduction in the cancer hospital adjustment requires a budget neutrality adjustment of 0.05 percent.

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 2024, CMS proposes to continue setting aside 1.0 percent of the estimated aggregate total payments for OPPS outlier payments. It proposes calculating the fixed-dollar threshold using the same methodology that was used to set the threshold for 2023 and previous years. CMS proposes to continue setting the 2023 outlier payment equal to 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount when both the 1.75 multiple payment threshold and the fixed-dollar threshold are met.

CMS proposes to set aside a portion of the 1.0 percent outlier pool—specifically, an amount equal to less than 0.01 percent of outlier payments—for CMHCs' partial hospitalization program outlier

payments. If a CMHC's cost for partial hospitalization services paid under APC 5853 (Partial Hospitalization for CMHCs) exceeds 3.40 times the payment rate for APC 5853, the outlier payment will be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 5853 payment rate.

Hospitals that fail to report data required for the quality measures selected by the Secretary incur a 2.0 percentage point reduction to their OPPS annual payment update factor, resulting in reduced OPPS payments for most services. For hospitals failing to satisfy the quality reporting requirements, a hospital's costs for the service are compared to the reduced payment level for purposes of determining outlier eligibility and payment amount.

CMS is proposing to use 2022 Medicare claims data to set the 2024 outlier threshold. To model hospital outlier payments and set the outlier threshold for the proposed rule, CMS applied a charge inflation factor of 1.118412 to approximate 2024 charges from 2022 claims.

The proposed rule indicates that CMS is proposing to use hospital-specific overall ancillary CCRs from the April 2023 update to the Outpatient Provider-Specific File to determine the 2024 proposed rule outlier threshold. CMS proposes to adjust the April 2023 CCRs by 0.977799 to approximate 2024 CCRs.

For 2024, CMS proposes a fixed dollar threshold of $8,350 (compared to $8,625 in 2023). 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.

For 2022, CMS estimates that it paid 0.88 percent of total OPPS payments as outliers or 0.12 percentage points less than the 1.0 percent target. Using 2022 Medicare utilization, CMS estimates that it will pay 0.78 percent of total OPPS payments as outliers or 0.22 percentage points than the 1.0 percent target.

III. 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).[3] 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/ASC

[3]CMS recognizes the following codes on OPPS claims: Category I CPT codes (surgical procedures, diagnostic and therapeutic services, and vaccine codes; Category III CPT codes (new and emerging technologies, services, and procedures: MAAA CPT codes (multianalyte assays with algorithmic analyses (MAAA); PLA CPT codes (proprietary laboratory analyses (PLA) services; and Level II HCPCS codes (primarily identify drugs, devices, supplies, temporary procedures and services not described by CPT codes).

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

1. April 2023 Codes - CMS Solicits Public Comments in this Proposed Rule

In the April 2023 OPPS quarterly update, CMS made effective 67 new Level II HCPCS codes and assigned them to interim OPPS status indicators and APCs (Table 6). These codes will be flagged with comment indicator "NP" in Addendum B, indicating the codes have an interim OPPS payment status for 2023.

2. July 2023 HCPCS Codes - CMS Solicits Public Comments in this Proposed Rule

In the July 2023 OPPS quarterly update, CMS made 97 new codes effective and assigned them to interim OPPS status indicators and APCs (Table 7). These codes will be flagged with comment indicator "NP" in Addendum B, indicating the codes have an interim OPPS payment status for 2023.

3. October 2023 HCPCS Codes - CMS Will Be Soliciting Public Comments in the 2024 Final Rule with Comment Period

CMS proposes to provide interim payment status indicators, APC assignments and payment rates, if applicable, for HCPCS codes that will become effective October 1, 2023 in Addendum B to the 2024 final rule. These codes will be flagged with comment indicator "NI" in Addendum B, indicating that the codes have an interim OPPS payment status for 2024. These status indicators and APC assignments will be effective October 1, 2023. CMS will invite public comment in the 2024 OPPS/ASC final rule about the status indicators, APC assignments, and payment rates for these codes and this information will be finalized in the 2025 OPPS/ASC final rule.

4. January 2024 HCPCS Codes

a. New Level II HCPCS Codes – CMS Will Be Soliciting Public Comments in the 2024 Final Rule with Comment Period

CMS will solicit comments on the new Level II HCPCS codes that will become effective January 1, 2024 in the 2024 OPPS/ASC final rule. Unlike the CPT codes that are effective January 1 and included in the OPPS/ASC proposed rules, and except for new C-codes and 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, 2024 will be flagged with comment indicator "NI" in Addendum B, indicating that the codes have an interim OPPS payment status for 2024. CMS will invite public comment in the 2024 OPPS/ASC final rule about the status

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

indicators, APC assignments, and payment rates for these codes and this information will be finalized in the 2025 OPPS/ASC final rule.

b. CPT Codes - CMS Solicits Public Comments in This Proposed Rule

For the 2024 OPPS/ASC update, CMS received the CPT codes that will be effective January 1, 2024 in time to be included in this proposed rule (available in Addendum B of this proposed rule). CMS will continue to assign a new comment indicator "NP" and is requesting comments on the proposed APC assignment, payment rates and status indicators. NP indicates that the code is new for the next CY or the code is an existing code with substantial revision to its code descriptor in the next CY as compared to the current CY, with a proposed APC assignment and comments will be accepted on the proposed APC assignment and status indicator. CMS proposes to finalize the status indicators and APC assignments for these codes in the 2024 OPPS/ASC final rule.

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

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

Table 8: Comment Timeframe for New or Revised HCPCS codes

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	Finalized
April 2023	HCPCS (CPT and Level II Codes)	April 1, 2023	2024 OPPS/ASC proposed rule	2024 OPPS/ASC final rule with comment period
July 2023	HCPCS (CPT and Level II Codes)	July 1, 2023	2024 OPPS/ASC proposed rule	2024 OPPS/ASC final rule with comment period
October 2023	HCPCS (CPT and Level II Codes	October 1, 2023	2024 OPPS/ASC final rule with comment period	2024 OPPS/ASC final rule with comment period
January 2024	CPT Codes	January 1, 2024	2024 OPPS/ASC proposed rule	2024 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2024	2024 OPPS/ASC final rule with comment period	2025 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 resource comparability, 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 Advisory Panel on Hospital Outpatient Payment (also known as the HOP Panel or the Panel) recommendations for specific services for the 2024 OPPS and CMS' responses will be discussed in the 2024 OPPS/ASC final rule.

For 2024, CMS has identified APCs with violations of the 2 times rules and proposes changes to the procedure codes assigned to these APCs in Addendum B (identified with comment indicator "CH"). CMS notes that in many cases, the proposed procedure code reassignments and associated APC configurations for 2024 are related to changes in costs of services that were observed in the 2022 claims data.

2. Proposed APC Exceptions to the 2 Times Rule

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

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

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

Table 9 (reproduced below) lists the 21 APCs that CMS proposes to exempt from the 2 times rule for 2022 based on claims data from January 1, 20212, through December 31, 2022 and processed on or before December 31, 2022.

Table 9: Proposed 2024 APC Exceptions to the 2 Times Rule

APC	APC Title
5012	Clinic Visits and Related Services
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5301	Level 1 Upper GI Procedures

Table 9: Proposed 2024 APC Exceptions to the 2 Times Rule	
APC	**APC Title**
5303	Level 3 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
5572	Level 2 Imaging with Contrast
5612	Level 2 Therapeutic Radiation Treatment Preparation
5627	Level 7 Radiation Therapy
5674	Level 4 Pathology
5691	Level 1 Drug Administration
5692	Level 2 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5741	Level 1 Electronic Analysis of Devices
5811	Manipulation Therapy
5822	Level 2 Health and Behavior Services
5823	Level 3 Health and Behavior Services

C. New Technology APCs

1. New Technology APC Groups

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

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

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

generally considered to be a significant contributor to the APC rate setting calculations and are not included in the assessment of the 2 times rule.

In the 2019 OPPS/ASC final rule, CMS finalized a payment methodology 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.[5] Beginning in 2022, CMS adopted a policy to use the equitable adjustment authority to determine costs for all low-volume services. CMS also designated clinical APCs and brachytherapy APCs with fewer than 100 single claims that can be used for rate-setting as low volume. For low volume APCs, CMS determines the relative weight based on the higher of the APC's geometric mean, median, or the arithmetic mean based on up to 4 years of claim data.

3. Procedures Assigned to New Technology APC Groups for 2023

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

a. Administration of Subretinal Therapies Requiring Vitrectomy (APC 1563)

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 CPT 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 2021 and 2022, CMS assigned C9770 to New Technology APC 1561. Based on the claims date for the 2023 OPPS/ASC final rule, the median cost was the statistical methodology that estimated the highest cost for the service. For 2023, CMS assigned C9770 to APC 1562 (New Technology Level 25 ($3501-$4000)).

CPT code 0810T (Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies) will be effective July 1, 2023. Based on the similarity between C9770 and 0810T, CMS proposes to delete C9770 effective December 31, 2023 and to recognize 0810T starting January 1, 2024. CMS proposes to determine the payment rate using the claims data for C9770. For 2024, there are only 10 single frequency claims from available 2022 claims data.

[5] 83 FR 58892-58893

Using all available claims from the 4-year lookback period, CMS arithmetic mean ($4,192) is the statistical methodology with the highest cost for the service. CMS proposes to use this cost to assign CPT code 0810T to APC 1563 (New Technology-Level 26 ($4001-4500)) for CY 2024 (Table 10).

b. 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 and assigned C9751 to APC 1562. For 2023, CMS continued to assign HCPCS code C9751 to APC 1562. For 2024, the only available claims continue to be from 2019; there were no claims reported for 2020-2022. For 2024, CMS proposes to continue to assign HCPCS code C9751 to APC 1562 (New-Technology-Level 25 ($3501-$4000)) (Table 11).

c. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies (APC 1518,1521, and 1522)
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). Using available 2022 claims data, CPT code 78431 had over 22,000 single frequency claims; CPT code 78432 had only six single frequency claims; and CPT code 78433 had over 1200 single frequency claims. The 2023 and proposed 2024 APC assignments for CPT codes 78431, 78432, and 78433 are included in Table 12. For 2024, CMS proposes to assign CPT codes 78431, 78432, and 78432 to New Technology APCs 1522, 1518, and 1521, respectively. CMS applies its universal low volume APC policy for CPT code 78433.

d. 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 2024, the only available claims continue to be from 2019; there were no claims reported for 2020-2022. For 2024, CMS proposes to continue to assign HCPCS code C9758 to APC 1590 (New-Technology-Level 39 ($15,001-$20,000)) (Table 13).

[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.

e. Corvia Medical Interatrial Shunt Procedure (APC 1592)
Corvia Medical pivotal trial for their interatrial shunt procedure started in Quarter 1 2017 and continued through Quarter 3 of 2021. CMS established HCPCS code C9760 to facilitate the implantation of the Corvia Medical interatrial shunt.[7] For 2022, CMS continued to assign HCPCS code C9760 to New Technology APC 1592. For 2023, there were no claims from 2021 billed with HCPCS code C9760; CMS continued to assign this procedure to APC 1592.

For 2024, there is only one claim for HCPCS code C9760 within the available 2022 claims data. CMS designates C9760 as a low volume service; with the cost approximately $7945 for this service. Based on information CMS received from the manufacturer, CMS is concerned the claim is an outlier and does not accurately reflect the cost of the service. CMS proposes to continue to assign HCPCS code C9760 to APC 1592 (New Technology-Level 41 ($25,001-$30,000)) (Table 14).

f. Supervised Visits for Esketamine Self-Administration (HCPCS codes G2082 and G2083)
Spravato™ (esketamine) nasal spray, was approved by the FDA on March 5, 2019 for treatment of depression in adults with treatment-resistant depression (TRD). Because of the risk of serious outcomes resulting from sedation and dissociated from Spravato administration and the potential for abuse and misuse of the product, Spravato is only available through a restricted distribution system under a REMS; patients must be monitored by a health care provider for at least 2 hours and can be administered only in a certified medical office.

Effective January 1, 2020, CMS created two HCPCS codes (G2082 and G2083) for an outpatient visit for the evaluation and management of an established patient that requires supervision of a physician or other qualified health care professional, provision of esketamine nasal self-administration and 2 hours post-administration observation (G2082 includes 56 mg of esketamine and G2083 is for administration of more than 56 mg esketamine). For 2022, CMS continued to assign HCPCS code G2082 to New Technology APC 1508 and assign HCPCS code G2083 to New Technology APC 1511.

The final 2023 and proposed 2024 APC assignments are summarized below (modified Table 15).

Final 2023 and Proposed 2024 OPPS New Technology APC Assignments for HCPCS Codes G2082 and G2083			
HCPCS Code	Esketamine dosage	Final 2023 APC	Proposed 2024 APC
G2082	Up to 56 mg	1512	1513
G2083	Greater than 56 mg	1516	1518

For 2024, based on available 2022 claims data, G2082 had 294 single frequency claims and G2083 had 1,581single frequency claims date. CMS notes that as it has begun to gather adequate claims

[7] The long descriptor for HCPCS code C9760 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.

data for these codes, it is considering placing these HCPCS codes in clinical APCs in future rulemaking.

g. 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 was effective January 1, 2022.

For 2024, there are no available 2022 claims data. CMS proposes to continue to assign CPT code 0693T to APC 1505 (New-Technology-Level 5 ($301-$400)) (Table 16).

h. Liver Histotripsy Service (APC 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 and 2023, CMS assigned CPT code 0686T to New Technology APC 1575.

For 2024, there were only two claims for CPT code 0686T within the available 2022 claims data. CMS notes that 0686T was still designated as a Category A IDE study for these claims and therefore, the payment for these claims only included payment for the cost of the service. CMS is concerned that the available claims data and universal low volume policy calculations (highest value was the arithmetic mean of $4,480) would not accurately capture the cost of the service following its approval as a Category B IDE study in March, 2023. As a Category B IDE study, Medicare coverage and payment of the device is no longer statutorily prohibited. CMS proposes to maintain CPT code 0686T's current APC assignment to APC 1575 (New Technology-Level 38 ($10,001-$15000)) (Table 17).

i. LiverMultiscan Service (APC 1505)
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. CMS finalized CPT code 0649T, an add-on code, as a packaged service (status indicator "N"). For 2023, CMS continued to assign CPT code 0648T to APC 1511.

For 2024, using available 2020 claims data, CMS identified 39 claims each for CPT codes 0648T and 0649T. Using its universal low volume APC policy, CMS found the arithmetic mean was the statistical methodology that estimated the highest cost for both CPT code 0648T ($320) and for CPT code 0649T ($136). However, in the 2023 OPPS/ASC FR,[8] CMS finalized that SaaS CPT add-on codes are assigned to identical APCs and have the same SI assignments as their standalone codes. Since 0684T is SaaS add-on-code, CMS proposes to assign CPT code 0649T to the identical APC and status indicator as the standalone code for this services, CPT code 0649T. CMS proposes

[8] 87 FR 72032-72033

to assign both CPT codes 0648T and 0649T to APC 1505 (New Technology-Level 5($301-$400)) (Level 18).

j. Minimally Invasive Glaucoma Surgery (MIGS) (APC 5493)
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. For 2023, CMS had no available claims data and continued to assign CPT codes 66989 and 66991 to APC 1526.

For 2024, based on analysis of available 2022 claims data, CMS found a total of 898 single frequency claims and an estimated geometric mean cost of $5,241.55 for CPT code 66989 and 5,576 single frequency claims and an estimated geometric mean cost of $4,957.01 for CPT code 6691. Given the claims volume, CMS believes it is appropriate to reassign these services to a clinical APC using its regular process of using the most recent year of claims data for a procedure. The most appropriate clinical APC family for these codes would be the Intraocular Procedures APC family (APC 5491-5495). CMS is concerned, however, that because of the large payment rate differences between the level 2 Intraocular Procedures APC (APC 5492 payment rate of $3,970.62) and the level 3 Intraocular Procedures APC (APC payment rate of $14,067.62) that assigning these CPT codes to either APC 5492 or 5493 would result in a payment rate that would not reflect the cost of these procedures.

CMS believes it is appropriate to restructure the Intraocular Procedures APC family and proposes to create a sixth level by dividing APC 5492 into two APCs – an APC for services with a geometric mean cost of less than $5,000 and an APC for services with a geometric mean cost of equal or greater than $5,000 (discussed below in section E). Although these services have different estimated geometric mean costs, interested parties have indicated to CMS it is preferable to assign these services within the same APC due to clinical similarities. For 2024, CMS proposes to reassign CPT codes 66989 and 66991 to proposed APC 5493 with a payment rate of approximately $5,110.58 (Table 19).

k. Scalp Cooling (APC 1514)
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 continued to assign CPT code 0662T to APC 1520.

For 2024, CMS identified 11 single frequency paid claims within the available 2022 data. Using its universal low volume APC policy, CMS found the arithmetic mean was the statistical methodology that estimated the highest cost ($1284.59). CMS proposes to reassign CPT code 0662T to APC 1514 (New Technology-Level 14 ($1202-$1300) (Table 20).

l. 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 codes 0721T and 0722T became effective July 1, 2022. For 2022, CMS assigned these codes to APC New Technology 1508. For 2023, CMS continued to assign them to APC 1508.

For 2024, there are no available claims for these codes in the available 2022 data. CMS proposes to continue assigning CPT codes 0721T and 0722T to New Technology APC 1508 (New Technology-Level 8 ($601-$700) (Table 21).

m. Quantitative Magnetic Resonance Cholangiopancreatography (QMRCP) (APC 1511)
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 and 0724T became effective July 1, 2022. For 2022, CMS assigned CPT code 0723T and 0724T to APC New Technology APC 1511. For 2023, CMS continued to assign these codes to APC 1511.

For 2024, there are no available claims for these codes in the available 2022 data. CMS proposes to continue assigning CPT codes 0723T and 0724T to New Technology APC 1511 (New Technology-Level 11 ($901-$1000) (Table 22).

n. CardiAMP (APC 1590)
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 continued to assign HCPCS code C9782 to APC 1590.

For 2024, there are no available claims for C782 in the available 2022 data. CMS proposes to continue assigning C782 to New Technology APC 1590 (New Technology-Level 39 ($15,001-$20,000) (Table 23).

o. Surfacer® Inside-Out® Access Catheter System (APC 1534)
HCPCS code C9780 describes the procedure associated with the use of the Surfacer Inside-Out Access Catheter System that is designed to address central venous occlusion. HCPCS code C9780 was established on October 1, 2021 and since its establishment has been assigned to APC 1534.

For 2024, there are no available claims for C9780 in the available 2022 data. CMS proposes to continue assigning C9780 to New Technology APC 1534 (New Technology-Level 34 ($8001-

$8500) (Table 24).

p. Insertion or replacement of neurostimulator system for treatment of central sleep apnea; complete system (APC 1580)
CPT code 0424T is associated with the use of the Remede® System used to treat adult patients with moderate to severe Central Sleep Apnea. The code was effective January 1, 2016 and assigned to Comprehensive APC 5464 (Neurostimulator and Related Procedures APC-Level 4). For 2021, CMS created a 5-level structure for the APC family and assigned CPT code 0424T to Level 5. In the 2023 OPPS/ASC final rule, CMS recognized that CPT code 0424T was not appropriately assigned to the C-APC 5465 and the code was assigned to New Technology APC 1581.

For 2024, there are only 30 claims for CPT code 0424T in the available 2022 data. Using its universal low volume APC policy, CMS found the arithmetic mean was the statistical methodology that estimated the highest cost ($49,468). CMS proposes to reassign this service to APC 1580 (New Technology-Level 43 ($40,001-$50,000). CMS notes that for 2024, CPT is deleting 0424T and replacing it with placeholder code 3X008 (Table 25).

q. Cleerly Labs (APC 1511)
Cleerly Labs is a SaaS that assesses the extent of coronary artery disease severity using Atherosclerosis Imaging-Quantitative Computer Tomography (AI-QCT). The procedure quantifies the extent of coronary plaque and stenosis in patients who had coronary computed tomography analysis (CCTA). CPT codes 0623T-0626T were effective January 1, 2021; CMS assigned these codes to status indicator "E1" to indicate these codes are not payable by Medicare on an outpatient claim because the service has not received FDA clearance. In the October 2022 OPPS Update CR9 CMS reassigned CPT 0625T to status indicator "S" (Significant Procedures, Not Discounted when Multiple. Paid under separate APC payment) and APC 1511.

For 2024, there are only 90 claims for CPT code 0625T in the available 2022 data. Using its universal low volume APC policy, CMS found the arithmetic mean was the statistical methodology that estimated the highest cost ($4.10) which would assign this code to New Technology 1491 (New Technology-Level 1A (0-$10). Because the CPT code was only made separately payable in October 2022 and only reflects two months of data, CMS is concerned that it does not have sufficient data to justify reassignment of this service to another New Technology APV. Therefore, for FY 2024, CMS proposes to continue to assign CPT code 0625T to New Technology APC 1511(New Technology-Level 11 ($901-$1000)) (Table 26).

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

[9] Change Request 12885, Transmittal 11594, dated September 9, 2022

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. CMS also excludes APC 2698 and 2999 for brachytherapy sources "not otherwise specified" from this policy because its methodology for determining non-specified brachytherapy sources is appropriate and uses external data sources.

For 2024, CMS proposes to apply this policy to five clinical APCs and five brachytherapy APCs, all of which are low-volume for 2022 (Table 27).

E. APC-Specific Policies: Intraocular Procedures

Based on its review of the available 2022 claims data, CMS proposes to establish a six-level APC structure for the Intraocular Procedure series. CMS believes this will allow for a smoother distribution of the costs between the different levels based on their resource costs and clinical characteristics. Specifically, CMS proposes to create a sixth level in this family by dividing APC 5492 into two APCs – an APC for services with a geometric mean cost of less than $5,000 and an APC for services with a geometric mean cost of equal or greater than $5,000. CMS proposes to reassign two codes for minimally invasive glaucoma surgery CPT codes 66989 and 66991) to proposed new Level 3 APC.

IV. Payment for Devices

A. Transitional Pass-Through Payments for Devices

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

Transitional device pass-through payments are intended for beneficiaries to have access to new and innovative devices by providing for adequate payments for new devices while the necessary cost data is collected to incorporate the device costs into the procedure APC rate.[10] 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/ASC final rule, CMS finalized a 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.

In the 2023 OPPS/ASC final rule, CMS finalized it would publicly post online OPPS device pass-through applications received on or after March 1, 2023, beginning with the issuance of the 2025 proposed rule.

[10] 87 FR 72032-72033

In the 2022 OPPS/ASC final rule, due to the PHE, CMS used 2019 claims data rather than 2020 claims data for ratesetting. CMS utilized its equitable adjustment authority at section 1833(t)(2)(E) of the Act to provide up to four quarters of separate payment for one device category (C1823) whose pass-through payment status expired between December 31, 2021 and September 30, 2022. Section 4141(a)(2) of the Consolidated Appropriations Act, 2023 (CAA, 2023) extended the device pass-through status for a 1-year period beginning January 1, 2023 for device categories whose period of pass-through status would have ended on December 31, 2022. Five device categories had their pass-through status extended under this provision; pass-through status for these device categories began on January 1, 2020.

Currently, there are 15 device categories eligible for pass-through payment. Table 28 (reproduced below) lists the devices and their pass-through expiration.

Table 28: Devices with Pass-Through Status Expiring in the Fourth Quarter of 2023, 2024 or 2025

HCPCS Codes	Long Descriptor	Effective Date	Pass-Through Expiration Date
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
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	9/20/2024
C1832	Autograft suspension, including cell processing and application, and all system components	1/1/2022	12/31/2024
C1833	Monitor, cardiac, including intracardiac lead and all system components (implantable)	1/1/2022	12/31/2024
C1826	Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system	1/1/2023	12/31/2025
C1827	Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller	1/1/2023	12/31/2025
C1747	Endoscope, single-use (i.e., disposable) urinary tract, imaging/illumination device (insertable)	1/1/2023	12/31/2025

*Device for which pass-through status was extended for a 1-year period by section (a)(2) of the CCA, 2023.

2. New Device Pass-Through Applications

a. Background

Criteria for New Device Pass-Through Applications.

Existing regulations at §419.66(b)(1) through (b)(3) specify that, to be eligible for transitional pass-through payment under the OPPS a device must meet the following criteria:

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

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

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

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

- Not appropriately described by an existing category or any category previously in effect established for transitional pass-through payments, and was not being paid for as an outpatient service as of December 31, 1996;

- Has an average cost that is not "insignificant" relative to the payment amount for the procedure or service with which the device is associated as determined under §419.66(d) by demonstrating all of the following:

(1) The estimated average reasonable costs of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices;
(2) The estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent; and
(3) The difference between the estimated average reasonable cost of the device in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service (with the exception of brachytherapy and temperature-monitored cryoablation, exempted from the cost requirements at §419.66(c)(3) and §419.66(e)); and

- Demonstrates a substantial clinical improvement: substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment, or, for devices for which pass-through payment status will begin on or after January 1, 2020, as an alternative pathway to demonstrating substantial clinical improvement, a device is part of the FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.

In 2016, CMS changed the OPPS device pass-through payment evaluation and determination process. Device pass-through applications are still submitted through the quarterly subregulatory process, but the applications are subject to notice-and-comment rulemaking in the next applicable OPPS/ASC 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.[11] 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

[11] 84 FR 61295

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 six complete applications by the March 1, 2023 quarterly deadline, the last quarterly deadline in time for this proposed rule; two of the applications were for devices eligible under the alternative pathway. In addition, an application was approved for device pass-through status during the quarterly review process: MY01 Continuous Compartmental Pressure Monitor was conditionally approved as HCPCS code C1834 on October 1, 2022. After addition review, CMS determined the conditional review was an error and deleted code C1834 on March 31, 2023.

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

i. Alternative Pathway Device Pass-Through Applications

(a) CavaClear Inferior Vena Cava (IVC) Filter Removal Laser Sheath

Phillips North America, LLS submitted an application for the CavaClear IVC Filter Removal Laser Sheath (CavaClear), a device intended for tissue ablation in the removal of embedded IVC filters that have failed a previous retrieval method. Per the applicant, the device facilitates detachment of IVC filters from the IVC wall using ultraviolet laser energy and subsequent collapse of the filter, partially within the laser sheath and entirely with the introducer sheath.

Eligibility
Newness. CavaClear was designated as a Breakthrough Device on April 23, 2021 for the ablation of tissue in the removal of IVC filters that have failed a previous retrieval method. FDA granted De Novo classification on December 21, 2021 for the same indication. CMS received the pass-through application on May 30, 2022, which is within 3 years of the date of the initial FDA marketing authorization.

Additional eligibility criteria. According to the applicant, CavaClear meets all the eligibility requirements at §419.66(b)(4).

Establishing a New Device Category
(i) Existing payment category. The applicant stated that no previous device categories for pass-through payment appropriately describe CavaClear. According to the applicant, existing pass-through code C2629 (Introducer/sheath, other than guiding, other than intracardiac electrophysiological, laser) does not appropriately describe CavaClear for several reasons: CavaClear uses a unique laser mechanism of action; CavaClear is not intended to remove pacemaker and defibrillator leads like the products described by C2629; and CavaClear impacts

different anatomy than the products described by C2629. In addition, the applicant noted that FDA granted CavaClear De Novo classification, indicating there is no legally marketed predicate device for CavaClear.

CMS notes that based on the description provided by the applicant, CavaClear is a laser sheath intended for use in the IVC, which is not intracardiac, and thus could be encompassed by the descriptor of C2629. CMS also believes that the existing pass-through payment category C1773 (Retrieval device, insertable (used to retrieve fractured medical device)) may appropriately describe CavaClear. CMS states C1773 is a broad category descriptor for a device that retrieves another device within a patient's vascular system. CMS believes CavaClear may be similar to devices described by C2629 and C1773 and therefore may be appropriate described by C2629 and C1773.

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

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

(iii) Cost. The applicant stated that CavaClear would be reported with HCPCS code 37193 (Table 29). CMS believes CavaClear meets all the cost criteria.

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

(b) CERAMENT® G

BONESUPPORT Inc. submitted an application for CERAMENT G, a single-use implantable bone-void filler combination device/drug that is an adjunct to systemic antibiotic therapy and is used when supplemental bone void filler material is needed. Per the applicant, CERAMENT G is comprised of three key components (hydroxyapatite (HA), calcium sulfate (CaS) and gentamicin sulfate) and five other components for delivery of the key components.

Eligibility

Newness. CERAMENT G was designated as a Breakthrough Device on March 12, 2020 as a resorbable, gentamicin-eluting ceramic bone graft substitute intended for use as a bone filler as an adjunct to systemic antibiotic therapy and surgical debridement (standard treatment for a bone infection) as part of the surgical treatment of osteomyelitis. FDA granted the applicant De Novo classification for CERAMENT G under the generic name (resorbable calcium salt bone void filter containing a single approved aminoglycoside antibacterial substance) on May 17, 2020 for the same indication as the Breakthrough Device designation. CMS received the pass-through application on May 17, 2022, which is within 3 years of the date of the initial FDA marketing authorization.

Additional eligibility criteria (§419.66(b)(4)). The applicant did not indicate that CERAMENT G meets the additional eligibility criteria. However, the applicant did indicate that CERAMENT G is used for only one patient, comes in contact with human tissue, and is surgically implanted or inserted into the patient. The applicant did not address whether CERAMENT F is equipment, an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered or if CERAMENT G is a supply or material furnished incident to a service.

CMS invites comments on whether CERAMENT G meets this eligibility requirements.

Establishing a New Device Category

(i) Existing payment category. The applicant stated that CERAMENT G differs from the bone substitutes AUGMENT® and AUGMENT® Injectable (devices described by HCPCS code C1734). CMS notes that it approved an application for AUGMENT Bone Graft as a new device category for transitional pass-through payment status and established HCPCS code C1734 as a new device category beginning in 2020.[12] The applicant describes how CERAMENT G and AUGMENT differ in terms of the composition and mechanism of action. In addition, the applicant stated these devices are intended for different groups of patients.

CMS notes that based on the description provided by the applicant, CERAMENT G and AUGMENT differ in terms of composition and intended use, but that device categories are not intended to be device specific. When CMS evaluates a potential pass-through device to determine whether it meets the device category criterion, it compares the subject device to the device category descriptor rather than to the specific device for which the device category was created. Device category C1734 describes any device that meets the following descriptor: Orthopedic/device/drug/matric for opposing bone-to-bone or soft-tissue-to-bone (implantable). The applicant described CERAMENT G as an implantable device/drug matrix intended to oppose soft-tissue-to-bone. CMS believes CERAMENT G may be similar to devices described by C1774 and therefore may be appropriate described by C1774.

CMS invites public comment on whether the CERAMENT G meets the device category criterion.

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

(iii) Cost. The applicant stated that CERAMENT G would be reported with 30 HCPCS codes (Table 30). CMS believes CERAMENT G meets all the cost criteria.

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

[12] 84 FR 61292-61294

ii. Traditional Device Pass-through Applications.

(a) Ambu® aScope™ 5 Broncho HC

Ambu Inc. submitted an application for the Ambu aScope 5 Broncho HD, a single-use imaging/illumination bronchoscope. The Ambu aScope 5 Broncho HD System consists of two components: the Ambu aScope 5 Broncho HD and the Ambu aBox, a compatible reusable display unit. The applicant is only seeking transitional pass-through payment status for the Ambu aScope 5 Broncho HD component.

Newness. The Ambu aScope 5 Broncho HD received 510(k) clearance on July 25, 2022 as a device to be used for endoscopic procedures and examination with the airways and tracheobronchial tree. CMS received the application on February 28, 2023, which is within 3 years of the date of the initial FDA market authorization.

Eligibility. With respect to the eligibility criteria at §419.66(b)(3), the applicant stated the Ambu aScope 5 Broncho HD is integral to the service provided and is used for only one patient, comes in contact with human tissue, and is surgically inserted. The applicant did not address whether the Ambu aScope 5 Broncho HD is equipment, an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered or if it is a supply or material furnished incident to a service.

CMS invites comments on whether the Ambu aScope 5 Broncho HD meets the eligibility criteria.

Establishing a New Device Category.
Existing Payment Category. The applicant identified two possible existing pass-through device categories: C1748 (Endoscope, single use (i.e., disposable), upper GI, imaging/illumination device (insertable)); and C1747 (Endoscope, single use (i.e., disposable), urinary tract imaging/illumination device (insertable)). The applicant noted that these two codes are for single-use endoscopic devices but they are appropriate for GI and urinary tract, respectively. CMS notes that while C178 and C1747 are intended to be used in different anatomical areas of the patient, the codes for both device categories describe devices that are single use and have imaging capabilities.

Substantial Clinical Improvement. The applicant stated that the Ambu aScope 5 Broncho HD represents a substantial clinical improvement because it is associated with (1) elimination of complex cleaning/reprocessing procedures; (2) reduction of microbial transmission infection since it is single-use; (3) elimination for continuous training of reprocessing staff; (4) minimization of the risk of patient cross-contamination; (5) assurance that a sterilized scope will be used each time; and (6) assurance there will be no biofilm from endoscope channels. The applicant provided four articles, an FDA guidance letter, and an FDA safety notice to support these assertions.

CMS summarizes this information and discusses specific concerns with the submitted information. CMS is concerned that the Ambu aScope 5 Broncho HD might not be sufficiently different from

similar devices on the market[13] and the earlier versions of the device to demonstrate substantial clinical improvement. CMS notes that the FDA 510(k) summary indicated that the Ambu aScope 5 Broncho HD shares similar technologic and technical characteristics to prior models. CMS is concerned that four of the articles submitted provided data on the applicant's earlier models of the device and did not provide comparisons to the nominated device. In addition, the studies did not compare the nominated device to an appropriate comparator such as a single-use bronchoscope from a different manufacturer or a standard reusable bronchoscope in a clinical trial. CMS concludes that none of the articles submitted show any clinical improvement results.

CMS also notes that the submitted FDA safety notice provided preliminary information regarding infections associated with the use of reprocessed flexible bronchoscopes, but did not discuss or recommend the use of disposable, single-use devices. CMS concludes it does not have sufficient information on the prevalence of infection to evaluate the applicant's substantial clinical improvement claims for the Ambu aScope 5 Broncho HD.

Cost. The applicant stated that Ambu aScope 5 Broncho HD would be reported with 43 HCPCS codes (Table 31). CMS believes the Ambu aScope 5 Broncho HD meets all the cost criteria.

CMS invites comments on whether the Ambu aScope 5 Broncho HD meets the device pass-through payment criteria.

(b) Praxis Medical CytoCore

Praxis Medical submitted an application for the Praxis Medical CytoCore (CytoCore), a motorized, single-use biopsy gear and an internal motor that spins a minimally invasive needle during biopsy to increase cellular yields in fewer passes.

Newness. The CytoCore received 510(k) clearance on March 31, 2020 as a device to hold a syringe for performing a biopsy of an identified mass with one hand. CMS received the application on August 31, 2022, which is within 3 years of the date of the initial FDA market authorization.

Eligibility. With respect to the eligibility criteria at §419.66(b)(3), the applicant did not indicate whether CytoCore is integral to the service provided. According to the applicant, CytoCore is used for only one patient, comes inro contact with human tissue, and is surgically inserted via the syringe attached to the motorized CytoCore device. The applicant indicated that CytoCore is used with a 22- to 25-gauge fine needle which is inserted into human tissues to collect cellular samples. CMS notes that the motorized CytoCore device itself is not surgically implanted or inserted (either permanently or temporarily) or applied in or on a wound or other skin lesion, as required at §419.66(b)(3). In addition, according to the FDA 510(k) Summary and Indication for Use, CytoCore is a device to hold a syringe for performing a biopsy of an identified mass with one hand

[26]The applicant identified six reusable devices it believed are most closely related to the Ambu aScope 5 Broncho HD: Olympus Evis Exera Iii Brochovideoscope Bf-h190; Pentax EB-J10 Video Bronchoscope; Fujifilm EV-580S Video Bronchoscope; Olympus BF-Q190; and Olympus BF-XT190.

and that the device never comes in contact with the patient. The applicant did not address the eligibility criteria at §419.66(b)(4).

CMS reviews prior rulemaking where it stated it does not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted.
In the 2000 OPPS interim final rule,[14] CMS stated it considers a device to be surgically implanted or inserted if it is surgically inserted or implanted via a natural or surgically created orifice, or inserted or implanted via a surgically created incision. CMS does not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted. CMS considers items used to create incisions, such as scalpels, electrocautery units, biopsy apparatuses, or other commonly used operating room instruments, to be supplies or capital equipment not eligible for transitional pass-through payments. In the 2006 OPPS final rule,[15] CMS adopted as final its interpretation that the surgical insertion or implantation criterion can be met by devices that are surgically inserted or implanted via a natural or surgically created orifice, as well as those devices that are inserted or implanted via a surgically created orifice.

CMS invites comments on whether the CytoCore meets the eligibility criteria.

Establishing a New Device Category.
Existing Payment Category. The applicant indicated there are no previous device categories for pass-through payment that encompassed the device. CMS has not identified an existing pass-through payment category that describes CytoCore.

Substantial Clinical Improvement. The applicant claimed that the use of CytoCore results in substantial clinical improvement over existing technologies by (1) reducing tissue trauma and bleeding; (2) increasing cellular harvest; (3) reducing passes required, clinical invasiveness; and (4) reducing nondiagnostic biopsy results follow-up. The applicant provided one article and one conference poster to support these claims.

CMS summarizes this information and discusses specific concerns with the submitted information. CMS is concerned that one study is an updated conference poster presentation and it is not clear whether it has been submitted for publication to a peer-reviewed journal. CMS notes the study used a small sample size and was limited to one radiology location. CMS is also concerned with the generalizability and validity of the findings. CMS has many concerns about the second document, an article that is undated and does not list the authors or location of the study. CMS discusses many limitations of the article, including the lack of a direct comparison group and no explanation of how the authors identified the articles used to compare the performance of CytoCore.

CMS is also concerned that CytoCore may not demonstrate that it substantially improves the diagnosis or treatment of an illness when compared to the benefits of other available treatments. The FDA 510(k) summary indicates that CytoCore was substantially equivalent to the TAO Aspirator and Plastic Finger. In addition, although the applicant distinguishes CytoCore from a

[14] 65 FR 67789, 65 FR 67804-67805
[15] 70 FR 68516, 70 FR 68629 and 68630.

comparator device, BioPince, CMS believes that BioPince is a large gauge full core firing biopsy that is not recommended for use in the head/neck, the anatomic region the applicant indicates CytoCore is used, Thus, CMS does not think that a comparison with BioPince supports the argument of substantial clinical improvement.

Cost. The applicant stated that CytoCore would be reported with 3 HCPCS codes (Table 32). CMS believes CytoCore meets all the cost criteria.

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

(c) EchoTip® Insight Portosystemic Pressure Gradient Measurement System (EchoTip)

Cook Medical submitted an application for EchoTip, a single-use disposable device used in conjunction with an ultrasound endoscope to directly measure pressures in the hepatic and portal venous vasculatures.

Newness. FDA granted De Novo classification on November 20, 2019 for EchoTip as a device to directly measure pressure in the hepatic and portal venous vasculatures and is used in conjunction with an ultrasound endoscope. CMS received the application on June 29, 2022, which is within 3 years of the date of the initial FDA market authorization.

Eligibility. The applicant stated the EchoTip meets all the eligibility criteria at §§419.66(b)(3) and 419.66(4).

CMS invites comments on whether the EchoTip meets the eligibility criteria.

Establishing a New Device Category.
Existing Payment Category. The applicant indicated there are no previous device categories for pass-through payment that encompassed the device. CMS has not identified an existing pass-through payment category that describes CytoCore.

Substantial Clinical Improvement. The applicant claimed that EchoTip represents a substantial clinical improvement over existing technologies in the diagnosis and management of chronic liver disease because (1) Endoscopic ultra-sound-guided direct portal-systemic pressure gradient measurement (EUS-PPG)-guided measurement is safer and more accurate than the current standard transjugular endovascular indirect measurement, the hepatic venous pressure gradient (HCPG); (2) EUS-PPG is technically feasible and superior to HVPG; (3) EUS-PPG has benefits in non-cirrhotic patients; and (4) EUS-PPG has utility in the evaluation of End-Stage Renal Disease (ESRD) patients and kidney transplant candidacy. The applicant provided four articles and a letter to a journal editor describing a study to support their claims. The applicant also included a background article that discussed social determinants of health and disparities in liver disease.

CMS summarizes this information and discusses specific concerns with the submitted information. CMS is predominately concerned that the evidence submitted does not include a direct comparison of EUS-PPG with HVPG and other non-invasive methods, a lack of consistent correlation with liver biopsy, the reliance on non-peer reviewed studies and small sample sizes.

CMS notes the letter to the editor indicated that future studies are needed to correlate EUS-PPG with HVPG. CMS states that additional supporting evidence, preferable published peer-reviewed clinical trials that show improved clinical outcomes would be helpful.

Cost. The applicant stated that EchoTip would be reported with 2 HCPCS codes, 43237 and 43238 (Table 33). CMS believes Echo Tip meets all the cost criteria.

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

(d) FLEX Vessel Prep™ System

Venture Med Group, Inc. submitted an application for the FLEX Vessel Prep System (FLEX VP), an endovascular, over-the-wire, retractable, sheathed catheter with a three-strut treatment element at the distal tip to help resolve stenoses occluding vascular access in patients with ESRD on hemodialysis.

Newness. The FLEX VP received 510(k) clearance on September 11, 2020 for use with percutaneous transluminal angioplasty (PTA) catheters to facilitate dilation of stenosis in the femoral and popliteal arteries and treatment of obstructive lesions or native or synthetic arteriovenous (AV) dialysis fistulae. The device is also indicated for treatment of in-stent restenosis of balloon expandable and self-expanding stents in the peripheral vasculature. CMS received the application on February 28, 2023, which is within 3 years of the date of the initial FDA market authorization.

Eligibility. The applicant stated the EchoTip meets all the eligibility criteria at §§419.66(b)(3) and 419.66(4).

CMS invites comments on whether the FLEX VP meets the eligibility criteria.

Establishing a New Device Category.
Existing Payment Category. The applicant indicated there are no previous device categories for pass-through payment that encompassed the device. CMS has not identified an existing pass-through payment category that describes FLEX VP.

Substantial Clinical Improvement. The applicant stated that FLEX VP represents a substantial clinical improvement over existing technologies by: (1) improving clinical outcomes for the hemodialysis patient population with dysfunctional AV access; and (2) reducing the rate of device-

rated complications. The applicant cited two studies describing the findings of a single clinical trial. The applicant also submitted an unpublished manuscript that did not identify an author.

CMS summarizes this information and discusses specific concerns with the submitted information. The applicant presented two studies with 6-month follow-up and an unpublished manuscript based on a single clinical trial of 114 patients followed for 12 months. The applicant stated that the results from the 6-months follow-up are not yet published and the 12-months post-treatment is also unpublished and only available at the FLEX VP registry. CMS is concerned that the evidence presented is not peer-reviewed. CMS notes as it considers supporting evidence, it prefers published peer-reviewed clinical trials that show improved clinical outcomes. CMS is also concerned that due to the clinical trial design, there is insufficient data on the impact of angioplasty with the drug-coated balloon. CMS also discusses concerns with the report of device-related complications observed in the trial and compared to referenced literature.

Cost. The applicant stated that FLEX VP would be reported with 4 HCPCS codes (Table 34). CMS believes the FLEX VP meets all the cost criteria.

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

B. Device-Intensive Procedures

1. Device-Intensive Procedure Policy for 2019 and Subsequent Years

For 2019 and subsequent years, in the 2019 OPPS/ASC final rule,[16] 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;

[16] 83 FR 58944-58948

- 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 temporarily assigning a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer.[17] 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. 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 its 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.

The full listing of proposed 2024 device-intensive procedures provided in Addendum P.[18]

2. Device Edit Policy

In the 2017 OPPS/ASC 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

[17] 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/ASC proposed rule or as a public comment to a proposed rule.
[18] Addendum P is available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.

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.

APC 5495 (Level 5 Intraocular APC). In the 2023 OPPS/ASC final rule (87 FR 71830), CMS described a commenter's concern about potential inadequate payment for APC 5495 and recommendation that CMS use its equitable authority to limit potential reductions in the payment rate by applying a 10 percent cap on the reduction in relative weights for Low Volume APCs (fewer than 100 claims in a claims year). CMS disagreed but stated it would continue to monitor the costs and payment rates for procedures assigned to Low Volume APCs.

CMS discusses its review of claims data for CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis). CMS noticed unusual coding, charge and cost data in claims from 2017-2021. Claims that reported the correct device code had an average device cost of $15,030.04 while claims that did not report the correct device code had an average device cost of $430.72. CMS notes that because of the very low volume of claims for this APC, although the vast majority of claims did report the correct device code, the limited number of claims that either reported the wrong procedure code or the wrong device code had an outsized impact on the APC payment rate. CMS concludes that because payment stability for this Low Volume APC is dependent on accurate reporting of the procedure's associated cost, it believes this APC would benefit from a procedure-to-device edit. The procedures associated with the Level 5 Intraocular APC are CPT codes 0308T and 0616T-0618T; CMS proposes to reassign these procedures to a new Level 6 Intraocular APC (APC 5496) (discussed above in section III.E).

CMS proposes to establish a procedure-to-device edit for the four CPT codes (0308T and 0616T-0618T) assigned to proposed APC 5496 and require hospitals to report the correct device HCPCS code when reporting any of the four procedures. CMS notes that some stakeholders have previously recommended that it reestablish all of the previous procedure-to-device edits but it does not plan to extend this policy to other procedures. CMS continues to rely on hospitals' accurate reporting and not establish an additional device reporting edit that is a burden on hospitals. CMS believes this APC represents a unique situation because the APC has been a Low Volume APC since establishment of the Low Volume APC policy and given the low volume would not be administratively burdensome to hospitals.

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.

CMS determines the procedures to which this policy applies using three criteria:

- All procedures must involve implantable devices that would be reported if device-insertion procedures were performed;
- The required devices must be surgically inserted or must be implanted devices that remain in the patient's body after the conclusion of the procedure (even if temporary); and
- The procedure must be device-intensive (devices exceeding 30% of the procedure's average costs).

For 2024, CMS is not making any changes to these policies.

V. Payment 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 transitional pass-through payments. 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 (proposed at $140 for 2024) to be paid separately. For a separately payable drug that exceeds the packaging threshold, CMS will make payment at average sales price (ASP)+6 percent (unless ASP is unavailable as explained below).

If a drug or biological is not policy packaged, threshold packaged or separately paid above the packaging threshold, it may be separately paid based transitional pass-through payments.

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

Section 1833(t)(6) of the Act provides for temporary additional payments or transitional pass-through payments for certain drugs and biologicals. For transitional pass-through payment

purposes, radiopharmaceuticals are "drugs." As required by statute, transitional pass-through payments for a drug or biological can be made for at least 2 years, but not more than 3 years, after the payment was first made under the OPPS. Proposed transitional pass-through drugs and biologicals for 2024 and their designated APCs are assigned status indicator "G" in Addenda A and B of the proposed rule. For 2024, CMS proposes to continue using ASP+6 percent as payment for transitional pass-through drugs and biologicals. CMS also proposes to pay for diagnostic and therapeutic radiopharmaceuticals receiving transitional pass-through payment at ASP+6 percent.

CMS approves transitional 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 35 of the proposed rule lists 43 drugs and biologicals where CMS proposes to expire transitional pass-through payment at the end of 2023. Each of the products will have received at least the full 3 years of transitional pass-through payments once the additional payments expire. Table 36 of the proposed rule lists 25 drugs where CMS proposes to end transitional pass-through payment status in 2024. Table 37 of the proposed rule lists 42 drugs and biologicals where CMS will continue transitional pass-through payment for all of 2024.

When policy packaged or threshold drugs and biologicals are paid on transitional 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 transitional pass-through as there is no payment included in the APC for the drug. Table 38 of the proposed rule lists the APCs where CMS will apply an offset for policy packaged drugs paid on transitional 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. However, the actual file does not appear to be available at the time of this writing.

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

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

a. Cost Threshold for Packaging of "Threshold-Packaged Drugs"

For 2024, CMS is proposing to establish a packaging threshold of $140 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 proposed 2024 threshold, CMS used the most recently available four quarter moving average Producer Price Index forecast levels for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) to trend the $50 threshold forward from the third quarter of 2005 to the third quarter of 2024. CMS rounds the resulting dollar amount ($138.44) to the nearest $5 increment ($140).

CMS proposes to continue using the following process to determine the 2024 packaging status for all non-transitional 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 2022 claims data processed through June 30, 2022,[19] 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 2022 and were paid (either as packaged or separate payment) under the OPPS.

To calculate the per day cost for the proposed rule, CMS uses ASP+6 percent for each HCPCS code with manufacturer-submitted ASP data from the 4th quarter of 2022 (data that will be used to pay for drugs and biologicals in physicians' offices effective April 1, 2023). For products that do not have an ASP, such as some therapeutic radiopharmaceuticals, CMS will use their mean unit cost derived from 2022 hospital claims data. CMS proposes to package payment for products with a per day cost of $140 or less and pay separately for items with a per day cost greater than $140 in 2024.

CMS uses quarterly ASP updates as follows:

- 4th quarter of 2022: Per day cost, budget neutrality estimates, packaging determinations, impact analyses, and Addenda A and B for the 2024 OPPS proposed rule;[20]
- 2nd quarter of 2023: Per day cost, budget neutrality estimates, packaging determinations, impact analyses, and Addenda A and B for the 2024 OPPS final rule; and
- 3rd quarter of 2023: Payment rates effective January 1, 2024 for separately payable drugs and non-implantable biologicals; these are the same ASP data used to calculate payment rates effective January 1, 2024 for drugs and biologicals furnished in the physician office setting.

ASP-based payment rates for both the OPPS and physician office settings are updated quarterly using reported ASP data with a two-quarter lag, and these updates are available on the CMS website. CMS is proposing to continue its policy of making an annual packaging determination for a HCPCS code in the OPPS final rule and not updating that code's packaging status during the year. Only HCPCS codes that are identified as separately payable in the 2024 final rule will be subject to quarterly updates.

[19] The proposed rule indicates that CMS will use claims processed and paid through June 30, 2022 but this is likely a typographical error and CMS meant to say March 31, 2023 consistent with past practice and the data it typically uses to set the relative weights. HPA has queried CMS about the accuracy of this sentence.
[20] There appears to be a typographical error here as well. CMS indicates that Addenda A and B are based on ASP data from the 2nd quarter of 2023. However, that data would not be available for the proposed rule but is traditionally the data that CMS would use for the final rule Addenda. CMS's historical practice is consistent with how we have stated this point.

As in past years, CMS is proposing to apply the following policies to determine the 2024 packaging status of a threshold-packaged drug when the drug's packaging status, as calculated for the final rule using more current data, differs from its status in the proposed rule.

- HCPCS codes that are separately payable in 2023 and were proposed for separate payment in 2024 are separately payable in 2024 even if the updated data used for the 2024 final rule indicate per day costs equal to or less than the $140 threshold.
- HCPCS codes that are packaged in 2023, proposed for separate payment in 2024, and have per day costs equal to or less than $140 based on the updated data used for the 2024 final rule are packaged in 2024.
- HCPCS codes for which CMS proposed packaged payment in 2024 and have per day costs greater than $140 based on the updated data used for the 2024 final rule are separately payable in 2024.

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

For 2024, CMS is proposing to continue its policy of making packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis in the case of multiple HCPCS codes describing the same drug or biological but with different dosages. The codes to which this policy applies, and their packaging status, are listed in Table 39 of the proposed rule.

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

As indicated above, CMS proposes to pay for separately payable drugs and biologicals at ASP+6 percent in 2024. Consistent with policy in the PFS, CMS will pay for drugs and biologicals under the OPPS during an initial sales period (2 quarters) for which ASP pricing data are not yet available from the manufacturer at wholesale acquisition cost (WAC)+3 percent. The WAC+3 percent payment under the OPPS will only apply to new drugs and biologicals in an initial sales period. Other drugs and biologicals where ASP data are not available will continue to be paid at WAC+6 percent as required by statute. If ASP and WAC are unavailable, Medicare will pay 95 percent of AWP.

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

The payment rates shown for drugs and biologicals in Addenda A and B of the proposed rule are not the payment rates that Medicare will pay on January 1, 2024. Payment rates effective January 2024 will be released near the end of December 2023 and will be based on ASP data submitted by manufacturers for the third quarter of 2023 (July 1, 2023 through September 30, 2023).

Payment rates for drugs and biologicals in Addenda A and B of the proposed rule for which there was no ASP information available for the 4th quarter of 2022 (used for payment in physician's offices for the 2nd quarter of 2023) are based on mean unit cost in the available 2022 claims data. If ASP information becomes available for the quarter beginning in January 2024, CMS will pay for these drugs and biologicals based on the newly available ASP information.

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

For 2024, CMS discusses how biosimilars are affected by two provisions of the Inflation Reduction Act (IRA). Effective July 1, 2024, the first provision limits payment for a biological in its initial period when ASP is unavailable to the lesser of:

> (1) an amount not to exceed 103 percent of the WAC of the biosimilar or the Medicare Part B drug payment methodology in effect on November 1, 2003, or
>
> (2) 106 percent of the lesser of the WAC or ASP of the reference biological, or in the case of a selected drug during a price applicability period, 106 percent of the maximum fair price of the reference biological.

The "price applicability period" refers to a Part B drug or biological that will be subject to a maximum fair price effective in 2028 that will be set as result of price negotiations between CMS and the drug manufacturer. CMS is proposing regulatory changes consistent with this statutory provision effective July 1, 2024.

The second provision establishes a temporary payment increase for qualifying biosimilars. Qualifying biosimilars are those with an ASP that is less than its reference product. These biosimilars will be paid their own ASP plus 8 percent of the reference product ASP for a 5-year period.

For qualifying biosimilars paid under the ASP methodology as of September 30, 2022, the 5-year period begins October 1, 2022. For qualifying biosimilars first paid under the ASP methodology after October 1, 2022 and before December 31, 2027, the 5-year period begins on the first day of the calendar quarter when Medicare first makes payment using the ASP methodology. CMS

implemented this provision through subregulatory guidance as authorized by statute but is also proposing conforming changes to its regulatory text consistent with the statutory provision.

CMS also raises an additional issue for 2024 with biosimilars concerning potential incentives that result when a reference product or its biosimilars have a different packaging status (e.g., one is paid separately while the other is packaged). While most biosimilars are separately paid, CMS has had a few instances where the biosimilar's per day cost fell below the packaging threshold while its reference product continued to be paid separately. CMS raises concerns that this situation may create incentives for a hospital to select a more expensive reference biological that is paid separately rather than its less expensive biosimilar that is packaged despite the clinical similarity of these products to treat the patient's condition.

To address this concern, CMS proposes to pay separately for a biosimilar—even if the biosimilar's per day costs are below the packaging threshold—if its reference biological is paid separately. Similarly, CMS proposes to package a biosimilar—even if the biosimilar's per day costs are above the packaging threshold—if its reference biological is packaged. CMS further solicits comments on whether to package both the reference product and all of its biosimilars if any one of these products has per day costs below the packaging threshold.

4. Payment Policy for Therapeutic Radiopharmaceuticals

For 2024, CMS proposes to continue paying for therapeutic radiopharmaceuticals at ASP+6 percent. For therapeutic radiopharmaceuticals for which ASP data are unavailable, CMS proposes to determine 2024 payment rates based on 2022 geometric mean unit cost.

5. Payment for Blood Clotting Factors

For 2024, CMS proposes to continue paying for blood clotting factors at ASP+6 percent and is updating the $0.250 per unit furnishing fee from 2023 by the Consumer Price Index (CPI) for medical care for 2024. Following longstanding practice, CMS will announce the updated fee through program instructions once it is available and will post the updated rate on the CMS website at: https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice.

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

CMS is proposing to continue the same payment policy in 2024 as in earlier years for non-pass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data. Because CMS has no claims data and must determine if these products exceed the per-day cost threshold, it estimates the average number of units of each product that would typically be furnished to a patient during 1 day in the hospital outpatient setting. CMS applies ASP+6 percent (or WAC or AWP as applicable) to determine their proposed payment status indicators. Table 40 provides a list of HCPCS codes for drugs and biologicals and radiopharmaceuticals without OPPS claims data and their proposed packaging status.

7. OPPS Payment Methodology for 340B Purchased Drugs

From January 1, 2018 through September 27, 2022, CMS' policy was to pay for drugs acquired under the 340B program at ASP-22.5 percent. To effectuate this policy, CMS required hospitals to use modifiers "JG" and "TB" on OPPS claims where a separately payable drug was acquired under the 340B program. While the payment adjustment no longer applies, modifiers "JG" and "TB" continue to be used. Modifier "JG" signified the drug was acquired under the 340B program and the policy adjustment was applicable. Modifier "TB" signified that the drug is acquired under the 340B program but the payment adjustment was not applicable because the hospital was exempted from the policy.

CMS' 340B drug policy was the subject of extensive litigation and found to be unlawful. While this policy has not been in effect since September 28, 2022, CMS has continued to require use of the "TB" and "JG" modifiers because they remain applicable to implement provisions of the IRA.

Section 1847A(i) of the Act, as added by the IRA, requires CMS to establish a Part B inflation rebate by manufacturers of single source drugs and biologicals with prices increasing faster than the rate of inflation. The statute excludes units of drugs and biologicals where the manufacturer provides a discount under the 340B program. In subregulatory guidance issued on December 20, 2022, CMS required all 340B covered entities to report modifiers "JG" and "TB" for 340B acquired drugs to assist CMS in subtracting the units associated with 340B acquired drugs and biologicals from those subject to the inflation rebate.

CMS has reconsidered this guidance and the necessity of needing both the "JG" and "TB" modifiers. The proposed rule states that use of a single modifier will allow for greater simplicity and less burden on providers as they would only have to report only one modifier for all scenarios where a 340B drug is acquired. Effective January 1, 2025, CMS proposes that all 340B covered entities report only the "TB" modifier when a drug is acquired under the 340B program. The "JG" modifier will remain effective through December 31, 2024, and providers will have the option to report either the "JG" or "TB" modifier during 2024.

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

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

APC	HCPCS	2023 Geometric Mean Cost
5053 (Level 3 Skin Procedures)	C5271, C5275, C5277	$580.95
5054 (Level 4 Skin Procedures	C5273, 15271, 15275,15277	$1,725.86
5055 (Level 5 Skin Procedures)	15273	$3,253.04

For 2024, CMS proposes to determine the high-cost/low-cost status for each skin substitute product based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold. CMS proposed to use 2022 claims data for this purpose.

The proposed 2024 MUC threshold is $47 per cm^2 rounded to the nearest $1, and the proposed 2024 PDC threshold is $817 rounded to the nearest $1. CMS proposes to assign a skin substitute with a MUC or a PDC that exceeds either the MUC threshold or the PDC threshold to the high-cost group. If the product is assigned to the high-cost group in 2023, CMS proposed to continue assigning it to the high-cost group in 2024. Otherwise, CMS proposed assigning the skin substitute to the low-cost group.

For 2024, CMS proposed to continue the following policies:

- Skin substitutes with transitional 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.
- Any skin substitute product that is assigned a code in the HCPCS A2XXX series would be assigned to the high-cost skin substitute group including new products without pricing information.
- New skin substitutes without pricing information not assigned a code in the HCPCS A2XXX series would be assigned to the low-cost category until pricing information is available.

Table 41 of the proposed rule lists the high/low-cost group assignment for each skin substitute.

9. 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. In the 2023 rulemaking cycle, CMS indicated that the Department of Energy expected that the last HEU reactor that produces Mo-99 for medical providers in the United States would finish its conversion to a non-HEU reactor by December 31, 2022. Therefore, CMS believed that the conversion to non-HEU sources of Tc-99m had reached a point where a reassessment of the policy of paying an add-on payment of $10 for non-HEU radioisotopes was necessary.

In the 2023 OPPS rulemaking cycle, 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 believed the policy of paying an extra $10 for non-HEU isotopes should be extended through the end of 2024 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 had fully transitioned to use of non-HEU sources based on information available to CMS in 2022).

In the 2024 OPPS proposed rule, CMS indicates that that the conversion of the last HEU reactor that produces Tc-99m to a non-HEU reactor did not occur until March 2023, so it is possible that some claims for diagnostic radiopharmaceuticals in 2023 would report the cost of HEU-sourced Tc-99m. This means that in 2025, as in 2024, there is the possibility that the payment rate for procedures using diagnostic radiopharmaceuticals could be lower than the costs providers will incur for these procedures because providers will only have access to non-HEU-sourced Tc-99m. For this reason, CMS proposes to extend the add-on payment for one additional year though the end of 2025. Once CMS engages in 2026 ratesetting using 2024 Medicare utilization, CMS believes the claims data will fully reflect the cost of non-HEU sourced radioisotopes and the add-on payment 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 implemented this provision through the 2023 physician fee schedule rule.

In the 2024 OPPS proposed rule, CMS advises hospitals and ASCs that the 2024 PFS proposed rule includes a proposal on this issue that will affect them. CMS directs interested parties to make their public comments on reporting discarded amounts from single use vials to the 2024 physician fee schedule proposed rule. The display copy of the 2024 PFS proposed rule can be found at: https://public-inspection.federalregister.gov/2023-14624.pdf. Discussion of this issue begins on page 417 or section III.A.3.

VI. Estimate of Transitional Pass-Through Spending

CMS estimates total transitional pass-through spending for pass-through payments under the proposed 2024 rule will be approximately $234.1 million, or 0.26 percent of total OPPS spending, which is less than the applicable transitional pass-through payment percentage statutory limit of 2.0 percent.

A. Devices

CMS estimates transitional pass-through spending of $134.1 million in 2024 for devices—$94 million for those recently eligible for transitional pass-through payments that will continue for 2024 and $40.1 million for those CMS knows or projects could be approved for transitional pass-through status in 2024.

B. Drugs and Biologicals

CMS estimates transitional pass-through spending of $100 million in 2024 for drugs and biologicals—$90 million for those recently eligible for transitional pass-through payments that will continue for 2024 and $10 million for those CMS knows or projects could be approved for transitional pass-through status in 2024.

VII. Hospital Outpatient Visits and Critical Care Services

CMS is soliciting comments but not proposing any changes to the current clinic and emergency department hospital outpatient visits payment policies or to the payment policy for critical care services when these services are provided on the campus of a hospital for 2024. For off-campus provider-based departments being paid a physician fee schedule equivalent rate, CMS proposes to continue paying 40 percent of the full OPPS rates. Beginning in 2023, CMS has exempted off-campus provider-based departments of rural sole community hospitals from being paid the physician fee schedule equivalent rate for a clinic visit.

VIII. Partial Hospitalization Program (PHP) Services

Section 4124(b) of CAA, 2023 amended the definition of partial hospitalization services under section 1861(ff) of the Act to create a new Medicare benefit category for intensive outpatient services furnished by hospital outpatient departments, community mental health centers, federally qualified health centers and rural health clinics. CMS adds its regulatory proposals for this new benefit category to the section of the OPPS/ASC rulemaking that, heretofore, was used only for partial hospitalization program services.

A. Partial Hospitalization Program

1. Background.

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

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

In the 2022 OPPS/ASC final rule (86 FR 63665 through 63666), CMS observed significant decreases in utilization and in the number of hospital-based PHP providers who submitted 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 2019 claims and the cost reports that were used for 2021 final rulemaking to calculate the 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).

In the 2023 OPPS/ASC final rule (87 FR 71995), CMS continued to observe decreases in the number of hospital-based and CMHC PHP days due to the continued effects of COVID-19 though service volumes appeared to be returning to pre-pandemic levels. It used the latest available 2021 claims, but used the cost information from before the COVID-19 PHE for calculating the 2023 CMHC and hospital-based PHP APC per diem costs. Notwithstanding these changes, the final calculated CMHC PHP APC payment rate was lower than the 2022 final CMHC PHP APC rate; thus, CMS used its equitable adjustment authority[21] to pay for CMHC PHP services at the same payment rate as in effect for 2022. CMS also clarified that payment under the OPPS for new HCPCS codes that designate non-PHP services provided for diagnosis, evaluation or treatment of a mental health disorder and furnished to beneficiaries in their homes by clinical staff of the hospital would not be recognized as PHP services.

2. Revisions to PHP Physician Certification Requirements

Section 4124 of CAA, 2023 amended the definition of partial hospitalization services to require that a physician determine that a patient needs a minimum of 20 hours of PHP services per week; additionally, the physician must make this determination at least once a month. CMS proposes to add this new condition to the list of requirements for physician certification for PHP services under §424.24(e)(1)(i); no other changes to physician certification are proposed. The agency does not believe its proposed change creates a new requirement for PHPs from a practical perspective because of its longstanding 20-hour minimum weekly regulatory requirement at §410.43(c)(1) and its current requirements for recertification every 30 days at §424.24(e)(3)(ii).

[21] See section 1833(t)(2)(E) of the Act.

B. Intensive Outpatient Program (IOP) Services

1. Establishment of Intensive Outpatient Services Benefit by Section 4124 of the CAA, 2023

Effective for items and services furnished on or after January 1, 2024, a new benefit category for intensive outpatient services is added to the scope of benefits that may be provided by CMHCs. Intensive outpatient services are also added as an "incident to" service under section 1861(s)(2)(B) of the Act and may also be furnished by hospital outpatient departments, CMHCs, FQHCs, and RHCs. These services are furnished under an intensive outpatient program (IOP). An IOP is similar to a PHP; it is a distinct and organized outpatient program of psychiatric services provided for individuals who have an acute mental illness, including depression, schizophrenia, or substance use disorders. However, it is considered to be less intensive than a PHP.

2. IOP Scope of Benefits

CMS proposes to codify conditions and exclusions applicable to intensive outpatient services in a new §410.44. Intensive outpatient services must be (i) reasonable and necessary, (ii) reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization, and (iii) furnished under a physician certification and plan of care.

a. Proposed Definition of Intensive Outpatient Services

CMS proposes to add the following definition of intensive outpatient services to §410.2:

> Intensive outpatient services mean a distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting and furnishes the services as described in §410.44. Intensive outpatient services are not required to be provided in lieu of inpatient hospitalization.

While the statutory and proposed regulatory definition of intensive outpatient services is largely consistent with the definition of partial hospitalization services, an important distinction between the two definitions is that intensive outpatient services are not required to be provided in lieu of inpatient hospitalization.

CMS proposes, in §410.44(a)(4), to list items and services that would be covered intensive outpatient services. They include individual and group therapy; occupational therapy; services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients; drugs and biologicals; individualized activity therapies; family counseling; patient training and education; and diagnostic services. They mirror the scope of services for partial hospitalization services, which is consistent with the statute. Section 1861(ff)(2) of the Act permits CMS to add other items and services to the list of services covered by the partial hospitalization and intensive outpatient service benefit categories; comment is sought on whether additional codes should be added to the list for both these benefit categories.

CMS considers nurses and other staff trained to work within their state scope of practice with patients who are receiving treatment for substance use disorder (SUD) to be included under the statutory definition of PHP, as currently implemented at §410.43(a)(4). CMS clarifies that Medicare covers PHP for the treatment of SUD and that services for the treatment of SUD and behavioral health generally are consistent with the statutory and regulatory definitions of PHP. It further clarifies that the terms "trained psychiatric nurses, and other staff trained to work with psychiatric patients," as currently used in §410.43(a)(4) and proposed to be used for IOPs in §410.44(a)(4), would include trained SUD nurses and other staff trained to work with SUD patients.

Consistent with the regulations for partial hospitalization services at §410.43(b), CMS proposes to specify that the following services are separately covered and not paid as intensive outpatient services: physician services, physician assistant services, nurse practitioner and clinical nurse specialist services, qualified psychologist services, and services furnished to skilled nursing facility residents.

CMS proposes to establish patient eligibility criteria for intensive outpatient services at §410.44(c), which are largely consistent with the regulations for partial hospitalization services on this issue. These services are intended for patients who require at least 9 hours per week of therapeutic services (per the plan of care), are likely to benefit from a coordinated program of services, require more than isolated sessions of outpatient treatment, do not require 24-hour care, have an adequate support system while not actively engaged in the program, have a mental health diagnosis, are not judged to be dangerous to self or others, have the cognitive and emotional ability to participate in the active treatment process, and can tolerate the intensity of the intensive outpatient program.

CMS clarifies that the reference to mental health diagnosis includes SUD and behavioral health diagnoses generally for both partial hospitalization services and intensive outpatient services.

b. Coverage of IOP as Medical and Other Health Services Paid under Part B

CMS proposes conforming amendments to §410.10(c) to add a reference to "intensive outpatient services" to the list of services that are covered as medical and other health services under Part B, when furnished as hospital or CAH services incident to a physician's professional services.

c. Technical Changes to Codify Coverage of and Requirements for IOP at CMHCs

CMS proposes a number of amendments to its regulations to implement the statutory mandates that CMHCs may furnish intensive outpatient services and be reimbursed for furnishing those services, clarifying that CMHCs may be participating providers that furnish both intensive outpatient services and partial hospitalization services.

d. Exclusion of Intensive Outpatient Services from the Outpatient Mental Health Treatment Limitation

CMS proposes to amend §410.155(b)(2)(iii) to codify the statutory exclusion of intensive outpatient services from the outpatient mental health treatment limitation by stating that intensive outpatient services not directly provided by a physician are not subject to the outpatient mental health treatment limitation.

3. IOP Certification and Plan of Care Requirements

CMS proposes to mirror the PHP content of certification and plan of care treatment requirements at §424.24(e) for IOPs, with some exceptions as directed by the statute. For example, the content of certification would have to include documentation that the individual requires such services for a minimum of 9 hours per week, with no requirement for the patient to need inpatient psychiatric care if the IOP services were not provided. Recertification of IOP services would have to occur no less frequently than every 60 days though CMS seeks comment on whether a shorter interval for the first recertification and for subsequent recertification for IOP patients would be appropriate. The physician's certification of the patient's need for either IOP or PHP services should be based on the physician's determination of the patient's needs and whether the patient meets the IOP or PHP patient eligibility criteria, respectively.

C. Coding and Billing for PHP and IOP Services under the OPPS

Because the statutory definitions of both IOP and PHP generally include the same types of covered items and services, CMS believes it is appropriate to align the programs using a consistent list of services; the only differentiating factor between partial hospitalization services and intensive outpatient services would be the level of intensity.

To differentiate between IOP and PHP for billing purposes, CMS proposes to require hospitals and CMHCs to report condition code 92 on claims for intensive outpatient services. Hospitals would continue to report condition code 41 for partial hospitalization claims, and CMS proposes to begin requiring CMHCs to also report condition code 41 for their partial hospitalization claims.

Table 42 shows the current list of HCPCS codes recognized for PHP payment. Table 43 shows the list of codes that CMS proposes would apply for the full range of services that may be furnished by both PHPs and IOPs. All of the codes in Table 42 would continue to apply, with the exception of 90865 Narcosynthesis. CMS would add 18 codes (recognized as mental health codes under the OPPS) to the list of recognized PHP/IOP codes in Table 43. It would also update the descriptions of five existing Level II HCPCS codes that are currently recognized for PHP to also refer to IOP. CMS proposes to add CPT code 90853 Group psychotherapy to the list of service codes recognized for PHP and IOP; however, it is concerned that there may be overlap between 90853 and two existing Level II HCPCS codes for PHP group psychotherapy (G0410 and G0411). Comment is sought on whether it should remove G0410 and G0411 from the list of recognized service codes for PHP and IOP, and retain only CPT code 90853.

The list of HCPCS codes in Table 43 would be used to determine the number of services per PHP or IOP day, and thus to determine the APC per diem payment amount for each day. CMS notes that to qualify for payment at the applicable PHP APC (5853 or 5863) one service must be from the Partial Hospitalization Primary list. It proposes to maintain this requirement and apply it to IOPs as well; the list would be renamed the Partial Hospitalization and Intensive Outpatient Primary list. To qualify for payment for the IOP APC (5851, 5852, 5861 or 5862) or the PHP APC (5853, 5854, 5863, or 5864), at least one service must be from this list, which is shown in Table 44 in the proposed rule.

Should the need arise to add more codes to Table 43, CMS proposes to do so through sub-regulatory guidance. However, if CMS exercises its authority to add new items and services to the scope of partial hospitalization and intensive outpatient services under section 1861(ff)(2)(I) of the Act, it would do so through rulemaking.

CMS seeks comment on its proposed consolidated list of HCPCS codes that would be payable when furnished in a PHP and IOP (as shown in Table 43), including whether codes should be added, modified or created to describe specific services. The agency seems particularly interested in caregiver-focused services for the list of recognized services for PHP and IOP, such as caregiver-focused health risk assessments, caregiver training, and family group behavior management/modification training for parents(s)/guardians(s)/caregivers(s) with a mental or physical health diagnosis. Comment is also sought on whether it would be appropriate to include costs for the role of caregivers in developing and implementing individualized treatment plans for patients in the calculation of PHP and IOP per diem payment rates. Additionally, CMS is interested in feedback on whether it would be appropriate to include peer services for PHPs and IOPs. The agency also seeks information from the public about why PHPs are not more frequently billing for testing and diagnostic services, including whether these services are typically furnished by the referring provider.

Current regulations require physicians, hospitals, and CMHCs to address discharge planning for PHP patients; CMS proposes to establish the same requirements for IOP patients.

D. Payment Methodology for PHP and IOP

CMS proposes a number of changes to its payment methodology for PHP services for 2024. It would establish four separate PHP APC per diem payment rates and four separate IOP per diem payment rates as follows:

Provider Type	# of Services per Day	IOP APC	PHP APC
CMHC	3	5851	5853
CMHC	4 or more	5852	5854
Hospital-based	3	5861	5863
Hospital-based	4 or more	5862	5864

Additionally, for hospital-based PHPs, CMS proposes to calculate payment rates using the broader OPPS data set instead of hospital-based PHP data only. The broader OPPS data set would permit the agency to capture data from claims not identified as PHP, but that include the service codes and intensity required for a PHP day. Because the goal is to establish consistent coding and payment between the PHP and IOP benefits, CMS proposes to consider all OPPS data for PHP days and non-PHP days that include 3 or more of the same service codes.

1. Current Payment Rate Methodology for PHP

The agency currently uses two separate PHP APC per diem payment rates: CMHC PHP APC 5853 (Partial Hospitalization (three or More Services Per Day)) using only CMHC data, and hospital-based PHP APC 5863 (Partial Hospitalization (three or More Services Per Day)) using only hospital-based PHP data. This rate setting methodology was finalized in the 2016 OPPS/ASC final rule 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.

2. Proposed 2024 Payment Rate Methodology for PHP and IOP

The agency initially notes that because IOPs furnish the same types of services as PHPs, but at a lower intensity, it is appropriate to use the same data and methodology for calculating payment rates for both PHP and IOP for 2024 and to set the same rates for both PHP and IOP services. This is because IOP is a newly established benefit, and CMS lacks definitive data on utilization.

Hospital-based PHP payment rates for 3 services per day and 4 services per day would be calculated based on cost per day using the broader OPPS data set. This would be a change from the current methodology of using only PHP data, and CMS believes it would result in more precise calculations. CMS would calculate the PHP rates for CMHCs and hospital-based programs separately.

CMS notes that the typical PHP day is typically four services or more per day and that payment for days of 3 services is currently limited to extenuating circumstances, such as when the patient transitions to discharge. However, starting in 2024, it proposes to pay for days with three or fewer services to accommodate occasional instances when a patient is unable to complete a full day of PHP or IOP. It expects that days with fewer than three services would be "very infrequent" and would monitor claims accordingly.

The 3 services per day hospital-based PHP APC per diem payment amount for APC 5863 would also be applied as the daily mental health cap, which serves as the upper limit on payment per day for individual OPPS mental health services.

Section 4124(c) of the CAA, 2023 mandates that payment for intensive outpatient services furnished in FQHCs and RHCs equal the payment amount that would have been paid for the same service furnished by a hospital outpatient department; however, it is silent on the payment rate for CMHCs. Thus, CMS believes it is appropriate to apply its policy of differences in cost structures for different providers of PHP to providers of IOP. While it proposes to continue calculating CMHC payment rates based solely on CMHC claims, CMS is considering whether establishing a

site-neutral payment for all providers of IOP using data from all providers of IOP would be more appropriate in order to increase access to mental health services. Stated differently, under this alternative, CMS would establish combined payment rates for hospitals and CMHCs based on the calculated costs per day for days with 3 services and 4 or more services, using all OPPS claims. Table 46 shows that this would result in lower geometric mean per diem costs for hospital-based providers and exponentially higher rates for CMHCs (almost three times as much). Comment is sought on this alternative. CMS is also interested in feedback on ways IOP days could differ from PHP days and considerations that could affect payment.

3. Proposed PHP APC Changes and Effects on Geometric Mean Per Diem Costs

For 2024, as noted above CMS proposes to revise 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 to incorporate the larger data set under the OPPS, including PHP and non-PHP hospital claims for mental health services. It would use the latest available 2022 claims data and 2021 cost data.

CMS developed a consolidated list of all HCPCS codes that would be appropriate to identify IOP and PHP services, and it did a preliminary ratesetting analysis of all CMHC and hospital claims for patients that had 9 or more hours of behavioral health services per week. It identified IOP as weeks with between 9 and 19 hours of services and PHP as weeks with 20 hours or more of services. It also determined that typical IOP days include about three services and typical PHP days include about four services. CMS then calculated payment rates using CMHC claims for CMHCs and hospital-based claims for hospitals. Costs for CMHC service days are calculated using cost report information from HCRIS.

The proposed 2024 geometric mean per diem costs and payment rates are as follows:

2024 APC	Group Title	Proposed PHP and IOP APC Geometric Mean Per Diem Costs*	Proposed Payment Rates**
5851	Intensive Outpatient (3 services per day) for CMHCs	$97.59	$96.49
5852	Intensive Outpatient (4 or more services per day) for CMHCs	$153.09	$151.36
5853	Partial Hospitalization (3 services per day) for CMHCs	$97.59	$96.49
5854	Partial Hospitalization (4 or more services per day) for CMHCs	$153.09	$151.36
5861	Intensive Outpatient (3 services per day) for hospital-based IOPs	$284.00	$280.80
5862	Intensive Outpatient (4 or more services per day) for hospital-based IOPs	$368.18	$364.04
5863	Partial Hospitalization (3 per day) for hospital-based PHPs	$284.00	$280.80
5864	Partial Hospitalization (4 or more services per day) for hospital-based PHPs	$368.18	$364.04

* Table 45 of the proposed rule shows the proposed 2024 PHP and IOP APC geometric mean per diem costs.
** The 2024 proposed payment rates are from Addendum A to the proposed rule.

E. Outlier Policy for CMHCs

For 2024, CMS proposes to update the calculations of the CMHC outlier percentage, cutoff point and percentage payment amount, outlier reconciliation, outlier payment cap, and fixed-dollar threshold determined under established policies to include intensive outpatient services.

In the preamble, CMS provides a more detailed explanation of the steps involved in calculating the CMHC outlier percentage, which would be calculated using the existing methodology. However, it would also be applied to payments for IOP services as well as PHP services beginning in 2024. CMS projects that CMHCs will receive 0.01 percent of total hospital outpatient payments in 2024 (excluding outlier payments), and it proposes to designate less than 0.01 percent of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHC outliers.

CMS proposes to continue to set the cutoff point for outlier payments for CMHCs for 2024 at 3.4 times the highest CMHC PHP APC payment rate, 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 or 5854 payment rate. The same policies would apply to intensive outpatient services paid under the CMHC IOP APCs.

For 2024, CMS proposes to continue to use its established outlier reconciliation policy to address charging aberrations related to OPPS outlier payments described in the 2023 OPPS/APC final rule (83 FR 58874 through 58875) and to extend it to intensive outpatient services. 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 proposes to continue this policy for 2024 and to apply it to include both PHP and IOP; this 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. It proposes to continue this policy for 2024 and to apply it to both PHP and IOP APCs.

F. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

Extensive background on the evolution of payment policies for RHCs and FQHCs is provided in the preamble. CMS notes that section 4124 of CAA, 2023 occasioned a number of changes to the RHC and FQHC policies, including scope of benefits and services, certification and plan of care requirements, and special payment rules for IOP services in RHCs and FQHCs.

1. IOP Scope of Benefits and Scope of Services in RHC and FQHC Settings

CMS proposes to amend its regulations for RHCs and FQHCs[22] to adopt the same standards for the scope of benefits for intensive outpatient services that apply to CMHC and hospital-based IOPs. This would include individual and group therapy, occupational therapy, drugs and biologicals, family counseling, beneficiary education, and diagnostic services.

Similarly, the same standards for physician certification and recertification and the same requirements for the plan of care that apply to CMHC and hospital-based IOPs would apply for RHCs and FQHCs. Thus, physicians would have to certify that an individual needs IOP services for a minimum of 9 hours per week and no more than 19 hours per week, and the certification would require documentation of that need. The first certification would have to be completed as of the 30th day of IOP services and recertification would have to occur at least every other month.

CMS also proposes to apply the same patient eligibility criteria for intensive outpatient services furnished by RHCs and FQHCs as are proposed in §410.44(c) for CMHCs and hospitals.

2. Special Payment Rules for Intensive Outpatient Services

Section 4124(c) of the CAA, 2023 established payment rules for intensive outpatient services furnished by RHCs and FQHCs. Payment to these facilities for these services must equal the amount that would have been paid under Medicare for IOP services had they been covered outpatient department services furnished by a hospital.

CMS believes the payment for these services furnished by RHCs and FQHCs should be structured to be days with three or fewer services. It proposes the following payment rates:

- For RHCs, the rate determined for APC 5861 (Intensive Outpatient (3 services per day) for hospital-based IOPs).
- For FQHCs, the lesser of a FQHC's actual charges or the rate determined for APC 5861.
- For grandfathered tribal FQHCs, payment would be based on the lesser of the FQHC's actual charges or the outpatient per visit rate.

The agency seeks comment on whether these proposed payment rates should be adjusted to reflect the variations in costs of furnishing services in different geographic areas and what approaches would be appropriate for determining the value of the adjustment. Comment is also sought on whether the hospital-based IOP APC 5862 for 4-service days would be appropriate for RHCs and FQHCs.

With respect to coding and billing, CMS proposes to require RHCs and FQHCs to report condition code 92 to identify intensive outpatient claims for the list of proposed HCPCS codes included in Table 43. This is because, per the statute, they are paid for IOP services outside of the RHC AIR

[22] §§405.2401, 405.2411 and 405.2446.

methodology and FQHC PPS, respectively. Additionally, at least one service must be from the Intensive Outpatient Primary list (identified in Table 44).

The statute requires that costs associated with intensive outpatient services are not to be used to determine the amount of payment for FQHC services or RHC services. CMS proposes conforming changes to its regulations; it states that revisions will be made to the cost reporting instructions to account for these changes.

FQHCs that contract with MA organizations must be paid at least the same amount they would have received for the same service under the FQHC PPS, with Medicare making up the difference between the FQHC PPS payment rate and a lower MA payment rate. CMS proposes to apply the same policy for IOP services furnished by FQHCs.

3. Multiple Visits

Generally, RHC and FQHC encounters with more than one health professional, and multiple encounters with the same health professional that take place on the same day and a single location, constitute a single visit. However, the following are exceptions:

- When a patient has a medical visit and a mental health visit on the same day; or
- When a patient has an initial preventive physical exam visit and a separate medical or mental health visit on the same day.

CMS believes it would be inappropriate to pay for a mental health visit and IOP services on the same day. In the case of a medical visit, an encounter can include a medical visit and a mental health visit or a medical visit and IOP services. An encounter cannot include two mental health visits on the same day. CMS proposes to modify §405.2463(c) to clarify that it will permit a mental health visit or IOP services on the same day as a medical visit.

G. Coverage of Opioid Use Disorder Treatment Services

CMS notes that many opioid treatment programs (OTPs) already provide IOP services and that IOP services can be effective in promoting greater treatment initiation and engagement, which may improve health outcomes. It proposes to establish payment under Part B for IOP services furnished by OTPs for the treatment of opioid use disorder (OUD) starting in 2024. CMS reasons that IOP services are intended to treat individuals with an acute mental illness and/or substance use disorder, including those with an OUD, and that IOP services are similar to the specific services enumerated in the Medicare benefit category for opioid use disorder treatment. It notes that the agency has authority under section 1861(jjj)(1)(F) of the Act to add other items and services furnished by an OTP for the treatment of OUD, as appropriate, to this benefit category.

1. Proposal to Include IOP Services Furnished by OTPs in the Definition of OUD Treatment Services

CMS proposes to define a new category of services called “OTP intensive outpatient services” and incorporate this new category in the definition of OUD treatment services that are covered under

the Part B OTP benefit. These intensive outpatient services would be the services specified in proposed §410.44(a)(4) described above.

To be covered, the services would have to be furnished by an OTP as part of a distinct and organized intensive ambulatory treatment program for the treatment of OUD and that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting. They would also have to be:

- Reasonable and necessary for the diagnosis or active treatment of the individual's condition;
- Reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization; and
- Furnished pursuant to a physician certification and plan of care, in which a physician certifies that the individual has a need for a minimum of 9 hours of services per week and requires a higher level of care intensity compared to other non-intensive outpatient OTP services.

CMS proposes to exclude the following from the definition of OTP intensive outpatient services: FDA-approved opioid agonist or antagonist medications for the treatment of OUD, opioid antagonist medications for the emergency treatment of known or suspected opioid overdose, or toxicology testing. These medications are already included as part of the weekly bundled payment for an episode of care or as an adjustment to the bundled payment

2. Proposal to Establish a Weekly Payment Adjustment for IOP Services Furnished by OTPs

To reflect the more intensive treatment profile for those individuals receiving IOP services versus OTP services, CMS proposes to establish a weekly payment adjustment through an add-on code for OTP intensive outpatient services. An OTP could bill for the weekly add-on code for OTP intensive services in the same week for the same beneficiary as the existing coding describing a weekly OTP bundle, as long as all applicable billing requirements for each code are met. However, each OTP intensive outpatient service must not be duplicative of any service(s) for which OTPs received a bundled payments for an episode of care in a given week.

OTPs would bill new HCPCS code GOTP1[23] that would be valued based on an assumption of a typical case of three IOP services furnished per day for approximately 3 days per week. CMS welcomes comments on whether its assumption of 9 services per week is representative of the typical number of services furnished to patients with an OUD who receive IOP services at OTPs.

The calculation of the weekly add-on payment rate for HCPCS code GOTP1 would be similar to the payment methodology proposed for IOP services furnished in other settings. Specifically, it

[23] Intensive outpatient services; minimum of nine services over a 7-contiguous day period, which can include individual and group therapy with physicians or psychologists (or other mental health professionals to the extent authorized under State law); occupational therapy requiring the skills of a qualified occupational therapist; services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients; individualized activity therapies that are not primarily recreational or diversionary; family counseling (the primary purpose of which is treatment of the individual's condition); patient training and education (to the extent that training and educational activities are closely and clearly related to individual's care and treatment); diagnostic services; List separately in addition to code for primary procedure.

would be based on the per diem payment rate for intensive outpatient services at hospital-based programs for 3 services per day (APC 5861), multiplied by three. However, CMS proposes to subtract an amount that corresponds to the individual and group therapy proposed rates in the non-drug component of the OTP bundled payment when establishing the amount of the OTP intensive outpatient services weekly add-on payment. Currently, the adjusted non-facility rates for group and individual psychotherapy are $28.36 and $94.17, respectively. Thus, assuming the estimated payment rate for APC 5861 is $280.80, CMS would first multiply this amount by 3, which equals $842.40, and then subtract from that product the sum of the rates for group and individual psychotherapy ($122.53). This would result in a weekly add-on payment of $719.67 for HCPCS code GOTP1 ($842.40 - $122.53 = $719.67).

Payment rates would be updated annually by the MEI, and they would be adjusted by the geographic adjustment factor under §414.26. Additionally, there would be no beneficiary copayment.

By billing HCPCS code GOTP1, the OTP would be attesting to the fact that it has furnished at least nine services for that week that would otherwise qualify as OTP intensive outpatient services. CMS acknowledges that not all OTP intensive outpatient services will last 60 minutes; thus, it proposes that furnishing nine OTP intensive outpatient services, regardless of the length of each service, would still meet the threshold to bill for HCPCS code GOTP1. CMS also acknowledges that this policy differs from the requirement that the physician must certify the individual requires nine hours of OTP intensive outpatient services, and not simply nine OTP intensive outpatient services.

The agency emphasizes that the same service may not be used to qualify to bill both the weekly bundle and the add-on payment adjustment for OTP intensive outpatient services.

3. Certification and Plan of Care Requirements for IOPs in OTP Settings

OTPs would have to meet the same requirements for certification, recertification and treatment plans as apply to other providers, which are described above and proposed to be added at §424.24(d)(1) through (3) of the regulations. For recertification, because OTP services are billed on a weekly basis, CMS proposes recertification could occur any time during an episode of care in which the 30th day from the start of IOP services (and every other month thereafter) falls. It notes that its proposal requires the physician to certify a need for at least 9 hours of services per week, which differs from the proposal that in order to bill for the add-on payment adjustment for OTP intensive outpatient services, the OTP must attest that it provided 9 services to the patient in a week. The agency believes it will be easier for OTPs to count the numbers of services than the number of hours services that were furnished during a week.

H. Payment Rates in Non-Excepted Off-Campus Provider-Based Departments (PBDs)

In the 2017 OPPS/ASC final rule (81 FR 79727), CMS implemented section 603 of the BBA 2015 with respect to payment for PHP services furnished by nonexcepted off-campus PBDs by setting the rate equal to the CMHC payment rate for 3 or more PHP services per day. It proposes to use the CMHC rates for PHP and IOP as the payment rates for PHP and IOP services furnished by nonexcepted off-campus hospital outpatient departments; it would use the 3 services rate or the 4 or

more-services rate based on how many services the non-exempted off-campus PBD furnished on that day.

I. Regulatory Impact

CMS estimates that payments to CMHCs for PHP services will increase by 5.8 percent in 2024.

The agency does not have any specific data from which to make projections for IOP services. However, it anticipates increased utilization for CMHCs beginning in 2024, and using claims with a comparable number and type of services, it estimates CMHCs would provide roughly 35,511 IOP days with three services and 22,558 IOP days with four or more services. This corresponds to an estimated $6,593,452 in additional payments to CMHCs for intensive outpatient services.

For both FQHCs and RHCs, CMS anticipates IOP services will be utilized, but it is unable to project utilization or associated Medicare expenditures. However, it does not believe providing coverage for IOP services in FQHCs and RHCs will have a significant impact on overall Medicare spending.

It estimates that the proposed policies to permit OTPs to bill for IOP services beginning in 2024 would result in a negligible cost increase. The estimated total annual cost per Medicare beneficiary with an OUD receiving IOP services at an OTP would be approximately $38,000, but this estimate assumes that a beneficiary would require this level of care every week of the year. CMS does not believe this is likely.

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 determine whether services should be added or removed. Stakeholders are 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. 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 2024

For 2024, CMS received several requests from interested parties recommending particular services to be removed from the IPO list. Using the five criteria listed above, CMS did not find sufficient evidence that these services meet the criteria for being removed from the IPO list for 2024. CMS does propose to add nine new CPT codes for 2024 to the IPO list. These codes can be found in Table 47 of the proposed rule.

CMS is seeking on whether the following services are appropriate to remove from IPO list:

- CPT code 43775 (Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy)),
- CPT Code 43644 (Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and roux-en-y gastroenterostomy (roux limb 150 cm or less)),
- 43645 (Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption), and
- 44204 (Laparoscopy, surgical; colectomy, partial, with anastomosis) are appropriate to be removed from the IPO list.

At this time, CMS does not believe it has adequate information to determine whether these services can be safely performed in the hospital outpatient department setting on the Medicare population but requests information whether these services meet any of the five criteria to be removed from the IPO list.

X. Nonrecurring Policy Changes

A. Supervision of Cardiac, Intensive Cardiac and Pulmonary Rehabilitation Services

Under current law, cardiac rehabilitation services (CR), intensive cardiac rehabilitation services (ICR) and pulmonary rehabilitation services (PR) must be provided under the direct supervision of a physician (medical doctor or doctor of osteopathy). Effective January 1, 2024, the Bipartisan Budget Act of 2018 authorizes CR, ICR and PR to be furnished under the direct supervision of a

physician assistant (PA), nurse practitioner (NP) or clinical nurse specialist (CNS). CMS is proposing conforming changes to the regulations effective January 1, 2024 consistent with the change in law.

During the COVID-19 PHE, CMS added CR, ICR and PR to the telehealth list when furnished to non-hospital patients and paid under the physician fee schedule (PFS). CMS permitted the direct supervision of CR, ICR and PR to be furnished remotely via two-way, audio/visual communication technology (but not audio only). These flexibilities were extended by law through December 31, 2024 by the CAA, 2023.

For consistency with the PFS rules, CMS extended these flexibilities for direct supervision to be furnished via two-way, audio/visual communication technology to CR, ICR and PR provided to hospital outpatients in prior rulemaking. CMS proposes to further extend these flexibilities to CR, ICR and PR furnished through December 31, 2024 consistent with the CAA, 2023 and extend the authority for the supervision of these services to be furnished by PAs, NPs and CNS as well beginning January 1, 2024.

B. Payment of Intensive Cardiac Rehabilitation (ICR) in a Non-Excepted Off-Campus PBD

By statute, Medicare' payment for ICR in a physician's office is equal to the payment rate for CR under the OPPS. However, CMS has been paying ICR at a PFS equivalent rate when furnished in a non-excepted off-campus PBD. A non-excepted off-campus PBD is an off-campus PBD of a hospital that first began providing services on or after November 2, 2015 and is not paid under the OPPS and is instead paid at PFS equivalent rate for its outpatient hospital services at 40 percent of the full OPPS rate.

Paying for ICR at a PFS equivalent rate has produced an anomalous result of ICR being paid at $120.47 in on-campus hospital departments, excepted off-campus PBDs and physician offices but $48.03 in a non-excepted off-campus PBD in 2023. CMS indicates that this disparity creates a significant barrier to beneficiary access to an already underutilized service that is arguably inconsistent with intent of the applicable statutory provisions which was to remove the significant payment disparity for the same services depending on whether they are furnished in a physician's office or an off-campus, non-excepted PBD of a hospital.

To address this anomaly, CMS proposes to pay for ICR in an off-campus non-excepted PBD at the full OPPS rate effective January 1, 2024. This policy would apply to the HCPCS codes G0422 and G0423 for ICR with and without exercise respectively.

C. OPPS Payment for Specimen Collection for COVID-19 Tests

In the May 8th, 2020 COVID–19 interim final rule with comment (IFC), CMS created a new evaluation and management code (C9803) for a hospital outpatient clinic visit with specimen collection to test for COVID-19. The code pays $24.96 for 2023. In the IFC, CMS indicated its expectation to retire the code at the conclusion of the COVID–19 PHE. While the code will remain

active for the remainder of 2023 for technical reasons, CMS is proposing to delete code C9803 effective January 1, 2024 now that the COVID-19 PHE has ended.

D. Remote Services

1. Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes

In the 2023 OPPS final rule, CMS created three HCPCS C-codes for mental health services furnished by hospital staff to beneficiaries in their homes through communications technology. CMS did not specify whether the codes should be used for individual or group services, preferring to keep the coding more general until the agency had experience with these codes.

In response to interested parties who are finding these codes burdensome when billing for multiple units of group therapy in a single day, CMS proposes to create a new, untimed, HCPCS C-code describing group therapy. CMS explicitly seeks comments on the descriptors of the remote group and individual psychotherapy codes to ensure they are sufficiently clear as to their use.

Table 50 of the proposed rule provides the proposed C-code and long descriptor for this new C-code. CMS proposes to assign this new C-code to APC 5821 that pays $28.62. This APC assignment was based on the facility PFS payment for a similar service (CPT code 90853 for group psychotherapy) to reflect that the hospital has less costs when providing a mental health service to a patient in the home than at the hospital.

Also, in response to interested parties, CMS further proposes to modify the individual psychotherapy codes to remove the word "initial" from the descriptor to make clear that the codes can be used for an initial or subsequent encounter.

2. Periodic In-Person Visits

In the 2023 OPPS final rule, CMS adopted a policy to allow OPPS payment for remote mental health services when a hospital outpatient is receiving these services in their home. Consistent with analogous statutory requirements that apply to the Medicare telehealth benefit under the PFS, CMS requires an in-person visit within 6 months prior to or after the remote mental health service. The visit after the first encounter must occur within 12 months.

CAA, 2022 delayed the application of these requirements under the PFS for 151 days after the end of the COVID-19 PHE. CAA, 2023 delayed the application of these requirements through December 31, 2024. CMS is proposing the same delay for remote outpatient mental health services provided by hospitals and CAHs.

3. Outpatient Therapy, Diabetes Self-Management Training (DSMT), and Medical Nutrition Therapy (MNT)

During the COVID-19 PHE, CMS allowed outpatient therapy services, DSMT and MNT to be furnished by hospital employed staff to patients in their homes through the use of real-time

interactive telecommunications technology. At the expiration of the COVID-19 waivers, CMS used subregulatory guidance to allow these services to continue to be provided and paid under the OPPS when provided by hospital employees to patients in their homes through the end of 2023.[24]

Another COVID-19 waiver allowed CMS to add outpatient therapy, DSMT and MNT to the list of telehealth services that could be paid under the PFS when provided by an eligible practitioner or supplier. Physical, occupational and speech language pathologists were temporarily designated as "eligible telehealth distant site practitioners" and able to bill for these services under the PFS when furnished via telehealth.

The CAA, 2023 extended most flexibilities for Medicare telehealth services, including retention of physical and occupational therapists and speech-language pathologists as eligible telehealth distant site practitioners through the end of 2024. In the 2024 PFS proposed rule, CMS is extending these telehealth waivers consistent with the CAA, 2023. CMS indicates that its proposal includes outpatient therapy, DSMT, and MNT services furnished via telehealth by staff of hospital outpatient departments.

E. OPPS Payment for Dental Services

1. Background

Section 1862(a)(12) of the Act generally precludes payment under Medicare Parts A or B for any expenses incurred for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth (collectively referred to by CMS as "dental services"). In the 2023 PFS final rule (87 FR 69663 through 69688), CMS identified clinical scenarios where payment is permitted under both Medicare Parts A and B for certain dental services where the services are not considered to be in connection with dental services. In these instances, the services are inextricably linked to and substantially related to the clinical success of other covered medical services.

The policies adopted in the 2023 PFS final rule allow payment for certain dental services performed in outpatient settings. However, the current dental codes assigned to APCs for 2023 do not fully describe the dental services that may be inextricably linked to covered medical services and payable under Medicare Part B. Only 57 Current Dental Terminology (CDT) codes are assigned to APCs in 2023. A limited number of CPT codes that describe dental services are also assigned to APCs.

In the 2023 OPPS final rule, CMS created HCPCS code G0330 to describe facility services for dental rehabilitation procedure(s) furnished to patients who require monitored anesthesia (e.g., general, intravenous sedation (monitored anesthesia care)) and use of an operating room. CMS assigned HCPCS code G0330 to APC 5871 (Dental Procedures) for 2023.

[24] See questions 21 and 22 at this link: https://www.cms.gov/files/document/frequently-asked-questions-cms-waivers-flexibilities-and-end-covid-19-public-health-emergency.pdf.

2. Proposed OPPS Payment for Additional Dental Codes

For 2024, CMS proposes to assign 229 additional dental codes to clinical APCs to enable them to be paid for under the OPPS when payment and coverage requirements are met. OPPS payment will only be made for a dental code if it is among the types of dental services that are Medicare covered when linked to covered medical services. The dental services for which CMS proposes APC assignments are those dental services for which Medicare Part B payment can be made when they are inextricably linked to other covered medical services.

Based on the dental services identified in 2023 PFS final rule, CMS generated a list of codes that describe those services for which it believes proposed APC assignments are needed. While it is appropriate for CMS to assign certain dental codes to APCs for payment under the OPPS, it does not believe that every dental code should be assigned to an APC and made payable under the OPPS. For instance, there are services described by CDT codes that may already be described by existing CPT codes assigned to clinical APCs. When this is the case, CMS is proposing that the hospital would use the existing CPT codes to bill for the services performed.

CMS is not proposing APC assignments for dental services that would not be paid under the OPPS because they describe only the service of a practitioner such as the services of a physician, physician assistant, nurse practitioner, clinical nurse specialist or anesthetist that are not paid under the OPPS. There are also dental codes that CMS believes would not meet the definition of dental services that may be inextricably linked to other covered medical services. For instance, there are CDT codes that describe removable prosthodontic procedures, including codes that describe complete or partial denture procedures (e.g., D5110; D5120; D5211-D5214). Because denture procedures are not covered medical procedures under Medicare, CMS is not proposing to assign these codes to clinical APCs.

3. Proposed APC Assignments for Additional Dental Codes

CMS explains how it uses the principles of clinical and cost similarity to assign dental codes to APCs. As dental services have not been paid historically, there is no utilization data on which to determine costs and APC assignments. While CMS considered using external data sources such as from Veteran's Affairs (VA), state Medicaid agencies and third-party databases, these data were unsuitable for CMS' purposes. VA data is proprietary and not publicly available. Medicaid data is inconsistent because of variation in payment rates between states. Private insurance payments are not relevant to Medicare as they would be for services provided in an office and not the hospital outpatient department.

For new CPT codes without prior utilization data, CMS assigns the services to APCs using crosswalk code analyses. Similar to its process for assigning new codes to APCs, CMS used a crosswalk code analysis and consulted with clinical experts to propose appropriate APC assignments for the 229 dental codes.

4. Proposed Packaged Payment and Associated Status Indicators for Dental Codes

For 2024, CMS proposes to package payments for dental services when they are performed with another covered dental or medical service consistent with its general OPPS packaging policies. The OPPS regularly packages payments for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. CMS believes applying these principles to the furnishing of dental services in the OPPS is appropriate and would incent clinical resource efficiencies. CMS refers readers to Addendum B for the proposed 2024 status indicators for dental codes.

F. Use of Claims and Cost Report Data Due to PHE for 2024 Ratesetting

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. As a result of these concerns, CMS believed that 2019 data, as the most recent complete calendar year of data prior to the COVID-19 PHE, were a better approximation of expected 2022 hospital outpatient service utilization than 2020 data. Therefore, CMS established rate-setting for the 2022 OPPS using 2019 claims data and cost reports prior to the PHE.

For 2023 ratesetting, CMS decided to use the 2021 utilization in the OPPS ratesetting process even though it continued to see limited effects of the PHE in the data. CMS believed the 2021 utilization was a better approximation of 2023 for ratesetting than the older 2019 data.
For cost reports, CMS used the same set originally used to set rates for 2021—which in most cases included those beginning in 2018 and ending before the PHE began in 2020—for both 2022 and 2023. CMS did not use cost reports spanning the 1st year of the COVID-19 PHE to set rates because of concerns about how cost-to-charge ratios were affected by the pandemic.

For 2024 ratesetting, CMS proposes to return to its historical practice of using the latest utilization and cost report data. CMS continues to observe some differences at the aggregate and service level volumes in the 2022 claims data relative to the pre-PHE period. However, CMS believes that it is reasonable to assume that there will be minor variations as a result of the COVID-19 PHE in claims data CMS uses for ratesetting for the foreseeable future.

For the cost reports, CMS' proposal will result in it using data predominantly from 2021 with some portion of the cost reports including cost reporting periods from prior years. However, CMS believes it is reasonable to assume there will continue to be a limited influence of the COVID-19 PHE on the cost report data. Given these factors, CMS believes that using the most recent cost report data available and resuming the regular cost report update process is appropriate for 2024 OPPS ratesetting.

G. High-Cost Drugs Provided by Indian Health Service (IHS) and Tribally-Owned Facilities

IHS and Tribally-owned facilities are not paid under the OPPS and are instead paid an All-Inclusive Rate (AIR) for their Medicare outpatient hospital services. IHS calculates and announces

the AIR annually in the *Federal Register*. For 2023, the AIR is $654 for all states except Alaska. The AIR is $862 in Alaska.

While CMS indicates that the majority of IHS and Tribally-owned facilities appear to be well served by the AIR, there are specialty facilities where the AIR might not be an adequate representation of Medicare costs. If an IHS or Tribally-owned facility provides a drug or service that costs more than the payment they receive through the AIR, it may not be financially feasible for these facilities to provide that drug or service. Expensive cancer drugs or oncology services are examples where the AIR may be inadequate. CMS is seeking comment on a number of potential policies to address payment to IHS and Tribally-owned facilities for certain high-cost drugs and services.

The proposed rule requests responses to a variety of questions. These include: what is the universe of drugs that would be subject to the policy; should these drugs only be paid separately above a cost threshold; how should these drugs be paid; should the AIR be adjusted to remove any drug costs that it may include; how should IHS and Tribally-owned facilities bill for these drugs; and should CMS develop an outlier-like policy to compensate IHS and Tribally-owned facilities for these drugs.

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 2024 payment status indicator assignments for APCs and HCPCS codes are shown in Addenda A and B respectively. The complete list of proposed 2024 payment status indicators and their definitions are in Addendum D1.

For 2024, CMS proposes change to status indicator "P" from "Partial Hospitalization" to "Partial Hospitalization or Intensive Outpatient Program."

Comment Indicator Definitions

For 2024, CMS is continuing to use the following comment indicators that are unchanged from 2022:

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

"NI"—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code [in the final rule].
"NP"—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.

The definitions of the OPPS comment indicators for 2024 are listed in Addendum D2 of the proposed rule.

XII. Medicare Payment Advisory Commission (MedPAC) Recommendations

OPPS Update: In its March, 2023 "Report to Congress: Medicare Payment Policy," MedPAC recommended that Congress update Medicare OPPS payment rates in 2024 by the amount specified in current law plus 1 percent. CMS is proposing to update OPPS rates consistent with current law at the market basket of 3.0 percent less 0.2 percentage points for total factor productivity.

Medicare Safety Net Index: In its March, 2023 "Report to Congress: Medicare Payment Policy," MedPAC recommended that Congress should begin a transition to redistribute disproportionate share hospital and uncompensated care payments through the Medicare Safety-Net Index (MSNI). Additionally, MedPAC recommended that Congress add $2 billion to the MSNI pool of funds and distribute such funds through a percentage add-on to payments under the IPPS and OPPS. CMS looks forward to working with Congress and seeking comments on approaches CMS could take with respect to the MedPAC recommendation.

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

XIII. Ambulatory Surgical Center (ASC) Payment System

Summary of Selected Key Elements of ASC Payment Rates for 2024		
	ASCs reporting quality data	**ASCs not reporting quality data**
2023 ASC Conversion Factor	$51.854	
Wage index budget neutrality adjustment	1.0017	
2024 Update		
Hospital market basket update	3.0%	
Productivity adjustment	-0.2%	
Net MFP adjusted update	2.8%	

Summary of Selected Key Elements of ASC Payment Rates for 2024		
Penalty for not reporting quality data	0.0%	-2.0%
Net MFP and quality adjusted update	2.8%	0.8%
2024 Proposed ASC Conversion Factor	$53.397	$52.358

The ASC update is based on the IPPS hospital market basket and is estimated to be 2.8 percent with a reduction 2.0 percentage points for ASCs that do not submit quality data. CMS estimates that under the proposed rule, total ASC Medicare payments for 2024 will be approximately $6.0 billion, an increase of $170 million compared with 2023 levels inclusive of changes in enrollment, utilization, and case mix changes.

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 procedure. Payment for ancillary items and services (with some exceptions) are packaged into the ASC payment. The ASC payment is generally a percentage of the OPPS payment rate unless the service is "office-based." Payment for office-based services is capped based on the PFS non-facility payment.

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

Until 2019, CMS defined a surgical procedure as any procedure in the surgery CPT code range (CPT codes 10000 through 69999) or Level II HCPCS codes or Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that meet the criteria to be paid in an ASC. Beginning with 2019, CMS included "surgery-like" procedures outside the CPT surgical range that meet the criteria to be on the ASC list.

B. ASC Treatment of New and Revised Codes

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

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

Table 56 in the proposed rule (shown below) provides the process and timeline for ASC list updates:

Comment and Finalization Timeframes for New and Revised HCPCS Codes				
ASC Quarterly Update CR	**Type of Code**	**Effective Date**	**Comments Sought**	**When Finalized**
April 2023	HCPCS (CPT and Level II codes)	April 1, 2023	2024 OPPS/ASC proposed rule	2024 OPPS/ASC final rule with comment period
July 2023	HCPCS (CPT and Level II codes)	July 1, 2023		
October 2023	HCPCS (CPT and Level II codes)	October 1, 2023	2024 OPPS/ASC final rule with comment period	2025 OPPS/ASC final rule with comment period
January 2024	CPT Codes	January 1, 2024	2024 OPPS/ASC proposed rule	2024 OPPS/ASC final rule with comment period
	Level II HCPCS Codes		2024 OPPS/ASC final rule with comment period	2025 OPPS/ASC final rule with comment period

April and July 2023 Codes - CMS Solicits Public Comments in this Proposed Rule

In the April 2023 ASC quarterly update, CMS states it made effective 23 new Level II HCPCS codes and no new CPT codes. Table 54 displays the codes and descriptors. In the July 2023 ASC quarterly update, CMS added 19 separately payable Level II HCPCS codes and 5 CPT codes to the list of covered surgical procedures and ancillary services. Tables 55 lists the codes and descriptors.

CMS notes that the proposed payment indicators, comments indicators, and payment rates, where applicable, can be found in Addendum BB for the Level II HCPCS codes and in Addendum AA for the new Category III codes at the CMS website referenced below. CMS proposes to finalize the payment indicators in the 2024 OPPS/ASC final rule with comment period.

October 2023 and January 2024 HCPCS Codes - CMS Will Be Soliciting Public Comments in the 2024 Final Rule with Comment Period

CMS proposes to continue to assign comment indicator "NI" in Addendum BB to the 2023 OPPS/ASC final rule for those new and revised Level II HCPCS codes that are effective October 1, 2023. This indicates that CMS has assigned the codes an interim ASC payment status for the remainder of 2023. CMS will invite comments in the 2024 OPPS/ASC final rule with comment period on the interim payment indicators which will then be finalized in the 2025 OPPS/ASC final rule with comment period.

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

CMS seeks comment on proposed new and revised CPT codes effective January 1, 2024 that were received in time to be included in this proposed rule. Status indicators and payment rates for these codes will be finalized in the 2024 OPPS/ASC final rule with comment period. Most Level II HCPCS codes are not released until sometime around November to be effective January 1. These

Level II HCPCS codes will be released to the public through the 2024 OPPS/ASC final rule with comment period. Interim status indicators and payment rates will be assigned for 2024 and will be subject to public comments in the final rule comment period. Status indicators and payments rates for these codes will be finalized in the 2025 OPPS/ASC final rule with comment period.

ASC Payment and Comment Indicators

For the 2024 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.

For 2024, CMS proposes to add two ASC payment indicators for new proposed dental codes. Proposed ASC payment indicators "D1" and "D2" are for the new dental codes that would be paid in 2024 and subsequent calendar years and would be added to Addendum DD1.

The first proposed payment indicator is "D1"— "Ancillary dental service/item; no separate payment made." The "D1" indicator would indicate an ancillary dental procedure that would be performed integral to a separately payable dental surgical procedure with a payment indicator of "D2." The second proposed payment indicator is "D2" – "Non-office-based dental procedure added in 2024 or later." The "D2" payment indicator would indicate a separately payable dental surgical procedure that would be subject to the multiple procedure reduction, but would not be designated as an office-based covered surgical procedure.

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

Proposed ASC Payment for Covered Surgical Procedures

CMS proposes to continue its policy to update payments for office-based procedures and device-intensive procedures using its established methodology and its modified definition for device-intensive procedures for all but low volume device-intensive procedures. Payment for office-based procedures will be the lesser of the 2024 PFS non-facility practice expense payment amount, or the 2024 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. Payment for device-intensive procedures would be based on the service portion (non-device portion) using the standard ASC ratesetting methodology and the payment amount for the device portion based on the proposed 2024 device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology.

Proposed Payment for ASC Add-on Procedures Eligible for Complexity Adjustments under the OPPS

In the 2023 OPPS/ASC final rule (87 FR 72078 to 72080), CMS finalized a new ASC payment policy that would apply to certain code combinations in the ASC payment system where CMS

would pay for these code combinations at a higher rate to reflect that the code combination is a more complex and costlier version of the procedure performed (similar to how the OPPS APC complexity adjustment is applied).

For 2024, CMS proposes to continue the special payment policy and methodology for OPPS complexity-adjusted C-APCs that was finalized in the 2023 OPPS/ASC final rule. The full list of the proposed ASC complexity adjustment codes for 2024 can be found in the ASC addenda (summarized below). Because the complexity adjustment assignments change each year under the OPPS, the proposed list of ASC complexity adjustment codes eligible for this proposed payment policy has changed slightly from the previous year.

Proposed C-Codes for 2024 – Combinations of Primary Procedure Code and Add-on Codes that are Eligible for a Complexity Adjustment

HCPCS Code	Short Descriptor	Proposed CY 2024 Payment Weight	Proposed CY 2024 Payment Rate
C7501	Perc bx breast lesions stero	20.9391	$1,118.09
C7502	Perc bx breast lesions MR	20.9391	$1,118.09
C7503	Open exc cerv node(s) w/ id	46.1948	$2,466.66
C7504	Perq cvt&ls inj vert bodies	62.1357	$3,317.86
C7505	Perq ls&cvt inj vert bodies	62.1357	$3,317.86
C7506	Fusion of finger joints	62.1357	$3,317.86
C7507	Perq thor&lumb vert aug	124.1101	$6,627.11
C7508	Perq lumb&thor vert aug	124.1101	$6,627.11
C7509	Dx bronch w/ navigation	28.5899	$1,526.61
C7510	Bronch/lavag w/ navigation	28.5899	$1,526.61
C7511	Bronch/bpsy(s) w/ navigation	28.5899	$1,526.61
C7512	Bronch/bpsy(s) w/ ebus	28.5899	$1,526.61
C7513	Cath/angio dialcir w/aplasty	28.4595	$1,519.65
C7514	Cath/angio dial cir w/stents	28.4595	$1,519.65
C7515	Cath/angio dial cir w/embol	28.4595	$1,519.65
C7516	Cor angio w/ ivus or oct	46.5834	$2,487.41
C7517	Cor angio w/ilic/fem angio	46.5834	$2,487.41
C7520	Cor/gft angio w/ilic/fem ang	46.5834	$2,487.41
C7521	R hrt angio w/ ivus or oct	46.5834	$2,487.41
C7522	R hrt angio w/flow resrv	46.5834	$2,487.41
C7523	L hrt angio w/ ivus or oct	46.5834	$2,487.41
C7524	L hrt angio w/flow resrv	46.5834	$2,487.41
C7525	L hrt gft ang w/ ivus or oct	46.5834	$2,487.41

HCPCS Code	Short Descriptor	Proposed CY 2024 Payment Weight	Proposed CY 2024 Payment Rate
C7526	L hrt gft ang w/flow resrv	46.5834	$2,487.41
C7527	R&L hrt angio w/ ivus or oct	46.5834	$2,487.41
C7528	R&L hrt angio w/flow resrv	46.5834	$2,487.41
C7529	R&L hrt gft ang w/flow resrv	46.5834	$2,487.41
C7530	Cath/aplasty dial cir w/stnt	89.3607	$4,771.59
C7531	Angio fem/pop w/ us	107.8132	$5,756.90
C7532	Angio w/ us non-coronary	104.5259	$5,581.37
C7533	PTCA w/ plcmt brachytx dev	107.1882	$5,723.53
C7535	Fem/pop revasc w/stent & us	194.1871	$10,369.01
C7537	Insrt atril pm w/L vent lead	183.5667	$9,801.91
C7538	Insrt vent pm w/L vent lead	186.4485	$9,955.79
C7539	Insrt a & v pm w/L vent lead	190.3746	$10,165.43
C7540	Rmv&rplc pm dul w/L vnt lead	186.6740	$9,967.83
C7545	Exch bil cath w/ rmv calculi	46.4971	$2,482.81
C7547	Cnvrt neph cath w/ dil stric	29.7372	$1,587.88
C7548	Exch neph cath w/ dil stric	29.7372	$1,587.88
C7550	Cysto w/ bx(s) w/ blue light	29.7372	$1,587.88
C7551	Exc neuroma w/ implnt nv end	56.2998	$3,006.24
C7554	Cystureth blu li cyst fl img	16.9983	$907.66
CXX56	Bronch lavage w/ebus	28.5899	$1,526.61
CXX57	Cor angio/vent w/ffr	46.5834	$2,487.41
CXX58	Cor angio/vent w/drug admin	46.5834	$2,487.41
CXX59	Trluml balo angiop all art	104.5259	$5,581.37
CXX60	Ercp remove forgn body&endo	34.3329	$1,833.27

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

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

Based on its analysis of claims data, CMS proposes to designate 5 brachytherapy APCs and 4 clinical APCs as Low Volume APCs under the ASC payment system. The relative weight for these APCs would be based on the greater of the median cost, arithmetic mean cost, or geometric mean cost using up to 4 years of claims data. Table 57 in the proposed rule compares the cost statistics and indicates the proposed 2024 APC cost for these 9 APCs.

Payment for Covered Ancillary Services

CMS proposes to update payments and make changes necessary to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services. It also proposes to continue to set the 2024 ASC payment rates and subsequent year payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for 2024 and subsequent year payment rates. For those covered ancillary services where the payment rate is the lower of the rate under the ASC standard rate setting methodology and the PFS proposed rates, the proposed payment indicators and rates are based on a comparison using the proposed PFS rates effective January 1, 2024.

Covered Surgical Procedures Designated as Office-Based

For 2024, CMS proposes to continue its historical practice of reviewing the most recent claims and utilization data (2022 claims in this case) for determining office-based assignments under the ASC payment system.

Based on its review of the 2022 utilization of covered surgical procedures, CMS identified two surgical procedures that it proposes to permanently designate as office-based for 2024 (listed in Table 58 in the proposed rule). These procedures are performed more than 50 percent of the time in physicians' offices and CMS believes are of a level of complexity consistent with other procedures performed routinely in physicians' offices. Codes on this list include 0448T and 38232.

CMS also reviewed the utilization for nine surgical procedures designated as temporarily office-based in the 2023 OPPS/ASC final rule. Four of these procedures had more than 50 claims with the utilization indicating that these procedures were performed predominantly in the office setting. CMS propose to permanently designate these procedures as office-based (Codes 0402T, 0512T, 93985, and 93986). It also determined that one of the nine surgical procedures is not performed predominantly in the office setting and assigned it a status indicator of "G2", or non-office based surgical procedure (Code 64454). CMS continues to designate four of the nine procedures as temporarily office-based as it had insufficient information to determine if the office setting was the predominant setting (less than 50 claims). Tables 59 and 60 in the proposed rule display the details for these codes.

Proposed Device-Intensive ASC Covered Surgical Procedures

Surgical procedures designated as device-intensive are subject to a special payment methodology. The device portion of the payment is determined by applying the device offset percentage to the standard OPPS payment. The service portion of the ASC payment for device-intensive procedures

is determined by applying the uniform ASC conversion factor to the non-device portion of the OPPS relative payment weight. The ASC device portion and ASC non-device portion are summed to establish the full payment for the device-intensive procedure under the ASC payment system. This policy applies only when the device-intensive procedure is furnished with a surgically inserted or implanted device (including single use medical devices). In the 2019 OPPS/ASC final rule, CMS lowered the device offset percentage threshold from 40 percent to 30 percent and aligned the device-intensive policy with the criteria used for device pass-through status.

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

For C-codes, or ASC complexity adjustment codes, the C code would retain the device-intensive status of the primary procedure as well as the device portion of the primary procedure and not the device offset percentage. The C-code device offset percentage would be established by dividing the device portion of the primary procedure by the OPPS complexity-adjusted APC payment rate based on the ASC standard ratesetting methodology. CMS applies its standard ASC payment system ratesetting methodology to the non-device portion of the ASC complexity adjustment code's APC payment rate.

The ASC covered surgical procedures that CMS proposes to designate as device-intensive, and therefore, subject to the device-intensive procedure payment methodology for 2024, are assigned payment indicator "J8" and are included in ASC Addendums AA and FF in the proposed rule. There are 501 codes in this proposed rule that are assigned the "J8" payment indicator, including 9 of the C codes.

CMS is not proposing any changes related to designating surgical procedures as device-intensive under the ASC payment system for 2024.

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.

Requirement in the Physician Fee Schedule 2024 Proposed Rule for HOPDs and ASCs to Report Discarded Amounts of Certain Single-dose or Single-use Package Drugs

CMS reminds readers of a proposal in the 2024 Physician Fee Schedule (PFS) proposed rule that has implications for HOPDs and ASCs. Section 90004 of the Infrastructure Investment and Jobs Act amended section 1847A of the Act to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The 2024 PFS proposed rule includes proposals to operationalize section 90004 of the Infrastructure Act, including a proposal that impacts HOPDs and ASCs. Comments on these proposals will be addressed in the 2024 PFS final rule with comment period.

D. Additions to List of ASC Covered Surgical Procedures and Covered Ancillary Services

Additions to the List of Covered Surgical Procedures

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

1. Meets general standards specified in 42 CFR 416.166(b): Surgical procedures specified by Secretary and published in the Federal Register and/or via the Internet on the CMS website that are separately paid under OPPS.

- *a. Not expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC*
- *b. Beneficiary would not typically expect to require active medical monitoring and care at midnight following the procedure*

2. Follows the general exclusion criteria set out in 42 CFR 416.166(c): ASC covered surgical procedures do not include surgical procedures that : (1) generally result in extensive blood loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; (4) are generally emergent or life threatening in nature; (5) commonly require systemic thrombolytic therapy; (6) are designated as requiring inpatient care under 42 CFR 419.22(n); (7) can only be reported using a CPT unlisted surgical procedure code; or (8) are otherwise excluded under 42 CFR 411.15.

Based on its review of procedures currently paid under the OPPS and not included on the ASC CPL, CMS proposes to update the ASC CPL by adding 26 dental surgical procedures to the list for 2024 (shown in Table 61 in the proposed rule). CMS states that it will continue to gradually expand the ASC CPL as medical practice and technology continue to evolve and advance in future years. **CMS seeks comment on its proposed additions to the ASC CPL.**

Covered Ancillary Services

As stated earlier, CMS makes separate ASC payments for ancillary items and services when they are provided integral to ASC covered surgical procedures that include the following: (1) brachytherapy sources; (2) certain implantable items that have pass-through payment status under the OPPS; (3) certain items and services designated as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPS; (5) certain radiology services for which separate payment is allowed under the OPPS; and (6) non-opioid pain management drugs that function as a supply when used in a surgical procedure. Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

CMS maintains consistency with the OPPS which may result in changes to ASC payment indicators for some covered ancillary services. For example, if a covered ancillary service was separately paid under the ASC payment system in 2023, but will be packaged under the 2024 OPPS, CMS would also package the ancillary service under the ASC payment system for 2024 to maintain consistency with the OPPS. Comment indicator "CH" is used in Addendum BB to indicate covered ancillary services for which a change is proposed in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for 2024.

In the 2022 OPPS/ASC final rule with comment period, CMS finalized its proposal to include, as ancillary items that are integral to a covered surgical procedure and for which separate payment is

allowed, non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS.

All ASC covered ancillary services and their proposed payment indicators for 2024 are also included in Addendum BB.

Claims Processing Limitations for Covered Ancillary Procedures Performed with G0330

HCPCS code G0330 (Facility services for dental rehabilitation procedure(s) performed on a patient who requires monitored anesthesia (e.g., general, intravenous sedation (monitored anesthesia care) and use of an operating room)) is a proposed addition to the ASC CPL for 2024, For 2024, CMS proposes that G0330 could only be billed with a covered ancillary procedure that has the proposed payment indicator of "D1," indicating an ancillary dental service or item with no separate payment made. While HCPCS code G0330 must be billed with a covered ancillary procedure with a proposed payment indicator of "D1", these covered ancillary procedures can be billed with procedures other than G0330. When billed with procedures other than G0330, these procedures would be packaged in accordance with CMS' policy for covered ancillary procedures. CMS notes that MACs will be involved in the final decision regarding whether a drug, device, procedure, or other service meets all program requirements and conditions for coverage and payment.

E. Non-Opioid Post-Surgery Pain Management Drugs. Biologicals, and Devices

Under a policy adopted in 2019, opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting are unpackaged and paid separately at ASP+6. For 2022, CMS finalized a policy to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under §416.174. In the 2023 OPPS/ASC final rule CMS determined that five products were eligible for separate payment in the ASC setting. (products listed in Table 62 in the proposed rule).

Proposed 2024 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 2024, the OPPS drug packaging threshold is proposed to be $140.

CMS discusses the evaluation of whether certain non-opioid alternatives meet the criteria established at §416.174. It re-evaluated the five non-opioid pain management drugs and biologicals that received separate payment in the ASC setting for 2023 to determine whether they continue to qualify for separate payment in 2024. Based on its evaluation CMS proposes that the drugs described by HCPCS codes C9290 (i.e., Exparel), J1097 (i.e., Omidria), C9089 (i.e., Xaracoll), and

J1096 (i.e., Dextenza) continue to meet the required criteria and should receive separate payment in the ASC setting. It proposes that the drug described by HCPCS code C9144 (i.e., Posimir) would not receive separate payment in the ASC setting under this policy as this drug will be separately payable during 2024 under OPPS transitional pass-through status. More details on CMS' evaluations can be found in the proposed rule.

CMS welcomes comments on additional non-opioid pain management drugs and biologicals that function as surgical supplies that may meet the criteria specified in §416.174 and qualify for separate payment under the ASC payment system. If it finds the additional drugs or biologicals satisfy the criteria, CMS will finalize their separate payment status for 2024 in the ASC setting in the 2024 OPPS/ASC final rule.

F. Request for Information (RFI) on Non-Opioid Treatments for Pain Relief

Section 4135(a) and (b) of the CAA, 2023, titled Access to Non-Opioid Treatments for Pain Relief, amended sections 1833(t)(16) and 1833(i) of the Act, respectively, to provide for temporary additional payments for non-opioid treatments for pain relief**.** Because the additional payments are required to begin on January 1, 2025, CMS plans to include its proposals to implement the section 4135 amendments in the 2025 OPPS/ASC proposed rule. CMS specifically seeks comment on the issues discussed in the following sections as well as comments on the implementation of all facets of this provision.

Potential Qualifying Drugs, Biologicals, and Devices

In preparation for implementing section 4135 of the CAA, 2023, for 2025, CMS seeks comment on any drug, biological, or medical device that a commenter believes would meet the definition of a non-opioid treatment for pain relief under section 1833(t)(16)(G)(iv) of the Act. It encourages commenters to submit appropriate FDA documentation, published peer-reviewed literature, or other evidence-based support in support of its comment. For these products, CMS also solicits comment on appropriate codes and descriptors if no HCPCS codes currently exist for the product.

Evidence Requirement for Medical Devices

Section 1833(t)(16)(G)(iv)(II)(bb) of the Act specifies an additional requirement for medical devices to meet the definition of non-opioid treatment for pain relief. This section requires that a medical device demonstrate the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal.

As the statute requires information from a clinical trial or data published in a peer reviewed journal, CMS seeks comment on the best way to obtain and evaluate that information. It also seeks comment on how it should assess information from a clinical trial or data published in a peer-reviewed journal, including how to assess for conflicts of interest or integrity concerns, whether to focus on outcomes rather than surrogate endpoints, and whether to require that all decreases in

opioid use be statistically and clinically significant compared to the usual standard of care (rather than placebo).

Amount of Payment

Section 1833(t)(16)(G)(ii)(I) of the Act states that, subject to the limitation in clause (iii), the amount of payment for a non-opioid treatment for pain relief that is a drug or biological product is the amount of payment for such drug or biological determined under section 1847A of the Act that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. CMS notes that this language is very similar to the transitional pass-through language at section 1833(t)(6)(D)(i) of the Act and it anticipates implementing a similar payment methodology for drugs and biologicals under this future policy.

Section 1833(t)(16)(G)(ii)(II) of the Act states that the amount of payment for a nonopioid treatment for pain relief that is a medical device is the amount of the hospital's charges for the device, adjusted to cost, that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the device. CMS notes that this language is very similar to the transitional pass-through language at section 1833(t)(6)(D)(ii) of the Act and it anticipates implementing a similar payment methodology for medical devices under this future policy.

Section 1833(i)(10) of the Act provides that the same payment rate shall apply in the ASC setting as the rates for hospital outpatient departments, subject to the payment limitation in section 1833(t)(16)(G)(iii) of the Act.

Payment Limitation

Section 1833(t)(16)(G)(iii) of the Act states that the additional payment amount specified in clause (ii), and as described in the previous section, shall not exceed the estimated average of 18 percent of the OPD fee schedule amount for the OPD service (or group of services) with which the non-opioid treatment for pain relief is furnished, as determined by the Secretary. CMS seeks comment on how it should determine the OPD service or groups of services with which non-opioid treatments for pain relief are furnished for purposes of calculating the payment limitation for each treatment.

Specifically, CMS seeks comment on the scenarios it outlines in the proposed rule. Additionally, it welcomes other recommendations from interested parties consistent with the statutory requirements.

Scenario 1: Payment Limitation Based on the Top Five Services by Volume with Known Claims Data

As one possible approach, CMS uses the top five services associated with a hypothetical drug, biological, or medical device to determine the volume-weighted payment rate and the payment

limit, based on the most recent claims data available. It predicts that the majority of utilization is focused in the top five mostly frequently performed services, thus using the top five services would provide a representative estimate for the payment limit. However, CMS solicits comment on this prediction and welcomes input from commenters if they believe another number of procedures, or another metric would be appropriate to determine the list of procedures in which the payment limitation would be calculated.

Table 84 in the proposed rule details an example of how the payment limitation could be calculated.

Table 64: Example of Payment Limitation Based on the Top Five Services by Volume

Service	**Volume** (claims)	**Payment**	**Total Payment** (volume * claims)	**Volume Weighted Payment per claim** (total payment / total volume)	**Payment Limit**
1	100	1000	100,000		
2	20	200	4,000		
				$\frac{(100{,}000 + 4{,}000 + 1{,}000 + 1{,}000 + 1{,}000)}{100 + 20 + 10 + 10 + 10}$	
3	10	100	1,000	= $700	$700 * 0.18
4	10	100	1,000		=$126
5	10	100	1,000		

CMS seeks comment on this approach. It also seeks comment on additional methodologies, such as determining the payment limit based on the top 10 services by volume, by total payment rather than volume, or and number of services with more than a certain percentage of overall utilization, such as 10 percent.

Scenario 2: Payment Limit Without Claims Data

Additionally, CMS seeks comment on the best approach for determining a payment limit, pursuant to section 1833(t)(16)(G)(iii) of the Act for drugs, biologicals, and devices when there are no claims data, such as for newly FDA-approved and marketed products. CMS details a potential approach where it could propose the services with which a product would be expected to be furnished and would typically be packaged absent this policy during calendar year rulemaking, based on expected clinical use patterns. It could then determine the service, or group of services, to use to calculate the payment limit through engagement with interested parties and a review by CMS Medical Officers and clinical staff. Absent engagement from interested parties, CMS could make its determination of the service, or group of services, to use to calculate the payment limit

based on expected clinical use patterns. CMS could then adjust the services that are used to calculate the payment limit as claims data becomes available in subsequent years.

CMS seeks comment on this approach as well as other approaches of interest to commenters. It will include proposals to implement the section 4135 amendments in the 2025 OPPS/ASC proposed rule.

G. New Technology Intraocular Lenses (NTIOL)

CMS did not receive any requests for review to establish a new NTIOL class for 2024 by the annual deadline (March 1, 2023 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.

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

CMS proposes to continue to update relative weights using the national OPPS relative weights and the PFS non-facility PE RVU-based amounts when applicable. CMS scales the relative weights as under prior policy. Holding ASC use, the ASC conversion factor, and mix of services constant from 2022, CMS computes the ratio of:

- Total payments using the 2023 relative payment rates, to
- Total payments using the 2024 relative payment rates.

The 2024 total payments will also include spending and utilization related to its proposed ASC complexity adjustment codes or C codes. CMS estimates the additional spending related to these codes to be approximately $5 million.

The resulting ratio, 0.8649, is the proposed weight scaler for 2024. The scaler would apply to the ASC relative payment weights of covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes. The scaler would not apply to ASC payments for separately payable covered ancillary services that have a predetermined national payment amount and are not based on OPPS relative payment weights (e.g., drugs and biologicals that are separately paid and services that are contractor-priced or paid at reasonable cost in ASCs). CMS proposes to use 2022 claims data to model its budget neutrality adjustment.[25]

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

[25] 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.

factor. Holding constant ASC use and mix of services in 2022 and the 2024 national payment rates after application of the weight scaler, CMS computes the ratio of:

- ASC payments using the 2023 ASC wage indices, to
- ASC payments using the 2024 ASC wage indices.

The resulting ratio, 1.0017, is the proposed wage index budget neutrality adjustment to the conversion factor for 2024.

To update ASC rates, CMS would utilize the hospital market basket update of 3.0 percent minus the productivity adjustment of 0.2 percent. This yields an update of 2.8 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 0.8 percent for such ASCs. The resulting proposed 2024 ASC conversion factor is $53.397 for ASCs reporting quality data, and $52.358 for those that do not, computed as follows:

	ASCs reporting quality data	**ASCs not reporting quality data**
2023 ASC conversion factor	$51.854	
Wage adjustment for budget neutrality	x 1.0017	
Net MFP-adjusted update	x 1.028	x 1.008
2024 Proposed ASC conversion factor	$53.397	$52.358

I. 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 2022 claims data. (Table 101 of the proposed rule and reproduced below.) The eye surgical specialty group remains the largest source of payments, with 6 percent increase in payments attributable to the changes proposed for 2024. This increase in payment rates for eye and ocular adnexa procedures is a result of an increase OPPS relative weights as a result of the APC restructuring to the Intraocular APC family. The second largest group, nervous system, is estimated to see a -6 percent decrease. This is largely based on an AMA RUC estimated shift in utilization from an existing high-cost neurostimulator procedure (CPT code 63685) to a new, lower-cost neurostimulator procedure (CPT code 0X43T) for 2024.

Table 101 – Estimated Impact of the Proposed 2024 Update to the ASC Payment System on Aggregate 2023 Medicare Program Payments by Surgical Specialty or Ancillary Items and Services Group

Surgical Specialty Group	Estimated 2023 ASC Payments (in Millions)	Estimated 2024 Percent Change
Total	**$6,309**	**3%**
Eye	$1,880	6%

Table 101 – Estimated Impact of the Proposed 2024 Update to the ASC Payment System on Aggregate 2023 Medicare Program Payments by Surgical Specialty or Ancillary Items and Services Group		
Surgical Specialty Group	Estimated 2023 ASC Payments (in Millions)	Estimated 2024 Percent Change
Nervous system	$1,274	-6%
Musculoskeletal system	$1,188	3%
Gastrointestinal	$937	7%
Cardiovascular	$276	4%
Genitourinary system	$225	6%

CMS provides estimated increases for 30 selected procedures in Table 102 in the proposed rule; the top 10 procedures are replicated below. CPT code 66984 (Cataract surgery with intraocular lens, 1 stage) is the largest aggregate payment procedure by far and is estimated to have a 6 percent increase in payment. The second largest aggregate payment procedure, CPT code 63685, is expected to see a -37 percent decrease. Total hip arthroplasty (new to the top 10 list) has $130 million in estimated 2023 ASC payments and is expected to increase by 1 percent.

Excerpt from Table 102: Estimated Impact of the 2024 Update to the ASC Payment System on Aggregate Payments for the Top 10 Procedures			
CPT/ HCPS Code	Short Descriptor	Estimated 2023 ASC Payments (in Millions)	Estimate 2024 Percent Change
66984	Xcapsl ctrc rmvl w/o ecp	$1,251	6
63685	Insrt/redo spine n generator	$314	-37
27447	Total knee arthroplasty	$263	1
45380	Colonoscopy and biopsy	$244	6
45385	Colonoscopy w/lesion removal	$213	6
63650	Implant neuroelectrodes	$194	-10
43239	Egd biopsy single/multiple	$158	7
27130	Total hip arthroplasty	$130	1
66991	Xcapsl ctrc rmvl cplx insj 1+	$113	15
64590	Insrt/redo pn/gastr stimul	$106	-15

As noted at the beginning of this ASC section, Addenda tables available only on the website provide additional details; they are at https://www.cms.gov/medicare/medicare-fee-service-payment/ascpayment/asc-regulations-and-notices/cms-1786-p. They include:

- AA – Proposed ASC Covered Surgical Procedures for 2024 (Including surgical procedures for which payment is packaged)
- BB – Proposed ASC Covered Ancillary Services Integral to Covered Surgical Procedures for 2024 (Including Ancillary Services for Which Payment is Packaged)
- DD1 – Proposed ASC Payment Indicators for 2024
- DD2 – Proposed ASC Comment Indicators for 2024
- EE – Surgical Procedures to be Excluded from Payment in ASCs for 2024

- FF – ASC Device Offset Percentages for 2024
- O – Long Descriptors for New Category I CPT Codes, Category III CPT Codes, C-Codes, and G-Codes for 2024

XIV. Hospital Outpatient Quality Reporting (OQR) Program

A. Background and Overview

CMS provides references to the legislative and regulatory histories of the OQR program.[26] Section 1833(t)(17)(A) of the Act provides a 2.0 percentage point reduction in the annual Outpatient Department (OPD) fee schedule increase factor (Annual Payment Update, APU) for each subsection (d) hospital that does not submit data as required for the OQR program's measures.[27] CMS proposes to continue to implement the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements by applying a reporting factor of 0.9805 to the OPPS payments and copayments for all applicable services.

CMS proposes the following changes to the OQR program measure set:

(1) Remove the Left Without Being Seen measure beginning with the 2024 reporting period/2026 payment determination;

(2) Modify 3 measures ((i) the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure, (ii) the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure, and (iii) the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients) beginning with the 2024 reporting period/2026 payment determination;

(3) Re-adopt with modification the Hospital Outpatient Volume Data on Selected Outpatient Procedures measure beginning with the voluntary 2025 reporting period and mandatory reporting beginning with the 2026 reporting period/2028 payment determination;

(4) Adopt the Risk-Standardized Patient-Reported Outcome-Based Performance Measure Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty in the HOPD Setting (THA/TKA PRO-PM) beginning with the voluntary 2025 and 2026 reporting periods, and mandatory reporting beginning with the 2027 reporting period/ 2030 payment determination; and

(5) Adopt the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Outpatient) measure, beginning with the voluntary 2025 reporting period and mandatory reporting beginning with the 2026 reporting period/2028 payment determination.

---

[26] 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.

[27] Certain requirements under the OQR program are codified at 42 CFR 419.46. A detailed discussion of the statutory history of the OQR program can be found in the 2011 Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) payment system final rule (75 FR 72064 through 72065).

For the 2023 payment determination, 3,020 of 3,097 eligible hospitals met reporting requirements including data submission, while 77 failed to do so.[28] CMS does not anticipate that any of the proposed policies would significantly impact the number of hospitals that will receive payment reductions.

CMS estimates a total information collection burden increase of 67,004 hours at a cost of $1,492,875 annually associated with the proposed OQR program policies for the 2024 reporting period/2026 payment determination and subsequent years.

CMS invites public comment on all proposals to the OQR program. CMS requests public comment on potential future measurement topic areas, specifically on: (1) patient and workforce safety (including sepsis); (2) behavioral health (including suicide prevention); and (3) telehealth.

B. OQR Program Quality Measures

1. Retention, Removal, Replacement, or Suspension of Quality Measures

a. Technical Changes

CMS proposes to amend the immediate measure removal policy at §419.46(i)(2) to replace references to "QualityNet" with "CMS-designated information system" or "CMS website" and make other conforming technical edits.

b. Proposed Removal of the Left Without Being Seen (LWBS) Measure Beginning with the 2024 Reporting Period

Measure description. The LWBS measure is a process measure that assesses the percent of patients who leave the emergency department (ED) without being evaluation by a physician, advanced practice nurse, or physician assistant and that was intended to be an indicator of ED overcrowding. Consensus-based entity (CBE) endorsement of the measure was removed in 2012.

Basis for Measure removal. Beginning with the 2024 reporting period/2026 payment determination, CMS is proposing to remove the measure under removal factor 2 (performance or improvement on the measure does not result in better patient outcomes). CMS does not believe the LWBS measure provides enough evidence to promote quality of care and improved patient outcomes to justify retaining the measure. The measure does not provide granularity for actionable data toward quality improvement.

In comparison, CMS points to the Median Time from ED Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients) measure, which is already adopted for reporting in the OQR program, as better for measuring ED performance because it provides more

[28] CMS posts lists of individual hospitals meeting or failing to meet OQR reporting requirements at https://qualitynet.cms.gov/outpatient/oqr/apu.

granular data on length of time in the ED and, since it shows stratified data for discharged ED patients in 4 groupings, is more meaningful for improvement efforts.

CMS estimates a reduction in data submission burden for hospitals of $29,100.

2. Proposed Modifications to Previously Adopted Measures

a. Modification to COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) Measure Beginning with the 2024 Reporting Period/2026 Payment Determination

Background. Subsequent to the COVID-19 public health emergency declaration by the Secretary of HHS on January 31, 2020, the HCP COVID-19 Vaccine measure was adopted across multiple quality reporting programs, including the OQR Program.[29] CMS describes that even though the PHE expired on May 11, 2023, COVID-19 remains a public health priority, vaccination is a critical component to effectively countering its spread, and it is important to incentivize and track HCP vaccination across care settings. Therefore, the agency believes it is important to update the specifications of the HCP COVID-19 Vaccine measure to reflect the most current guidance for HCP to receive primary series and booster vaccine doses in a timely manner.[30]

Overview of Measure and Proposed Modification. The HCP COVID-19 Vaccine measure is a non-risk-adjusted process measure developed by the CDC to track COVID-19 vaccination coverage among HCP, and is reported through the CDC's National Healthcare Safety Network (NHSN).

Proposed Modifications. CMS proposes the following modifications to the measure:

- Replace the term "complete vaccination course" with the term "up to date" in the HCP vaccination definition;
- Update the numerator to specify the time frames within which an HCP is considered up to date with recommended COVID-19 vaccines, including booster doses; and
- Reduce the measure's target population from seven HCP categories to four.

Modified Measure Calculation.

Denominator. The number of HCP eligible to work in the hospital for at least one day during the week of data collection, excluding persons with contraindications to COVID-19 vaccination that

[29] 86 FR 63824 through 63833.

[30] The proposed modifications are the same as proposed for the Hospital Inpatient Quality Reporting Program, the Long-Term Care Hospital Quality Reporting Program and the PPS-Exempt Cancer Hospital Quality Reporting Program (88 FR 27074), the Inpatient Psychiatric Facility Quality Reporting Program (88 FR 21290), the Skilled Nursing Facility Quality Reporting Program (88 FR 21332), the End-Stage Renal Disease Quality Incentive Program (87 FR 67244), and the Inpatient Rehabilitation Facility Quality Reporting Program (88 FR 20985).

are described by the CDC.[31] HCP include employees of the facility, licensed independent practitioners, and adult students/trainees and volunteers.[32]

Numerator. The number of HCP in the denominator population who are considered up to date[33] with CDC recommended COVID-19 vaccines.

Data collection, submission, and reporting. The measure is calculated quarterly by averaging the hospital's most recently submitted self-selected 1 week of data. It includes at least 1 self-selected week of data for each of the 3 months in a reporting quarter that the hospital would submit to the NHSN Healthcare Personnel Safety (HPS) Component.

Public reporting. Would begin with the Fall 2024 Care Compare refresh, or as soon as technically feasible.

The same proposal is made under section XV.B of the proposed rule for the ASCQR Program.

Pre-Rulemaking. The current version of the HCP COVID-19 Vaccine measure received endorsement by the CBE on July 26, 2022 (CBE #3636). An updated version of the measure was included on the MUC List for the 2022-2023 pre-rulemaking cycle. Comments were mixed and raised concern about the difficulty of defining "up to date" for purposes of the measure and about data collection burden. The developer noted that the model used for this measure is based on the Influenza Vaccination Coverage among HCP measure (CBE #0431). The MAP conditionally supported the rulemaking pending testing that indicates the measure is reliable and valid, and pending endorsement by the CBE. The CDC is pursuing CBE endorsement of the modified version.

b. Proposed Modification of Survey Instrument Use for the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (Cataracts Visual Function) Measure Beginning with the Voluntary 2024 Reporting Period

Background. The Cataracts Visual Function measure was adopted into the OQR program measure set beginning with the 2014 reporting period/2016 payment determination.[34] The measure assesses the percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function within 90 days following the surgery via the administration of pre-operative and post-operative survey instruments (i.e., validated assessment tools). The measure has been available for voluntary reporting, with a number of facilities reporting on it consistently using the survey instrument-collection method of their choice.[35]

---

[31] Centers for Disease Control and Prevention. (2022). Contraindications and precautions. Available at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#contraindications.

[32] Hospitals are required to report data on "other contract personnel" as well for submission in the NHSN, but data on that category of HCP are not included in the HCP COVID-19 measure.

[33] The definition of up to date is as of the first day of the applicable reporting quarter, and can be found at https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf.

[34] The measure was adopted in the 2014 OPPS/ASC final rule (78 FR 75102 through 75103).

[35] 16 survey instruments are currently accepted for collecting data for this measure, including the National Eye Institute Visual Function Questionnaire (NEI-VFQ), the Visual Function (VF-14), the modified Visual Function (VF-8), the

CMS believes the survey instruments should be standardized to minimize collection and reporting burden and improve the measure reliability. It therefore proposes to limit the allowable survey instruments that may be used for the purposes of the measure to the following:

- The National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25);[36]
- The Visual Functioning Patient Questionnaire (VF-14);[37] and
- The Visual Functioning Index Patient Questionnaire (VF-8R).

Considerations for Standardization of Survey Instruments. CMS considered factors including comprehensiveness, validity, reliability, length, and burden when selecting the 3 proposed survey instruments. All are based on the 51-item National Eye Institute Visual Function Questionnaire (NEI VFQ-51) and have been validated as providing results comparable to the NEI VQF-51 but with fewer questions (NEI-VFQ-25 with 25 questions, VF-14 with 14 questions, and VF-8R with 8 questions).

Considerations for Data Collection Modes. The measure requires coordination among opticians and ophthalmologists, which raises concern of administrative burden for reporting. CMS states that the survey instruments can be administered by the HOPD itself via phone, by the patient via regular or electronic mail, or during clinician follow-up.

CMS estimates no increase in information collection burden resulting from this proposal.

c. Proposed Modification of the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (Colonoscopy Follow-Up Interval) Measure Denominator Change to Align with Current Clinical Guidelines Beginning with the 2024 Reporting Period/2026 Payment Determination

In May 2021, the United States Preventive Services Task Force (USPSTF) issued a revised Final Recommendation Statement on Colorectal Cancer (CRC) Screening, recommending that adults who do not have signs or symptoms of CRC and who are at average risk for CRC begin screening at age 45 instead of the previous recommendation of age 50.

Currently, the Colonoscopy Follow-Up Interval measure assesses the "percentage of patients aged 50 years to 75 years receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report."[38]

Activities of Daily Vision Scale (ADVS), the Catquest, and the modified Catquest-9, as examples.

[36] CMS proposes the NEI VQF-25 particularly for individuals with chronic eye diseases. Further details on the NEI VQF-25 may be found at https://www.rand.org/health-care/surveys_tools/vfq.html and https://www.nei.nih.gov/learn-about-eye-health/outreach-resources/outreach-materials/visual-function-questionnaire-25.

[37] CMS notes the VF-14 is the most commonly used survey instrument, and therefore this option allows many physicians to continuing using the instrument they are familiar with. Further details may be found at https://pubmed.ncbi.nlm.nih.gov/8185520/ and https://yorkeyeinstitute.com/sites/default/files/VF-14%20Questionnaire.pdf. Note that CMS indicates in the proposed rule there are 14 questions, but the questionnaire appears to consist of 18 questions covering 14 aspects of visual function affected by cataracts.

[38] Centers for Medicare & Medicaid Services. (2023). Measures Inventory Tool. Available at:

CMS proposes to modify the Colonoscopy Follow-Up Interval measure, by changing the measure denominator to "all patients aged 45 to 75 years". CMS estimates there would be no burden increase associated with this proposal.

3. Proposed Adoption of New Measures for the Hospital OQR Program Measure Set

a. Proposed Re-adoption with Modification of the Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures (HOPD Procedure Volume) Measure Beginning with the Voluntary 2025 Reporting Period Followed by Mandatory Reporting Beginning with the 2026 Reporting Period/2028 Payment Determination

Background. CMS describes the growing volume of services performed in HOPDs. The agency also describes the association between volume of services and patient outcomes attributable to greater experience with more services performed, greater application of best practices, and more effective teamwork. The OQR program does not currently include a quality measure for facility-level volume data, but it used to include the HOPD Procedure Volume measure. The HOPD Procedure Volume measure is a structural measure that collected surgical procedure volume data on specified categories of procedures. The measure was removed in the 2018 OPPS/ASC final rule[39] based on lack of evidence to support its link to a facility's overall performance or quality improvement with respect to surgical procedures.

In the 2023 OPPS/ASC proposed rule, CMS proposed readoption of the measure, referring to more recent scientific literature that concludes that volume metrics serve as an indicator of which facilities are experienced with certain outpatient procedures and can be informative to patients. In this proposed rule, the agency proposes readoption of the measure, reiterating its belief that volume metrics are an indicator for identifying facilities with experience with certain procedures, and thus the usefulness of the data to assist patients in informed decision-making given the trend to more procedures in outpatient settings.

Overview of Proposed Measure with Modification. The proposed measure collects data on the aggregate volume of selected surgical procedures, which are included in one of the following 8 categories: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin. CMS proposes to readopt the measure with the modification that instead of collecting and publicly displaying data on the 8 categories broadly, it would collect and display more granular data for each category on the top 5 most frequently performed procedures in HOPDs in the category. The top 5 for each category would be updated annually.

Data Submission. Data on the top 5 procedures in each category would be submitted through the Hospital Quality Reporting (HQR) system and publicly displayed on Care Compare. Data would be submitted to CMS during January 1 through May 15 in the year prior to the payment determination

https://cmit.cms.gov/cmit/#/MeasureView?variantId=793&sectionNumber=1.

[39] 82 FR 59429 through 59430.

year. For 2028 payment determination, the data submission would be January 1, 2027, through May 15, 2027 (covering the performance period of January 1, 2026 to December 31 2026).

Pre-Rulemaking. The MAP conditionally supported the measure for rulemaking, pending testing indicating measure reliability and validity and CBE endorsement.

CMS estimates an annual burden for participating hospitals of $5,822 for the voluntary reporting period 2025 and $29,099 beginning with the 2026 mandatory reporting period.

b. Proposed Adoption of the Risk-Standardized Patient-Reported Outcome-Based Performance Measure Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty in the HOPD Setting (THA/TKA PRO–PM) Beginning with Voluntary 2025 and 2026 Reporting Periods Followed by Mandatory Reporting Beginning with the 2027 Reporting Period/2030 Payment Determination

Background. The THA/TKA PRO-PM was adopted in the FY 2023 IPPS/LTCH PPS final rule[40] into the Hospital Inpatient Quality Reporting (IQR) Program. CMS proposes to adopt the measure into the OQR program, using the same measure specifications as used in the IQR program, but with modifications to include HOPD procedures. CMS notes that the volume of THA and TKA procedures for Medicare beneficiaries has been increasing in outpatient settings since the removal of the procedures from the Medicare inpatient-only procedures list in the 2021 OPPS/ASC final rule.[41]

Overview and Calculation. The measure uses standardized, validated survey instruments completed within 3 months pre- and at about 1-year post-operatively to assess patient-perceived pain and function. Risk adjustment includes numerous variables.

Numerator. Risk-standardized proportion of patients meeting pre-defined thresholds for substantial clinical improvement measured (90 to 0 days before surgery) from the preoperative assessment to the post-operative assessment (300-425 days after surgery).

Denominator. Medicare beneficiaries 65 years of age or older (enrolled in Medicare FFS parts A and B for the 12 months prior to the date of the procedure and during the procedure) undergoing elective primary outpatient THA or TKA procedures performed in HOPDs.

Exclusions. Patients with hip/knee fractures who have staged procedures or procedures that were started but not completed.

Calculation. All patient-level results for an HOPD facility are aggregated to produce a case-mix adjusted risk-standardized improvement rate (RSIR). Patient Reported Outcome (PRO) tool response rates utilize completed matched pre- and post-operative assessments.

[40] 87 FR 49246 through 49257
[41] 85 FR 86146.

Data Sources. PRO data directly reported by the patient, Medicare claims data, Medicare enrollment and beneficiary data, and Census Bureau survey data.

Data Submission and Reporting. Multiple submission mode options are available. There will be two voluntary reporting periods (one each in 2025 and 2026) followed by mandatory reporting starting in 2027 for payment determination year 2030. Data from the voluntary periods will not be publicly reported, but indicators will identify hospitals choosing to voluntarily report. Public release of results and response rates will start with the first mandatory reporting cycle.

Pre-rulemaking. The measure was on the 2022 MUC List. The MAP supported it for rulemaking. CBE endorsed the hospital level measure adopted in the Hospital IQR program in November 2020 (CBE #3559). CMS intends to seek CBE endorsement of the HOPD version.

CMS estimates the annual burden for data collection across all hospitals to be for the 2025 and 2026 reporting periods $329,579, and beginning with 2027 mandatory reporting $1,318,274. CMS estimates the annual burden for data submission to be $14,552 for the 2026 reporting period for all participating hospitals, $29,099 for the 2027 reporting period for all participating hospitals, $43,651 for the 2028 reporting period for all such hospitals, and $58,202 for the 2029 reporting period and subsequent years.

c. Proposed Adoption of the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography in Adults Measure (Excessive Radiation eCQM) Beginning with the Voluntary 2025 Reporting Period followed by Mandatory Reporting Beginning with the 2026 Reporting Period/2028 Payment Determination

Background. The increased use of computed tomography (CT) scans, while improving the diagnosis and treatment of many conditions, has also increased patients' exposure to ionizing radiation, which contributes to the development of cancer. CMS emphasizes the importance of ensuring exposure from a CT scan being the lowest possible level of radiation while preserving image quality.

Overview and Calculation of Measure. The Excessive Radiation eCQM provides a standardized method for monitoring the performance of diagnostic CT. The measure is not risk-adjusted and is expressed as a percentage of eligible CT scans that are out-of-range based on having either excessive radiation dose or inadequate image quality, relative to evidence-based thresholds based on the clinical indication for the exam. Measure testing showed that availability, accuracy, validity, and reproducibility were high for all of the measures' required data elements; reporting burden was small to moderate (as compared to reporting burden for other measures); and assessing radiation doses and providing radiologists audit feedback reduced unsafe doses levels and helped identify areas for quality improvement.

Numerator. The number of diagnostic CT scans that have a size-adjusted radiation dose greater than the threshold defined for the specific CT category[42] and diagnostic CT scans with a noise value greater than a threshold specific to the CT category.

[42] The threshold is determined by the body region being imaged and the reason for the exam, which affects the radiation dose and image quality required for that exam.

Denominator. The number of all diagnostic CT scans performed on patients 18 years and older during the one-year measurement period which have an assigned CT category, a size-adjusted radiation dose value, and a global noise value.

Exclusions. CT scans that cannot be categorized by the area of the body being imaged or reason for imaging and CT scans missing information on the patient's age, Calculated CT Size-Adjusted Dose, or Calculated CT Global Noise.

Data Sources. The measure uses hospitals' EHR data and radiology electronic clinical data systems, including the Radiology Information System (RIS) and the Picture Archiving and Communication System (PACS). Since eCQMs cannot access and process data elements in the Digital Imaging and Communications in Medicine (DICOM) standard format, and medical imaging information is stored according to that format, the measure developer created translation software (Alara Imaging Software for CMS Measure Compliance), which would be made available to all reporting entities for free. However, hospitals may choose any software that performs the required functions.

Pre-Rulemaking. The measure (CBE #3663e) received CBE endorsement on August 2, 2022, and, in the 2022-2023 pre-rulemaking cycle, received a recommendation from the MAP in support of rulemaking.

CMS estimates for the 2025 reporting period a burden for all participating hospitals of $5,822; for the 2026 reporting period, $58,202; and for the 2027 reporting period, $116,400.

4. Previously Finalized and Proposed OQR Program Measure Sets

Tables 66 and 67 in the rule list the previously finalized and proposed measure sets for 2026 and 2027 payment determinations, respectively, and are consolidated into the table below.

Proposed Hospital OQR Program Measure Sets for 2026 and 2027 Payment Determination

CBE	Measure	2026	2027
0514+	OP-8: MRI Lumbar Spine for Low Back Pain	X	X
	OP-10: Abdomen CT – Use of Contrast Material	X	X
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery	X	X
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients	X	X
0499+	OP-22: ED- Left Without Being Seen	*Proposed Removal*	
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

CBE	Measure	2026	2027
0658*	OP-29: Colonoscopy Follow-Up Interval (Previously referred to as Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients)	X	X
1536**	OP-31: Cataracts Visual Function (Previously referred to as 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
3490	OP-35: Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	X	X
2687	OP-36: Hospital Visits After Hospital Outpatient Surgery	X	X
***	OP-37a Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS-CAHPS) - About Facilities and Staff	X	X
***	OP-37b Communication About Procedure (OAS-CAHPS)	X	X
***	OP-37c Preparation for Discharge and Recovery (OAS-CAHPS)	X	X
***	OP-37d Overall Rating of Facility (OAS-CAHPS)	X	X
***	OP-37e Recommendation of Facility (OAS-CAHPS)	X	X
3636*	OP-38 COVID-19 Vaccination Coverage Health Care Personnel	X	X
	OP-39 Breast Cancer Screening Recall Rates	X	X
***	OP-40 ST-Segment Elevation Myocardial Infarction (STEMI) eCQM	X	X
##	HOPD Procedure Volume (Previously referred to as Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures)		*Voluntary*
###	THA/TKA PRO-PM		*Voluntary*
3663e ##	Excessive Radiation eCQM		*Voluntary*

+CBE endorsement removed
* Modifications are proposed to these measures in the proposed rule.
** In the 2023 OPPS/ASC final rule (87 FR 72097 through 72099), CMS finalized keeping data collection and submission voluntary for the Cataracts Visual Function measure for the 2025 reporting period and subsequent years. In this proposed rule, CMS propose to standardize the surveys offered to patients beginning with the 2024 reporting period.
***Per the 2022 OPPS/ASC final rule (86 FR 63837-63840) mandatory reporting begins with the 2024 reporting period/2026 payment determination.
Proposed adoption with voluntary reporting for the 2025 reporting period and mandatory beginning with the 2026 reporting period/2028 payment determination.
Proposed adoption with voluntary reporting for the 2025 and 2026 reporting periods and mandatory beginning with the 2027 reporting period/2030 payment determination.

4. Public Display of Median Time for Discharged ED Patients-Transfer Patients and Median Time for Discharged ED Patients-Overall Rate measures

The Median Time for Discharged ED Patients is a chart-abstracted measure that evaluates the time between the arrival to and departure from the ED, also known as ED throughput time. It is calculated in stratified subgroups for certain patients. Measure data for the "Transfer Patients" and "Overall Rate" subgroups of the measure are not currently publicly displayed on Care Compare. CMS believes all strata of data should be publicly reported. Therefore, beginning with 2024, the agency proposes to make this data publicly available on CARE Compare.

C. Request for Comment: Topics for Potential Future Consideration

CMS seeks public comment on potential measurement topics for the OQR program, including on the topics of promoting safety (patient and workforce), behavioral health, and telehealth; and specifically to address: (1) quality measurement gaps in the HOPD setting, including the ED, (2) changes in outpatient care (such as shifts in volume, technology, case complexity), (3) concerns around workforce and patient safety, (4) transitioning to digital quality measurement, and (5) interest in patient-reported outcomes.

Solicitation of Comments on Patient and Workforce Safety Measures

CMS expresses a particular interest in sepsis care as a patient safety measure for potential future inclusion in the OQR program because of the important role HOPDs and EDs play in the timely diagnosis and treatment of sepsis. The agency asks if it should consider adopting into the OQR program the Severe Sepsis and Septic Shock: Management Bundle measure (CBE #0500), which was adopted into the Hospital IQR program and proposed for adoption in the HVBP program in the FY 2024 IPPS/LTCH PPS proposed rule,[43] or if it should consider an alternative sepsis care measure. CMS requests comment on the following questions:

- What are the highest priority outcomes for ensuring safety in the outpatient setting, including overall priorities, priorities for specific settings and services (for example, observation care, emergent and non-emergent surgeries, procedures, and imaging), safety related to transitions between care settings, and safety around access to care (such as a patient who lacks access to life-saving medications)?
- What outcomes should be measured across all settings within the OQR program?
- CMS describes that individual harms occur at low frequencies, presenting a challenge for the development of risk-adjusted quality measures that can be used to compare facilities. Existing measures in the OQR program have used approaches such as the capture of utilization (for example, the Hospital Visits After Hospital Outpatient Surgery Measure (CBE #2687)) to indicate potential harm and longer measurement periods to improve measurement reliability.
  ++ Are there other methodological approaches or data to identify harm to patients receiving care in the outpatient setting?

[43] 88 FR 27027 through 27030.

++ What approaches could CMS use to capture harms associated with outpatient services (HOPD procedures, ED visits, outpatient clinic visits, outpatient imaging)?
++ How could electronic data sources or monitoring systems be leveraged to gather timely data on such errors?

- What aspects of workforce safety are important to consider for the OQR program?
- CMS describes a potential for new technologies (such as artificial intelligence (AI) for diagnoses, robotic surgery, and EHRs) or their application to cause harm to patients. It also observes technology could mitigate AI risks, improve safety, or facilitate quality measurement.
  ++ Which technologies are of the most concern in terms of potential for harm?
  ++ What measurable safety-related outcomes should CMS consider for the Hospital OQR Program?
  ++ What technologies could be leveraged to improve safety or facilitate its measurement?

Solicitation of Comments on Behavioral Health and Suicide Prevention

CMS seeks comment on behavioral health topics under consideration for measure development, including availability and access, coordination of care, patient experience, patient-centered clinical care, prevention and treatment of chronic conditions, prevention of harm resulting from medical care, equity across all domains, and suicide prevention. CMS expresses specific interest in measuring suicide screening in the HOPD, including ED, setting. The agency specifically asks about adoption of the Adult Major Depressive Disorder (MDD): Suicide Risk Assessment measure (CBE #0104), which is adopted under MIPS, as well as other measures, such as a universal screening measure. CMS requests comment on the following questions:

- Are there additional behavioral health topic areas that CMS should prioritize? Of the topics outlined in this RFC, which are the highest priority? What are the most relevant quality gaps and outcomes related to behavioral health for hospital outpatient settings and services?
- What measurement approaches could be used to drive improvements in access?
- Should CMS consider substance use disorder-related screening and counseling measures in regards to behavioral health outcomes for the outpatient setting, and, if so, what specific quality measures?
- Should CMS consider a measure related to universal suicide risk in the ED? Are there other interventions or measurement approaches targeted at suicide prevention that CMS should consider?

Solicitation of Comments on Telehealth as a Measurement Topic Area

CMS is considering a measure focused on telehealth quality based on a framework developed by the CBE. CMS seeks comment on the telehealth-related topics of (1) inclusion and prioritization of areas of outpatient telehealth-related care, (2) addressing quality gaps, (3) capturing utilization and disparities in utilization, and (4) understanding patient experience. It specifically seeks comment on the following questions:

- In reference to the telehealth-related topics outlined above, are there additional matters that CMS should prioritize? Which subjects are of the highest priority?

- What are the most relevant clinical issues addressable through telehealth in outpatient settings, and gaps in care that telehealth can address?
- What are the highest priority concerns regarding disparities in access, use, or outcomes related to telehealth in the outpatient setting? Are there any settings or services that should be prioritized?
- Which existing outpatient quality measures should be stratified by telehealth as the mode of delivery?
- What are the most relevant patient-experience-related telehealth outcomes that should be measured?

D. Administrative Requirements

CMS proposes to amend the participation regulation codified at §419.46(b)(1) and (2) and the policy for withdrawal from the OQR program at §419.46(c) to replace references to "QualityNet" with "CMS-designated information system" or "CMS website," and to make related conforming technical edits.

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

1. Annual Submission Deadlines

Beginning with the 2024 reporting period/2026 payment determination, CMS aligned the patient encounter quarters for chart-abstracted measures with the calendar year, with 2025 payment determination using only 3 quarters as a transition.[44] Tables 68, 69, and 70 of the proposed rule show the patient encounter quarters for 2024, 2025, and 2026 payment determination, respectively. A combined table is shown below:

OQR PATIENT ENCOUNTER QUARTERS AND DATA SUBMISSION DEADLINES	
Patient Encounter Quarter	**Data Submission Deadline***
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
2025 – Finalized Transition Year Methodology	
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
2026 – Finalized Subsequent Years Methodology	
Q1 2024 (January 1-March 31)	8/1/2024

[44] The alignment for chart-abstracted measures was finalized in 2023 OPPS/ASC final rule (87 FR 72110 through 72112).

OQR PATIENT ENCOUNTER QUARTERS AND DATA SUBMISSION DEADLINES	
Patient Encounter Quarter	**Data Submission Deadline***
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. Data Submission Requirements for Measures Submitted via a Web-based Tool

Proposed HOPD Procedure Volume Measure. CMS proposes for this measure a voluntary 2025 reporting period followed by mandatory reporting beginning with the 2026 reporting period/2028 payment determination. Hospitals would submit these data to CMS during the time period of January 1 to May 15 in the year prior to the affected payment determination year. After a 30-day preview period data on the top 5 most performed procedures in each of the 8 specified categories would be publicly displayed on Care Compare.

- Example: For the 2025 reporting period (i.e., January 1, 2025-December 31, 2025 performance period) hospitals would submit data through the HQR system January 1, 2026 to May 15, 2026.

Proposed Modification of Survey Instrument Use for the Cataracts Visual Function Measure. CMS proposes the data for this measure be submitted during the period of January 1 to May 15 in the year prior to the affected payment determination year.

- Example: For the voluntary 2024 reporting period (i.e., January 1, 2024-December 31, 2024 performance period) hospitals would submit data through the HQR system January 1, 2025 to May 15, 2025.

Measures Submitted via the CDC NHSN Website. No changes are proposed to the requirements for measure data submitted through the NHSN website, including for the COVID–19 Vaccination Coverage Among HCP measure proposed to be modified in section XIV.B.2.a of the proposed rule.

3. eCQM Reporting and Submission Requirements

STEMI eCQM. As finalized in the 2022 OPPS/ASC final rule (86 FR 63867 through 63868), hospitals must report one self-selected quarter of data for the STEMI eCQM for the 2024 reporting period/2026 payment determination.

Proposed Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults eCQM. The measure is proposed for adoption in section XIV.B.3.c of the proposed rule, with the voluntary 2025 reporting period followed by mandatory reporting beginning with the 2026 reporting period/2028 payment determination. CMS proposes that for the voluntary reporting period hospitals report up to 4 quarters of data. CMS proposes a phased-in

submission of data for mandatory reporting, with hospitals reporting 2 self-selected quarters of data for the 2026 reporting period and then, beginning with the 2027 reporting period, all 4 quarters of data. The data submission deadline would be May 15 in the year prior to the affected payment determination year (i.e., May 15, 2027, for the 2026 reporting period/2028 payment determination).

4. Patient-Reported Outcome-Based Performance Measures (PRO–PMs) Data Submission and Reporting

Adoption of the hospital-level THA/TKA PRO–PM is proposed in section XIV.B.3.b of the rule. A PRO-PM is a new type of measure for the OQR program. Data collection would include pre-operative PRO data collection from 90 to 0 days before the procedure and post-operative PRO data collection from 300 to 425 days after the procedure. There would be 2 voluntary reporting periods (2025 and 2026) with mandatory reporting beginning with reporting period 2027 and impacting the 2030 payment determination. Results of voluntary reporting would not be made publicly available, but CMS would publicly report which facilities voluntarily report and the percent of eligible procedures for which the hospital reports the pre-operative and matching post-operative data. For mandatory reporting, at least 50 percent of eligible complete pre-operative data with matching eligible complete post-operative data would be required, and there would be public posting of the data on Care Compare beginning in 2030.

Tables 72 and 73 in the proposed rule show the proposed pre-operative and post-operative periods, data collection periods and submission dates, and preview dates for the voluntary and mandatory reporting, respectively. A table that combines this information is below.[45]

Pre-Operative and Post-Operative Periods for THA/TKA PRO-PM For 2025-2027 Reporting Periods

Reporting Cycle	THA/TKA Procedures Performed	Pre-Procedure Data Collection	Pre-Procedure Data Submission	Post-Procedure Data Collection	Post-Procedure Data Submission	Preview Confidential Feedback Reports
Voluntary Reporting 2025	January 1, 2025-December 31, 2005	October 3, 2024-December 31, 2025	May 15, 2026	October 28, 2025-February 28, 2027	May 15, 2027	2028
Voluntary Reporting 2026	January 1, 2026-December 31, 2006	October 3, 2025-December 31, 2026	May 15, 2027	October 28, 2026-February 28, 2028	May 15, 2028	2029

[45] Note that hospitals would submit both pre-operative data for the second voluntary period and post-operative data for the first voluntary period by the same data submission deadline, but for the different voluntary reporting periods. For example, hospitals would need to submit: (1) post-operative data for the first voluntary reporting (for procedures performed between January 1, 2025, and December 31, 2025); and (2) pre-operative data for the second voluntary reporting (for procedures performed between January 1, 2026, and December 31, 2026) of the THA/TKA PRO–PM by May 15, 2027.

Reporting Cycle	THA/TKA Procedures Performed	Pre-Procedure Data Collection	Pre-Procedure Data Submission	Post-Procedure Data Collection	Post-Procedure Data Submission	Preview Confidential Feedback Reports
Mandatory Reporting 2027 with 2030 payment determination	January 1, 2027-December 31, 2007	October 3, 2026-December 31, 2027	May 15, 2028	October 28, 2027-February 28, 2029	May 15, 2029	2030

3. OQR Program Validation Requirements

CMS reviews the regulatory history of the OQR validation selection process.[46] This includes the most recent addition to the targeting criteria finalized in the 2023 OPPS/ASC final rule (87 FR 72115 through 72116), which is the addition to the criteria of any hospital with a two-tailed confidence interval that is less than 75 percent and that had less than four quarters of data due to receiving an ECE for one or more quarters. No changes are proposed.

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

CMS proposes that existing policies with respect to computing and applying the payment reduction for hospitals that fail to meet the OQR program requirements would be continued for the 2024 update factor. The resulting reduction ratio for hospitals that fail to meet OQR Program requirements, called the "reporting ratio", is 0.9805. It is calculated by dividing the proposed reduced conversion factor of $85.782 by the proposed full conversion factor of $87.488. Continuing previous policies, the reporting ratio would be applied to all services calculated using the OPPS conversion factor and applied to all HCPCS codes to which CMS has assigned status indicators J1, J2, P, Q1, Q2, Q3, R, S, T, V, or U, excluding services paid under the New Technology APCs to which CMS has assigned status indicators S and T.

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

CMS reports that for 2023 payment, 77 of the 3,097 hospitals failed to meet the OQR Program requirements for a full update factor, compared to 88 of 3,356 hospitals failing in 2022. CMS does not anticipate that policies proposed for the OQR program for 2024 if finalized will impact the number of facilities that will receive payment reductions.

[46] See §419.46(f)(3) for policies regarding the validation selection process and targeting criteria.

XV. Ambulatory Surgery Center Quality Reporting (ASCQR) Program

A. Background and Overview

Under section 1833(i)(7) of the Act, an ambulatory surgical center (ASC) that does not submit for a year required data on quality measures specified by the Secretary receives a 2.0 percentage point reduction to the annual increase. Payment determinations are linked to a quality reporting period that occurs two years in advance of the payment determination year (i.e., 2024 reporting is linked to 2026 payment). An exemption from program participation and payment reduction is given to an ASC that has fewer than 240 Medicare claims per year (the minimum case volume threshold).[47] Many of the statutory provisions applied to the Hospital OQR program are applied by statute to the ASCQR program. CMS provides references to the legislative and regulatory histories of the program.[48]

CMS proposes the following changes to the ASCQR measure set:

(1) Modify 3 measures ((i) the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure, (ii) the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure, and (iii) the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients) beginning with the 2024 reporting period;
(2) Re-adopt with modification the ASC Facility Volume Data on Selected ASC Surgical Procedures measure beginning with the voluntary 2025 reporting period and mandatory reporting beginning with the 2026 reporting period; and
(3) Adopt the Risk Standardized Patient-Reported Outcome-Based Performance Measure Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty in the ASC Setting (THA/TKA PRO-PM) beginning with the voluntary 2025 and 2026 reporting periods and mandatory reporting beginning with the 2027 reporting period.

CMS estimates a total information collection burden increase for 5,057 ACSs of 7,689 hours at a cost of $238,675 annually associated with the policies proposed in for the ASCQR program.

CMS invites comment on all proposals for the ASCQR program under this section.

[47] 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.
[48] 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.

B. ASCQR Program Quality Measures

1. Technical Change

Similar to as CMS proposes under the OQR program, CMS proposes to replace references to "QualityNet" with references to "CMS-designated information system" or "CMS website" and to make other conforming technical edits to effectuate that proposal.

2. Modifications to Previously Adopted Measures

a. COVID-19 Vaccination Coverage Among HealthCare Personnel (COVID-19 HCP Vaccination) Measure Beginning with 2024 Reporting Period/2026 Payment Determination

In response to the COVID-19 PHE, the COVID-19 HCP Vaccination measure was adopted across multiple quality programs, including the ASCQR program.[49]

CMS proposes, beginning with the 2024 reporting period/2026 payment determination, to adopt the same modifications to the measure for the ASCQR program as CMS proposes for the OQR program in section XIV.B.2.a of the proposed rule (as summarized in section XIV.B.2.a. above). The modifications include using the term "up to date" in the HCP vaccination definition and updating the numerator to specify the timeframes within which an HCP is considered up to date with CDC recommended COVID-19 vaccines.

ASCs would collect data on the measure for at least one self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personnel Safety (HPS) Component before the quarterly deadline to meet ASCQR program requirements. The measure would be calculated for a month using the most recent self-selected week of data submitted, and a single HCP vaccination coverage rate for an ASC for each quarter would be calculated by the CDC as the average of the 3 weekly rates used for the quarter. CMS would publicly report each quarterly COVID–19 HCP vaccination coverage rate as calculated by the CDC.

b. Proposed Modification of the Survey Instrument Used for the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure Beginning with the Voluntary 2024 Reporting Period

CMS finalized the adoption of this measure in the ASCQR program in the CY 2014 OPPS/ASC final rule (78 FR 75129). The measure assesses the percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function within 90 days following the cataract surgery via the administration of pre-operative and post-operative survey instruments.

CMS proposes, beginning with the voluntary 2024 reporting period, to adopt the same modifications to the measure for the ASCQR program as CMS proposes for the OQR program in section XIV.B.2.b of the proposed rule (as summarized in section XIV.B.2.b above). The

[49] 86 FR 63875 through 63833.

modifications would limit the survey instruments that an ASC may use to assess changes in a patient's visual function for purposes of the measure to the following:

- The National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25).
- The Visual Functioning Patient Questionnaire (VF-14).
- The Visual Functioning Index Patient Questionnaire (VF-8R).

CMS estimates no increase in burden resulting from this proposal.

c. Proposed Modification of Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure Denominator Change to Align with Current Clinical Guidelines Beginning with the 2024 Reporting Period/2026 Payment Determination

In May 2021, the United States Preventive Services Task Force (USPSTF) issued a revised Final Recommendation Statement on Colorectal Cancer (CRC) Screening, recommending that adults who do not have signs or symptoms of CRC and who are at average risk for CRC begin screening at age 45 instead of the previous recommendation of age 50.

CMS therefore proposes the same modification to the Colonoscopy Follow-Up Interval measure in the ASCQR program, as it is proposing for the OQR program in section XIV.B.2.c of the proposed rule (as summarized in section XIV.B.2.c. above), that is to change the measure denominator to "all patients aged 45 to 75 years".

CMS estimates no increase in burden.

3. Proposed Adoption of New Measures for the ASCQR Program Measure Set

a. Proposed Re-adoption with Modification of the ASC Facility Volume Data on Selected ASC Surgical Procedures Measure Beginning with the Voluntary 2025 Reporting Period Followed By Mandatory Reporting Beginning with the 2026 Reporting Period/2028 Payment Determination

Background. CMS describes how, as with the OQR program, the ASCQR program no longer includes a quality measure for facility-level volume data, but it used to include the ASC Facility Volume Data on Selected ASC Surgical Procedures (ASC Procedure Volume) measure. The structural measure collected surgical procedure volume data on 7 categories of procedures frequently performed in ASCs. CMS removed the measure in the CY 2018 OPPS/ASC final rule,[50] based on its belief that other measures in the measures set could provide patients with more valuable ASC quality of care. CMS now points to the trend in higher volume for outpatient procedures and more recent scientific studies showing that volume is an indicator of quality, and therefore believes measuring volume of services at ASCs is valuable in determining the quality of ASC services. The same as it proposes in section XIV.B.3.a of the proposed rule to readopt the HOPD Procedure Volume measure for the OQR program, CMS proposes to re-adopt the ASC Procedure Volume measure for the ASCQR program, with modification.

[50] 82 FR 59449 through 59450.

Proposed readoption with modification. The proposed measure collects data on the aggregate volume of selected surgical procedures, which are included in one of the following 8 categories: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin. CMS proposes to readopt the measure with modification; the data collected will be, for each category, the more granular data on the top 5 most frequently performed procedures in ASCs in that category. The top 5 for each category would be updated annually.

Data Submission. ASCs would submit data on the top 5 procedures in each category through the HQR system and the data would be publicly displayed on Care Compare. There would be a 2025 voluntary reporting period and mandatory reporting beginning with the 2026 reporting period/2028 payment determination. Data would be submitted to CMS during January 1 through May 15 in the year prior to the payment determination year. For 2028 payment determination, the data submission would be January 1, 2027 through May 15, 2027 (covering the performance period of January 1, 2026 to December 31 2026).

Pre-Rulemaking. The MAP conditionally supported the measure for rulemaking, pending testing indicating measure reliability and validity and CBE endorsement.

CMS estimates an annual burden of $8,782 for the voluntary reporting period 2025 (assuming 20 percent of ASCs report) and an annual burden of $43,937 for mandatory reporting beginning with the 2026 reporting period.

b. Proposed Adoption of the Risk Standardized Patient-Reported Outcome-Based Performance Measure Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty in the ASC Setting (THA/TKA PRO-PM) for Voluntary 2025 and 2026 Reporting Periods and Mandatory Reporting Beginning with the 2027 Reporting Period/2030 Payment Determination

Background. The THA/TKA PRO-PM was adopted in the FY 2023 IPPS/LTCH PPS final rule[51] into the Hospital Inpatient Quality Reporting (IQR) Program. CMS proposes to adopt the measure into the ASCQR program, using the same measure specifications as in the Hospital IQR program, but with modifications to include ASC procedures. The same proposal is made in section XIV.B.3.b of the proposed rule to adopt the measure into the OQR program, with modifications to include HOPD procedures.

Overview. The measure uses standardized, validated survey instruments completed within 3 months pre- and at about 1-year postoperatively to assess patient-perceived pain and function. Risk adjustment includes numerous variables.

Numerator. Risk-standardized proportion of patients meeting pre-defined thresholds for substantial clinical improvement measured (90 to 0 days before surgery) from the preoperative assessment to the postoperative assessment (300-425 days after surgery).

[51] 87 FR 49246 through 49257.

Denominator. Medicare beneficiaries 65 years of age or older (enrolled in Medicare FFS parts A and B for the 12 months prior to the date of the procedure and during the procedure) undergoing elective primary outpatient THA or TKA procedures performed in ASCs.

Exclusions. Patients with hip/knee fractures who have staged procedures or procedures that were started but not completed.

Calculation. All patient-level results for an ASC facility are aggregated to produce a case-mix adjusted risk-standardized improvement rate (RSIR). PRO tool response rates utilize completed matched pre- and postoperative assessments.

Data Sources. PRO data directly reported by the patient, Medicare claims data, Medicare enrollment and beneficiary data, and Census Bureau survey data.

Data Submission and Reporting. Multiple submission mode options are available. HOPD facilities submit multiple data elements, drawn from prespecified reporting periods, during preset submission windows. There will be two voluntary reporting periods (one each in 2025 and 2026) followed by mandatory reporting starting in 2027 for payment determination year 2030. Data from the voluntary periods will not be publicly reported but indicators will identify ASCs choosing to voluntarily report. Public release of results and response rates will start with the first mandatory reporting cycle.

Pre-rulemaking. The measure was on the 2022 MUC List. It was supported by the MAP for rulemaking. CBE endorsed the hospital level measure adopted in the Hospital IQR program in November 2020 (CBE #3559). CMS intends to seek CBE endorsement of the ASC version.

CMS estimates for data collection, an annual burden of $26,716 across ASCs for the voluntary 2025 and 2026 reporting periods, and of $106,864 across ASCs beginning with the mandatory 2027 reporting period. CMS estimates for data submission, an annual burden of $21,995 across ASCs for the voluntary 2026 reporting period, of $43,937 for the 2027 reporting period, of $65,880 for the 2028 reporting period, and $87,874 for the 2028 and subsequent reporting periods.

4. ASCQR Program Quality Measure Set

Tables 75 and 76 in the rule list the previously finalized and proposed measure sets for the 2024 reporting period/2026 payment determination and 2025 reporting period/2027 payment determination and are consolidated into the table below.

ASCQR Program Measures by Reporting Period/Payment Determination Year		
	2024/2026	**2025/2027**
CMS WEB-BASED TOOL REPORTING		
ASC-1: Patient Burn (CBE #0263)+	X	X
ASC-2: Patient Fall (CBE #0266) +	X	X
ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (CBE #0267)+	X	X
ASC-4: All-Cause Hospital Transfer/Admission (CBE #0265)+	X	X

ASCQR Program Measures by Reporting Period/Payment Determination Year		
	2024/2026	**2025/2027**
ASC-7: ASC Procedure Volume (Previously referred to as ASC Facility Volume on Selected ASC Surgical Procedures)*		V##
ASC-9: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (CBE #0658)	X*	X
ASC-11: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (CBE #1536)+	*V***	*V***
ASC-13: Normothermia Outcome	X	X
ASC-14: Unplanned Anterior Vitrectomy	X	X
ASC-21: Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PROPM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO–PM)* (CBE #3636)		V#
CLAIMS-BASED REPORTING		
ASC-12: Facility 7-Day Risk Standardized Hospital Visit Rate after Outpatient Colonoscopy (CBE #2539)	X	X
ASC-17: Hospital Visits After Orthopedic ASC Procedure (CBE #3470)	X	X
ASC-18: Hospitals Visits After Urology ASC Procedure CBE #3366)	X	X
ASC-19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at an ASC (NQF #3357)	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		X***
CDC NHSN WEB REPORTING		
ASC-20: COVID-19 Vaccination Coverage Health Care Personnel	X*	X

+ CMS notes that CBE endorsement for the measure has been allowed to lapse by the measure steward.
* In this proposed rule, CMS proposes measure modifications to the Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients and COVID-19 Vaccination Coverage Among HCP measures that begin with the 2024 reporting period/ 2026 payment determination.
*V*** In the CY 2023 OPPS/ASC final rule (87 FR 72118 through 72120), CMS finalized to keep data collection and submission voluntary for this measure for the 2025 reporting period and subsequent years. In this proposed rule, CMS proposes to standardize the surveys offered to patients pre- and post-surgery beginning with the 2024 reporting period/2026 payment determination.
*X**** Reporting on a set of OAS CAHPS measures: 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.
V# In the proposed rule, CMS proposes this measure as voluntary for the 2025 reporting period followed by mandatory reporting beginning with the 2027 reporting period/2030 payment determination.

ASCQR Program Measures by Reporting Period/Payment Determination Year		
	2024/2026	2025/2027
V## CMS proposes to readopt the ASC Procedure Volume measure as a voluntary measure for the 2025 reporting period followed by mandatory reporting beginning with the 2026 reporting period/2028 payment determination.		

C. Administrative Requirements

CMS refers readers to §416.310(c)(1)(i) for current policies on submission of data through the online data submission tool, and to §416.305 for current policies on participation status requirements for the ASCQR program. CMS proposes to replace references in these provisions to "QualityNet" with references to "CMS-designated information system" or "CMS website", with relating conforming technical edits.

D. Form, Manner and Timing of Data Submitted for the ASCQR Program

Background. Regulatory policies regarding data collection and submission under the ASCQR program are under §416.310. For claims-based measures using Quality Data Codes (QDCs), requirements for data processing and collection periods are under §416.310(a)(1) and (2), and requirements on minimum threshold, minimum case volume, and data completeness are under §§416.310(a)(3) and 416.305(c). For non-QDC claims-based measures, requirements for data processing and collection periods are under §416.310(b). For data submitted through an online data submission tool (currently the HQR system and formerly the QualityNet Secure Portal), see the requirements under §416.310(c)(1). Submission requirements for measures submitted through a non-CMS online data submission tool (specifically, the CDC's NHSN) are under §416.310(c)(2).

Data Submission and Reporting for Proposed ASC Procedure Volume Measure. Voluntary reporting would be for the 2025 reporting period with mandatory reporting beginning with the 2026 reporting period/2028 payment determination. Data would be submitted through the HQR system during the period of January 1 to May 15 in the year prior to the affected payment determination year. For example, for the 2025 reporting period, the data would be collected during January 1, 2026-May 15, 2026.

Data Submission and Reporting for Proposed Modified Cataracts Visual Function Measure. Standardization of the survey instruments would begin with the 2024 reporting period. Data would be submitted through the HQR system during the period of January 1 to May 15 in the year prior to the affected payment determination year.

Data Submission and Reporting Requirements for Patient-Reported Outcome-Based Performance Measures (PRO-PMs)

PRO-PMs (such as the proposed the THA/TKA PRO-PM) are a new type of measure in the ASCQR program. CMS proposes providing ASCs with flexibility to choose from multiple

submission approaches. For the THA/TKA PRO PM, CMS proposes that ASCs and vendors use the HQR system.

Data collection for the THA/TKA PRO PM would include pre-operative PRO data collection from 90 to 0 days before the procedure and post-operative PRO data collection from 300 to 425 days after the procedure. There would be 2 voluntary reporting periods (2025 and 2026) with mandatory reporting beginning with reporting period 2027 and impacting the 2030 payment determination. Results of voluntary reporting would not be made publicly available, but CMS would publicly report which facilities voluntarily report and the percent of eligible procedures for which the hospital reports the pre-operative and matching post-operative data. For the voluntary reporting periods, CMS proposes that participating ASCs submit at least 45 percent of eligible complete pre-operative data with matching eligible complete port-operative data. For mandatory reporting, at least 45 percent of eligible complete pre-operative data with matching eligible complete post-operative data would be required, and there would be public posting of the data on Care Compare beginning in 2030.

Tables 77 and 78 in the proposed rule show the proposed pre-operative and post-operative periods, data collection periods and submission dates, and preview dates for the voluntary and mandatory reporting, respectively. A table that combines this information is below.[52]

Pre-Operative and Post-Operative Periods for THA/TKA PRO-PM For 2025-2027 Reporting Periods

Reporting Cycle	THA/TKA Procedures Performed	Pre-Procedure Data Collection	Pre-Procedure Data Submission	Post-Procedure Data Collection	Post-Procedure Data Submission	Preview Confidential Feedback Reports
Voluntary Reporting 2025	January 1, 2025-December 31, 2025	October 3, 2024-December 31, 2025	May 15, 2026	October 28, 2025-February 28, 2027	May 15, 2027	2028
Voluntary Reporting 2026	January 1, 2026-December 31, 2026	October 3, 2025-December 31, 2026	May 15, 2027	October 28, 2026-February 28, 2028	May 15, 2028	2029
Mandatory Reporting 2027 with 2030 payment determination	January 1, 2027-December 31, 2027	October 3, 2026-December 31, 2027	May 15, 2028	October 28, 2027-February 28, 2029	May 15, 2029	2030

[52] Note that ASCs would submit both pre-operative data for the second voluntary period and post-operative data for the first voluntary period by the same data submission deadline, but for the different voluntary reporting periods. For example, ASCs would need to submit: (1) post-operative data for the first voluntary reporting (for procedures performed between January 1, 2025, and December 31, 2025); and (2) pre-operative data for the second voluntary reporting (for procedures performed between January 1, 2026, and December 31, 2026) of the THA/TKA PRO–PM by May 15, 2027.

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

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

CMS states that of 5,697 ASCs eligible for the ASCQR program for 2023 payment determinations, 5,181 met all the requirements and received the full annual payment update under the ASC fee schedule. In addition, 687 ASCs that were not required to report did so, along with 195 Hospitals Without Walls that returned to active ASC billing, making a total of 6,063 facilities participating in the ASCQR program.[53]

XVI. Rural Emergency Hospital Quality Reporting (REHQR) Program

A. Background and Overview

Section 1861(kkk) of the Act establishes rural emergency hospitals (REHs) as a Medicare provider type that furnishes 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 began on January 1, 2023.

Section 1861(kkk)(7) of the Act establishes the REHQR program, by requiring the Secretary to establish quality reporting requirements for REHs, require data submission at least quarterly, and publicly post-performance data. There is no statutory incentive for submitting this data, nor statutory penalty for failing to submit the data. CMS proposes to codify at 42 CFR §419.95 the statutory authority for the program.

In addition, for the REHQR program, CMS proposes to:

(1) Adopt and codify policies related to measure retention, removal, and modification; public reporting; the form, manner, and timing of data submission; a review and corrections period for submitted data; and an Extraordinary Circumstances Exception (ECE) process;

[53] CMS posts individual facility payment determination result lists on the website https://qualitynet.cms.gov/asc/ascqr/apu#tab1.

(2) Adopt 1 chart-abstracted measure and 3 claims-based measures and establish related reporting requirements beginning with the 2024 reporting period; and
(3) Codify requirements related to REHQR program participation.

CMS estimates 746 hospitals would be both eligible to transition to REH status and are located in a state where legislation has passed as of March 2023 enabling transition to occur. It estimates that the REHQR proposals would result in an initial annual information collection burden of 9,101 hours at a cost of $474,344 for those 746 REHs beginning with the 2024 reporting period, as reflected in table 96 of the rule.

CMS invites public comment on all the proposals for the REHQR program. CMS requests comment on potential measures and approaches for implementing quality reporting under the REHQR Program, specifically on (1) electronic clinical quality measures (eCQMs); (2) care coordination measures; and (3) a tiered quality measure approach.

B. REHQR Program Quality Measures

1. Considerations in Selection of REHQR Program Quality Measures

CMS describes its considerations for selecting REHQR program quality measures. It describes its goal to adopt measures that are concise, important, impactful, reliable, accurate, and clinically relevant to inform consumer decision-making and further quality improvement. The agency prioritized measures that were CBE-reviewed for the HOPD setting and that adhere to current CMS and HHS initiatives, such as the CMS National Quality Strategy goals, CMS Strategic Plan, Meaningful Measures 2.0, and the HHS Strategic Plan;[54] and focused on service and patient volume, care accountability and quality, rurality and setting relevance, and health equity.
In accordance with section 1861(kkk)(7)(C)(i) of the Act, a measure must be CBE-endorsed to be selected for the REHQR, unless the exception under section 1861(kkk)(7)(C)(ii) applies that no CBE-endorsed measure addresses a specific area or medical topic involved.

2. Retention of Measures Previously Adopted

CMS proposes a measure retention policy that is reflective of the policy used for other quality reporting programs, such as the OQR and ASCQR programs. The policy is that once a measure is adopted into the REHQR program measure set it is retained in the set until the agency proposes removal, suspension, or replacement.

3. Removal of Measures

CMS proposes an immediate measure removal policy that would allow CMS to remove a measure outside of rulemaking if it believes that the continued use of the measure would raise potential

[54] For CMS National Quality Strategy see CMS National Quality Strategy | CMS, CMS Strategic Plan see CMS Strategic Plan | CMS, Meaningful Measures 2.0 see Meaningful Measures 2.0: Moving from Measure Reduction to Modernization | CMS, and HHS Strategic Plan see Strategic Plan FY 2022 – 2026 | HHS.gov.

patient safety concerns. REHs and the public would be notified through standard hospital communication channels, and CMS would confirm the removal in the next rulemaking cycle. This is similar to the OQR program policy.[55]

CMS proposes to codify a measure removal factors policy that uses a similar set of 8 factors as are used in the OQR and ASCQR programs. The following are the proposed 8 factors:

- Factor 1: The measure performance among REHs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made ("topped-out").
- Factor 2: Performance or improvement on the measure does not result in better patient outcomes.
- Factor 3: The measure does not align with current clinical guidelines or practice.
- Factor 4: The availability of a more broadly applicable measure for the topic.
- Factor 5: The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.
- Factor 6: The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.
- Factor 7: Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.
- Factor 8: The costs associated with the measure outweigh the benefit of its continued use.

CMS proposes that a measure would be removed, suspended, or replaced pursuant to rulemaking (unless it raises specific safety concerns), and that a measure would not be removed solely based on meeting any specific factor.

4. Modifications to Previously Adopted Measures

CMS proposes a sub-regulatory process to adopt any non-substantive updates to measure specifications. CMS will develop a specifications manual for measures. CMS would revise the manual and provide notification on a designated website (currently QualityNet) when sub-regulatory updates are made. Substantive changes are those so significant that the measure is no longer the same measure, and would be made through rulemaking. The determination of what is substantive versus non-substantive would be made on a case-by-case basis. This policy would align with the policies under the OQR and ASCQR programs.

CMS will maintain technical specifications for adopted REHQR measures. CMS proposes to adopt a policy for maintaining the measure specifications that aligns with the OQR program's policy.[56]

[55] 74 FR 60634 through 60635.
[56] For the OQR program policy, see 83 FR 59104 through 59105. The manuals containing specifications for previously adopted measures can be found at https://qualitynet.cms.gov/outpatient/specifications-manuals.

5. Proposed New Measures

CMS proposes to adopt 4 measures into the REHQR program beginning with the 2024 reporting period. All of the proposed measures are included in the OQR program. Three are calculated from Medicare FFS claims and enrollment data and the fourth is chart-abstracted. CMS analyzed data on the number of hospitals already publicly reporting on the measures that are being proposed and determined there was a relatively high percentage of hospitals and CAHs eligible to convert to REH status that have reported on the measures as part of the OQR program. Table 79 of the proposed rule shows the results of the analysis for each measure being proposed.

a. Abdomen Computed Tomography (CT) – Use of Contrast Material Measure

Background. CMS describes that duplicate CT scans (performed with and without contrast) increase the radiation doses to patients. The Abdomen CT measure is used in the OQR program and the agency believes it may be effective in lowering patient risks by identifying performance gaps between hospitals and reducing duplicate abdomen CTs. CMS notes that analysis of Care Compare data shows that nearly half of hospitals reporting duplicate scans were rural hospitals. CMS proposes adoption of the measure for the REHQR program measure set beginning 2024.

Measure Overview and Calculation. The claims-based, non-risk-adjusted measure calculates the percentage of CT abdomen and abdominopelvic studies performed with and without contrast out of all CT abdomen studies performed. It is calculated based on a 12-month period of claims data.

- *Numerator*. Patients who had a combined CT abdomen study (documented using the with and without contrast CPT code).
- *Denominator*. Medicare FFS beneficiaries who underwent an abdomen or abdominopelvic CT study at an REH. Each eligible CT is counted even if for the same eligible person.
- *Exclusions*. Inpatients and patients with a clinical diagnosis with any condition for which duplicate imaging is considered appropriate.

Data Sources. The measure is calculated using Medicare FFS final action claims and enrollment data.

Pre-Rulemaking. The measure was on the 2022 MUC list. It received conditional support by the MAP, pending CBE endorsement and testing indicating the measure is reliable and valid. The MAP noted the measure addresses patient safety in rural hospitals and the Health Equity Advisory Group notes its potential to advance health equity.

No additional burden to REHs is estimated since the measure uses data already reported.

b. Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients Measure

Measure Overview. The Median Time for Discharged ED Patients measure is a chart-abstracted measure to evaluate the period between arrival to departure from the ED (ED throughput time). Measure data are stratified into 4 calculations:

- The overall rate: The median throughput time for all discharged ED patients.
- The reported measure: The median throughput time for all ED discharged patients excluding psychiatric/mental health patients and transfer patients.
- Psychiatric/mental health: The median throughput time for psychiatric/mental health patients discharged from the ED.
- Transfers: The median throughput time for transfer patients transferred from the ED.

Exclusions. Patients who died in the ED, left against medical advice, or whose discharge was undocumented/undetermined.

Data Sources. The measure is calculated using chart-abstracted data on a rolling quarterly basis. Sources may include claims forms, electronic health data, EHRs, or paper records.

Pre-Rulemaking. The measure was on the 2022 MUC list. The MAP did not provide support for inclusion in the REHQR program, expressing concern that changes in wait times do not directly influence patient outcomes and that there are issues affecting transfer wait times beyond a facility's control (such as weather). The Health Equity Advisory Group expressed potential of measure to advance health equity.

Acknowledging MAP concerns raised, CMS believes studies have shown long wait times associated with worse patient experience, which is associated with outcomes, and that data on the measure is useful to beneficiaries for informed decision-making. It therefore proposes adoption beginning with the 2024 reporting period.

CMS estimates for all participating REHs an annual chart-abstraction burden of $474,344.

c. Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy Measure

Measure Overview and Calculation. The outcome measure estimates a facility-level rate of risk-standardized, all-cause, unplanned hospital visits within 7 days of an outpatient colonoscopy among Medicare FFS patients 65 years or older. A hospital visit includes any ED visit, observation stay, or unplanned inpatient admission to any short-term, acute-care facility. The measure score is the ratio of predicted hospital visits to expected hospital visits multiplied by the national observed rate.[57]

- *Numerator*. The number of unplanned hospital visits the REH is predicted to have within 7 days of the procedure, accounting for the observed unplanned visit rate, number of colonoscopies performed at the REH, and ASC's case mix.
- *Denominator*. The number of expected hospital visits (Medicare patients) based on the REH's case mix (i.e., the sum of all patients' expected probabilities of a hospital visit given their risk factors and the average facility risk of readmission).
- *Exclusions*. Patients with specified high risks and those without continuous Medicare FFS part A and B enrollment in the month after the procedure.

[57] For further details see Colonoscopy Measure Overview (cms.gov).

Data Sources. The measure uses Medicare FFS claims and enrollment data. The initial reporting period, consistent with the OQR program, is a 3-year period beginning with patient encounters from January 1, 2024, through December 31, 2026, with annual updates.

Pre-Rulemaking. The measure was on the 2022 MUC list. The MAP supported it for rulemaking for the REHQR program in its February 1, 2023, Final Recommendations, based on a previous version of the measure specific to ASCs and HOPDs (and currently in use in the ASCQR and OQR programs) receiving CBE endorsement (CBE #2539).

CMS proposes adoption of the measure beginning with the 2024 reporting period.

No additional burden to REHs is estimated since the measure uses data already reported.

d. Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery Measure

Measure Overview. The outcomes measure calculates unplanned hospital visits occurring seven days after a surgery performed at an REH that are an inpatient admission at a separate hospital or an ED visit or observation stay at the REH or other hospital after discharge. Only the first unplanned hospital visit within the outcome timeframe (if more than one occurs) is counted. The measure is the ratio of predicted to expected number of post-surgical hospital visits. A ratio that is less than one shows the REH's patients have fewer than expected post-surgical visits.

- *Numerator*. The number of visits predicted for the REH's patients accounting for its observed rate, the number of surgeries performed at the REH, case-mix, and surgical procedure mix.
- *Denominator*. The expected number of hospital visits post-surgery (for Medicare FFS patients aged 65 years or older undergoing same-day, outpatient surgery in the REH) given the hospital's case-mix and surgical procedure mix.
- *Inclusions and exclusions*. Eligible outpatient same-day surgeries occurring within a 1-year period. Same-day surgeries are substantive surgeries listed on Medicare's list of covered ASC procedures (other than specified exclusions).
- *Exclusions*. Eye surgeries and colonoscopies (other than with biopsy).

Data Sources. The measure is calculated from Medicare parts A and B administrative claims data for FFS beneficiaries.

Pre-Rulemaking. The measure was on the 2022 MUC list. The CBE recommended the measure for rulemaking (CBE #2687).

CMS proposes adoption of the measures beginning with the 2024 reporting period.

No additional burden to REHs is estimated since the measure uses data already reported.

6. Summary of Proposed REHQR Program Measure Set

Table 80 of the proposed rule shows the measure set proposed beginning with the 2024 reporting period and is shown below.

CBE #	Measure Name
None	Abdomen Computed Tomography (CT) – Use of Contrast Material
None	Median Time from ED Arrival to ED Departure for Discharged ED Patients
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy*
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery
* Reporting period for this measure is a three-year period, beginning 2024-2026.	

7. REHQR Program Measures and Topics for Future Consideration

a. ***Request for Comment****: ECQMs for Reporting Quality Data Under the REHQR Program*

ECQMs use data electronically extracted from EHRs or other health information technology systems. CMS acknowledges potential technological, monetary, and staffing barriers that may be of concern for use of eCQMs at REHs. Tables 81 and 82 of the proposed rule compare urban and rural hospital eCQM reporting for the Medicare PI Program for 2021, and show eCQM compliance percentages for smaller hospitals and rural hospitals as slightly lower than for larger or urban hospitals. CMS believes some eCQMs could provide useful data for monitoring REHs and lowering provider burden. Specifically, the agency points to the Excessive Radiation eCQM proposed for adoption for the OQR program in section XIV.B.3.c of the proposed rule.

CMS invites public comment on the use of eCQMs in the REHQR Program, any specific eCQM measures that should be considered (including the Excessive Radiation eCQM), and any considerations or criteria it should use in identifying eCQM measures for future inclusion.

b. ***Request for Comment****: Care Coordination Measures*

CMS describes that it may consider adding measures relevant to coordination of care between REHs and other providers, especially given the specific challenges experienced by REHs, such as geographic isolation, workforce shortages, transportation issues, and information technology challenges. CMS specifies measures identified by the CBE as relevant to telehealth, such as measures CBE #0006 Care Coordination, CBE #0097 Medication Reconciliation Post-Discharge, and CBE #0326 Advance Care Plan. The agency also refers to the Emergency Department Transfer Communication, Discharge Planning, and Medication Reconciliation measures used in the Medicare Beneficiary Quality Improvement Project (MBQIP).

CMS invites public comment on the use of care coordination measures in the REHQR program, any specific care coordination-related measures that should be considered, and any considerations or criteria it should use in determining which if any of such measures to propose in the future.

c. ***Request for Comment****: Tiered Approach Framework*

In response to the RFI on REHs in section XVII of the 2022 OPPS/ASC proposed rule, CMS received a suggestion to implement a multi-tiered approach for quality measures and requirements. CMS describes that under such an approach tier 1 could include a set of required measures for all REHs on ED and observation services required at REHs and tier 2 could include measures related to additional outpatient services that REHs may choose to provide.

CMS invites public comment on the implementation of a tiered measure approach, considerations in designating the structure of such an approach, the number of measures in each tier, and considerations for designating measures for the tiers.

8. Proposals on Public Display of Quality Measure Data

a. General Information

Section 1861(kkk) of the Act requires quality measure data submitted by REHs be made available to the public and that REHs have the opportunity to review the data before they are made public. CMS proposes for the REHQR program the same public display of measures policy as used in the OQR and ASCQR programs. Data would be made available beginning with data submitted for the 2024 reporting period on Care Compare and in files located in the Provider Data Catalog at http://data.cms.gov. REHs would have a 30-day review and correction period before information is publicly posted.

b. Proposed Claims-Based Measures

CMS proposes to make measure scores for the proposed claims-based measures (the Abdomen CT measure, 7-Day Hospital Visit Rate After Outpatient Colonoscopy measure, and 7-Day Hospital Visit Rate After Outpatient Surgery measure) publicly available beginning with the data reported for services furnished in 2024. Data would be made public after completion of the data collection period specific to the measure (for example, for the 7-Day Hospital Visit Rate After Outpatient Colonoscopy Measure that would be after completion of the initial 3-year data collection period (i.e., 2027)) and only if the hospital had sufficient case volumes.

c. Proposed Median Time from ED Arrival to ED Departure for Discharged ED Patients Measure

CMS proposes to make publicly available data received from REHs to calculate each of the 4 strata of the measure (Overall Rate, Reported Measure, Psychiatric/Mental Health Patients, and Transfer Patients – described in section XVI.B.5.b of the proposed rule and above) beginning with the first quarter of measure data submitted for the 2024 reporting period.

C. Administrative Requirements

CMS reviews the administrative requirements for REHs participating in the REHQR program finalized in the CY 2023 OPPS/ASC final rule,[58] including requiring REHs to register on a CMS website before starting to report data and to identify and register a security official as part of the registration process. The agency proposes to codify the participation requirements at §419.95(b).

D. Form, Manner and Timing of Data Submitted for the REHQR Program

CMS proposes to align policies for submission of REHQR program data with those from the OQR program[59] and codify the policy at §419.95. Data collection and submission would be required, for public reporting purposes, to be combined across campuses of REHs sharing the same CMS Certification Number (CCN).

CMS proposes that measure data for the Median Time for Discharged ED Patients (the only chart-abstracted measure proposed beginning for the 2024 reporting period) be submitted through the HQR system for each calendar quarter in the reporting period (aligning with the OQR program). The 2024 reporting period quarters and corresponding clinical data submission deadlines are shown in table 83 of the proposed rule.[60]

For the 3 claims-based measures proposed beginning for the 2024 reporting period, CMS proposes to use Medicare claims data for services with encounter dates on or after January 1, 2024.

CMS proposes to adopt and codify the same policy as in the OQR program[61] for a review and corrections period for data submitted to the REHQR program. REHs would have a review and corrections period, which runs concurrently with the data submission period, for all quality data submitted during which they would be able to enter, review, and correct data submitted prior to the submission deadline. The data would not be able to be changed after the submission deadline.

CMS also proposes an Extraordinary Circumstances Exceptions (ECE) process under which it would have authority to grant, upon the request of an REH or at its discretion (without such a request), an exception to one or more data submission deadlines or requirements when there are extraordinary circumstances beyond the control of the REH. CMS describes specific requirements for submission of such a request and specifies the information that must be included on the REH request form, which would be required to be submitted not later than 90 days after the extraordinary circumstances occurred.

XVII. Changes to the Community Mental Health Centers Conditions of Participation (CoPs)

Changes are required to the regulations establishing conditions of participation (CoPs) for CMHCs to account for the statutory addition of the new Medicare benefit category for intensive outpatient

[58] 87 FR 71752, and 72149 through 72150.
[59] The OQR requirements were codified at §419.46(d).
[60] See the CY 2015 OPPS/ASC and CY 2023 OPPS/ASC final rules for submission deadline policies under the OQR program for chart-abstracted measures (79 FR 66964; 87 FR 72110 to 72112).
[61] See 79 FR 66964 for the OQR program review and corrections policy.

services, which is described in detail above in section VIII. CMS proposes changes throughout these regulations to include intensive outpatient services, which CMHCs may furnish. It also proposes to revise the personnel qualifications of mental health counselors (MHCs) and add personnel qualifications for marriage and family therapists (MFTs) to the CMHC CoPs.

Under the statute[62] a CMHC must provide at least 40 percent of its services to individuals who are not eligible for Medicare Part B. CMS seeks comment on how providing intensive outpatient program (IOP) services might impact the ability of CMHCs to satisfy this requirement, including on the following specific questions:

- Do you expect the total number of clients served in your CMHC to increase with the addition of IOP?
- Do you expect that your CMHC would admit new clients directly into the IOP program, and do you have a sense of their anticipated insurance status?
- Do you expect that any of your PHP clients would step down to the IOP program? If so, can you provide an estimated percentage of PHP clients who would step down to the IOP program?
- Do you expect any of your outpatient treatment clients, such as office-based therapy, to step up to the IOP program?

CMS proposes the following changes to the CMHC CoP regulations.

1. Basis and Scope (§485.900)

The CoPs would be updated to reflect the statutory addition of IOP services provided by CMHCs to protect the health and safety of clients. The modifications would allow CMHCs to receive Medicare Part B payment for IOP services, establish requirements for the provision of IOP services in CMHCs, provide IOP services to clients, and include IOP services in the Medicare provider agreement.

2. Personnel Qualifications (§485.904)

Section 4121 of CAA, 2023 established a new Medicare benefit category for MFT and MHC services in section 1861(lll) of the Act, which included definitions for MFTs and MHCs. The statutory requirements for MHCs and MFTs are proposed to be codified in the 2024 Physician Fee Schedule proposed rule; CMS proposes to modify the MHC personnel requirement for CMHCs at §485.904(b)(5) by cross-referencing the definition of an MHC at §410.54 and adding a new requirement at §485.904(b)(12) and cross-referencing the definition of an MFT at §410.53.

[62] Section 1861(ff)(3)(B)(iii) of the Act

3. Admission, Initial Evaluation, Comprehensive Assessment, and Discharge or Transfer of the Client (§485.914)

These CoPs identify general areas that would be included in a client assessment and timeframes for completing the assessments to help CMHCs ensure they are identifying patient needs in all areas in a timely fashion with respect to PHP services. CMS proposes to add IOP requirements and reference requirements the CMHC must meet that are specific to IOP services.

Updates to a comprehensive assessment of a patient for PHP services are required, at a minimum, every 30 days. CMS proposes to apply this same standard for IOP services.

4. Treatment Team, Person-centered Active Treatment Plan, and Coordination of Services (§485.916)

PHP active treatment plans must be updated by CMHCs with current information from the patient's comprehensive assessment and information concerning their progress toward achieving outcomes and goals specified in the active treatment plan at least every 30 days. CMS proposes to include IOP requirements in this section of the regulations and to specifically refer to the proposed requirement at §424.24(d) described above. Thus, CMHCs would have to meet IOP program requirements specified under that section if the services are included in the active treatment plan.

5. Organization, Governance, Administration of Services, Partial Hospitalization Services (§485.918)

This CoP is designed to ensure the management structure of a CMHC is organized and accountable. It includes a list of services the CMHC must furnish. CMS proposes to add IOPs to this CoP, and to specifically add intensive outpatient services to the list of required services.

XVIII. Updates to Hospital Requirements to Make Public Standard Charges

A. Introduction and Overview

Section 2718(e) of the Public Health Service Act requires each hospital operating within the United States to make its standard charges publicly available. In the Hospital Price Transparency (HPT) final rule published November 27, 2019,63 CMS adopted requirements for hospitals to make public their standard charges in two ways: (1) as a comprehensive machine-readable file (MRF); and (2) in a consumer-friendly format.

[63] https://www.govinfo.gov/content/pkg/FR-2019-11-27/pdf/2019-24931.pdf.

B. Changes to Requirements

1. Definitions

CMS proposes the following definitions:

- "CMS template" means a CSV format or JSON schema that CMS makes available for purposes of compliance with the price transparency requirements.
- "Consumer-friendly expected allowed amount" means the average dollar amount that the hospital estimates it will be paid by a third-party payer for an item or service.
- "Encode" means to enter data items into the fields of the CMS template.
- "Machine-readable file" means a single digital file that is in a machine-readable format.

CMS proposes to make conforming changes to its regulations consistent with these proposed new definitions.

2. Affirming the Accuracy and Completeness of Standard Charge Information in the MRF

CMS proposes to require that each hospital affirm directly in its MRF (using a CMS template described below) that it has included all applicable standard charge information in its MRF as of the date in the MRF. This proposal is intended to address confusion about whether blanks in the MRF reflect the absence of data or that the hospital does not have a standard charge for that particular item or service. By affirming its accuracy within the MRF itself, CMS believes the public will understand that blanks mean the hospital does not have a standard charge for that item or service.

3. Improving Standardization of MRF Formats and Data Elements

In the 2020 HPT final rule, CMS expressed concern that lack of uniformity in the way that hospitals display their standard charges leaves the public unable to meaningfully use, understand, and compare standard charge information across hospitals. Since that time, CMS has received feedback that more standardization of the files (including a specified template and standardization of additional contextual data elements) may be necessary to improve the public's use and understanding of, and ability to make comparisons among, hospital standard charge information. CMS further indicates that lack of standardization has impeded its enforcement efforts.

After engaging in a public comment solicitation, CMS requested the HHS Health Federally Funded Research and Development Center (FFRDC) identify technical specifications and categories of information (referred to as "data elements") that CMS could consider proposing in future rulemaking to improve the usability and meaningfulness of the standard charges display. The Health FFRDC convened a technical expert panel (TEP) to consider these issues under the auspices of the MITRE Corporation.

The TEP agreed on including the following data elements in standard template: (1) general

information such as file version and date of most recent update of the file; (2) hospital-specific information (such as hospital name and location, license number, financial aid policy); (3) data elements corresponding to the types of standard charges defined by the HPT regulation; and (4) data elements that enhance understanding of the item or service to which the standard charge applies. TEP participants also suggested including an open field that a hospital could use, as needed, to provide additional contextual information should it believe the template's data elements are insufficient to ensure a user's understanding of a standard charge displayed in the file.

MITRE presented its findings and recommendations to CMS in the fall of 2022. After considering them, CMS announced the availability of several sample formats that may be found on the HPT website that hospitals could voluntarily use to make public their standard charge information in an MRF. At the same time, CMS developed and made available a supplemental data dictionary that provides technical instructions to hospitals on how to conform to the sample formats and encode standard charge information. The sample formats and data dictionary can be found on the HPT website: https://www.cms.gov/hospital-price-transparency/resources.

As part of its efforts to improve standardization, CMS is making the following proposals with respect to how information is presented in the MRF:

- *Proposals to Encode, as Applicable, All Data Items in the MRF*. This proposal would require hospitals to encode, as applicable, all standard charge information corresponding to each required data element in its MRF. The discussion of this proposal is complex and nuanced but CMS distinguishes the term "standard charge information" or data values from "data elements," which are the categories of data that form the basis of the CMS template.
- *Proposals to Revise and Expand the Required Data Elements*. This proposal would require expansion of the data elements (or categories) of hospital charge information that must be included in the MRF to include:
    - Hospital name(s), license number, location name(s) and addresses under the single hospital license to which the list of standard charges applies.
    - The file version and most recent update to the standard charge information in the MRF.
- *Proposals for Data Elements Related to Types of Standard Charges*. This proposal would require hospitals to:
    - Consolidate standard charges (gross charge, payer-specific negotiated charge, de-identified minimum and maximum negotiated charge, and discounted cash price) into a single data element.
    - Require that the payer-specific negotiated charges be displayed by name of the third-party payer and plan(s), each indicated as a separate data element (for example, "payer name" and "plan name"). Hospitals may indicate plan(s) as categories (such as "all PPO plans") when the established payer-specific negotiated charges are applicable to each plan in the indicated category.
    - Require that hospitals indicate the contracting method they used to establish the payer-specific negotiated charge.

    - Require that hospitals indicate whether the payer-specific standard charge listed should be interpreted by the user as a dollar amount, percentage, or, if the standard charge is based on an algorithm, the algorithm that determines the dollar amount for the item or service.
    - Post an "expected allowed amount" where the payer-specific negotiated charge cannot be expressed as a dollar figure such as when the expected payment is based on an algorithm. The expected allowed amount, also called the "consumer-friendly expected amount," may represent reimbursement for an average patient and is an amount that can be used to compare prices across hospitals.
- *Proposals for Data Elements Related to Hospital Items and Services*. This proposal would require hospitals to:
    - Indicate whether the item or service is connected to an inpatient admission or outpatient department visit.
    - For drugs, indicate the drug unit and type of measurement as separate data elements.
- *Proposals for Data Elements Related to Item or Services Billing*. This proposal would require hospitals to specify any relevant modifiers that would change the standardized charge and its relevant code (HCPCS, CPT, APC, DRG, etc.) that it is modifying.
- *Proposals to Specify Formatting Requirements*. This proposal would:
    - Require hospitals to conform their formatting with CMS' template layout, data, specifications and data dictionary, to be provided through separate technical instructions. Layouts could be done in (1) JSON schema (plain format), (2) CSV ("wide" format), and (3) CSV ("tall" format).
    - Not conforming to CMS' template layout, data specifications, and data dictionary would be determined to be noncompliant and could be subject to a compliance action (although CMS reiterates that the presence of blanks for some data elements does not necessarily mean the hospital is non-compliant with the requirement).
    - Allow for a 60-day enforcement grace period to conform with the CMS template layout and encoding of standard charge information of the newly proposed data elements.

4. Improving Accessibility of Hospital MRFs.

As indicated above, this proposal would require hospitals to improve the accessibility of the MRFs by including a .txt file in the root folder that includes a direct link to the MRF and a link in the footer on its website that links directly to the publicly available webpage that hosts the link to the MRF.

C. Changes to Improve and Enhance Enforcement

CMS indicates that compliance with the hospital price transparency requirements has improved significantly over time. However, it also distinguishes "monitoring" hospital compliance—which may include evaluating complaints, reviewing an analysis of non-compliance or auditing hospitals' website—from "assessment," which is a formal evaluation of whether hospitals are in compliance with the price transparency requirements. CMS believe this distinction is necessary because monitoring can be used by anyone while a compliance assessment can only be done by CMS.

- Proposals for Improving Assessment of Hospital Compliance:
    - Revise the regulation to indicate that CMS may conduct a compliance review of a hospital's standard charges information posted on a publicly available website.
    - Require an authorized hospital official to submit to CMS a certification to the accuracy and completeness of standard charge information posted in the MRF and for the hospital affirm within the MRF the accuracy and completeness of standard charge information.
    - Require submissions to CMS of additional documentation as may be necessary to assess hospital compliance.
- CMS further proposes to:
    - Require hospitals to acknowledge receipt of a warning notice.
    - Notify the health system leadership of a compliance action so it may work with the hospital system leadership to address similar deficiencies for hospitals across the health system.
    - Indicate that it may publicize on its website information related to CMS' assessment of a hospital's compliance, any compliance actions taken against a hospital, the status of such compliance and its outcome.

D. Alignment with Transparency in Coverage and No Surprises Act

CMS describes the Transparency in Coverage rule that requires most group health plans and issuers of group or individual health insurance coverage to disclose personalized pricing information for covered items and service to their participants, beneficiaries, and enrollees through an online consumer tool, or in paper form, upon request. The proposed rule also describes the No Suprises Act (NSA). The NSA contains many provisions to protect consumers from surprise medical bills and to improve price transparency. CMS indicates NSA will help patients understand health care costs in advance of care and minimize unforeseen medical bills.

As these new consumer-friendly requirements are in the process of becoming fully realized, CMS is interested in hearing from the public how the HPT requirements can best support and complement the consumer-friendly requirements found in these other price transparency initiatives. CMS asks the public to respond to a number of specific questions on how the information being required can be improved to help consumers make better informed decisions.

XIX. Changes to the Inpatient Medicare Code Editor

The Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare inpatient claims data. CMS has typically addressed the addition or deletion of MCE edits in its annual inpatient prospective payment system (IPPS) rulemakings. However, CMS makes changes to an analogous code editor for the OPPS through quarterly releases with effective dates of January 1, April 1, July 1, and October 1 of each year. Consistent with the process that is used for the OPPS code editor, CMS proposes to address any future revisions to the MCE outside of the annual IPPS rulemakings.

CMS anticipates generally announcing MCE changes as part of instructions issued to the MACs in connection with the April 1 and October 1 ICD-10 code updates. Beginning with FY 2025, CMS would no longer address the addition or deletion of MCE edits or ICD-10 diagnosis and procedure codes in annual IPPS rulemakings.

XX. REH Proposals for Indian Health Service (IHS) and Tribally-Owned Hospitals

Effective January 1, 2023, section 125 of the CAA, 2021 establishes REHs as a new Medicare provider type that only furnishes emergency department services and observation care and not inpatient care. Providers that are CAHs and small rural hospitals (50 or fewer beds) as of December 27, 2020, may convert to REHs. REHs will receive 105 percent of payment for OPPS services and a monthly facility payment of $272,866 for 2023 that is updated annually.

Indian Health Service (IHS) and Tribally-owned facilities are not paid under the OPPS and are instead paid an All-Inclusive Rate (AIR) for their Medicare outpatient hospital services. IHS calculates and announces the AIR annually in the *Federal Register*. For 2023, the AIR is $654 for all states except Alaska. The AIR is $862 in Alaska.

IHS and Tribally-owned facilities may be eligible to convert to REHs. However, because they are not paid under the OPPS, there is no OPPS amount upon which to determine a payment. When an REH provides a service that is not payable under the OPPS, the regulations allow the REH to be paid under the payment system applicable to the service, provided the requirements for that payment system are met. For this reason, CMS proposes to pay IHS and Tribally-owned facility that convert to REH status at the AIR. IHS and Tribally-owned facilities that are REHs would also receive the monthly facility payment of $272,866 for 2023 updated annually.

XXI. Request for Information on Establishing and Maintain Access to Essential Medicines

A. Overview

The proposed rule indicates that over the last few years, shortages for critical medical products have persisted and continued to increase. CMS believes it is necessary to support practices that can curtail pharmaceutical shortages of essential medicines and promote resiliency in order to safeguard and improve the care hospitals are able to provide to beneficiaries.

CMS is seeking comment on separate payment under the IPPS for establishing and maintaining access to a buffer stock of essential medicines to foster a more reliable, resilient supply of these medicines. This separate payment would not be budget neutral. An adjustment under the OPPS could be considered for future years. Based on the public comments, CMS would consider adopting a policy that would be effective as soon as cost reporting periods beginning on or after January 1, 2024.

B. Establishing and Maintaining a Buffer Stock of Essential Medicines

A report from the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) prioritized 86 essential medicines as either critical for minimum patient care in acute settings or important for acute care or acute care of respiratory illnesses/conditions, with no comparable alternative available. CMS expects that the resources required to establish and maintain access to a minimal "buffer stock" of essential medicines, such as a 3-month supply, will generally be greater than the resources required to establish and maintain access to these medicines through alternative means that are more susceptible to supply chain disruptions (for example, through so-called "just-in-time" inventory practices).

Given these additional resource costs, CMS is considering separate payment under the IPPS for 2024, and the OPPS for future years, for the costs of establishing and maintaining access to a buffer stock of essential medicines. This approach would be similar the policy adopted for FY 2023 under the IPPS and 2023 under the OPPS to maintain a supply of domestically sourced N-95 respirator masks. CMS would use its non-budget neutral "exceptions and adjustments" authority under section 1886(d)(5)(i) for the IPPS payments and its budget neutral section 1833(t)(2)(E) authority for OPPS payments.

FDA is leading an effort to develop this list of essential medical devices that are critical to have on hand at all times for patients, healthcare workers, and the U.S. public because of their clinical need. The list is expected to be available by the end of 2023. CMS may consider expanding a potential Medicare payment policy in future years to include critical medical devices once the FDA's Critical Medical Device List becomes available.

C. Separate Payment Under IPPS and OPPS for a Buffer Stock of Essential Medicines

CMS believes it may be appropriate to pay separately for the additional resource costs associated with establishing and maintaining access, including through contractual arrangement, to a buffer stock of essential medicines. These potential separate payments would be in addition to payment for the essential medicines themselves, whether that payment is bundled with other items or services or the essential medicines are separately paid.

The proposed rule indicates that it is challenging to quantify these additional resource costs precisely based on currently available information. Thus, CMS could initially base the IPPS payment on the IPPS shares of the additional reasonable costs of a hospital to establish and maintain access to its buffer stock. The use of IPPS shares in this payment adjustment would be consistent with the use of these shares for the payment adjustment for domestic NIOSH approved surgical N95 respirators.

Costs could include those to hold essential medicines directly at the hospital or contractually with a distributor or wholesaler. A hospital would report these costs in the aggregate on its cost report to CMS. These costs would not include the costs of the essential medicine itself. This information could be used to calculate a Medicare payment to establish and maintain access to a buffer stock of

these essential medicines. Payments would be in accordance with reasonable cost principles through a biweekly payment with reconciliation during settlement of the cost report.

D. Comment Solicitation on Additional Considerations

CMS solicits public comments on a variety of additional considerations that would be associated with this policy. Among the questions CMS asks are whether the policy it is contemplating could be improved upon; alternatives to the proposed policy; what are other types of costs would hospitals have to maintain this buffer stock; should there be standards to define domestic production like there are with the subsidies for N95 masks; are there are other medications besides the 86 essential medicine listed in the ASPR report that should be added; frequency for updating the list of essential medicines; and whether a 3-month supply sufficient or should the buffer stock have a larger supply. These are among a variety of other questions CMS asks in this comment solicitation.

Table 100: Estimated Impact 2024 OPPS Proposed Rule

	(1)	(2)	(3)	(4)	(5)
	Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 & 3) with Market Basket Update**	**All Changes**
ALL PROVIDERS *	3,567	0.0	0.1	2.9	2.9
ALL HOSPITALS (excludes hospitals held harmless and CMHCs)	3,472	0.1	0.2	3.0	3.0
URBAN HOSPITALS	2,761	0.0	0.0	2.8	2.8
LARGE URBAN	1,430	0.0	-0.1	2.7	2.8
(GT 1 MILL.)					
OTHER URBAN	1,331	0.0	0.2	3.0	2.8
(LE 1 MILL.)					
RURAL HOSPITALS	711	0.4	1.4	4.7	4.4
SOLE COMMUNITY	375	0.3	1.7	4.9	4.4
OTHER RURAL	336	0.6	0.9	4.4	4.3
BEDS (URBAN)					
0 - 99 BEDS	934	0.5	0.1	3.4	3.2
100-199 BEDS	778	0.5	-0.1	3.2	3.2
200-299 BEDS	421	0.2	0.1	3.1	3.0
300-499 BEDS	397	0.0	0.7	3.4	3.2
500 + BEDS	231	-0.4	-0.4	2.0	2.1
BEDS (RURAL)					
0 - 49 BEDS	342	0.8	1.2	4.9	4.6
50- 100 BEDS	213	0.5	2.1	5.5	5.1
101- 149 BEDS	81	0.4	1.2	4.4	3.7
150- 199 BEDS	42	0.2	1.4	4.5	4.0
200 + BEDS	33	0.0	0.8	3.6	3.7
REGION (URBAN)					
NEW ENGLAND	131	0.1	-2.4	0.5	0.6
MIDDLE ATLANTIC	306	-0.1	1.4	4.1	4.2
SOUTH ATLANTIC	458	0.0	-0.6	2.2	2.3
EAST NORTH CENT.	419	0.0	-0.8	2.0	2.1
EAST SOUTH CENT.	158	-0.3	-0.2	2.3	2.3
WEST NORTH CENT.	183	-0.2	0.3	2.9	1.7
WEST SOUTH CENT.	459	0.2	-0.5	2.5	2.6
MOUNTAIN	210	0.0	-1.7	1.1	0.9
PACIFIC	388	0.2	2.7	5.7	5.8
PUERTO RICO	49	0.2	-0.6	2.3	2.3
REGION (RURAL)					
NEW ENGLAND	19	0.2	-1.0	2.0	2.4

	(1)	(2)	(3)	(4)	(5)
	Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 & 3) with Market Basket Update**	**All Changes**
MIDDLE ATLANTIC	47	0.3	8.3	11.6	11.5
SOUTH ATLANTIC	106	0.5	0.5	3.9	3.8
EAST NORTH CENT.	112	0.4	0.7	3.9	3.9
EAST SOUTH CENT.	139	0.7	0.2	3.6	3.6
WEST NORTH CENT.	85	0.2	1.8	4.8	3.7
WEST SOUTH CENT.	133	1.0	0.3	4.2	4.1
MOUNTAIN	46	0.2	0.9	3.9	2.0
PACIFIC	24	0.2	3.9	7.0	7.0
TEACHING STATUS					
NON-TEACHING	2,186	0.4	0.4	3.6	3.5
MINOR	872	0.1	0.3	3.2	3.0
MAJOR	414	-0.3	-0.2	2.2	2.4
DSH PATIENT PERCENT					
0	7	-0.9	-0.7	1.1	3.4
GT 0 - 0.10	247	-0.1	-0.3	2.4	2.2
0.10 - 0.16	248	0.3	-0.1	3.0	3.0
0.16 - 0.23	568	0.3	0.0	3.1	3.0
0.23 - 0.35	1,135	0.0	0.1	2.9	2.7
GE 0.35	852	-0.2	0.6	3.3	3.4
DSH NOT AVAILABLE **	415	7.1	1.5	11.7	12.2
URBAN TEACHING/DSH					
TEACHING & DSH	1,142	-0.1	0.0	2.6	2.6
NO TEACHING/DSH	1,197	0.3	0.1	3.3	3.2
NO TEACHING/NO DSH	7	-0.9	-0.7	1.1	3.4
DSH NOT AVAILABLE2	415	7.1	1.5	11.7	12.2
TYPE OF OWNERSHIP					
VOLUNTARY	1,985	0.0	0.3	3.1	3.0
PROPRIETARY	1,047	0.7	-0.1	3.5	3.4
GOVERNMENT	440	-0.2	0.0	2.7	2.8
CMHCs	27	4.0	-1.0	5.9	5.8

Column (1) shows total hospitals and/or CMHCs.
Column (2) includes all proposed CY 2024 OPPS policies and compares those to the CY 2023 OPPS.
Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2024 hospital inpatient wage index. The proposed rural SCH adjustment would continue our current policy of 7.1 percent, so the budget neutrality factor is 1. The proposed budget neutrality adjustment for the cancer hospital adjustment is 1.0005 because the proposed CY 2024 target payment-to-cost ratio is less than the CY 2023 PCR target
Column (4) shows the impact of all budget neutrality adjustments and the addition of the proposed 2.8 percent OPD fee schedule update factor (3.0 percent reduced by 0.2 percentage point for the productivity adjustment).

Column (5) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate and adding estimated outlier payments. Note that previous years included the frontier adjustment in this column, but we have included the frontier adjustment to Column 3 in this table.
*These 3,567 providers include children's and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.
** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.