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Medicare Program: 2025 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 2025[1] proposed rule for Medicare's hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system (CMS-1809-P) on July 10, 2024. Policies in the proposed rule will generally go into effect on January 1, 2025 unless otherwise specified. The proposed rule will be published in the July 22, 2024 issue of the *Federal Register*. **The public comment period will end on September 9, 2024.**

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.

CMS proposes to pay separately for diagnostic radiopharmaceuticals with a cost of more than $630 per day. In addition, CMS implements a provision of law that provides three years of separate payment under specific conditions for non-opioid drugs and devices that provide pain relief. There are also proposed new conditions of participation for hospitals and Critical Access Hospitals (CAH) that provide obstetrical services.

Addenda containing relative weights, payment rates, wage indices and other payment information are available on the CMS website at: https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1809-p.

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

I. Overview

A. Estimated Impact on Hospitals

The increase in spending due only to changes in the 2025 OPPS proposed rule is estimated to be approximately $1.78 billion. Taking into account estimated changes in enrollment, utilization, and

case-mix for 2025, CMS estimates that OPPS expenditures, including beneficiary cost-sharing, will be approximately $88.2 billion, which is approximately $5.2 billion higher than estimated expenditures in 2024.

CMS estimates that the update to the conversion factor net of the productivity will increase payments 2.6 percent in 2025 (market basket of 3.0 percent less 0.4 percentage points for productivity). Including changes to outlier payments, pass-through payment and the application of the frontier state wage adjustment, CMS estimates a 2.3 percent increase in payments between 2024 and 2025.

Hospitals that satisfactorily report quality data will qualify for the full update of 2.6 percent, while hospitals that do not will be subject to an update of 0.6 percent (a statutory reduction of 2.0 percentage points). All other adjustments are the same for the two sets of hospitals. Of the approximately 3,062 hospitals that meet eligibility requirements to report quality data, CMS determined that 175 hospitals will not receive the full OPPS increase factor (117 hospitals that did not meet the requirements and another 58 hospitals that chose not to participate).

Medicare makes payments under the OPPS to approximately 3,511 facilities (3,413 hospitals excluding CMHCs, cancer and children's hospitals held harmless to their pre-OPPS payment to cost ratios). Table 131 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 2.3 percent for all facilities and hospitals. The following table shows components of the 2.3 percent total:

	% Change All Facilities
Fee schedule increase factor	2.6
Difference in pass through estimates for 2024 and 2025	-0.44
Difference from 2024 outlier payments (0.85% vs. 1.0%)	0.15
All changes	2.3

For 2024, CMS estimates pass-through spending will be 0.27 percent of OPPS spending. For 2025, CMS estimates that pass-through spending for drugs, biologicals and devices will be $625 million, or 0.71 percent of OPPS spending. The difference between these figures (0.27 – 0.71 = -0.44 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 2024 will represent 0.85 percent of total OPPS payments compared to the 1.0 percent set aside for 2025, a 0.15 percentage point change in 2025 payments. Taken together, these factors produce the total increase in 2025 OPPS payments of 2.3 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 2.3 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	2025 Impact
All Hospitals	2.3%
All Facilities (includes CMHCs and cancer and children's hospitals)	2.4%
Urban	2.4%
Large Urban	2.2%
Other Urban	2.5%
Rural	2.8%
Beds	
0-99 (Urban)	2.8%
0-49 (Rural)	2.9%
500+ (Urban)	2.2%
200+ (Rural)	3.1%
Major Teaching	2.1%
Type of ownership	
Voluntary	2.3%
Proprietary	3.5%
Government	2.4%

The payment impacts are largely consistent between the different categories of hospitals. Generally, an increase or decrease larger than the average will be accounted for by recalibration of APC weights or changes to the wage index. The higher increase for proprietary hospitals appears to be accounted for by APC recalibration and wage index changes and provider adjustments, according to table 131.

B. Estimated Impact on Beneficiaries

CMS estimates that the aggregate beneficiary coinsurance percentage will be 17.8 percent for all services paid under the OPPS in 2025. 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 ($1,632 in 2024), 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 2025, CMS is using 2023 hospital final action claims for services furnished from January 1, 2023 through December 31, 2023 processed through the Common Working File as of December 31, 2023 (approximately 73 million claims). CMS is using 2022 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/2025-nprm-opps-claims-accounting.pdf.

Continuing past years' methodology, CMS calculated the cost of each procedure only from single procedure claims. CMS creates "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 2025 proposed rule, CMS is bypassing the 173 HCPCS codes identified in Addendum N. There are 5 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 2023 but were deleted for 2024.

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 2025, CMS is employing the same basic approach used for APC rate construction since 2007. CMS applies the relevant hospital-specific CCR to the hospital's charges at the most detailed level possible based on a revenue code-to-cost center crosswalk containing a hierarchy of CCRs for each revenue code. The current crosswalk is available for review and continuous comment on the CMS website at the link provided at the beginning of this summary.

CCRs are calculated for the standard and nonstandard cost centers accepted by the electronic cost report data at its most detailed level. Generally, the most detailed level will be the hospital-specific departmental level. 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 2025. CMS eliminates 2023 claims 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.

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 2025.

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 no claims for HCPCS code C2645 in the 2023 utilization data. 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 2025 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. For 2025, CMS proposes to price six low volume brachytherapy APCs under this policy (excluding those that are priced using external data).

Recommendations for HCPCS codes that describe new brachytherapy sources should be directed to: 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 Social Security Act (henceforth, "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. 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.

CMS is proposing to exclude specific gene therapies listed in Table 1 of the proposed rule from the C-APC policy for 2025 only. If HCPCS codes for these cell and gene therapies appear on the same claim as a HCPCS code that is subject to the C-APC policy, CMS proposes to pay separately for the cell and gene therapy and not package payment into the C-APC. The rationale underlying CMS' proposal is that when these products are administered, they are the primary treatment being administered to a patient and are not integral, ancillary, supportive, dependent, or adjunctive to any primary C-APC services.

The proposal is for one year only in order to allow CMS to gather more information from interested parties as to whether this proposed policy appropriately captures all of the unique therapies, such as the cell and gene therapies listed in Table 1, that function as primary treatments and do not support C-APC primary services. CMS will assess whether to continue this policy, or a modified version of this policy, beyond one year in future rulemaking, taking into consideration the comments received.

If commenters request that other classes of drug, biologicals or other products to be subject to this policy, **CMS expects these comments will be supported by clinical evidence that these products are not supportive of a C-APC service but may appear on the same claim as one.** CMS' comment solicitation on this issue also raises whether and how to structure a new APC that recognizes the costs of gene and cell therapies.

CMS further notes that the Consolidate Appropriations Act (CAA), 2023 includes a provision that requires separate payment under the OPPS for three years beginning January 1, 2025 for non-opioid drugs and devices that treat pain. Accordingly, CMS is proposing to exclude non-opioid treatments for pain relief that meet the criteria for separate payment from C-APCs. Further information about CMS' implementation of this provision is in section XIII.F. of this summary.

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. 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 2025.

For the mental health composite APC 8010, CMS policy through 2023 had been to cap 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 CMS created APC 5864, which is for 4 or more partial hospitalization services per day. Beginning with 2024, CMS has been capping the mental health composite APC 8010 to APC 5864. For 2025, CMS proposes to continue this policy.

3. Changes to Packaged Items and Services

The proposed rule indicates that section 4135(a) and (b) of CAA, 2023 prohibits packaged payment for non-opioid pain relief treatments effective January 1, 2025 through December 31, 2027. CMS includes proposals to implement this CAA provision in the 2025 OPPS rule. These proposals are described in detail in section XIII.F. 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. Separate OPPS Payment for Diagnostic Radiopharmaceuticals

a. Background on OPPS Packaging Policy for Diagnostic Radiopharmaceuticals

Under § 419.2(b)(15), payment for drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure is packaged with the payment for the related procedure or service. Since 2008, CMS has packaged diagnostic radiopharmaceuticals as they are always intended to be used with a diagnostic nuclear medicine procedure and function as supplies. As the OPPS payment is based on hospital charges and costs, CMS believes the costs of the diagnostic radiopharmaceutical reflected within the payment for the primary procedure with which it is used.

In the years since CMS packaged payment for diagnostic radiopharmaceuticals and in response to a comment solicitation on the 2024 OPPS rule, public commenters have raised a variety of issues including that, for newer, more innovative radiopharmaceuticals, the current OPPS packaging policy has led to a lack of patient access to the technologies after the radiopharmaceutical's pass-through status expires, especially if there is no clinical alternative to the radiopharmaceutical.

b. Proposed Packaging Threshold for Diagnostic Radiopharmaceuticals

CMS believes there are certain situations in which the packaged payment amount attributed to the diagnostic radiopharmaceutical used in an imaging procedure assigned to a nuclear medicine APC may not adequately account for the cost of a diagnostic radiopharmaceutical that has a significantly higher cost, but lower utilization relative to the other diagnostic radiopharmaceuticals that may be used with the procedure. To address these concerns, CMS proposes to pay separately for any diagnostic radiopharmaceutical with a per day cost greater than $630.

To determine an appropriate threshold, CMS estimated the approximate payment that would typically be attributable to diagnostic radiopharmaceutical payment within each nuclear medicine APC (APCs 5591, 5592, 5593, and 5594). This amount was $314.28, which CMS refers to as the

"offset amount." CMS proposes to double the offset amount to ensure that separate payment would apply only to diagnostic radiopharmaceuticals whose costs significantly exceed the approximate amount of payment already attributed to the product in the nuclear medicine APC payment. Multiplying the offset amount by 2 and rounding it to the nearest $5 increment results in the proposed packaging threshold of $630.

CMS indicates that its doubling approach is consistent with logic underlying the two-times rule where a significant service that has a cost greater than two times the lowest cost significant service in an APC is generally moved to a higher level APC in the series. It is also consistent with the outlier threshold where CMS makes an outlier payment if a hospital's cost exceeds 1.75 times the APC payment.

Alternatively, CMS could use the standard drug packaging threshold, proposed to be $140 for 2025 in this rule, as the threshold for separate payment for diagnostic radiopharmaceuticals. However, CMS does not believe the standard drug packaging threshold is applicable as diagnostic radiopharmaceuticals function as supplies in the diagnostic procedures in which they are used, in contrast to therapeutic drugs, biologicals, and therapeutic radiopharmaceuticals that could be the only therapeutic modality provided to a patient during an encounter.

c. Calculating the Per Day Cost of Diagnostic Radiopharmaceuticals

CMS goes through a detailed 9-step process for how it determined the $630 packaging threshold that mirrors the process CMS used to calculate the OPPS drug packaging threshold beginning in 2006 but is, in summary, as described above (that is, reflective of the double the amount of packaged costs currently reflected in the nuclear medicine APCs). CMS proposes to continue to package payment for diagnostic radiopharmaceuticals with per day costs less than or equal to $630 and pay separately for other diagnostic radiopharmaceuticals.

Similar to its policy for the drug packaging threshold, CMS proposes to use updated claims data to make final determinations of the packaging status of HCPCS codes for diagnostic radiopharmaceuticals in each year's OPPS final rule. Similar to its historical practice for the drug packaging threshold, CMS proposes:

- HCPCS codes for diagnostic radiopharmaceuticals that are proposed for separate payment in 2025, and that then have per day costs equal to or less than the 2025 final rule diagnostic radiopharmaceutical packaging threshold, based on the updated hospital claims data used for the 2025 final rule, would remain packaged in 2025.
- HCPCS codes for diagnostic radiopharmaceuticals for which CMS proposed packaged payment in 2025 but that then have per-day costs greater than the 2025 final rule drug packaging threshold, based on updated hospital claims data used for the 2025 final rule, would receive separate payment in 2025.

d. Proposal to Update the Diagnostic Radiopharmaceutical Packaging Threshold in 2026

Starting in 2026 and subsequent years, CMS proposes to update the proposed threshold amount of $630 by the Producer Price Index (PPI) for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from IHS Global, Inc (IGI). This is the same as the update factor used for the OPPS drug packaging threshold. CMS would use the most recently available four quarter moving average PPI levels to trend the final 2025 threshold forward from the third quarter of 2024 to the third quarter of 2025 and round the resulting dollar amount to the nearest $5 increment.

e. Amount of Separate Payment for Diagnostic Radiopharmaceuticals

While CMS would ordinarily use the ASP methodology to pay for separately payable diagnostic radiopharmaceuticals, very few manufacturers are reporting ASP for their products currently. ASP reporting is voluntary for manufacturers of radiopharmaceuticals, according to CMS.[2] Of those few manufacturers reporting ASP, the ASP values generally do not align with the ASP CMS would expect based on the cost and mean unit cost (MUC) data submitted to CMS by hospitals. Therefore, CMS believes a reasonable alternative for separate payment of diagnostic radiopharmaceuticals that exceed the per day cost threshold is the use of their MUC from claims data.

While CMS is proposing to use MUC to pay for separately payable diagnostic radiopharmaceuticals in 2025, manufacturers can begin, or continue, to report ASP data for potential future use in paying for diagnostic radiopharmaceuticals. In instances where there is more than one manufacturer of a particular diagnostic radiopharmaceutical, CMS proposes that all manufacturers submit ASP information in order for payment.

CMS notes that ASP submissions for radiopharmaceutical payment under the OPPS would need to meet all of the existing regulatory and sub-regulatory requirements of the ASP reporting process under sections 1847A and 1927(b)(3) of the Act. Specifically, the ASP data submitted would need to be provided for a patient-specific dose, or patient-ready form. A "patient-ready" dose for OPPS purposes includes all component materials of the radiopharmaceutical, at a minimum, and any other processing the manufacturer requires to produce the radiopharmaceutical that it sells that are reflected in the sales price, including radiolabeling, as long as any fees paid for such processing done on behalf of the manufacturer meet the definition of "bona fide service fees" under § 414.802 (74 FR 60525).

The proposed rule indicates that there could be situations in which it is appropriate to use ASP currently, such as for diagnostic radiopharmaceuticals on OPPS transitional pass-through status. In this situation, CMS believes the use of ASP is appropriate as the manufacturer of that diagnostic

[2] This statement is arguable. Although not mentioned by CMS, section 401 of Division CC, Title IV of the Consolidated Appropriations Act (CAA), 2021 requires that manufacturers of products that are paid as Medicare Part B drugs and biologicals report ASP information to CMS effective January 1, 2022. If these diagnostic radiopharmaceuticals are paid separately under the OPPS as Medicare Part B drugs and biologicals, the manufacturers of these products may be required to report ASP under the CAA provision.

radiopharmaceutical is actively involved in the radiopharmaceutical's pass-through application, and CMS can ensure that pricing is reported appropriately for purposes of the drug pass-through cost significance tests and for purposes of payment if pass-through status is approved. Typically, there is only one manufacturer for a diagnostic radiopharmaceutical applying for pass-through status, so CMS does not have to ensure all manufacturers are reporting ASP for that particular HCPCS code prior to establishing a separate payment amount based on ASP.

CMS proposes to base the initial payment for new diagnostic radiopharmaceuticals with HCPCS codes, but which do not have pass-through status and are without claims data, on ASP or WAC if ASP data is not available. If the WAC also is unavailable, CMS proposes to make payment at 95 percent of the products' most recent AWP. Payment based these drug pricing methodologies would be temporary until a MUC is available. For radiopharmaceuticals on pass-through, CMS raises the possibility of continuing to use of ASP once its pass-through status has ended given that its ASP may be reliable.

The proposed rule indicates that MUC is an appropriate proxy for the average price for a diagnostic radiopharmaceutical for a given year, as it is directly reflective of the actual cost data that hospitals submit to CMS. CMS does not believe that WAC or AWP is an appropriate proxy to provide OPPS payment for average therapeutic radiopharmaceutical acquisition cost and associated handling costs when manufacturers are not required to submit ASP data.

For separately payable drugs and biologicals, WAC or AWP is only used until a manufacturer is able to submit the required ASP data in accordance with the quarterly ASP submission timeframes for reporting under section 1847A of the Act. That is, for separately payable drugs and biologicals, use of WAC or AWP is temporary until statutorily required ASP is reported. CMS believes the same policy should apply to radiopharmaceuticals until MUC is available from the claims data.

CMS also expresses concern that WAC and AWP reported to compendia may not be reflective of a patient-ready dose. The proposed rule further notes that WAC and AWP do not capture all of the pricing discounts that are reflected in ASP. If CMS were to use the more favorable WAC and AWP pricing methodologies that do not reflect pricing discounts, it could continue indefinitely as CMS cannot compel ASP reporting and manufacturers would not be incented to report ASP.

CMS believes diagnostic and therapeutic radiopharmaceuticals are clinically similar and use comparable manufacturing process. It believes Medicare should use the same methodology for payment. In future rulemaking, CMS will consider aligning the payment methodologies between therapeutic and diagnostic radiopharmaceuticals, either based on ASP or MUC. If commenters do not believe it is appropriate for CMS to base the payment amount for diagnostic radiopharmaceuticals on MUC for 2025, it proposes in the alternative to maintain its current policy of unconditionally policy packaging all diagnostic radiopharmaceuticals regardless of their cost until an appropriate payment methodology can be established to determine a separate payment amount.

Under CMS' proposal, HCPCS codes for diagnostic radiopharmaceuticals with per day costs that exceed $630 would be assigned status indicator of "K", indicating separate payment. An APC and a payment rate would be assigned as shown in Addendum B of proposed rule. HCPCS codes that describe diagnostic radiopharmaceuticals with per day costs that are at or below the proposed diagnostic radiopharmaceutical packaging threshold would continue to be assigned to a status indicator of "N", indicating packaged payment. Table 5 of the proposed rule includes a proposed list of diagnostic radiopharmaceuticals that have calculated per day costs that exceed $630 and their proposed status indicators.

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 (2023) to determine budget neutrality for changes in the OPPS relative weights for the proposed rule year (2025). Holding all other variables constant, CMS multiplies the 2024 final relative weights and the 2025 proposed relative weights respectively for each APC by its associated volume from 2023. It sums the 2024 and proposed 2025 relative weights respectively, and divides the 2024 aggregate relative weights by the 2025 aggregate unscaled relative weights to determine the weight scaler. Using this process, CMS is adopting a weight scaler of 1.4405. The unscaled proposed 2025 relative payments are multiplied by 1.4405 to determine the proposed 2025 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 2024 and 2025 do not increase or decrease expenditures. However, SCODs are not affected by the budget neutrality adjustment.

B. Conversion Factor Update

The proposed 2025 conversion factor is $89.379 for hospitals receiving the full update for outpatient quality reporting. The components of the update are shown below:

	Full Update		Reduced Update	
2024 Conversion Factor (CF)	**$87.382**	**Resulting CF**	**$87.382**	**Resulting CF**
Remove pass-through & outliers from prior year CF	1.0129	$88.506	1.0290	$88.506
Wage Index Budget Neutrality	1.0026	$88.736	1.0026	$88.736

	Full Update		Reduced Update	
2024 Conversion Factor (CF)	**$87.382**	**Resulting CF**	**$87.382**	**Resulting CF**
Cap on Wage Index Reductions	0.9982	$88.576	0.9982	$88.576
Cancer Hospital Adjustment	1.0006	$88.630	1.0006	$88.629
Rural Hospital Adjustment	1.0000	$88.630	1.0000	$88.629
Update	1.0260	$90.934	1.0060	$89.161
Pass-Through/Outlier	0.9829	$89.379	0.9829	$87.636
2025 Conversion Factor	**$89.379**	**$89.379**	**$87.636**	**$87.636**

Note: CMS provides a similar table to this one in the proposed rule but only for the full update. HPA's calculation is $0.01 lower after applying the cancer hospital adjustment but matches CMS' final conversion factor calculation if unrounded values are used in each step. The reduced update columns are created by HPA.

CMS removes the prior year's pass-through (0.0027) and outlier adjustment (0.0100) from the 2024 conversion factor, which equals 1.0129 (1.29 percent).[3] Wage index budget neutrality is 1.0026 (0.26 percent) for 2025. The cap on reductions to the wage index requires a budget neutrality adjustment of 0.9982 (-0.18 percent) for 2025. The cancer hospital adjustment is 1.0006 (0.06 percent). The rural sole community hospital adjustment is 1.0000 (0.0 percent) for 2025.

The update of 1.026 (2.6 percent) equals the market basket of 3.0 percent less 0.4 percentage points for productivity for 2025. This update is the same as was proposed in the FY 2025 IPPS proposed rule and is based on the IGI fourth quarter 2023 forecast of the FY 2025 hospital market basket with historical data through the third quarter of 2023. The final rule market basket will be based on the IGI second quarter 2024 forecast of the FY 2025 hospital market basket used for the IPPS update. The productivity estimates are from the same period.

CMS estimates that pass-through spending for drugs, biologicals and devices for 2025 will be just over $625 million, or 0.71 percent of OPPS spending. The outlier adjustment is 0.99 (-1.0 percent). The combined adjustment for pass-through and outliers is 0.9829 (-1.71 percent).

The proposed 2025 conversion factor for hospitals that submit quality data is $89.379. The conversion factor for hospitals that do not submit quality data is subject to all of the same adjustments except the update is 1.006 (0.6 percent) instead of 1.026 (2.6 percent). The proposed conversion factor for hospitals that do not submit quality data is $87.636, according to CMS.

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 2025. The proposed rule directs readers to the IPPS rule for more details regarding specific policies affecting the proposed 2025 wage index including revisions to Core-Based Statistical Areas (CBSA) that serve as the labor market areas for determining the area wage index under both the IPPS and the OPPS. For FY 2025, CMS is using the IPPS proposed rule to update labor market areas based on CBSA revisions issued by the Office

[3] Removing the budget neutrality adjustment from the prior year requires division so the factor equals 1.0/(1-0.01-0.0027) or 1.0129.

of Management and Budget following the 2020 Census. These same changes proposed for the IPPS are proposed to apply to hospitals paid under the OPPS.

For non-IPPS hospitals paid under the OPPS for 2025, 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 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/payment/prospective-payment-systems/hospital-outpatient/annual-policy-files/2025.

E. Sole Community Hospital (SCH) Adjustment

For 2025, 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 2025 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 2025 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 2022 and 2023. CMS estimates a PCR of 0.87 (or 87 percent) for non-cancer hospitals. After reducing this PCR by 1.0 percentage point, the target PCR would be 0.86 (or 86 percent).

For 2024, the target PCR was appreciably lower than it had been since CMS has been applying this methodology beginning in 2012. CMS' concern was that the lower PCR reflected an aberration due to the COVID-19 public health emergency and not on ongoing trend. As a result, CMS adopted a policy to limit the reduction in the target PCR to 1.0 percentage point annually. As the 2024 target PCR including the 1.0 percentage point limit on the reduction was 0.88 and the otherwise applicable proposed 2025 PCR without a limit would be 0.86, CMS is proposing a target PCR of 0.87 that reflects a cap on the reduction of 0.01.

Table 8 in the proposed rule shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals, with increases in OPPS payments for 2025 ranging from 16 percent to 56.3 percent. CMS indicates that the reduction in the cancer hospital adjustment requires a budget neutrality adjustment of +0.06 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 2025, 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 2024 and previous years. For 2025, CMS proposes to continue setting the outlier payment equal to 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount when both the 1.75 multiple payment threshold and the fixed-dollar threshold are met.

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 2023 Medicare claims data to set the 2025 outlier threshold. To model hospital outlier payments and set the outlier threshold for the proposed rule, CMS applied a charge inflation factor of 1.084555 to approximate 2025 charges from 2023 claims.

The proposed rule indicates that CMS is proposing to use hospital-specific overall ancillary CCRs from the April 2024 update to the Outpatient Provider-Specific File to determine the 2025 proposed rule outlier threshold. CMS proposes to adjust the April 2024 CCRs by 1.03331 to approximate 2025 CCRs.

For 2025, CMS proposes a fixed dollar threshold of $8,000 (compared to $7,750 in 2024). 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 2023, CMS estimates that it paid 0.68 percent of total OPPS payments as outliers, or 0.32 percentage points less than the 1.0 percent target. Using 2023 Medicare utilization, CMS estimates that it will pay 0.85 percent of total OPPS payments as outliers in 2024, or 0.15 percentage points less 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).[4] 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 final rule. The proposed status indicators, APC assignments, and payment rates can be found in Addendum B of this proposed rule.[5]

1. April 2024 Codes - CMS Solicits Public Comments in this Proposed Rule

In the April 2024 OPPS quarterly update, CMS created 74 new Level II HCPCS codes effective and assigned them to interim OPPS status indicators and APCs (Table 10). These codes will be flagged with comment indicator "NP" in Addendum B, indicating the codes have an interim OPPS payment status for 2024 and are subject to public comment in this proposed rule.

2. July 2024 HCPCS Codes - CMS Solicits Public Comments in this Proposed Rule

In the July 2024 OPPS quarterly update, CMS established 127 new codes effective July 1 and assigned them interim OPPS status indicators and APCs (Table 11). These codes will be flagged

[4]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: multianalyte assays with algorithmic analyses (MAAA) CPT codes; proprietary laboratory analyses (PLA) services CPT codes; and Level II HCPCS codes (codes that primarily identify drugs, devices, supplies, temporary procedures and services not described by CPT codes).

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

with comment indicator "NP" in Addendum B, indicating the codes have an interim OPPS payment status for 2024 and are subject to public comment in this proposed rule.

3. October 2024 HCPCS Codes - CMS Will Be Soliciting Public Comments in the 2025 Final Rule

CMS proposes to provide interim payment status indicators, APC assignments and payment rates, if applicable, for HCPCS codes that will become effective October 1, 2024 in Addendum B to the 2025 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 the remainder of 2024 and all of 2025. These status indicators and APC assignments will be effective October 1, 2024. CMS will invite public comment in the 2025 OPPS/ASC final rule about the status indicators, APC assignments, and payment rates for these codes and this information will be finalized in the 2026 OPPS/ASC final rule.

4. January 2025 HCPCS Codes

a. New Level II HCPCS Codes – CMS Will Be Soliciting Public Comments in the 2025 OPPS Final Rule

CMS will solicit comments on the new Level II HCPCS codes that will become effective January 1, 2025 in the 2025 OPPS final rule. Unlike the CPT codes that are effective January 1, 2025 and made subject to comment in this proposed rule 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, 2024 to be effective January 1, 2025 and CMS is not able to include them in the proposed rule.

New Level II HCPCS codes that will be effective January 1, 2025 will be flagged with comment indicator "NI" in Addendum B, indicating that the codes have an interim OPPS payment status for 2025. CMS will invite public comment in the 2025 OPPS final rule about the status indicators, APC assignments, and payment rates for these codes and this information will be finalized in the 2026 OPPS/ASC final rule.

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

For the 2025 OPPS update, CMS received the CPT codes that will be effective January 1, 2025 in time to be included in 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 year or the code is an existing code with substantial revision to its code descriptor in the next year as compared to the current year with a proposed APC assignment and 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 2025 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 12 (reproduced below) summarizes the process used by CMS for updating codes.

Table 12: Comment Timeframe for New or Revised HCPCS codes				
OPPS Quarterly Update CR	**Type of Code**	**Effective Date**	**Comments Sought**	**Finalized**
April 2024	HCPCS (CPT and Level II Codes)	April 1, 2024	2025 OPPS/ASC proposed rule	2025 OPPS/ASC final rule
July 2024	HCPCS (CPT and Level II Codes)	July 1, 2024	2025 OPPS/ASC proposed rule	2025 OPPS/ASC final rule
October 2024	HCPCS (CPT and Level II Codes	October 1, 2024	2025 OPPS/ASC final rule	2026 OPPS/ASC final rule
January 2025	CPT Codes	January 1, 2025	2025 OPPS/ASC proposed rule	2025 OPPS/ASC final rule
	Level II HCPCS Codes	January 1, 2025	2025 OPPS/ASC final rule	2026 OPPS/ASC final rule

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 2025 OPPS and CMS' responses will be discussed in the 2025 OPPS/ASC final rule.

For 2025, 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") other than those for which CMS is proposing an exception to the 2 time rule. CMS notes that in many cases, the proposed procedure code reassignments and associated APC configurations for 2025 are related to changes in costs of services that were observed in the 2023 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 13 (reproduced below) lists the 23 APCs that CMS proposes to exempt from the 2 times rule for 2025 based on 2023 claims data.

Table 13 : Proposed 2025 APC Exceptions to the 2 Times Rule

APC	APC Title
5012	Clinic Visits and Related Services
5053	Level 3 Skin Procedures
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
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
5593	Level 3 Nuclear Medicine and Related Services
5611	Level 1 Therapeutic Radiation Treatment Preparation
5627	Level 7 Radiation Therapy
5691	Level 1 Drug Administration
5692	Level 2 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5733	Level 3 Minor Procedures
5734	Level 4 Minor Procedures
5741	Level 1 Electronic Analysis of Devices
5743	Level 3 Electronic Analysis of Devices

Table 13 : Proposed 2025 APC Exceptions to the 2 Times Rule	
APC	**APC Title**
5791	Pulmonary Treatment
5811	Manipulation Therapy
5821	Level 1 Health and Behavior Services
5823	Level 3 Health and Behavior Services

C. New Technology APCs

1. New Technology APC Groups

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

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

One of CMS' objectives of establishing New Technology APCs is to generate sufficient claims data for a new procedure for assignment to an appropriate clinical APC. CMS considers procedures with fewer than 100 claims annually as low-volume procedures. CMS is concerned 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.[6] Beginning in 2022, CMS adopted the same policy for all low-volume APCs. Under this policy, CMS determines the relative weight for APCs with fewer than 100 claims in a single year based on the higher of the APC's geometric mean, median, or the arithmetic mean based on up to 4 years of claim data.

For 2025, CMS proposes to exempt services assigned to New Technology APCs with fewer than 10 claims in the 4-year lookback period from the low-volume APC policy. To improve payment stability, CMS is proposing to maintain the existing New Technology APC assignment when a new service has fewer than 10 claims in the 4-year lookback period rather than establish a New Technology APC based on the higher of the geometric mean, median or arithmetic mean costs.

[6] 83 FR 58892-58893

3. Procedures Assigned to New Technology APC Groups for 2025

CMS generally retains services within New Technology APC groups until 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 the agency 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 to retain a service in a New Technology APC for more than 2 years if there is not sufficient claims data for basing a reassignment.

Based on the policies described above, the below table reflects CMS' proposed New Technology APC assignments for 2025:

Proposed 2025 New Technology APC and Status Indicator Assignments				
HCPCS	**Long Descriptor**	**Proposed 2025 SI**	**Proposed 2025 APC**	**Notes**
0810T	Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies	T	1563	Xwalk from C9770 that has less than 10 claims over 4 years. CMS proposes maintaining current APC assignment
C9794	Therapeutic radiology simulation-aided field setting; complex, including acquisition of PET and CT imaging data required for radiopharmaceutical-directed radiation therapy treatment planning (i.e., modeling)	S	1521	Code created 1/1/2024 and assigned to APC 1521. No claims. CMS proposes maintaining 2024 interim assignment
C9795	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance and real-time positron emissions-based delivery adjustments to 1 or more lesions, entire course not to exceed 5 fractions	S	1525	Code created 1/1/2024 and assigned to APC 1525. No claims. CMS proposes maintaining 2024 interim assignment
C9758	Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study	T	1590	Fewer than 10 claims in the 4-year lookback period. CMS proposes maintaining the current APC assignment
C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g., aspiration[s]/biopsy[ies]	T	1562	No new claims and less than 10 claims in the 4-year lookback period. CMS proposes maintaining current APC assignment.

Proposed 2025 New Technology APC and Status Indicator Assignments				
HCPCS	**Long Descriptor**	**Proposed 2025 SI**	**Proposed 2025 APC**	**Notes**
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	S	1522	Sufficient 2023 claims data to change interim assignment from APC 1521 to 1522.
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability);	S	1521	Using 4 years of claims data to maintain assignment to APC 1521.
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability); with concurrently acquired computed tomography transmission scan	S	1522	Sufficient 2023 claims data to change interim assignment from APC 1521 to 1522
C9782	Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study	T	1590	Fewer than 10 claims in the 4-year lookback period. CMS proposes maintaining the current APC assignment
0625T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography	S	1511	Low claims volume and claims data suggest a very low cost (<$10) which seems unlikely. CMS proposes to maintain APC assignment to 1511.
C9760	(Non-randomized, non-blinded procedure for NYHA class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (for example, ultrasound, fluoroscopy) performed in an approved investigational device exemption (IDE) study	T	1592	Fewer than 10 claims in the 4-year lookback period. CMS proposes maintaining the current APC assignment
06093T	Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report	S	1505	There have been no claims for the code since it was made effective in 2022. CMS proposes maintaining its current APC assignment.

Proposed 2025 New Technology APC and Status Indicator Assignments				
HCPCS	**Long Descriptor**	**Proposed 2025 SI**	**Proposed 2025 APC**	**Notes**
C9789	Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed	T	1559	Procedure first effective October 1, 2023. Only six claims available. CMS proposes maintaining initial APC assignment.
0620T	Endovascular venous arterialization, tibial or peroneal vein, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed	S	1579	Proposed APC assignment based on the low volume methodology. Assignment changed from 1578 to 1579.
0686T	Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance	S	1576	Fewer than 10 claims in the 4-year lookback period. CMS proposes maintaining the current APC assignment
0648T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session; single organ	S	1504	Proposed APC assignment based on the low volume methodology. Assignment changed from 1511 to 1504.
0649T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	S	1504	Proposed APC assignment based on the low volume methodology. Assignment changed from 1511 to 1504. Add-on code to 0648T assigned to the same APC.
0721T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging	S	1508	Fewer than 10 claims in the 4-year lookback period. CMS proposes maintaining the current APC assignment
0722T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset (list separately in addition to code for primary procedure)	S	1508	Fewer than 10 claims in the 4-year lookback period. CMS proposes maintaining the current APC assignment
0697T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (e.g.,	S	1509	Proposed APC assignment based on the low volume methodology. Assignment changed from 1511 to 1509.

Proposed 2025 New Technology APC and Status Indicator Assignments				
HCPCS	**Long Descriptor**	**Proposed 2025 SI**	**Proposed 2025 APC**	**Notes**
	organ, gland, tissue, target structure) during the same session; multiple organs			
0698T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure); multiple organs (list separately in addition to code for primary procedure)	S	1509	Proposed APC assignment based on the low volume methodology. Assignment changed from 1511 to 1509. Add-on code to 0697T assigned to the same APC.
0723T	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session	S	1511	Fewer than 10 claims in the 4-year lookback period. CMS proposes maintaining the current APC assignment.
0724T	Quantitative magnetic resonance cholangiopancreatography (QMRCP), including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) (list separately in addition to code for primary procedure)	S	1511	Fewer than 10 claims in the 4-year lookback period. CMS proposes maintaining the current APC assignment. Add-on code to 0723T assigned to the same APC.
0662T	Scalp cooling, mechanical; initial measurement and calibration of cap	S	1515	Proposed APC assignment based on the low volume methodology. Assignment changed from 1514 to 1515.
G0282	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours postadministration observation	S	1512	Sufficient claims to determine a geometric mean cost. Proposed APC assignment to 1512 in 2025 from 1513.
G0283	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation	S	1518	Sufficient claims to determine a geometric mean cost. Proposed APC assignment to 1518 in 2025 from 1520.
C9780	Insertion of central venous catheter through central venous occlusion via inferior and superior approaches (e.g., inside-out technique), including imaging guidance	S	1534	Fewer than 10 claims in the 4-year lookback period. CMS proposes maintaining the current APC assignment
C9792	Blinded or nonblinded procedure for symptomatic New York Heart Association (NYHA) Class II, III, IVa heart failure; transcatheter implantation of left atrial to coronary sinus shunt using jugular vein access, including all imaging necessary to intra procedurally map the coronary sinus for optimal shunt placement (e.g., TEE or ICE ultrasound, fluoroscopy), performed under general	S	1537	Code effective October 1, 2023. No claims. CMS proposes maintaining the 2024 APC assignment.

Proposed 2025 New Technology APC and Status Indicator Assignments				
HCPCS	**Long Descriptor**	**Proposed 2025 SI**	**Proposed 2025 APC**	**Notes**
	anesthesia in an approved investigational device exemption (IDE) study			
C9791	Magnetic resonance imaging with inhaled hyperpolarized xenon-129 contrast agent, chest, including preparation and administration of agent	T	1551	Code effective October 1, 2023. No claims. CMS proposes maintaining the 2024 APC assignment.

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

Beginning in 2022, CMS adopted a policy to use its 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 that spans the COVID-19 PHE) to make determinations when a clinical APC or brachytherapy APC is designated as low volume. For clinical and brachytherapy APC designated as low volume, CMS determines the relative weight based on the higher of the APC's geometric mean, median, or the arithmetic mean. CMS does not apply this policy to APC 5853 Partial Hospitalization for CMHCs or APC 5863 Partial Hospitalization for Hospital-based PHPs because of the different nature of policies that affect partial hospitalization programs. 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 2025, CMS proposes to apply this policy to six clinical APCs and five brachytherapy APCs, all of which are low-volume in the 2023 utilization used for developing the 2025 OPPS. See Table 35 of the proposed rule for APCs (other than New Technology APCs listed above) where CMS is using the low-volume rate setting methodology.

E. APC-Specific Policies

1. Request for Information on Cardiac CT Services

Since 2015, CPT codes 75572, 75573, and 75574 for cardiac CT services have been assigned to APCs based on their geometric mean cost. Payments have ranged between $175 and $265 for these codes but, with one exception, have declined annually since 2017. Public commenters notified CMS of a specific claims edit that may have affected the revenue codes reported with the cardiac CT codes in prior years' claims data. CMS confirmed the existence of the revenue code edit and removed it in early December 2023—too late to appreciably affect the 2023 utilization data used to set 2025 OPPS rates.

The revenue code edit may have resulted in a lower payment rate for cardiac CT services based on the imaging CCR rather than the cardiology CCR. CMS conducted a study of CPT codes 75572-

77574 to determine the extent to which the revenue edit may have affected geometric mean costs for these codes. Based upon the results of the study, CMS found that if 50 percent or more of HOPDs had billed these services with the cardiology revenue code (048X) and cardiology cost center (03140), the geometric mean costs for these codes would have increased and would have resulted in a revised APC assignment from APC 5571 (Level 1 Imaging with Contrast) to APC 5572 (Level 2 Imaging with Contrast)—an increase from $182 to $386.

CMS is requesting comments on how hospitals perform and bill for these services (e.g., do they use the radiology or cardiology department and which cost and revenue centers do they report costs and charges). Based on the public comments, CMS will decide whether to revise the payment methodology for 2025 using a simulated geometric mean cost based on the study it conducted.

2. Neurostimulator and Related Procedures (APCs 5461 Through 5465)

CMS reviews the history associated with the 5-level APC structure for neurostimulator and related procedures and public interest in creating a 6-level APC structure. While CMS is not proposing a change to the 5-level APC structure for these APCs, it is proposing to assign HCPCS codes 0266T and 33276 from New Technology APC 1580 to Level 5 neurostimulator APC (5465). **CMS also requests public comment on whether to adopt a 6-level structure for these APCs even though it has rejected those comments in the past.**

3. Focal Laser Ablation (APC 5374)

CPT code 0655T is used for focal laser ablation, an MRI directed and image guided, minimally invasive procedure that targets prostate cancer tissue. For 2024, CMS assigned CPT code 0655T to APC 5374 (Level 4 Urology and Related Services) with a payment rate of $3,321.58 based on its geometric mean cost of approximately $10,323, which was calculated using the available 16 single-frequency claims from the 2022 claims data.

Based on seven-single frequency claims available in the 2023 utilization data with a geometric mean cost of $12,777, CMS is proposing to move CPT code 0655T from APC 5374 to APC 5375 (Level 5 Urology and Related Services) with a payment rate of $5,057.16 proposed for 2025.

4. Bone Mass Measurement: Biomechanical Computed Tomography (BCT) Analysis with Vertebral Fracture Assessment (APCs 5521, 5523, and 5731)

CMS had originally assigned CPT codes 0554T-0558T and CPT code 0743T a status indicator of "E1" to indicate that codes are not paid by Medicare as CMS did not believe these services met the requirements to be covered as bone mass measurement services. Upon further consideration in the 2024 OPPS rule, CMS assigned CPT codes 0555T, 0556T and 0558T to clinical APCs and provided them with OPPS payment. CPT codes 0554T, 0557T and 0743T were assigned a status indicator of "M" which prohibits payment under the OPPS because these services only include physician work and no hospital practice expenses.

In the 2025 OPPS proposed rule, CMS is proposing to assign CPT code 0743T to APC 5523 (Level 3 Imaging without Contrast) and allow separate payment as the agency now believes this code has a technical component that can be billed by hospitals. CMS is proposing to continue to assign a status indicator of "M" to CPT codes 0554T and 0557T indicating these codes are not billable under the OPPS because they are physician work only codes.

IV. Payment for Devices

A. 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 adequate payments for new devices while the necessary cost data is collected to incorporate the device costs into the procedure APC rate.[7] 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 publicly posting online OPPS device pass-through applications received on or after March 1, 2023, beginning with the issuance of the 2025 proposed rule.

Currently, there are 15 device categories eligible for pass-through payment. Table 42 (reproduced below) lists the devices and their pass-through expiration.

Table 42 Devices with Pass-Through Status Expiring in 2024, 2025 or 2026

HCPCS Codes	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1831	Personalized, anterior and lateral interbody cage (implantable)	10/01/2021	09/30/2024
C1832	Autograft suspension, including cell processing and application, and all system components	01/01/2022	12/31/2024
C1833	Monitor, cardiac, including intracardiac lead and all system components (implantable)	01/01/2022	12/31/2024
C1826	Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system	01/01/2023	12/31/2025

[7] 87 FR 72032-72033

Table 42 Devices with Pass-Through Status Expiring in 2024, 2025 or 2026			
HCPCS Codes	**Long Descriptor**	**Effective Date**	**Pass-Through Expiration Date**
C1827	Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller	01/01/2023	12/31/2025
C1747	Endoscope, single-use (i.e., disposable), urinary tract, imaging/illumination device (insertable)	01/01/2023	12/31/2025
C1600	Catheter, transluminal intravascular lesion preparation device, bladed, sheathed (insertable)	01/01/2024	12/31/2026
C1601	Endoscope, single-use (i.e., disposable), pulmonary, imaging/illumination device (insertable)	01/01/2024	12/31/2026
C1602	Orthopedic/device/drug matrix/absorbable bone void filler, antimicrobial-eluting (implantable)	01/01/2024	12/31/2026
C1603	Retrieval device, insertable, laser (used to retrieve intravascular inferior vena cava filter)	01/01/2024	12/31/2026
C1604	Graft, transmural transvenous arterial bypass (implantable), with all delivery system components	01/01/2024	12/31/2026
C1605	Pacemaker, leadless, dual chamber (right atrial and right ventricular implantable components), rate-responsive, including all necessary components for implantation	07/01/2024	06/30/2027
C1606	Adapter, single-use (i.e., disposable), for attaching ultrasound system to upper gastrointestinal endoscope	07/01/2024	06/30/2027

2. New Device Pass-Through Applications for 2025

a. Background

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:

1. 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;

2. 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

3. 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:
    a) 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;
    b) 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
    c) 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

In 2016, CMS changed the OPPS device pass-through payment evaluation and determination process. Device pass-through applications are still submitted through the quarterly sub-regulatory 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.[8] Under this alternative pathway, FDA Breakthrough Device designation is considered a proxy for the device meeting substantial clinical improvement criterion. The device still must 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: https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/pass-through-payment-status-new-technology-ambulatory-payment-classification-apc. CMS notes it is also available to meet with applicants or potential applicants to discuss research trial design in advance of submitting any application.

b. Applications Received for Device Pass-Through Payments

CMS received 14 complete applications by the March 1, 2024 quarterly deadline, the last deadline in time for applications to be included this proposed rule. CMS approved the following applications:

1. The DETOUR™ System: Preliminarily approved upon quarterly review under the alternative pathway effective January 1, 2024.
2. AVEIR™ DR Dual Chamber Leadless Pacemaker System: Preliminarily approved upon quarterly review under the alternative pathway effective July 1, 2024
3. EndoSound Vision System® (EVS). Preliminarily approved upon quarterly review under the alternative pathway effective July 1, 2024.

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

Alternative Pathway Device Pass-Through Applications

1. AGENT™ Paclitaxel-Coated Balloon Catheter (Boston Scientific).

Summary: AGENT Paclitaxel-Coated Balloon Catheter is a device/drug combination product

[8] 84 FR 61295

consisting of a semi-compliant intracoronary balloon catheter with a paclitaxel/acetyl tributyl citrate drug coating on the balloon component that delivers paclitaxel, an antiproliferative drug, directly to the arterial tissue which inhibits the proliferation of neointimal smooth muscle cells without introducing an additional stent layer, thereby reducing the rate of restenosis. The product is intended for use in adult patients, after appropriate vessel preparation, undergoing percutaneous coronary intervention in coronary arteries 2.0 mm to 4.0 mm in diameter and lesions up to 26 mm in length for the purpose of improving myocardial perfusion when treating in-stent restenosis and the management of atherosclerotic coronary artery disease

Newness: AGENT Paclitaxel-Coated Balloon Catheter received FDA Breakthrough Device designation effective January 22, 2021 and pre-market approval (PMA) on February 29, 2024. The pass-through application was received within three years of the FDA marketing approval.

Inclusion and Exclusion Criteria: One criterion for a device to be eligible for pass-through is that it is not appropriately described by an existing category or any category previously in effect established for transitional pass-through payments. CMS raises a potential concern as to whether the device is described by a category previously in effect. The proposed rule indicates that HCPCS code C2623 may appropriately describe the AGENT Paclitaxel-Coated Balloon Catheter because it is a non-laser, drug-coated catheter used for transluminal angioplasty procedures. When C2623 was established as a device category effective April 1, 2015, the procedure codes with which C2623 could be reported (CPT codes 37224 and 37226) were limited to use in the femoral or popliteal arteries.

However, based on the subsequent changes that were made to the procedure codes with which C2623 could be reported, CMS does not agree with the applicant that C2623 is limited to use with femoral or popliteal revascularization procedures. The proposed rule cites specific instances where additional CPT codes 36902 and 36903 could be used with HCPCS code C2623 for peripheral dialysis segments in the upper extremities The proposed rule further indicates that upon becoming packaged, C2623 effectively became reportable with other transluminal angioplasty including percutaneous procedures and related coronary procedures.

Substantial Clinical Improvement: AGENT Paclitaxel-Coated Balloon Catheter has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation and therefore is not evaluated for substantial clinical improvement.

Cost Significance: The proposed rule indicates that AGENT Paclitaxel-Coated Balloon Catheter meets the three tests to determine cost significance.

2. Aveir™ DR Dual Chamber Leadless Pacemaker System (Abbott Laboratories).

Summary: The Aveir DR System is comprised of two leadless pacemakers, one atrial and one ventricular with each containing a generator and electrodes, that provide dual-chamber pacing therapy after being placed within the heart's myocardium through a minimally invasive catheter-based procedure. The system is programmable equipped with bidirectional implant-to-implant

communication without the need for traditional wire electrodes and can provide beat-to-beat communication and synchrony between the two pacemakers for the treatment of arrhythmia/bradycardia. Per the applicant, patients with indication for dual-chamber pacing would benefit from a dual-chamber leadless pacemaker system that provides atrial and ventricular bradycardia therapy, while eliminating the complications associated with conventional pacing systems.

Newness: The Aveir DR System received FDA Breakthrough Device designation effective March 27, 2020 and a PMA on June 29, 2023 for the indication covered by the Breakthrough Device designation. The pass-through application was received within three years of the FDA marketing approval.

Inclusion and Exclusion Criteria: CMS did not raise any concerns regarding whether the Aveir DR System would be ineligible for pass-through based on the inclusion or exclusion criteria.

Substantial Clinical Improvement: The Aveir DR System has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation, and therefore, is not evaluated for substantial clinical improvement.

Cost Significance: The proposed rule indicates that Aveir DR System meets the three tests to determine cost significance.

3. CANTURIO™ Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP®) System (Canary Medical)

Summary: CTE implant is a physical implant that is attached to the tibial baseplate as part of a total knee arthroplasty (TKA) to form the patient's knee prosthesis and provide additional stability to the replacement knee joint. The software and electronics within the CTE implant with CHIRP system collects unprocessed 3-D accelerometer and 3-D gyroscopic sensor data using its Inertial Measurement Unit on the patient's functional movement and gait parameter post-surgery, and transmits the encrypted data via the Home Base Station to the cloud platform. The CTE implant with CHIRP System is indicated for use in patients undergoing a cemented TKA procedure that are normally indicated for at least a 58 mm sized tibial stem extension.

Newness: The CTE implant with CHIRP System received FDA Breakthrough Device designation effective October 24, 2019 and a De Novo classification for the CTE implant with CHIRP System on August 27, 2021. The pass-through application was received within three years of the FDA marketing approval.

Inclusion and Exclusion Criteria: To be eligible for pass-through, the device must be an integral part of the service furnished. CMS questions whether the CTE implant is integral to the service furnished because CTE implant appears to be purely additive in nature and not necessary to furnish or deliver TKA. Nor does it appear that the data generated from the CTE implant post-procedure is necessary to furnish or deliver the primary service.

Substantial Clinical Improvement: The CTE implant with CHIRP system has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation and therefore is not evaluated for substantial clinical improvement.

Cost Significance: The proposed rule indicates that CTE implant with CHIRP System meets the three tests to determine cost significance.

4. The DETOUR™ System (Endologix)

Summary: The DETOUR System is an implantable component, used to create a femoropopliteal bypass routed through the femoral vein. The DETOUR System is comprised of two main components: (1) the TORUS™ Stent Graft System, which is comprised of the TORUS Stent Graft and the TORUS Stent Graft Delivery System, and (2) the ENDOCROSS™ Device.

The DETOUR System is used to treat patients with advanced peripheral vascular disease, specifically those with long complex femoropopliteal artery stenoses and occlusions resulting in lifestyle limiting claudication or severe lower limb threatening ischemia. The DETOUR System can restore arterial blood flow to the lower limb around the blocked femoral artery and allows for venous blood flow around the conduit for normal venous return, to reduce signs and symptoms of lower limb ischemia and prevent amputation.

Newness: The DETOUR System received FDA Breakthrough Device designation effective September 2, 2020 and a PMA from the FDA on June 7, 2023. The pass-through application was received within three years of the FDA marketing approval.

Inclusion and Exclusion Criteria: CMS did not raise any concerns regarding whether the DETOUR System would be ineligible for pass-through based on the inclusion or exclusion criteria. The pass-through application received preliminary approval effective January 1, 2024.

Substantial Clinical Improvement: The DETOUR System has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation and therefore is not evaluated for substantial clinical improvement.

Cost Significance: The proposed rule indicates the DETOUR System that meets the three tests to determine cost significance.

5. EndoSound Vision System™ (EVS™, Endosound)

Summary: The EVS is an ultrasound system designed to externally attach to an upper gastrointestinal (GI) endoscope (gastroscope/upper (EGD) endoscope). Once attached to an EGD endoscope, it temporarily converts the EGD endoscope to a fully capable endoscopic ultrasound (EUS) endoscope. The EVS can be coupled with an upper GI endoscope device to enable real-time ultrasound imaging, ultrasound guided needle aspiration, and other EUS guided procedures within

the upper GI tract and surrounding organs. The EVS consists of: (1) the EVS Scanner, a beamformer/scanner that performs ultrasound signal processing; (2) the Ultrasound Transducer Module (UTM), a reusable transducer assembly that converts the electrical signals from the scanner into ultrasound energy; (3) the Transducer Extension Cable (TEC), a cable/connector to interface the UTM to the EVS Scanner; and (4) the UDK-T, a disposable mounting kit with an operator control mechanism used to externally affix the EVS to a standard EGD endoscope and to provide needle and transducer angulation while maintaining the native gastroscope controls.

Newness: The EVS, which includes the UDK-T, received FDA Breakthrough Device designation effective July 29, 2021 and 510(k) clearance on December 27, 2023. The pass-through application was received within three years of the FDA marketing approval.

Inclusion and Exclusion Criteria: CMS did not raise any concerns regarding whether the EVS would be ineligible for pass-through based on the inclusion or exclusion criteria. The pass-through application received preliminary approval effective July 1, 2024.

Substantial Clinical Improvement: The EVS, inclusive of the UDK-T, has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation and therefore is not evaluated for substantial clinical improvement.

Cost Significance: The proposed rule indicates that EVS™ meets the three tests to determine cost significance.

6. iFuse Bedrock Granite™ Implant System (SI-Bone)

Summary: The iFuse Bedrock Granite™ Implant System consists of iFuse Granite™ implants of various lengths and diameters and associated instruments sets. The titanium (Ti-6Al-4V ELI) iFuse Granite™ implant consists of a porous fusion sleeve with threaded length attached to a solid post that has connection and implant placement features of a typical pedicle fixation screw. The iFuse Granite™ implant is intended to provide sacropelvic fusion of the sacroiliac joint (when placed in the sacral-alar-iliac trajectory) and fixation to the pelvis when used in conjunction with commercially available pedicle screw fixation systems as a foundational element for segmental spinal fusion only when performing both a lumbar and a sacroiliac joint (SIJ) fusion procedure in the same operative session. The joint fusion occurs as a result of the device's porous surface and interstices and fixation occurs through the device's helical threaded design and traditional posterior fixation rod connection.

Newness: The iFuse Bedrock Granite™ Implant System received FDA Breakthrough Device designation effective November 23, 2021, an FDA 510(k) clearance on May 26, 2022 and approval for an additional indication on December 22, 2022. The pass-through application was received within three years of the FDA marketing approval.

Inclusion and Exclusion Criteria: CMS indicates that the application did not include sufficient information to determine if the associated instruments sets included in the iFuse Bedrock Granite™

Implant System meet the criterion specified in § 419.66(b)(3) ("an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion.").

CMS believes that the device category C1889 may appropriately describe the iFuse Bedrock Granite™ Implant System because C1889 may be used to describe any implantable/insertable device that is not otherwise described by a more specific device category and is, therefore, sufficiently broad to include implantable devices that allow for simultaneous fusion of the SIJ and fixation of the pelvis.

Substantial Clinical Improvement: The iFuse Bedrock Granite™ Implant System has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation and therefore is not evaluated for substantial clinical improvement.

Cost Significance: The proposed rule indicates the iFuse Bedrock Granite™ Implant System that meets only the first of three tests of cost significance. It must meet all three tests to be approved for pass-through payment.

7. Paradise® Ultrasound Renal Denervation (RDN) System (ReCor Medical)

Summary: The Paradise Ultrasound RDN System is a catheter-based system that delivers ultrasound energy in the location of sympathetic nerves surrounding the renal arteries. The Paradise Ultrasound RDN System is indicated to reduce blood pressure as an adjunctive treatment in patients with hypertension in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure. The product, when used with the other Paradise Ultrasound RDN System components, provides complete 360-degree energy delivery and targeted ablation depth with each energy emission with the goal of disrupting the nerves and consequently achieving a reduction in systemic arterial blood pressure. The Paradise Catheter protects the artery walls using a cooling system during periods of ultrasound energy emission.

Newness: The Paradise Ultrasound RDN System received FDA Breakthrough Device designation effective December 4, 2020 and a PMA on November 7, 2023. The pass-through application was received within three years of the FDA marketing approval.

Inclusion and Exclusion Criteria: The Paradise Generator, Paradise Remote, and Paradise Cart are reusable and constitute capital equipment. Therefore, these components of the system would be ineligible for pass-through payment. The Paradise Catheter, Paradise Cartridge, and Paradise Connection Cable are single-use only and would meet the relevant inclusion criteria for pass-through payment.

CMS notes that the Paradise Ultrasound RDN System provides renal denervation using ultrasound while the Symplicity Spyral™ Catheter provides renal denervation using radiofrequency. As detailed below, Medtronic has applied for a pass-through application for Symplicity Spyral™

Catheter. CMS questions whether the device descriptions provided in the respective applications support establishing two modality-specific pass-through payment device categories or a single device category that would encompass both RDN device modalities. This issue is described in more detail below.

Substantial Clinical Improvement: The Paradise Ultrasound RDN System has Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation and therefore is not evaluated for substantial clinical improvement.

Cost Significance: The proposed rule indicates that the Paradise Ultrasound RDN System meets the three tests to determine cost significance.

8. Precision GI (Limaca Medical)

Summary: Precision GI is a motorized, battery operated, single-use, fully disposable endoscopic ultrasound-guided (EUS) fine needle biopsy device used to obtain biopsies of tissue for definitive diagnosis of pancreatic cancer and other life-threatening GI abnormalities. Precision GI is untethered and battery operated with an internally powered and controlled motor, featuring a long flexible shaft transferring the proximal force of the motor through the inserted endoscope to the needle circumferential cutting tip. The device is controlled by a physician, who inserts the device into the patient's gastrointestinal tract via the ultrasound endoscope. Upon reaching the designated biopsy site, the physician operates the device's motorized mechanism that automatically rotates the needle (which is included in the device's package) to cut and extract tissue. The biopsy site is accessed through the instrument channel of an ultrasound imaging endoscope that detects the device's echogenic needle tip.

Newness: Precision GI received FDA Breakthrough Device designation effective March 24, 2022 and 510(k) clearance on August 28, 2023. The pass-through application was received within three years of the FDA marketing approval.

Inclusion and Exclusion Criteria: Based on the description of the device as a biopsy device, CMS questions whether Precision GI may be considered a supply or material furnished incident to a service and excluded from device pass-through payment eligibility under § 419.66. 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 as is required for a device to be eligible for pass-through payment. Additionally, CMS questions whether Precision GI, which is described as a biopsy device, may be considered a supply or material furnished incident to a service and therefore excluded from device pass-through payment eligibility under § 419.66(b)(4).

Substantial Clinical Improvement: Precision GI has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device and therefore is not evaluated for substantial clinical improvement.

Cost Significance: The proposed rule indicates that Precision GI meets the three tests to determine

cost significance.

9. PulseSelect™ Pulsed Field Ablation (PFA) System (Medtronic)

Summary: The PulseSelect PFA™ System is used to perform pulmonary vein isolation (PVI) via cardiac catheter ablation to treat atrial fibrillation. The PulseSelect PFA™ System uses non-thermal irreversible electroporation (IRE) to induce cardiac tissue cell death. The pulsed field ablation, or IRE for PVI during cardiac catheter ablation, is performed as a percutaneous, transvenous procedure under imaging guidance. The PulseSelect PFA™ System consists of three elements: (1) the PulseSelect PFA™ Loop Catheter (Loop Catheter), a one-time use, steerable, multi-electrode loop catheter used to deliver IRE in pulmonary vein isolation as a treatment for atrial fibrillation; (2) the PulseSelect PFA™ Catheter Interface Cable (Catheter Interface Cable), a one-time use interface cable used to connect the Loop Catheter to the PulseSelect PFA™ Generator system; and (3) the PulseSelect PFA™ Generator system (Generator system) used to deliver IRE in pulmonary vein isolation as a treatment for atrial fibrillation.

Newness: The PulseSelect PFA™ System received FDA Breakthrough Device designation effective September 27, 2018, for the treatment of drug refractory recurrent symptomatic atrial fibrillation and a PMA on December 13, 2013. The pass-through application was received within three years of the FDA marketing approval.

Inclusion and Exclusion Criteria: CMS indicates that neither the PulseSelect PFA™ Generator system nor the PulseSelect PFA™ Catheter Interface Cable which is used to connect the Loop Catheter to the PulseSelect PFA™ Generator system appear to come in contact with the patient's tissue, be surgically implanted or inserted, or applied in or on a wound or other skin lesion, as required by § 419.66(b)(3) and therefore, CMS does not believe that either component is eligible for device pass-through payments.

Additionally, CMS indicates the applicant stated that the PulseSelect PFA™ Catheter Interface Cable is a one-time use cable that cannot be reprocessed which appears to conflict with its inpatient prospective payment system new technology add-on application (NTAP) where the applicant stated that the PulseSelect PFA Interface Cable is a component of the PulseSelect PFA™ Generator Reusable Accessories.

CMS also stated there were other inconsistencies between the NTAP and pass-through application. The NTAP application is only for the PulseSelect PFA™ Loop Catheter and not the entire PulseSelect PFA™ System. However, the application for a new device category for transitional pass-through payment status is for the PulseSelect PFA™ System, which includes the PulseSelect PFA™ Generator system which qualifies as capital equipment and is ineligible for pass-through payment.

With respect to whether there is/was a category that describes the PulseSelect PFA™ System, CMS believes that C1733 may appropriately describe the PulseSelect PFA™ System because it includes a catheter used for ablation of tissue without a cool-tip. C1733 does not specify the modality

needed to deliver the ablation, whether thermal or by electroporation. In this context, CMS believes the PulseSelect PFA™ System may be similar to the devices described by C1733.

Substantial Clinical Improvement: The PulseSelect PFA™ System has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation and therefore is not evaluated for substantial clinical improvement.

Cost Significance: CMS indicates that the PulseSelect PFA™ System met the first test of cost significance but not the second or the third.

10. Symplicity Spyral™ Renal Denervation (RDN) System (Medtronic)

Summary: The Symplicity Spyral™ RDN System consists of the Symplicity Spyral™ Catheter and the Symplicity G3 generator. Medtronic is only requesting device pass-through status for the catheter component of the system only. The Symplicity Spyral™ RDN System is indicated to reduce blood pressure as an adjunctive treatment in hypertension patients in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure. The Symplicity Spyral™ Catheter, when used with the Symplicity G3 generator, delivers radiofrequency (RF) energy through the wall of the renal artery to disrupt the surrounding renal nerves with the aim of modulating or suppressing sympathetic nerve hyperactivity. According to the applicant, the Symplicity Spyral™ Catheter is a single-use catheter used to deliver multiple ablations in both kidneys, in the renal main, accessory, and branch arteries, based on a patient's artery anatomy and size.

Newness: The Symplicity Spyral™ RDN System received FDA Breakthrough Device designation effective March 27, 2020 and a PMA on November 17, 2023. The pass-through application was received within three years of the FDA marketing approval.

Inclusion and Exclusion Criteria: CMS did not raise any concerns about whether the catheter component of the Symplicity Spyral™ RDN System is ineligible for pass-through based on the inclusion or exclusion criteria.

Substantial Clinical Improvement: The Symplicity Spyral™ Catheter has Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation and therefore is not evaluated for substantial clinical improvement.

Cost Significance: The proposed rule indicates that the Symplicity Spyral™ Catheter meets the three tests to determine cost significance.

One Category or Two: As noted above, CMS has received two pass-through applications for technologies that treat high blood pressure through renal denervation. CMS notes the following similarities between the Paradise Ultrasound RDN System and the Symplicity Spyral™ RDN System:

- Both are authorized by FDA to reduce blood pressure as an adjunctive treatment in patients with hypertension in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure.
- Paradise Ultrasound RDN System and the Symplicity Spyral™ RDN System use the same procedure, to treat the same disease, in the same patient population and aim to achieve the same therapeutic outcome, using the same or similar mechanism of action.
- Both the Paradise Ultrasound RDN System and the Symplicity Spyral™ RDN System may be used with the same HCPCS procedure codes: 0338T or 0339T.

Each applicant has proposed its own device category description:

- Paradise Ultrasound RDN System: Catheter, intravascular renal denervation, ultrasound, with balloon cooling;
- Symplicity Spyral™ RDN System: Ablation catheter, renal nerve, via endovascular approach, any modality.

The latter proposed category descriptor would work for both devices while the former would only be applicable to Paradise Ultrasound RDN System because it is specific to the modality used for denervation.

CMS notes several differences in procedural technique with each of the products:

- The Paradise Ultrasound RDN System delivers ablation while positioned in the main renal arteries only, whereas the Symplicity Spyral™ RDN System may deliver ablation while positioned in the main renal, accessory and branch arteries and therefore may require advancing the catheter beyond the main renal arteries.
- The Paradise Ultrasound RDN System procedural technique requires the measurement of the main renal artery diameter to select the appropriate size cooling balloon catheter, whereas the Symplicity Spyral™ RDN System's one size catheter does not require this measurement.
- The Paradise Catheter's cooling balloon requires specific procedural techniques to ensure the balloon is appropriately inflated and deflated during the procedure, but the Symplicity Spyral™ Catheter does not have this requirement.

The applicant for the Paradise Ultrasound RDN System asserted that its request for a unique category is supported by differences in clinical efficacy between RDN devices using ultrasound and RDN devices using radiofrequency ablation. CMS did not evaluate the validity or generalizability of these claims nor is it is clear if the two different ablation modalities (i.e., ultrasound and radiofrequency) would render different clinical results in larger studies or in the long term.

CMS indicates that it does not establish pass-through device categories for the purposes of describing specific devices, but rather, device categories which are intended to encompass all devices that can be appropriately described by a category. However, CMS indicates that there are

examples in both CPT and agency created HCPCS codes where specific ablation modalities are included in the code descriptor. [9]

While CMS raises issues and questions regarding whether one or two category descriptors are necessary for each of these technologies, it does not make a proposal. **Rather, it requests public comment on whether the device descriptions provided in the Paradise Ultrasound RDN System and the Symplicity Spyral™ RDN System applications support establishing two modality specific pass-through payment device categories or a single device category that would encompass both RDN device modalities.**

Traditional Device Pass-Through Applications

1. Ambu® aScope™ Gastro

Summary: The Ambu® aScope™ Gastro is a sterile, single-use, flexible gastroscope intended to be used for: (1) endoscopic access to and examination of the upper gastrointestinal (GI) anatomy; and (2) upper GI endoscopy or esophagogastroduodenoscopy (EGD) to diagnose and treat problems in the upper GI tract, including dysphagia, gastroesophageal reflux disease, narrowing or blockages, esophageal varices, inflammation, ulcers, tumors, hiatal hernia, Celiac disease, Crohn's disease, and infections of the upper GI tract in adult patients.

The Ambu® aScope™ Gastro works with the Ambu® aBox™ 2, a compatible, reusable displaying unit. The Ambu® aScope Gastro endoscope is inserted into the upper GI anatomy airway through the mouth, while the Ambu® aBox™ 2 is a non-sterile digital monitor intended to display live imaging data from Ambu visualization devices. The applicant is only seeking a new device category for transitional pass-through payment status for the Ambu aScope™ Gastro.

Newness: The Ambu® aScope™ Gastro, Ambu® aBox™ 2 received a 510(k) clearance from the FDA on February 3, 2023. The pass-through application was received within three years of the FDA marketing approval.

Inclusion and Exclusion Criteria: CMS indicates that the applicant stated that the Ambu® aScope™ Gastro is a supply furnished incident to a service rendered. As described, Ambu® aScope™ Gastro would be considered a supply or material furnished incident to a service and excluded from device pass-through payment eligibility under § 419.66(b)(4).

Substantial Clinical Improvement: The applicant indicates that Ambu® aScope™ Gastro would provide a substantial clinical improvement through:

- Elimination of the risk of cross-contamination between patients and scopes.
- Elimination of the risk of cross-contamination for reusable gastroscopes.
- Elimination of the risk of resistant infections that originate from reusable gastroscopes.

[9] CMS' discussion appears to lead to a conclusion that different HCPCS codes could be created for renal denervation via ultrasound versus radiofrequency with a single pass-through category for all modalities of renal denervation.

- Avoidance of scope damage and debris after reprocessing.
- Avoidance of damaged and contaminated scopes from being used on patients.
- Elimination of the risk of patient-to-patient infections associated with contaminated scopes.
- Avoidance of infection and death associated with reusable gastroscope contamination.

The applicant provided seven background articles about reusable GI endoscopes to support its claims.

CMS raised the following concerns regarding substantial clinical improvement:

- There are 11 other devices that are similar to Ambu® aScope™ Gastro. The applicant did not provide any comparative data that demonstrates that the Ambu® aScope™ Gastro offers a substantial clinical improvement when compared to the other 11 devices.
- The 510(k) application to the FDA used the OLYMPUS EVIS EXERA II Gastrointestinal Videoscope as the predicate device. While the Ambu® aScope™ Gastro is difference than the predicate device, it is unclear whether this difference represents a substantial clinical improvement.
- While the applicant claims that the Ambu® aScope™ Gastro eliminates cross-contamination associated with reusable gastroscopes and eliminates the risk of infections that originate from reusable gastroscopes, the evidence submitted to support this claim appear to apply to flexible, reprocessed gastroscope or endoscopes, broadly, but not to disposable, single-use devices comparable to the nominated device.

Cost Significance: The proposed rule indicates that the Ambu® aScope™ meets the three tests to determine cost significance.

2. OMEZA Wound Care Matrix (OCM™, Omeza LLC)

Summary: OCM is an amorphous, solid, malleable sheet comprised of hydrolyzed fish peptides infused with cod liver oil, which acts as an anhydrous skin protectant. OCM is indicated for the management of wounds. When applied to a clean wound surface, OCM is naturally incorporated into the wound over time. Per the applicant, OCM's cold water fish peptides provide building blocks for tissue regeneration and cell signaling molecules stimulate tissue growth. Additionally, OCM's matrix-like device also contains active pharmaceutical ingredient(s) (API) and nutrients that continuously reduce biofilm impact, reduce inflammation, increase tissue proliferation, and support remodeling of tissue.

Newness: OCM received 510(k) clearance from FDA on September 1, 2021. The pass-through application was received within three years of the FDA marketing approval.

Inclusion and Exclusion Criteria: CMS indicates that skin substitutes are supplies used in a surgical procedure because, as a part of a surgical repair procedure, they reinforce and aid the healing of tissue like implantable biologicals, but with skin substitutes, the tissue is skin instead of internal connective tissues. (78 FR 74931). As such, CMS raises the question as to whether OCM would be

considered a supply, and excluded from device pass-through payments under § 419.66(b)(4).

Substantial Clinical Improvement: The applicant claimed that OCM demonstrates:

- Superior clinical outcomes and healing for diabetic foot ulcers (DFU) compared to standard of care.
- Faster healing rates than standard of care for venous leg ulcers (VLUs).
- Superior clinical outcomes for patients who could not qualify for clinical trials due to comorbidities.
- Improved results when compared to results with standard of care for patients who failed prior treatment.
- In vitro/in vivo antimicrobial properties and patient safety.
- Improved patient safety.

The applicant provided support for its claim from: (1) two randomized controlled trials (a single-site trial of patients with DFUs to evaluate percent area reduction, and a randomized, multicenter, open label study for a patient group with VLUs); (2) two real-world trials comprised of two separate case studies of patients receiving follow-up care at two different wound treatment centers; (3) one in vitro study; (4) one in vivo porcine study; and (5) one consumer research study assessing the safety of OCM using the skin prick method.

CMS raised the following concerns regarding the evidence supplied by the applicant to support substantial clinical improvement:

- Lack of direct comparison between the nominated device and the predicate or reference devices for skin substitutes, particularly with respect to treatment of deep or persistent chronic wounds in people with DFUs and VLUs.
- Reliance on non-peer-reviewed studies, such as unpublished abstracts or conference posters, the results of which are only presented in a final data table.
- Reliance on studies which were sponsored by the device manufacturer rather than independent research.

CMS raised detailed concerns about each of the claims asserted by the applicant and its supporting evidence.

Cost Significance: The proposed rule indicates that OCM meets the three tests to determine cost significance.

3. OPN NC (SIS Medical)

Summary OPN NC percutaneous transluminal coronary angioplasty (PTCA) dilatation catheter is a sterile, single-use, rapid exchange catheter with a distal non-compliant double layer balloon attached to a flexible distal polymer shaft. OPN NC is intended for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial

perfusion. The balloon dilatation catheter is also indicated for post deployment expansion of balloon expandable coronary stents.

The device is inserted to position a balloon in a calcified coronary lesion where super-high pressure is used with the intention of achieving acceptable expansion of the lesion. Radiopaque balloon marker bands enable accurate positioning of the device, and shaft markers for brachial and femoral techniques are also in place. OPN NC is intended for all patient populations.

Newness: OPN NC received 510(k) clearance from FDA on March 14, 2022. The pass-through application was received within three years of the FDA marketing approval.

Inclusion and Exclusion Criteria: Based on the description the applicant provided, OPN NC is a transluminal vascular dilatation catheter with a balloon intended for dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion, which is consistent with the devices described by C1725. The implication of CMS' assertion is that the technology is described by a prior category that would make OPN NC ineligible for pass through as there is an already an existing code for the product.

Substantial Clinical Improvement: According to the applicant, OPN NC represents a substantial clinical improvement over existing technologies in the management of patients with highly calcified coronary lesions by providing optimal lumen expansion and demonstrating better outcomes in lesion treatment compared to other devices.

The applicant provided support for its claim from: three peer-reviewed studies; a PowerPoint presenting an indirect comparison of OPN NC versus another device, Shockwave Intravascular Lithotripsy (IVL) System with Shockwave C2 Coronary Intravascular Lithotripsy (IVL) Catheter (Shockwave), that uses intravascular lithotripsy (IVL) to treat calcium lesions; a spreadsheet summarizing the data presented in the PowerPoint document comparing OPN NC and Shockwave; and a background article providing an expert consensus statement from the Society for Cardiovascular Angiography & Interventions on management of in-stent restenosis and stent thrombosis.

CMS raised the following concerns about the evidence the applicant submitted to support its substantial clinical improvement claim:

- The studies were not randomized clinical trials with a comparator to demonstrate clinical improvement. Instead, the applicant presented results from registries using non-randomized, retrospective study designs without a control group.
- One of the studies (Natalia Pinilla-Echeverri, et al., 2023) indicated that use of other calcium lesion modification devices prior to applying OPN NC to the patients in that study is a potential confounder that could result in overestimation of OPN NC effectiveness.
- The application did not address whether the use of the device is safe beyond the data on safety endpoints presented in the studies provided.

- The evidence may not demonstrate that OPN NC substantially improves the treatment of an illness when compared to the benefits of other available treatments.

Cost Significance: The proposed rule indicates that OPN NC meets the three tests to determine cost significance.

4. OSCAR® Peripheral Multifunctional Catheter (Biotronik)

Summary: OSCAR® is a tool used to simplify the treatment of peripheral artery disease (PAD), a disease process characterized by the narrowing of arteries that supply blood to the limbs, usually the legs. In severe cases PAD can cause tissue death and gangrene, leading to amputation. OSCAR® can simplify the process of peripheral interventions, reduce the time required to perform the procedure and the need for repeat procedures, reduce the risk of complications associated with changing out multiple medical devices, minimize radiation exposure, and enhance patient comfort.

Newness: The applicant received 510k clearance from FDA for OSCAR® on July 5, 2022. The pass-through application was received within three years of the FDA marketing approval.

Inclusion and Exclusion Criteria: CMS indicates that when the OSCAR support catheter and OSCAR® dilator are combined with the OSCAR PTA balloon, the device is used to complete a transluminal angioplasty which is consistent with the devices described by C1725. The implication of CMS' assertion is that the technology is described by a prior category that would make OSCAR ineligible for pass through as there is an already an existing code for the product.

Substantial Clinical Improvement: The applicant claimed that OSCAR® represents a substantial clinical improvement over existing technologies in the diagnosis and management of peripheral artery disease because it uses less equipment, cuts down procedure time, and mitigates risks like vascular damage, infections, and radiation exposure, thereby enhancing clinical efficiency and safety. The applicant provided four background documents supporting its substantial clinical improvement claim.

CMS raises the following concerns about whether OSCAR® represents a substantial clinical improvement:

- The applicant did not submit peer-reviewed or published clinical evidence to substantiate clinical improvement over existing devices. The four documents presented in support of OSCAR's application rely on data from the Evaluation of Market Acceptance. These documents are not published or peer-reviewed, and reflect data collected for marketing purposes rather than clinical improvement purposes.
- CMS did not receive comparative data supporting the claim that OSCAR® offers superiority over currently available treatments in terms of clinical benefit or safety. The evidence provided did not discuss any advantages of using a single system of devices rather than multiple individual devices with diverse functionalities.

- The applicant did not provide clinical information to support claims that OSCAR® elevates the success rate of these procedures, enhances patient safety, and streamlines institutional operations.
- The FDA 510(k) summary for OSCAR® indicated that it shares similar technological characteristics with the INFINITY Angioplasty Balloon Catheter, and that OSCAR® differs only in that it combines support catheters to be used with the dilator and balloon catheter. CMS did not receive data demonstrating how OSCAR offers a substantial clinical improvement compared to the INFINITY Angioplasty Balloon Catheter.
- The applicant indicated that OSCAR® is similar to six device types including those using workhorse guidewires and premium guidewires. CMS does not believe OSCAR is similar to these products because it does not use guidewires nor did CMS receive data demonstrating how OSCAR® is a substantial clinical improvement over any of these comparable device types.

Cost Significance: The proposed rule indicates that OSCAR® meets the three tests to determine cost significance.

B. Device-Intensive Procedures

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

For 2019 and subsequent years,[10] 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.

For 2019 and subsequent years, CMS also aligned its device-intensive policy with the criteria used for device pass-through status by requiring that a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA IDE and has been classified as a Category B device by the FDA in accordance with 42 CFR 405.203 – 405.207 and 405.211 – 405.215, or meets another appropriate FDA exemption from premarket review.
- Is an integral part of the service furnished.
- Is used for one patient only.
- Comes in contact with human tissue.
- Is surgically implanted or inserted (either permanently or temporarily).

[10] 83 FR 58944-58948

- 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 although CMS indicates this would happen very rarely.[11]

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. Additional information about new HCPCS codes, such as pricing data or invoices from a manufacturer, should be directed to the Division of Outpatient Care, Mail Stop C4-01-26, CMS, 7500 Security Blvd, Baltimore, Md 21244-1850 or electronically at outpatientpps@cms.hhs.gov.

For 2025, CMS proposes to modify its default device offset percentage policy for new device-intensive procedures. For new HCPCS codes that describe a procedure that requires the implantation or insertion of a single-use device that meets the requirements of a device and the procedure lacks claims data (from either the new HCPCS code or any predecessor code), CMS would apply a default device offset percentage that is the greater of 31 percent or the device offset percentage of the APC to which the procedure has been assigned. If finalizing, this policy would apply to both the OPPS and ASC payment systems for 2025 and subsequent calendar years

The full listing of proposed 2025 device-intensive procedures is provided in Addendum P.

2. Device Edit Policy

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

[11] 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.

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 percent of the procedure's average costs).

For 2025, CMS is not making any changes to these policies.

V. Payment for Drugs, Biologicals, and Radiopharmaceuticals

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, 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 (as well as some medical supplies and devices furnished incident to a physician service) 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 and $630 for diagnostic radiopharmaceuticals for 2025) 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 2025 and their designated APCs are assigned status indicator "G" in Addenda A and B of the proposed rule. For 2025, 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 62 of the proposed rule lists 25 drugs and biologicals where CMS proposes to expire transitional pass-through payment at the end of 2024. Each of the products will have received the full 3 years of transitional pass-through payments once the additional payments expire. Table 63 of the proposed rule lists 28 drugs where CMS proposes to end transitional pass-through payment status in 2025. Table 64 of the proposed rule lists 57 drugs and biologicals where CMS will continue transitional pass-through payment for all of 2025.

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. For diagnostic radiopharmaceuticals that are paid on pass-through that would otherwise be 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.

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 2025, CMS is proposing to establish a packaging threshold of $140 for drugs, biologicals, and therapeutic radiopharmaceuticals that are not new and do not have pass-through status. Prior to 2025, diagnostic radiopharmaceuticals were threshold packaged and not paid separately except when receiving transitional pass-through payments. Beginning with 2025, CMS is proposing to threshold package diagnostic radiopharmaceuticals with per day costs equal to or below $630.

The packaging threshold was initially set at $50 in 2005 for drugs, biologicals and therapeutic radiopharmaceuticals. To calculate the proposed 2025 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 2025. CMS rounds the resulting amount ($140.81) to the nearest $5 increment ($140). CMS is proposing to use the same methodology to update the diagnostic radiopharmaceutical packaging threshold beginning in 2026.

CMS proposes to continue using the following process to determine the 2025 packaging status for all non-transitional pass-through drugs, biologicals and therapeutic radiopharmaceuticals 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 2023 claims data processed through December 31, 2023, 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 2023 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 2023 (data that will be used to pay for drugs and biologicals in physicians' offices effective April 1, 2024). For products that do not have an ASP, other than diagnostic and therapeutic radiopharmaceuticals, CMS will use WAC or AWP pricing to determine the per day cost. If neither of these is available, CMS will use mean unit cost derived from 2023 hospital claims data.

For diagnostic and therapeutic radiopharmaceuticals that do not have pass-through status as of October 1, 2024, CMS will use mean unit cost derived from the 2023 hospital claims data to determine their per day cost. CMS is not using an ASP-based, WAC-based, or AWP-based payment rate for those items unless there is no mean unit cost reported for the product

CMS proposes to package payment for products with a per day cost of $140 or less ($630 for diagnostic radiopharmaceuticals) and pay separately for items with a per day cost greater than $140 ($630 for diagnostic radiopharmaceuticals) in 2025.

CMS uses quarterly ASP updates as follows:

- 4th quarter of 2023: Per day cost, budget neutrality estimates, packaging determinations, impact analyses, and Addenda A and B for the 2025 OPPS proposed rule;[12]
- 2nd quarter of 2024: Per day cost, budget neutrality estimates, packaging determinations, impact analyses, and Addenda A and B for the 2025 OPPS final rule; and

[12] On page 412, CMS says the packaging determinations are based on ASP data from the 4th quarter of 2023—the most recent data available to use for the proposed rule. However, on page 414, CMS says that 2nd quarter 2024 ASP data is used for Addenda A and B rates shown in the proposed rule. This statement must be incorrect as it is inconsistent with the statement on page 412 that earlier data is the most recent available. Also, CMS would not receive 2nd quarter 2024 ASP data until July, 2024 which would be too late to include in the 2025 OPPS Proposed Rule.

- 3rd quarter of 2024: Payment rates effective January 1, 2025 for separately payable drugs and non-implantable biologicals (these are the same ASP data used to calculate payment rates effective January 1, 2025 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 2025 final rule will be subject to quarterly updates.

As in past years, CMS is proposing to apply the following policies to determine the 2025 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 2024 and were proposed for separate payment in 2025 are separately payable in 2025 even if the updated data used for the 2025 final rule indicate per day costs equal to or less than the $140 threshold.
- HCPCS codes that are packaged in 2024, proposed for separate payment in 2025, and have per day costs equal to or less than $140 based on the updated data used for the 2025 final rule are packaged in 2025.
- HCPCS codes for which CMS proposed packaged payment in 2025 and have per day costs greater than $140 based on the updated data used for the 2025 final rule are separately payable in 2025.

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

For 2025, 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 65 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 2025. 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, 2025. Payment rates effective January 2025 will be released near the end of December 2024 and will be based on ASP data submitted by manufacturers for the third quarter of 2024 (July 1, 2024 through September 30, 2024), or WAC+3 percent or 95 percent of AWP if ASP is unavailable. These will be the same payment rates that are used to pay for drugs and biologicals in a physician's office effective January 1, 2025.

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 2023 (used for payment in physician's offices for the 2nd quarter of 2024) are based WAC, AWP or mean unit cost in the available 2023 claims data. If ASP information becomes available for the quarter beginning in January 2025, CMS will pay for these drugs and biologicals based on the newly available ASP information. For diagnostic radiopharmaceuticals with a per day cost over $630, the rate in Addenda A and B are based on mean unit cost in the 2023 data.

3. Biosimilar Biological Products

CMS pays for biosimilar biological products using policies that parallel those used for other drugs and biologicals with the 6 percent add-on to ASP 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. Beginning in 2024, CMS also adopted a policy to allow separate payment for a biosimilar when its per day cost are below the packaging threshold if its reference product is paid separately.

Section 11403 of the Inflation Reduction Act 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.

4. Invoice Drug Pricing Proposal for 2026

CMS has observed that in recent years there has been an increasing number of drug and biological HCPCS codes for which ASP, WAC, AWP, and mean unit cost information is not available. Table 66 of the proposed rule shows the number of these HCPCS codes increasing from 77 to 109 between 2022 and 2024. CMS will continue to assign an unpayable status indicator to these drugs for 2025 but, beginning in 2026, proposes to allow payment based on invoice cost consistent with how these products are paid in physician offices. CMS is not proposing beginning this policy until 2026 to allow time for systems changes to accommodate the policy.

The drug or biological invoice cost would be the acquisition cost net of any rebates, chargebacks, or post-sale concessions. Before calculating an invoice-based payment amount, the Medicare Administrative Contractor would use the provider invoice to determine that: (a) the drug is not policy packaged; and (b) the per-day cost of the drug, biological, therapeutic radiopharmaceutical or diagnostic radiopharmaceutical is above the threshold packaging amount.

5. Payment Policy for Radiopharmaceuticals

Therapeutic Radiopharmaceuticals. For 2025, CMS will continue paying for therapeutic radiopharmaceuticals at ASP+6 percent. For therapeutic radiopharmaceuticals for which ASP data are unavailable, CMS will continue its past policy of determining 2025 payment rates based on 2023 geometric mean unit cost. CMS does not use WAC or AWP to price therapeutic radiopharmaceuticals.

Diagnostic Radiopharmaceuticals. For 2025, CMS is proposing to pay separately for diagnostic radiopharmaceuticals with a per day cost above $630. CMS proposes to base the payment rate for separately payable non-pass-through diagnostic radiopharmaceuticals on mean unit cost data derived from hospital claims. CMS is considering pricing separately payable diagnostic radiopharmaceuticals using ASP in the future if valid ASP data is reported.

For new diagnostic radiopharmaceuticals with HCPCS codes that do not have pass-through status, claims data or ASP, CMS proposes to use WAC. If WAC also is unavailable, CMS proposes to base payment on 95 percent of AWP.

6. Payment for Blood Clotting Factors

CMS proposes to continue paying for blood clotting factors at ASP+6 percent and is updating the $0.250 per unit furnishing fee from 2024 by the Consumer Price Index (CPI) for medical care for 2025. 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.

7. 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 2025 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.

8. Reporting Discarded Amounts for Single Use Package Drugs

Section 90004 of the Infrastructure Act requires manufacturers to provide a refund to CMS for discarded amounts from a refundable single-dose container or single-use package drug. This provision may impact hospital outpatient departments and ASCs. CMS includes proposed policies related to this provision in the 2025 PFS proposed rule. Readers are referred to the 2025 PFS proposed rule for a full description of the proposed policy. Interested parties are asked to submit comments on the discarded drug policy to 2025 physician fee schedule rule.

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

Since 2014, CMS has been packaging skin substitutes as drugs and biologicals that function as supplies when used in a surgical procedure. 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	2024 Geometric Mean Cost
5053 (Level 3 Skin Procedures)	C5271, C5275, C5277	$599.02
5054 (Level 4 Skin Procedures	C5273, 15271, 15275,15277	$1,739.33
5055 (Level 5 Skin Procedures)	15273	$3,481.02

For 2025, 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 2023 claims data for this purpose.

The proposed 2025 MUC threshold is $50 per cm^2 rounded to the nearest $1, and the proposed 2025 PDC threshold is $840 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 2024, CMS proposes to continue assigning it to the high-cost group in 2025. Otherwise, CMS proposes assigning the skin substitute to the low-cost group.

For 2025, CMS proposes 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 67 of the proposed rule lists the high/low-cost group assignment for each skin substitute.

10. 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 U.S. 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.

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 indicated 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 extended the add-on payment for one additional year though the end of 2025.

While CMS anticipated ending this additional $10 payment for non-HEU-sourced Tc-99m beginning in 2025, the Department of Energy and other interested parties raised another issue affecting the domestic supply chain for Mo-99 and Tc-99. Foreign Mo-99 production has historically been subsidized by foreign governments, resulting in prices below the true cost of production. These artificially low, government-subsidized prices have created a disincentive for investments in Mo-99 production infrastructure, and they also created a barrier to entry for new producers, including U.S. companies.

Based in part on the differences in pricing models, U.S. companies have experienced challenges in competing with foreign producers for customers. Currently, there is no domestic production of Mo-99. Once U.S. companies initiate or resume Mo-99 production, the difference in pricing models will likely create a payment inequity, as hospitals purchasing Tc-99m derived from domestically produced Mo-99 would likely pay higher prices than those purchasing Tc-99m derived from imported Mo-99.

To address the difference in costs between purchasing domestically produced Mo-99 and imported Mo-99, CMS proposes to establish a new add-on payment of $10 per dose for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99 starting on January 1, 2026, using its section 1833(t)(2)(E) equitable adjustment authority. CMS will provide further information through sub-regulatory guidance regarding how to bill for Tc-99 produced domestically.

VI. Estimate of Transitional Pass-Through Spending

CMS estimates 2025 proposed rule transitional pass-through payments of approximately $625 million, or 0.71 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 $614.8 million in 2025 for devices—$91.1 million for those recently eligible for transitional pass-through payments that will continue for 2025 and $523.7 million for those CMS knows or projects could be approved for 2025.

B. Drugs and Biologicals

CMS estimates transitional pass-through spending of $10.2 million in 2025 for drugs and biologicals—$0.2 million for those recently eligible for transitional pass-through payments that will continue for 2025 and $10 million for those CMS knows or projects could be approved in 2025.

VII. Hospital Outpatient Visits and Critical Care Services

CMS is 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 2025. It is also not proposing any changes to its policy for how it pays for services provided in off-campus provider-based departments.

VIII. Partial Hospitalization Program (PHP) Services

A. Background

1. Partial Hospitalization

CMS describes the evolution of its payment policies for partial hospitalization program (PHP) services. In past 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 2023 OPPS/ASC final rule (87 FR 71995), CMS observed 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[13] 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.

In the 2024 OPPS/ASC final rule (87 FR 71995), CMS established separate payment rates for PHP days with 3 services and days with 4 or more services, which resulted in four separate PHP APC per diem payment rates: one for CMHCs for 3-service days and another for CMHCs for 4-service days (APC 5853 and APC 5854, respectively), and one for hospital-based PHPs for 3-service days and another for hospital-based PHPs for 4-service days (APC 5863 and APC 5864, respectively). It

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

also finalized a policy to use the separate CMHC rates for 3-service and 4-service PHP days as the Medicare Physician Fee Schedule (MPFS) rates, depending upon whether a nonexcepted off-campus hospital outpatient department furnishes 3 or 4 PHP services in a day. That final rule required a physician certification for PHP services to include a determination that the patient requires such services for a minimum of 20 hours per week, as required by section 1861(ff)(1) of the Act; that determination must be made at least monthly. CMS also finalized changes to align coding, billing, and payment between PHPs and intensive outpatient programs.

2. Intensive Outpatient Program Services

Section 4124(b) of the CAA, 2023 established Medicare coverage for intensive outpatient services effective for items and services furnished on or after January 1, 2024. CMS implemented this requirement in the 2024 OPPS/ASC final rule. Thus, effective for items and services furnished on or after January 1, 2024, a new benefit category for intensive outpatient services was added to the scope of benefits that may be provided by CMHCs. Because intensive outpatient services were added as an "incident to" service under section 1861(s)(2)(B) of the Act, they may also be furnished by hospital outpatient departments, 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, an IOP is considered to be less intensive than a PHP.

CMS established payment and program requirements for the IOP benefits furnished by a hospital to its outpatients, or by a CMHC, an FQHC, or an RHC.[14] Additionally, it established Part B coverage for IOP services furnished by Opioid Treatment Programs (OTPs) for the treatment of opioid use disorder (OUD). Section 410.44 sets forth conditions and exclusions for intensive outpatient services, §410.111 establishes conditions for coverage of IOP services furnished in CMHCs, and §410.173 lists the conditions for payment IOP services furnished in CMHCs. Of note, the outpatient mental health treatment limitation does not apply to IOP services.

The agency established four separate IOP APC per diem payment rates at the same rates it established for the PHP APCs. As it did for PHP payment, it uses the CMHC rates for 3-service and 4-service IOP days as the MPFS rates, depending upon whether a nonexcepted hospital outpatient department furnishes 3 or 4 IOP services in a day.

B. Coding and Billing for PHP and IOP Services

Because the statutory definitions of both IOP and PHP generally include the same types of covered items and services, CMS aligns 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

[14] The 2025 payment policies for IOP services furnished by FQHCs and RHCs are proposed in the 2025 Physician Fee Schedule proposed rule.

requires hospitals and CMHCs to report condition code 92 on claims for intensive outpatient services. Hospitals and CMHCs report condition code 41 for their partial hospitalization claims.

The Partial Hospitalization and Intensive Outpatient Primary list contains the HCPCS codes recognized under the PHP and IOP benefit categories that are used to determine the number of services per PHP or IOP day, which also determine the APC per diem payment amount for each day.[15] To qualify for payment for the PHP APC or the IOP APC, one service must be from this list. If CMS needs to add more codes to the list, it does so through sub-regulatory guidance. However, CMS goes through notice and comment ruling 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 does not propose adding any new services in this rulemaking cycle.

Beginning in 2024, CMS recognized caregiver training services and Principal Illness Navigation (PIN) services as PHP and IOP services, but those services do not count when determining whether a PHP or IOP days is paid at the 3-service or 4-service rate. Costs for those services are included when calculating the PHP and IOP payment rates.

C. Payment Rates for PHP and IOP

1. Background

In 2024, CMS established 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 calculates payment rates using the broader OPPS data set instead of hospital-based PHP data only. The broader OPPS data set allows the agency to capture data from claims not identified as PHP, but that include the service codes and intensity required for a PHP day. CMS considers all OPPS data for PHP days and non-PHP days that include 3 or more of the same service codes. Because CMS uses the broader OPPS data set, it does not apply PHP-specific trims and data exclusions; instead, it applies the same trims and data exclusions consistent with the OPPS.

Because IOPs are a new benefit category and they furnish the same types of services as PHP, albeit at a lower intensity, CMS believes it is appropriate to use the same data and methodology for calculating payment rates for both PHP and IOP. Thus, CMS applies the same per diem rates for

[15] The full list of HCPCs codes recognized under the PHP and IOP benefits are found in the Medicare Claims Processing Internet Only Manual, Chapter 4, Sections 260.1 and 261.1, respectively, which is available at https://www.cms.gov/regulations-andguidance/guidance/manuals/downloads/clm104c04.pdf.

IOP and PHP services; however, it notes that if future data analysis supports calculating rates independently, it may do so.

2. Proposed 2025 Payment Rate Methodology for PHP and IOP

CMS proposes to use data from cost reports beginning three fiscal years before the year that is the subject of the rulemaking, as well as 2023 OPPS claims to update the payment rates for the four PHP APCs and the four IOP APCs finalized in the 2024 OPPS/ASC final rule.

CMS proposes to calculate the PHP rates for CMHCs and hospital-based programs separately. 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 is consistent with the change CMS made in the 2024 OPPS/ASC final rule to the methodology applied previously, which only used PHP data. CMS believes the broader OPPS data set will result in more precise calculations. It also proposes to set the payment rates for the four IOP APCs based on the geometric mean per diem cost for PHP days with 3 services and 4 or more services, calculated separately for CMHCs and hospital outpatient departments.

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. Even though it pays 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, CMS expects that days with fewer than three services would be "very infrequent" and will monitor claims accordingly.

The proposed 2025 geometric mean per diem costs and payment rates are as follows:

2025 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	$118.69	$114.79
5852	Intensive Outpatient (4 or more services per day) for CMHCs	$164.84	$159.43
5853	Partial Hospitalization (3 services per day) for CMHCs	$118.69	$114.79
5854	Partial Hospitalization (4 or more services per day) for CMHCs	$164.84	$159.43
5861	Intensive Outpatient (3 services per day) for hospital-based IOPs	$279.97	$270.77
5862	Intensive Outpatient (4 or more services per day) for hospital-based IOPs	$428.39	$414.33
5863	Partial Hospitalization (3 per day) for hospital-based PHPs	$279.97	$270.77
5864	Partial Hospitalization (4 or more services per day) for hospital-based PHPs	$428.39	$414.33

* Table 68 of the proposed rule shows the proposed 2025 PHP and IOP APC geometric mean per diem costs.
** The 2025 proposed payment rates are from Addendum A to the proposed rule.

D. Outlier Policy for CMHCs

For 2025, 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 and would also be applied to payments for IOP services as well as PHP services for 2025. CMS projects that CMHCs will receive 0.01 percent of total hospital outpatient payments in 2025 (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 2025 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 2025, 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 2025 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 2025 and to apply it to both PHP and IOP APCs.

E. Regulatory Impact

CMS estimates that payments to 32 CMHCs for PHP services will increase by 7.2 percent in 2025 relative to their 2024 payments. The 2023 claims data used for rate-setting in the proposed rule does not include any specific data from which to make projections for IOP services.

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 below five criteria to determine whether a procedure should be removed from the IPO list. It incorporated these criteria into the regulations beginning with 2023:

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.

B. Changes to the IPO List for 2025

For 2025, 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 2025. CMS does propose to add three new CPT codes for 2025 to the IPO list. These codes are:

- 0894T - Cannulation of the liver allograft in preparation for connection to the normothermic perfusion device and decannulation of the liver allograft following normothermic perfusion.
- 0895T - Connection of liver allograft to normothermic machine perfusion device, hemostasis control; initial 4 hours of monitoring time, including hourly physiological and

laboratory assessments (e.g., perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary bicarbonate, lactate levels, macroscopic assessment).

- 0896T - Connection of liver allograft to normothermic machine perfusion device, hemostasis control; each additional hour, including physiological and laboratory assessments (e.g., perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary bicarbonate, lactate levels, macroscopic assessment) (List separately in addition to code for primary procedure).

X. Nonrecurring Policy Changes

A. Remote Services

1. 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 sub-regulatory 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.[16]

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 rule, CMS extended these telehealth waivers consistent with the CAA, 2023. CMS also extended its OPPS policies that allowed outpatient therapy, DSMT, and MNT services furnished via telehealth by staff of hospital outpatient departments to patients in their homes to continue being billed under the PFS—the payment mechanism for these services when provided by hospitals.

The telehealth waivers are slated to expire on December 31, 2024. At that time, the flexibilities for hospital-employed therapists and staff furnishing DSMT and MNT to patients in their homes will expire as well. If the telehealth waivers were to be extended, CMS expects to align payment policies for outpatient therapy, DSMT, and MNT services furnished remotely by hospital staff to beneficiaries in their homes with policies for Medicare telehealth services.

[16] 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. Periodic In-Person Visits for Mental Health Visits Furnished by Hospital Staff to Beneficiaries in their Homes

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, 2023 delayed the application of the telehealth in-person visit requirements through December 31, 2024 for professionals billing for mental health services via Medicare telehealth and for RHCs/FQHCs furnishing remote mental health visits. CMS adopted the same delay for remote outpatient mental health services provided by hospitals and CAHs through December 31, 2024.

As the CAA, 2023 delay to the in-person visit requirements furnished under the telehealth benefit will expire on December 31, 2024, the same policies that apply when hospital employed staff provide mental health services to beneficiaries in their homes will also expire. To the extent that these in-person visit requirements are delayed by statute for the telehealth benefit, CMS anticipates aligning its policies that apply to hospitals with the statutory extension through rulemaking.[17]

3. Proposed HOPD Payment for Telemedicine Evaluation and Management (E/M) Services

The CPT Editorial Panel created 17 new codes describing audio/video and audio-only telemedicine E/M services that are discussed in more detail in the 2025 PFS proposed rule. CMS is proposing not to pay for these codes under the PFS because it believes they would be duplicative of office E/M codes already paid under the section 1834(m) of the Act telehealth benefit.

Under the OPPS, CMS does not recognize the CPT E/M codes and instead uses HCPCS G0463 for all clinic visits. CMS believes the telemedicine E/M codes fall within the scope of the hospital outpatient clinic visit policy because they substitute for the office/outpatient E/M code set that would be reported by hospitals using HCPCS code G0463. Therefore, CMS proposes not to recognize the telemedicine E/M code set under OPPS.

However, CMS is seeking comment on the hospital resources associated with the telemedicine E/M services, particularly any resource costs that would not be included in the payment for HCPCS code G0463. Should CMS finalize separate payment for these telemedicine E/M codes under the PFS, CMS is interested in comments on the resource costs that would be associated with these services for hospitals and whether to develop separate coding for telemedicine hospital E/M

[17] As legislation on this and the prior issue would be expected to occur before the next rulemaking cycle, it may be notable that CMS explicitly indicated it would use rulemaking to align the mental in-person visit policy with the statutory telehealth extension but did not say the same thing on the policy for therapists, DMST and MNT. This is notable because CMS used sub-regulatory guidance to establish the policy for therapists, DMST and MNT furnished by hospitals, raising the question as to whether CMS would expedite the alignment of the policy on therapists, DMST and MNT through sub-regulatory guidance while delaying the alignment of the policy for in-person mental health visits if CMS uses rulemaking.

services.

B. Virtual Direct Supervision for Specific Services

During the COVID-19 PHE, CMS adopted policies to allow direct supervision of cardiac rehabilitation services (CR), intensive cardiac rehabilitation services (ICR), pulmonary rehabilitation services (PR) and diagnostic services 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 after the COVID-19 PHE ended.

In the 2025 PFS proposed rule, CMS is proposing to revise the definition of direct supervision at § 410.32(b)(3)(ii) to extend the availability of virtual direct supervision of therapeutic and diagnostic services under the PFS through December 31, 2025. Similarly, CMS is proposing to allow for the direct supervision of CR, ICR, PR services and diagnostic services via audio-video real-time communications technology (excluding audio-only) under the OPPS through December 31, 2025.

C. Add-On Payment for High-Cost Drugs: Indian Health Service (IHS) and Tribal Facilities

IHS and tribal facilities are paid under an All-Inclusive Rate (AIR) rather than under the OPPS for outpatient hospital services.[18] For 2024, the AIR is $667 for the lower 48 states and $961 for Alaska. The AIR will include Medicare payment for drugs and biologicals that are separately paid under the OPPS.

CMS is concerned that this policy creates equity and access concerns if IHS and tribal hospitals provide drugs that cost more than the AIR. In response to public comments on this issue in the 2024 OPPS rule, commenters expressed universal support for establishing a policy that would allow IHS and tribal healthcare facilities to receive separate payment for drugs that cost more than the AIR.

Beginning January 1, 2025, CMS proposes to separately pay IHS and tribal hospitals for drugs furnished in hospital outpatient departments through an add-on payment to the AIR with per day costs that exceed twice the AIR in the lower 48 states ($1,334 in 2024). CMS proposes only paying separately when a drug's cost exceeds two times the lower 48 states AIR to ensure that the add-on payment only applies to drugs whose costs significantly exceed the AIR.

This cost-multiplier approach is consistent other OPPS thresholds for making additional payment such as the outliers where a hospital's costs must exceed 1.75 times the payment amount to qualify for additional payment and the 2 times rule where the highest cost service in an APC cannot be more than double the lowest cost service. CMS seeks comment on the alternatives such as paying separately when a drug's cost exceeds 1.75 times the lower 48 AIR or always paying separately for a biosimilar if its reference product's cost exceeds the OPPS drug packaging threshold of $140 in 2025.

[18] Sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248), Public Law 83–568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.) provide authority for the AIR.

CMS proposes to pay ASP drugs with costs above the $1,334 threshold without the 6 percent add-on. The justification for not paying the add-on is that IHS and tribal facilities, unlike hospitals paid under the OPPS, primarily obtain their drugs through the federal supply schedule, whose rates are significantly lower than ASP. This approach is also consistent with paying ASP without the add-on to certain Opioid Treatment Program drugs.[19]

In the event ASP pricing information is not available for a particular drug, CMS proposes to pay WAC without an add-on. If WAC pricing information is not available, CMS proposes to pay 89.6 percent of AWP (the effective equivalent of 95 percent of AWP absent a 6 percent add-on, e.g., 100/106 x 95 = 89.6).

CMS would follow its existing methodology to calculate per day costs that it uses for OPPS drugs to determine whether an OPPS drug is above the packaging threshold for drugs that could be paid in addition to the AIR in IHS and Tribal facilities. The list of drugs would be updated on a quarterly basis using existing drug compendia and CMS ASP quarterly reporting only to account for newly introduced drugs.

D. Paying all IHS and Tribally Operated Clinics the Outpatient All Inclusive Rate (AIR)

In June 2022, the Tribal Technical Advisory Group (TTAG) requested that CMS make all IHS and tribally-operated outpatient facilities eligible for Medicare payment at the AIR. The TTAG explained that IHS and Tribal outpatient clinics are paid differently based on regulatory definitions rather than their actual costs. CMS responded that that non-IHS and Tribal facilities are also paid differently based on their regulatory status (e.g., hospital outpatient departments are paid differently than ASCs, which are paid differently than physicians' offices).

Nevertheless, CMS acknowledged the TTAG's concerns and solicited comments on the TTAG's request in the 2022 PFS rule. In response, CMS did not receive specific information on costs or specific types of clinics but expressed an interest in a continuing dialog on this topic.

Beginning in the Fall of 2023, CMS began participating in a workgroup related to the TTAG's Medicare priority to make the AIR available to all IHS and tribally operated outpatient facilities. While CMS has received some information from the TTAG on this topic, CMS would like to request the same information from the public that it requested in the 2022 rulemaking including:

- The kinds of and number of facilities or clinics where the AIR could apply;
- Whether the facilities are freestanding physician offices or provider-based;
- Relative operating costs of tribally operated outpatient clinics, as well as feedback and supporting evidence to address whether or why payment set at the AIR would be more appropriate than payment rates under the FQHC PPS, the physician fee schedule, or other Medicare payment systems; and

[19] Not mentioned but another argument could also be that the AIR is more than double the highest cost drug administration service.

- Concerns that the Tribal communities may have regarding access to or inequity of care in situations where a payment differential exists.

E. Coverage Changes for Colorectal Cancer (CRC) Screening Services

In the 2025 PFS rule, CMS is modifying its policies on payment for CRC screening services by:

- Removing coverage for the barium enema procedure;
- Adding coverage for computed tomography colonography (CTC) procedure; and
- Expanding the existing definition of a "complete colorectal cancer screening" to include a follow-on screening colonoscopy after a positive Medicare covered blood-based biomarker CRC screening test.

Consistent with these proposals in the PFS rule, CMS proposes to make the following OPPS changes for 2025:

- Delete screening barium enema HCPCS codes G0106, G0120 (which will no longer be necessary), and already non-covered code G0122;
- Change the status indicator for CPT code 74263 (screening computed tomography colonography (CTC)/virtual colonoscopy) from "E1" (not covered/not payable) to "S" (Separate payment under the OPPS)
- Assign CPT code 74263 to APC 5522.

F. Payment Adjustments for Domestic Personal Protective Equipment

1. Background

The COVID-19 pandemic demonstrated that sufficient availability of personal protective equipment (PPE) in the health care sector is a critical component of preparedness. Early on "just-in-time" supply chains, minimal stockpiling, and overreliance on foreign imports left hospitals unable to obtain enough N95 respirators. Prices for a surgical N95 soared from $0.25–$0.40 to $5.75 (and up to $12.00 in some reported cases). As a result, hospitals turned to KN95s—a Chinese standard respirator—and other non-NIOSH-approved respirators under Emergency Use Authorization (EUA).

2. Potential Modifications to Payment Adjustments for N95 Respirators

The 2023 OPPS/ASC final rule implemented payment adjustments under the OPPS and IPPS to offset the marginal costs hospitals face in obtaining domestically made NIOSH-approved and FDA-certified surgical N95 respirators. However, use of the payment adjustments has been limited (cost reporting periods beginning on or after January 1, 2023). Market data suggests that a majority of surgical N95 respirators purchased by hospitals are not wholly domestically made.[20] HHS has

20 The U.S. government has committed to purchase wholly domestically made PPE in line with section 70953 of the Infrastructure Investment and Jobs Act (P.L. 117-58).

conducted stakeholder outreach to understand barriers to awareness and uptake and to seek feedback on potential modifications to the payment adjustment in order to reduce reporting burden and achieve the policy goal to maintain a baseline domestic production capacity of PPE.

Related to domestically produced PPE, CMS lists several questions, listed below, for which it seeks comment, addressing three issue areas: (1) payment adjustment methodology, (2) payment adjustment eligibility, and (3) types of N95 respirators.

a. Payment Adjustment Methodology

The 2023 OPPS/ASC final rule permitted payment adjustments on the IPPS and OPPS shares of the estimated difference in the reasonable costs, based on a new supplemental cost reporting form to enable calculation of a hospital-specific unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators. At the time, CMS' best estimate of the difference in the average unit cost of domestic and non-domestic NIOSH-approved surgical N95 respirators was $0.20. Although MedPAC did not support the proposed payment adjustments, it said CMS should set the unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators at a national level (rather than on a hospital-by-hospital basis), in order to reduce administrative burden on hospitals, encourage hospitals to purchase the most economical domestically made product, and reduce the ability of hospitals to increase their payments by artificially inflating reported N95 costs.

CMS poses the following questions for comment:

- Should CMS consider modifying the payment adjustment methodology calculation to provide a national standard unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators (rather than on a hospital-by-hospital basis)?
- If so—
    - How should CMS calculate that standard unit cost differential, and what should the current unit cost differential be?
    - Would it be appropriate to calculate the payment adjustment by multiplying the unit cost differential by the total quantity of domestic NIOSH-approved surgical N95 respirators used by the hospital, and then multiplying by the Medicare Part A hospital inpatient cost share (to calculate the IPPS payment adjustment) or the Medicare Part B hospital outpatient cost share (to calculate the OPPS payment adjustment)?
- Do hospitals need additional support to purchase domestic-made surgical N95 respirators, and if so, how much support is needed and in what form?

b. Payment Adjustment Eligibility

Because a hospital cannot fully independently determine if a NIOSH-approved surgical N95 respirator it purchases is domestic under the CMS definition, the agency permitted a hospital to rely

on a written statement from the manufacturer stating that the NIOSH-approved surgical N95 respirator is domestic under the CMS definition.

CMS poses the following questions for comment:

- Do hospitals have sufficient access to information on which surgical N95 models on the market are wholly domestically made?
- Have hospitals been able to obtain written statements from manufacturers stating that the NIOSH-approved surgical N95 respirator the hospital purchased is domestic under the CMS definition?
- Would a publicly available list of products eligible for the payment adjustment—for example, if provided by CMS, NIOSH, or another government entity—make it easier for hospitals to locate products eligible for the payment adjustment?
- If CMS modified the payment adjustment so that hospitals that attested to purchasing respirators from such a list did not need to obtain a written statement from the manufacturer, would hospitals more easily be able to utilize the payment adjustment?

c. Types of N95 Respirators

Feedback on the 2023 OPPS/ASC proposed rule suggested it is a challenge for the payment adjustment to be limited to *surgical* N95 respirators, given that some hospitals also procure *non-surgical* N95 respirators. Both are primarily used to protect from inhaling airborne particles, including infectious bacteria and viruses. Both filter out at least 95 percent of airborne particles and are commonly used by healthcare workers during procedures that may generate aerosols, such as intubation or suctioning, or when caring for patients with infectious respiratory diseases like tuberculosis or coronavirus. Surgical N95 respirators have the added protection against fluid penetration, most useful in specialized health care settings (e.g., ICU, Emergency Department, Operating Room).

CMS poses the following questions for comment:

- Do hospitals procure both surgical and non-surgical N95 respirators?
- Has the payment adjustment's current focus on surgical N95 respirators inhibited uptake of the payment adjustments?
- Are the quality differentials between domestic and non-domestic surgical respirators also applicable to non-surgical respirators, and is a sustained and reliable source of domestically made non-surgical N95 respirators important for strengthening hospitals' ability to protect personnel and patients in a public health emergency?
- Should CMS consider expanding the payment adjustments to include all domestic NIOSH-approved N95 respirators—that is, both non-surgical and surgical N95 respirators?
- If the payment adjustments were expanded to include all domestic NIOSH-approved N95 respirators, and if the payment adjustment methodology calculation provided a *national* standard unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators (rather than on a hospital-by-hospital basis), would the unit cost

differential for *non-surgical* N95 respirators be different than the one for surgical N95 respirators?

3. Potential Modifications to Include Nitrile Gloves

CMS lists a number of reasons why nitrile gloves are another type of PPE that is particularly crucial to have in a resilient, high-quality supply and how the COVID-19 pandemic limited that supply. During the pandemic, the federal government invested approximately $290 million in domestic glove manufacturing capabilities, which resulted in an increase of 3.91 billion in annual production capacity for domestically manufactured nitrile gloves. The federal government also invested in manufacturing capacity for nitrile glove inputs, such as nitrile butadiene rubber, which is expected to become available in 2026.

Some U.S. factories have been forced to consolidate operations or exit the industry. Foreign producers have deployed cost-cutting tactics such as using lower-grade raw materials, prompting some purchasers to seek other sources out of concern for quality. As of 2024, only three producers of nitrile gloves are left in the United States, supplying 0.05% percent of U.S. demand.

Although certain federal departments have committed to purchase wholly domestically made nitrile gloves in line with the requirements in section 70953 of the Infrastructure Investment and Jobs Act, federal demand alone cannot sustain a baseline level of nitrile glove production in the United States. Private medical and health care users are the primary purchasers and users of medical-grade PPE, including nitrile gloves. To ensure access to high quality products, CMS says it is critically important to ensure that a sufficient share of nitrile gloves is wholly made in the United States, including raw materials and components.

The 2023 OPPS/ASC rule pointed to the Berry Amendment as the most appropriate framework for determining if a NIOSH-approved surgical N95 respirator is wholly made in the U.S. and therefore considered domestic for purposes of the proposed adjustments. The Berry Amendment is a statutory requirement that restricts the Department of Defense (DoD) from using funds appropriated or otherwise available to DoD for procurement of food, clothing, fabrics, and hand or measuring tools that are not grown, reprocessed, reused, or produced in the United States.

For nitrile gloves, which are not covered by the Berry Amendment, CMS believes the Make PPE in America domestic content requirements outlined in section 70953 of the Infrastructure Investment and Jobs Act is the most appropriate framework for determining if a nitrile glove is wholly made in the U.S. These statutory requirements apply to procurement of nitrile gloves and other PPE by HHS and the U.S. Departments of Veterans Affairs and Homeland Security. With respect to domestic manufacturing capabilities for raw materials and components, CMS understands that nitrile butadiene rubber (NBR), a key nitrile glove input, is currently not yet available domestically in sufficient quantity or quality to meet market needs and that U.S. manufacturers do anticipate having the capability to source and manufacture all glove components domestically within the next two years.

Wholly domestically made, high quality nitrile gloves are generally more expensive than foreign-made ones, especially those of lower quality, primarily from higher costs of manufacturing labor and higher quality standards in the U.S. These higher prices mean higher marginal costs for hospitals for procuring wholly domestically made nitrile gloves. Based on available data, CMS' best estimate of the difference in the average unit cost of domestic and non-domestic nitrile gloves is $0.13 per glove.

CMS poses the following questions for comment:

- Would modifying the payment adjustment to include nitrile gloves—
    - Help offset the marginal costs that hospitals face in procuring high quality domestically made nitrile gloves?
    - Help to sustain a baseline level of domestic manufacturing of nitrile gloves to ensure that hospitals and other stakeholders have ongoing, reliable access to an adequate supply?
- Would having access to a sustained and reliable source of domestically made nitrile gloves strengthen hospitals' ability to protect the health and safety of personnel and patients in a public health emergency?
- Are there other reasons why hospitals would benefit from an extension of the payment adjustment to include nitrile gloves?
- Do stakeholders believe a significant portion of hospitals would use domestic nitrile gloves if the payment adjustment were offered?
- If the payment adjustment was modified to include nitrile gloves—

    - How should CMS define wholly domestically made nitrile gloves?
    - Would it be appropriate to categorize all nitrile gloves purchased by hospitals into two categories: (1) domestic nitrile gloves that (with the exception of nitrile butadiene rubber (NBR)) comply with the Infrastructure Investment and Jobs Act's Make PPE in America Act domestic content requirements; and (2) non-domestic nitrile gloves?
    - If so, would it be appropriate to eliminate the domestic content exception for NBR if domestic NBR production reaches a sufficient level to meet market needs?
    - Should a national standard unit cost differential between domestic and non-domestic nitrile gloves be used to calculate the payment adjustment, and if so, what should the current unit cost differential be (or what data source)?

4. Potential Modifications to Include Other PPE and Medical Devices

In the 2023 OPPS/ASC final rule, CMS received many comments urging an expansion of the policy to cover other forms of PPE and critical medical supplies due to shortages similar to surgical N95 respirators. **CMS seeks comment on other PPE types and medical devices that could be appropriate for a similar payment adjustment.**

G. Payment for HIV Pre-Exposure Prophylaxis (PrEP) in Hospital Outpatient Departments

On July 12, 2023, CMS published a "Proposed National Coverage Determination [NCD] for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention" for covering PrEP under Medicare Part B. This would include coverage for the HIV PrEP drugs, drug administration, HIV and hepatitis B screening, and individual counseling performed by either physicians or certain other health care practitioners. If finalized as proposed, all components would be covered as an additional preventive service without Part B cost sharing (i.e., deductibles or co-pays). The final NCD has not yet been issued.

Table 72 (duplicated below) lists the seven applicable HCPCS codes and the descriptions of each.

HCPCS	Long Descriptor
J0739	Injection, cabotegravir, 1mg, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment for hiv)
J0750	Emtricitabine 200mg and tenofovir disoproxil fumarate 300mg, oral, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv)
J0751	Emtricitabine 200mg and tenofovir alafenamide 25mg, oral, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv)
G0011	Individual counseling for pre-exposure prophylaxis (prep) by physician or qualified health care professional (qhp)to prevent human immunodeficiency virus (hiv), includes hiv risk assessment (initial or continued assessment of risk), hiv risk reduction and medication adherence, 15-30 minutes
G0012	Injection of pre-exposure prophylaxis (prep) drug for hiv prevention, under skin or into muscle
G0013	Individual counseling for pre-exposure prophylaxis (prep) by clinical staff to prevent human immunodeficiency virus (hiv), includes: hiv risk assessment (initial or continued assessment of risk), hiv risk reduction and medication adherence
J0799	Fda approved prescription drug, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv), not otherwise classified

If covered in the final NCD, CMS proposes to pay for HIV PrEP drugs and related services as additional preventive services under the OPPS beginning in 2025. CMS believes the resource costs for these HCPCS codes would be similar across different settings of care, including the HOPD and physician office, and therefore proposes that payment amounts for these services in the 2025 PFS proposed rule would be appropriate for use under the OPPS, as well.

CMS will publish the proposed 2025 payment rates in Addendum B to this proposed rule on the CMS website. CMS proposes that G0012 would be assigned to APC 5692 (Level 2 Drug Administration) and G0013 would be assigned to a clinical APC with a payment rate that approximates the payment rate in the physician office setting.[21] For the drugs themselves (J0739, J0750 and J0751), CMS proposes that the payment amount utilize the ASP methodology under

21 CMS is not proposing to pay for HIV PrEP counseling performed by physicians under the OPPS as this is a physician-only service.

section 1847A of the Act when ASP data is available. As also described in the 2025 PFS proposed rule, CMS believes the use of ASP data is preferable because it (1) is the same approach for most drugs that are separately payable under Part B and (2) reflects volume discounts, prompt pay discounts, rebates,[22] etc., and thus would likely better reflect the drugs' acquisition cost, compared to list prices such as Wholesale Acquisition Cost (WAC).

If ASP data for HIV PrEP is not available, CMS proposes to determine the payment amount using the most recently published amount for the drug in Medicaid's National Average Drug Acquisition Cost (NADAC) survey. Because NADAC pricing is only available for drugs typically dispensed through retail community pharmacies, there could be circumstances where ASP and NADAC are not available. If both ASP and NADAC pricing data are not available, CMS proposes to use the most recently published and listed prices for pharmaceutical products in the Federal Supply Schedule (FSS). The most recently updated FSS survey is available 30 days after the close of the quarter for which ASP data would have been reported if it were available. FSS pricing is publicly available at the NDC level from the Veteran Affairs' (VA's) pharmaceutical pricing database.

CMS refers readers to the PFS proposal for more details on this pricing methodology for the physician office setting, which includes a final step of invoice pricing not available under the OPPS. (In section V.B.2.d of this rule, CMS offers an Invoice Drug Pricing Proposal for 2026.) Because invoice pricing is not available in the OPPS, CMS proposes that if ASP, NADAC, and FSS pricing are not available for a particular drug covered as an additional preventive service, WAC plus 6 percent, or 3 percent if in an initial sales period, would be used, consistent with payment for separately payable drugs paid under the OPPS. Although this would result in different pricing between the OPPS and PFS in that circumstance, CMS believes it is appropriate because invoice pricing is not an option under the OPPS and this pricing metric would only apply to a small subset of drugs covered as additional preventive services, until another pricing metric becomes available. Other drugs covered as additional preventive services would be treated under this same methodology.

If the HIV PrEP drugs are covered as additional preventive services, CMS proposes to update the payment rates on January 1, 2025 or the date of coverage, whichever is later, which would be further updated on the same schedule as the ASP pricing file (every calendar quarter).

For HCPCS code J0799 (an HIV PrEP drug that is FDA approved but does not yet have a HCPCS code), CMS proposes to pay 95 percent of AWP, consistent with other unclassified drugs or biologicals under the OPPS (C9399) and section 1833(t)(15) of the Act. CMS describes this 2003 statutory provision, how it has been implemented, and how it ensures that a hospital does not have to wait for the next quarterly release or for approval of a product-specific HCPCS code to receive payment for a newly approved drug/biological. Although the statute does not require drugs covered as additional preventive services to be paid at 95 percent of AWP when not assigned to a product specific HCPCS code, the agency believes it appropriate to create a parallel policy given that HCPCS code J0799 and HCPCS code C9399 both describe drugs that are unclassified or not

22 Excluding rebates under the Medicaid drug rebate program, discounts under the 340B Program, and rebates under the Part B and Part D Medicare inflation rebate program.

otherwise classified. Because the payment amount for C9399 is statutorily mandated at 95 percent of AWP, CMS believes that the payment amount for J0799 should also be 95 percent of AWP.

H. Clinical Trials under Coverage with Evidence Development (CED)

Items and services furnished as placebo controls may not be considered reasonable and necessary under section 1862(a)(1)(A) of the Act because they have no health benefit. However, these items and services can be necessary in order to conduct a scientifically valid clinical study and covered by Medicare under section 1862(a)(1)(E) of the Act when furnished in the context of a qualifying clinical study. Also, CMS may cover and pay for routine costs of an approved clinical trial in both the treatment arm and the control (standard of care or placebo) under section 1862(a)(1)(E) of the Act. Routine costs include all items and services that are otherwise generally available to Medicare beneficiaries in either the experimental or the control arms of a clinical trial.

In the 2023 OPPS final rule, CMS adopted a policy to create a unique HCPCS code and make a single blended payment for devices and services in Category B IDE studies. The purpose of this payment is to preserve the scientific validity of the study by avoiding differences in Medicare payment methods that would otherwise reveal the group (treatment or control) to which a patient has been assigned.

In the 2025 OPPS proposed rule, CMS is proposing to expand the policy to national coverage determinations (NCDs) that provide Medicare coverage for drugs using CED. Under the proposed policy, CMS will create a new HCPCS code, or revise an existing HCPCS code, to describe a study under CED. The HCPCS code will be for the treatment and control arms, related drugs in the study, as well as routine care items and services. The single blended payment rate would be dependent on the specific trial protocol and would account for the frequency with which the drug is used compared to the control, or comparator.

Under the proposal, the blended payment would reflect a weighted average of the costs of the experimental drug in the treatment arm (or arms) and $0 for the product in the control arm (or arms). If the control arm (or arms) uses an active drug, the blended payment would be based on that drug's ASP (if available, or WAC or AWP if ASP is unavailable). CMS proposes to base the payment amount for the study drug, or active comparator drug, on ASP+6 percent if ASP data is available. If ASP data is not available, CMS proposes to base the payment on WAC+3 percent during the initial sales period and WAC+6 percent if ASP remains unavailable two calendar quarters after the drug is first used. If WAC is not available, CMS proposes to pay 95 percent of AWP.

The HCPCS code would be billed for both patients in the experimental arm and the control. CMS proposes assigning the HCPCS code to its own APC reflecting the payment amount determined appropriate based on available pricing information and the frequency with which the study drug and placebo, or comparator drug, is used.

No unique coding would be needed for single arm studies as there would be no differential payment or coding from a placebo or comparator that could result in unblinding the study. Similarly, the policy would be unneeded when the routine costs are exactly the same between different arms of a trial and routine billing and payment of those routine costs would not unblind a study.

An alternate method of payment would be established only when necessary to maintain the scientific validity of the trial, such as to prevent the billing and payment of routine costs from unblinding the trial. These determinations will be made based on the clinical trial protocol communicated to CMS by the clinical trial sponsor, before CMS would establish an appropriate code with an adjusted payment level for routine costs for CED trials. Clinical trial sponsors should work with CMS to ensure timely establishment of payment and coding for drugs being studied under a CED designation requiring an adjusted level of payment.

Interested parties are encouraged to submit HCPCS coding and payment requests to CMS through the New Technology APC application process and include the submission of cost information. The agency has encountered difficulties determining accurate payment rates for Category B IDE studies in the absence of New Technology APC applications such as when coding for Category B IDE studies is developed through the CPT Editorial Panel process. Absent this cost information, CMS has no way to price the study and may assign a status indicator to the new CPT code that it is not paid by Medicare when submitted on an outpatient claim.

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 2025 payment status indicator assignments for APCs and HCPCS codes are shown in Addenda A and B respectively. The complete list of proposed 2025 payment status indicators and their definitions are in Addendum D1.

For 2025, CMS proposes to create two new status indicators:

Proposed Status Indicator	Proposed Descriptor	Proposed OPPS Payment Status
K1	Non-Opioid Drugs and Biologicals For Post-Surgical Pain Relief	Paid under OPPS; separate APC payment. Subject to criteria and payment limitation under Section 4135 of the CAA, 2023.
H1	Non-Opioid Medical Devices For Post-Surgical Pain Relief	Separate payment based on hospital's charges adjusted to cost. Subject to criteria and payment limitation under Section 4135 of the CAA, 2023.

CMS is proposing these two new status indicators to identify the products that qualify for separate payment for non-opioid post-surgical pain management drugs, biologicals, and devices for three years beginning January 1, 2025 under section 4135 of the CAA, 2023.

In addition, CMS proposes to modify the definition of status indicator "K" to remove the word "therapeutic" before radiopharmaceuticals consistent with CMS' proposed policy to pay separately for diagnostic radiopharmaceuticals with per day costs above $630. The revised status indicator would now appear as follows in Addenda D1:

Proposed Status Indicator	Proposed Descriptor	Proposed OPPS Payment Status
K	Non-pass-Through Drugs and Non-implantable Biologicals, Including Radiopharmaceuticals	Paid under OPPS; separate APC payment.

Comment Indicator Definitions

For 2025, CMS is continuing to use the following comment indicators that are unchanged from 2024:

- 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 2024 "Report to Congress: Medicare Payment Policy," MedPAC recommended that Congress update Medicare OPPS payment rates in 2025 by the amount specified in current law plus 1.5 percent. CMS responded that it cannot adopt the MedPAC recommendation to Congress as the statute requires CMS to update OPPS rates consistent with current law at the market basket of 3.0 percent less 0.4 percentage points for productivity.

Medicare Safety Net Index: In its March, 2023 "Report to Congress: Medicare Payment Policy," MedPAC stated that their recommended update to IPPS and OPPS payment rates of current law

plus 1.5 percent may not be sufficient to ensure the financial viability of some Medicare safety-net hospitals with a poor payer mix.

MedPAC recommended that Congress should begin a transition to redistribute disproportionate share hospital and uncompensated care payments through a new Medicare Safety-Net Index (MSNI). Additionally, MedPAC recommended that Congress add $4 billion to the MSNI pool of funds and distribute such funds through a percentage add-on to payments under the IPPS and OPPS. CMS reiterated its statutory obligation for how it is to update OPPS rates.

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, it continues to seek public comment on methods that would mitigate the burden of reporting costs on ASCs while also collecting enough data to reliably use such data in the determination of ASC costs.

XIII. Ambulatory Surgical Center (ASC) Payment System

Summary of Selected Key Elements of ASC Payment Rates for 2025		
	ASCs reporting quality data	**ASCs not reporting quality data**
2024 ASC Conversion Factor	$53.514	
Wage index budget neutrality adjustment	0.9958	
2025 Update		
Hospital market basket update	3.0%	
Productivity adjustment	-0.4%	
Net MFP adjusted update	2.6%	
Penalty for not reporting quality data	0.0%	-2.0%
Net MFP and quality adjusted update	2.6%	0.6%
2025 Proposed ASC Conversion Factor	$54.675	$53.609

The ASC update is based on the IPPS hospital market basket and is estimated to be 2.6 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 2025 will be approximately $7.4 billion, an increase of $202 million compared with 2024 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
- Codes for which it will be seeking comments in the forthcoming final rule with comment period.

Table 77 in the proposed rule (shown below) provides the process and timeline for ASC list updates and is a duplicate of Table 12 shown earlier in the rule and in this summary:

Comment and Finalization Timeframes for New and Revised HCPCS Codes				
ASC Quarterly Update CR	**Type of Code**	**Effective Date**	**Comments Sought**	**When Finalized**
April 2024	HCPCS (CPT and Level II codes)	April 1, 2024	2025 OPPS/ASC proposed rule	2025 OPPS/ASC final rule with comment period
July 2024	HCPCS (CPT and Level II codes)	July 1, 2024		
October 2024	HCPCS (CPT and Level II codes)	October 1, 2024	2025 OPPS/ASC final rule with comment period	2026 OPPS/ASC final rule with comment period
January 2025	CPT Codes	January 1, 2025	2025 OPPS/ASC proposed rule	2025 OPPS/ASC final rule with comment period
	Level II HCPCS Codes		2025 OPPS/ASC final rule with comment period	2026 OPPS/ASC final rule with comment period

April and July 2024 Codes - CMS Solicits Public Comments in this Proposed Rule

For the April 2024 ASC quarterly update, there were 27 new Level II HCPCS codes. Table 75 displays the codes and descriptors. In the July 2024 ASC quarterly update, CMS added several separately payable Level II HCPCS codes and CPT codes to the list of covered surgical procedures and ancillary services. The Level II HCPCS codes are listed in Table 76 of the proposed rule. CMS did not publish the list of new CPT codes in the proposed rule, but notes that they are available at the CMS website in Addenda AA and BB of the 2025 OPPS/ASC NPRM.

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 2025 OPPS/ASC final rule with comment period.

October 2024 and January 2025 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 2025 OPPS/ASC final rule for those new and revised Level II HCPCS codes that are effective October 1, 2024. This indicates that CMS has assigned the codes an interim ASC payment status for the remainder of 2024. CMS will invite comments in the 2025 OPPS/ASC final rule with comment period on the interim payment indicators which will then be finalized in the 2026 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, 2025 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 2025 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 2025 OPPS/ASC final rule with comment period. Interim status indicators and payment rates will be assigned for 2025 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 2026 OPPS/ASC final rule with comment period.

ASC Payment and Comment Indicators

For the 2025 ASC update, the new and revised codes can be found in Addenda AA and BB. The codes are assigned comment indicator "NP" indicating the code is new or has had substantial revision. The comment indicator "NI" is used in the OPPS/ASC final rule with comment period to indicate new codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator "NI" also is assigned to existing codes with substantial revisions to their descriptors such that CMS considers them to be describing new services, and the interim payment indicator assigned is subject to comment. The "CH" comment indicator is used in

Addenda AA and BB to the proposed rule to indicate that the payment indicator assignment has changed for an active HCPCS code in the current year and the next calendar year. In addition, long descriptors are available in Addendum O.

For 2025, CMS finalized two ASC payment indicators for dental codes proposed in 2025. ASC payment indicators "D1" and "D2" are for the new dental codes that would be paid in 2025 and subsequent calendar years and are added to Addendum DD1.

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

As noted above, for 2025, CMS proposes several new and revised Category I and Category III CPT codes and revised Level II HCPCS codes. CMS also proposes to modify the descriptor of ASC payment indicator ''L6'' – "New Technology Intraocular Lens (NTIOL); special payment" to "Special payment; New Technology Intraocular Lens (NTIOL) or qualifying non-opioid devices" to account for non-opioid devices paid for under the ASC payment system pursuant to section 4135 of the CAA, 2023.

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 2025 PFS non-facility practice expense payment amount, or the 2025 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 (78 FR 75081). Payment for device-intensive procedures would be based on the service portion (non-device portion) using the standard ASC rate-setting methodology and the payment amount for the device portion based on the proposed 2025 device offset percentages that have been calculated using the standard OPPS APC rate-setting 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 2025, 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. 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. CMS indicates that the full list of the proposed ASC complexity adjustment codes for 2025 can be found in the ASC addenda and the supplemental policy file at the link for the ASC files found at the end of this section but it is unclear where within these files the information can be found.

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. 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 four 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 six brachytherapy APCs and four 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 four years of claims data. Table 78 in the proposed rule lists the number of 2023 claims used to set payment rates for these 10 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 2025 ASC payment rates and subsequent year payment rates for brachytherapy sources and separately-payable drugs and biologicals equal to the OPPS payment rates for 2025 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, 2025. Covered ancillary services and their proposed payment indicators for 2025 are listed in Addendum BB of this proposed rule (available on the CMS website).

Covered Surgical Procedures Designated as Office-Based Procedures

For 2025, CMS proposes to continue its historical practice of reviewing the most recent claims and utilization data (2023 claims in this case) for determining office-based assignments under the ASC payment system.

Based on its review of the 2023 utilization of covered surgical procedures, CMS identified two surgical procedures that it proposes to permanently designate as office-based for 2025 (listed in Table 79 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 0447T and 21127.[23]

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 that had more than 50 claims with utilization indicating that these procedures were performed predominantly in the office setting (Codes 0402T, 0512T, 93985, and 93986) were permanently designated as office-based in the 2024 final rule. In that rule, CMS designated 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). In this proposed rule, CMS determined that one additional procedure (67516)[24] is predominantly office-based, and proposes a permanent office-based designation accordingly. For 2025, CMS has identified three new CPT codes as temporarily office based: XX34T (Removal of integrated neurostimulation system, vagus nerve), 15XX3 (Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin), and 5XX06 (Catheterization with removal of temporary device for ischemic remodeling (i.e., pressure necrosis) of bladder neck and prostate).

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.

[23] 0447T - Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision; 21127 - Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft).
[24] 67516 - Suprachoroidal space injection of pharmacologic agent (separate procedure).

For 2022 and subsequent years, CMS modified its approach to assigning device-intensive status to surgical procedures under the ASC payment system. First, it assigns device-intensive status to procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures if their device offset percentage exceeds 30 percent under the ASC standard rate-setting methodology, even if the procedure is not designated as device-intensive under the OPPS. In addition, CMS assigns device-intensive status under the ASC payment system with a default device offset percentage of 31 percent if a procedure is assigned device-intensive status under the OPPS, but has a device offset percentage below the device-intensive threshold under the standard ASC rate-setting methodology. For 2025 and subsequent payment years, however, CMS proposes to modify the device offset percentage for new device-intensive procedures for which the device costs are estimated to be greater than 30 percent of the total procedure cost and lack claims data. For these HCPCS codes, CMS proposes to apply a default device offset percentage that is the greater of: 31 percent or the device offset percentage of the APC to which the procedure has been assigned.

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.

CMS is not proposing any changes to policies related to no cost/full credit or partial credit devices for 2025.

Requirement in the Physician Fee Schedule 2025 Proposed Rule for HOPDs and ASCs to Report Discarded Amounts of Certain Single-dose or Single-use Package Drugs

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 2025 PFS proposed rule includes proposals to operationalize section 90004 of the Infrastructure Act, including a proposal that impacts HOPDs and ASCs. ASCs are directed to the 2025 PFS rule for more information. Comments on these proposals will be addressed in the 2025 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

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.

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.

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 20 medical and dental surgical procedures to the list for 2025 (shown in Table 82 in the proposed rule). **CMS encourages interested parties to submit procedure recommendations to be added to the ASC CPL, particularly if there is evidence that these procedures meet its criteria and can be safely performed in the ASC setting**. 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.

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 2024, but will be packaged under the 2025 OPPS, CMS would also package the ancillary service under the ASC payment system for 2025 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 2025. All ASC covered ancillary services and their proposed payment indicators for 2025 are also included in Addendum BB.

Claims Processing Limitations for Covered Ancillary Procedures Performed with G0330

In the 2024 OPPS/ASC final rule, CMS finalized its proposal to add 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)) to the ASC CPL (88 FR 81924), with the provision that this service could only be billed with a covered ancillary procedure that has the 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. Existing ASC Payment Policy for Non-Opioid Drugs, Biologicals, and Devices

Under a policy adopted in 2019, certain non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting may be unpackaged and paid separately at ASP+6 if they meet the criteria for separate payment under §416.174. There are currently four drugs eligible for separate payment in the ASC setting under this provision of regulation (products listed in Table 83 in the proposed rule).

F. Proposed New OPPS/ASC Policy for Non-Opioid Drugs, Biologicals and Devices

Section 4135(a) and (b) of the CAA, 2023 directs CMS to unpackage and provide separate payment for three years beginning January 1, 2025 for non-opioid treatments for pain relief. A non-opioid treatment for pain relief is defined as having a "demonstrated 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."

With respect to devices, **CMS encourages interested parties to submit with their public comments any relevant literature that demonstrates that the named medical device replaces, reduces, or avoids opioid use per this statutory provision**. If there is no data or literature submitted for a medical device, or if the materials submitted do not demonstrate any ability of the medical device to replace, reduce, or avoid opioids, CMS asserts that the medical device will not meet the evidence criterion to qualify for separate payment under section 4135.

CMS proposes only to approve separate payment for drug or biological products with an FDA-approved indication that closely aligns with the statutorily required indication language to reduce post-operative pain or produce post-surgical or regional analgesia. CMS lists the products that it expects meet this criterion in Table 84 of the proposed rule, reproduced here.

TABLE 84:
Products Qualifying for Separate Payment as Non-Opioid Pain Relief Products

Brand Name	HCPCS Code	Long Descriptor
Exparel	C9290	Injection, bupivacaine liposome, 1mg
Omidria	J1097	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml
Dextenza	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg
Xaracoll	C9089	Bupivacaine, collagen-matrix implant, 1 mg
Zynrelef	C9088	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg
Ketorolac tromethamine Injection	J1885	Injection, ketorolac tromethamine, per 15 mg
ON-Q Pump	C98X4	Elastomeric infusion pump, non-opioid pain management delivery system, including catheter and other system component(s)

For a drug or biological that qualifies for separate payment, the statute sets payment at the methodology used under section 1847A (generally, ASP+6 percent) less the amount included in the OPPS or ASC payment for the product up to 18 percent of the OPPS or ASC payment. For a device that qualifies for separate payment, the statute sets payment at the charges for the device adjusted to cost less the amount included in the OPPS or ASC for the product up to 18 percent of the OPPS or ASC payment.

In implementing this provision, CMS indicates the similarity between the statutory language to allow separate payment for non-opioid pain products and transitional pass-through. While CMS will apply an offset to the APC for pass-through products paid separately, CMS is not proposing to

apply a payment offset for non-opioid products paid separately as some of these products are new and their costs may not be fully reflected in the data that CMS uses for rate-setting.

CMS proposes to apply the 18 percent payment limitation per date of service billed, rather than per HCPCS dosage unit. This is due to the fact that there are typically multiple HCPCS dosage units (also called billing units) of each drug or biological billed per claim. Thus, the total units of a drug billed on a date of service is more reflective of the cost of the drug in that encounter. CMS also proposes to create new status indicators for non-opioid drugs and devices to implement this payment limitation. Under the OPPS, non-opioid drugs and biologicals under this policy would be assigned a status indicator of K1, while non-opioid devices would be assigned a status indicator of H1.

G. New Technology Intraocular Lenses (NTIOLs)

New Technology Intraocular Lenses (NTIOLs) are intraocular lenses that replace a patient's natural lens that has been removed in cataract surgery and that also meet the requirements listed in § 416.195. CMS did not receive any requests for review to establish a new NTIOL class for 2025 by March 1, 2024, the due date published in the 2024 OPPS/ASC final rule with comment period (88 FR 81956). CMS does not propose to revise the current payment adjustment ($50 per lens) for NTIOLs.

H. 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 2023[25], CMS computes the ratio of:

- Total payments using the 2024 relative payment rates, to
- Total payments using the 2025 relative payment rates.

The 2025 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 $24 million in 2023, and projects that there will not be an additional increase in spending for these codes in 2025. Further, CMS reduces its estimated 2025 total payments by $9 million in its weight scalar calculation as a result of Section 4135 of the CAA, 2023 (which reflects the application of the 18 percent payment limitation for separately payable non-opioid treatments for pain relief).

The resulting ratio, 0.876, is the proposed weight scaler for 2025. 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

[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.

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).

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)[26] to the conversion factor in the same manner as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor. Holding constant ASC utilization from 2023 and using 2024 and the 2025 national payment rates after application of the weight scaler, CMS computes the ratio of:

- ASC payments using the 2024 ASC wage indices, to
- ASC payments using the 2025 ASC wage indices.

The resulting ratio, 0.9958, is the proposed wage index budget neutrality adjustment to the conversion factor for 2025.

To update ASC rates, CMS would utilize the hospital market basket update of 3.0 percent minus the productivity adjustment of 0.4 percent. This yields an update of 2.6 percent for ASCs meeting quality reporting requirements. CMS would continue its policy of reducing the update by 2.0 percentage points for ASCs not meeting the quality reporting requirements, yielding an update of 0.6 percent for such ASCs. The resulting proposed 2025 ASC conversion factor is $54.675 for ASCs reporting quality data, and $53.609 for those that do not, computed as follows:

	ASCs reporting quality data	**ASCs not reporting quality data**
2023 ASC conversion factor	$53.514	
Wage adjustment for budget neutrality	x 0.9958	
Net MFP-adjusted update	x 1.026	x 1.006
2024 Proposed ASC conversion factor	$54.675	$53.609

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 2023 claims data.

[26] Consistent with CMS's proposed changes to other FY and 2025 fee-for-service payment systems, CMS here proposes to update the labor market definitions used to adjust ASC payments for geographic differences in wages using the most recent labor market definitions issued via OMB Bulletin No. 23-01 (86 FR 37770, July 21, 2023). Similarly, CMS proposes to limit reductions in the wage index values to 5 percent. All of these changes would be implemented in a budget-neutral manner.

(Table 132 of the proposed rule and reproduced below.) The eye surgical specialty group remains the largest source of payments, with 2 percent increase in payments attributable to the changes proposed for 2025.

Table 101: Estimated Impact of Proposed Rule on Surgical Specialty Groups		
Surgical Specialty Group	Estimated 2025 ASC Payments (in Millions)	Estimated 2025 Percent Change
Total	**$6,810**	**2%**
Eye	$2,003	2%
Musculoskeletal	$1,320	2%
Nervous system	$1,227	2%
Gastrointestinal	$1,005	3%
Cardiovascular	$332	2%
Genitourinary	$257	2%

CMS provides estimated increases for 30 selected procedures in Table 133 in the proposed rule; the top 10 procedures are replicated below. CPT code 66984 (Cataract surgery with intraocular lens, 1 stage) is the largest aggregate payment procedure by far and is estimated to have a 2 percent increase in payment. The second largest aggregate payment procedure, CPT code 27447 (total knee arthroplasty), is also expected to see a 2percent increase.

Excerpt from Table 102: Estimated Impact of the 2025 Update to the ASC Payment System on Aggregate Payments for the Top 10 Procedures			
CPT/ HCPS Code	Short Descriptor	Estimated 2024 ASC Payments (in Millions)	Estimate 2025 Percent Change
66984	Xcapsl ctrc rmvl w/o ecp	$1,329	2
27447	Total knee arthroplasty	$336	2
45380	Colonoscopy and biopsy	$256	3
45385	Colonoscopy w/lesion removal	$241	3
63685	Ins/rplc spi npg/rcvr pocket	$214	4
63650	Implant neuroelectrodes	$181	3
43239	Egd biopsy single/multiple	$177	6
27130	Total hip arthroplasty	$168	2
66991	Xcapsl ctrc rmvl cplx insj 1+	$127	0
64483	Njx aa&/strd tfrm epi l/s 1	$107	2

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 2025 (Including surgical procedures for which payment is packaged)
- BB – Proposed ASC Covered Ancillary Services Integral to Covered Surgical Procedures for 2025 (Including Ancillary Services for Which Payment is Packaged)

- DD1 – Proposed ASC Payment Indicators for 2025
- DD2 – Proposed ASC Comment Indicators for 2025
- EE – Surgical Procedures to be Excluded from Payment in ASCs for 2025
- FF – ASC Device Offset Percentages for 2025
- O – Long Descriptors for New Category I CPT Codes, Category III CPT Codes, C-Codes, and G-Codes for 2025

XIV. Cross-Program Proposals for Quality Reporting Programs

A. Background and Overview

Background information on each of the Hospital OQR, REHQR, and ASCQR programs is under section XV.A, XVI.A, and XVII.A of this summary, respectively.

CMS proposes the adoption of three health equity measures: (1) the Hospital Commitment to Health Equity (HCHE) measure for the Hospital OQR and REHQR programs and the Facility Commitment to Health Equity (FCHE) Measure for the ASCQR program, (2) the Screening for Social Drivers of Health (SDOH) measure for all three programs, and (3) the Screen Positive Rate for SDOH measures for all three programs. The agency also proposes to replace the Hospital OQR and ASCQR programs' immediate measure removal policies for measures potentially raising patient safety concerns with an immediate measure suspension policy.

B. Advancing Health Equity Using Quality Measurement

CMS describes significant and persistent disparities in health care outcomes and points to studies demonstrating that facility leadership can influence patient outcomes, health care quality, and experience of care. The agency stresses its continued commitment to advancing health equity and improving health outcomes through its quality reporting programs, including by assessing health related social needs (HRSNs) and collecting and publicly reporting health equity focused measures.

CMS invites public comments on its proposals under this section.

1. Proposal to Adopt the HCHE Measure for the Hospital OQR and REHQR Programs and the FCHE Measure for the ASCQR Program Beginning with the 2025 Reporting Period/2027 Payment (or Program) Determination

Background. CMS believes that health facility leadership is essential to efforts toward achieving equity goals and ensuring accessibility to high-quality care. The agency sought comment in its FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25592 and 25593) on future efforts to address health equity in the Hospital Inpatient Quality Reporting (IQR) Program, specifically on ways to facilitate organizational commitment to improve health equity and on a potential measure on organization commitment to health equity and accessibility for individuals with intellectual and developmental disabilities. The agency continues to emphasize its goal to align health equity measures across

Medicare quality reporting programs (across both inpatient and outpatient settings over the continuum of care of patients).

The HCHE and FCHE measures are attestation-based structural measures that assess hospitals' and other facilities' commitment to health equity. The measures and domains aim to incentivize hospitals and facilities to collect and use data to identify equity gaps, implement plans to address the gaps, and provide for resources for initiatives on health care equity. CMS initially developed the HCHE measure for the Hospital IQR program and the FCHE measure for the Inpatient Psychiatric Facility Quality Reporting (IPFQR) program. The HCHE measure is currently part of the Hospital IQR and PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) programs and the FCHE measure is currently included in the IPFQR program and ESRD QIP.

In this proposed rule, CMS is now proposing the HCHE measure for the Hospital OQR and REHQR programs and the FCHE measure for the ASCQR program.

Overview of Measures. The HCHE and FCHE measures assess (and require hospital or facility, respectively, attestation on) the hospital's or facility's commitment to health equity across 5 domains (equity in a strategic priority, data collection, data analysis, quality improvement, and leadership engagement). Some of the domains have multiple elements. A point is awarded for each domain to which the hospital or facility attests affirmatively. For a hospital or facility to attest "yes" to a domain and receive credit for that domain, the hospital or facility will evaluate and determine whether it engages in each of the elements that comprise that domain. A complete list of domains and elements for the HCHE measure and the FCHE measure are described in Table 86 and Table 87, respectively, in section XIV of the rule.

There are two differences between the HCHE and FCHE measure specifications (as seen in Tables 86 and 87 of the rule). Otherwise, the two measures consist of the same five domains. The differences are:

- The HCHE measure specifications reference hospitals and the FCHE measure specifications reference facilities.
- Domain 2C of the HCHE measure requires hospitals to use certified electronic health record (EHR) technology (CEHRT) to attest "yes", while domain 2C of the FCHE measure requires facilities to use EHR technology to attest "yes", but does not require the EHR technology to be CEHRT.

Measure calculation.

- Numerator. Total number of domains for which the hospital or facility attests affirmatively ("yes"), meaning attests "yes" to *all* of the required elements of the domain. The hospital or facility would receive one point for each *domain* for which it attests affirmatively. If the hospital or facility is not able to attest "yes" for each element of a domain it would receive zero points for that domain.
- Denominator. Five points (one for each domain available for attestation).

Pre-Rulemaking. The measures were reviewed by the Hospital Recommendation Group in January 2024 as part of Pre-Rulemaking Measure Review (PRMR). The group recommended the FCHE measure without conditions for the ASCQR program. The group recommended the HCHE measure for the Hospital OQR and REHQR programs with conditions of obtaining consensus-based entity (CBE) endorsement, having additional specificity around attestation requirements, and ongoing data collection for further measure testing (especially regarding smaller entities). CMS responds that the condition relating to additional specificity around attestations has already been addressed since the measure domains were developed based on recommendations from a technical expert panel (TEP) and because there are guidance documents with additional information for the HCHE measure.[27] In response to the condition relating to ongoing data collection, CMS notes that the measure is being proposed for a pay for reporting program (the Hospital OQR program) and a reporting program with no associated payment adjustment (the REHQR). It therefore believes there are strong benefits of using the measure that outweigh the concern and that concerns raised have been addressed.[28]

Data Submission Requirements. Hospitals and ASCs would submit their attestation responses on these measures in the Hospital OQR, REHQR, and ASCQR programs, as applicable, by an annual deadline using the CMS-designated information system, which is currently the Hospital Quality Reporting (HQR) system. Details on data submission deadlines for web-based measure reporting (which includes the HCHE and FCHE measures) for the Hospital OQR program, REHQR program, and ASCQR program are under sections XV.E.2.a, XVI.E.3.b, and XVII.E.2.a, respectively.

2. Proposal to Adopt the SDOH Measure for the Hospital OQR, REHQR, and ASCQR Programs Beginning with Voluntary Reporting for 2025 Reporting Period Followed by Mandatory Reporting for the 2026 Reporting Period/2028 Payment or Program Determination

Background. SDOH refers to community-level factors that impact health and well-being. HRSNs refer to social and economic needs that affect an individual's health and well-being. CMS believes that screening individuals for HRSNs helps facilities identify individuals who have been historically underserved, to improve patient care and to refer these individuals to appropriate services. The agency also believes such screening could provide data to address SDOH, such as for stratifying patient risk.

CMS describes the CMMI Accountable Health Communities (AHC) Model, which extensively tested and assessed the relationship between identifying core HRSNs and improving healthcare

[27] Attestation Guidance for the Hospital Commitment to Health Equity Measure is available at: https://qualitynet.cms.gov/files/659c609eca7fd3001b35edab?filename=AttstGdnceHCHEMeas_v1.2.pdf.; and Frequently Asked Questions Hospital Commitment to Health Equity, HIQR is available at: https://qualitynet.cms.gov/files/659c60afd4b704001df0af51?filename=FAQ_HCHE_HIQR.pdf.

[28] Regarding CBE endorsement, CMS notes that section 1833(t)(17) of the Act does not require that each measure adopted for the Hospital OQR program or the ASCQR program be CBE-endorsed. For the REHQR Program, section 1861(kkk)(7)(C)(i) of the Act requires that REHQR program quality measures be endorsed by a CBE, but there is an exception under section 1861(kkk)(7)(c)(ii) of the Act that authorizes the Secretary to specify a measure for the REHQR program that is not CBE-endorsed if there is a specified area or medical topic determined appropriate by the Secretary for which there is not a feasible or practicable CBE-endorsed measure. CMS was unable to find another feasible and practicable measure that is endorsed and addresses the topic of leadership commitment on health equity.

costs, utilization, and outcomes. The 5 core domains[29] to screen for HRSNs that were applied in the AHC Model are used in the Screening for SDOH measure being proposed in this section and the Screen Positive Rate for SDOH measure proposed in section XIV.B.3. The Screening for SDOH and Screen Positive Rate for SDOH measures have been adopted in other quality reporting programs, including in the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule.[30]

Measure Overview. The Screening for SDOH measure is a process measure that assesses the total number of patients (18 years of age or older on the date of service) screened for 5 HRSNs (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety). The measure is calculated as a percentage equal to the numerator over the denominator as follows:

- *Numerator.* Number of patients (18 or older) admitted to an HOPD, REH, or ASC who are screened during their receipt of services at the hospital or facility for all of the five HRSNs.
- *Denominator.* Number of patients admitted to an HOPD, REH, or ASC, as applicable, who are 18 years or older.
- *Exclusions.* Patients who opt out of screening and patients who are unable to complete the screening themselves and lack a guardian or caregiver available to do so on the patient's behalf.

Pre-Rulemaking. The Hospital Recommendation Group in its January 2024 meeting recommended the Screening for SDOH measure for all three quality reporting programs, but with a condition specific to the Hospital OQR program. That condition was to allow hospitals to report the measure one time each year jointly for both the Hospital IQR and OQR programs, as applicable. CMS considered allowing for joint reporting but because patient populations for each program are different, making the denominator (and thus measure calculation) different for each, and because separate Compare tool data for inpatient and outpatient departments could be useful for patients, CMS is proposing separate data submission for each of the Hospital IQR and OQR programs. However, CMS proposes that HOPDs, REHs, and ASCs could confirm the current status of any previously reported HRSNs in another care setting and inquire about others not previously reported, instead of rescreening a patient within the reporting period. If the information is in the EHR in another health setting during the same reporting period, CMS proposes that the HOPD, REH, or ASC could use that information to report the measure instead of screening the patient.

The measure is not CBE-endorsed, but the agency will consider submitting it to the CBE for endorsement in the future.[31]

Data Sources, Submission and Reporting. CMS proposes that hospitals and other facilities would use a self-selected screening tool to collect data on the measure and points to the AHC HRSN

[29] The 5 domains are described in detail in Table 88 of the rule.
[30] FY 2023 IPPS/LTCH PPS final rule (87 FR 49191 through 49220).
[31] CBE endorsement is not required under section 1833(t)(17) of the Act for measures adopted for the Hospital OQR or ASCQR program. CMS is proposing adoption of the measure under the REHQR program under the exception under section 1861(kkk)(7)(C)(ii) based on there being no CBE-endorsed measure that addresses the specific area or medical topic involved.

Screening Tool[32] as an example as well as the Social Interventions Research and Evaluation Network (SIREN) website for information on HRSN screening tools.[33]

CMS proposes voluntary reporting of the measure during the 2025 reporting period, during which facilities may choose to submit aggregate data for the measure and would then require reporting beginning with the 2026 reporting period/2028 payment or program determination. Hospitals and other facilities would not be required to submit patient-level data, but would instead aggregate data they collect for the numerator and denominator. Hospitals and other facilities would submit data on the measure annually using the CMS-designated information system, which is currently the HQR system. Details on data systems for the Hospital OQR, REHQR, and ASC programs are in sections XV.E.2.a, XVI.E.3.b, and XVII.E.2.a, respectively.

3. Proposal to Adopt the Screen Positive Rate for SDOH Measure for the Hospital OQR, REHQR, and ASCQR Programs Beginning with Voluntary Reporting for the 2025 Reporting Period Followed by Mandatory Reporting Beginning with the 2026 Reporting Period/2028 Payment or Program Determination

Background. The Screen Positive Rate for SDOH process measure is a companion measure to the Screening for SDOH measure proposed in section XIV.B.2. While the Screening for SDOH measure enables identification of individuals with HRSNs, the Screen Positive Rate for SDOH measure captures the extent of such needs and estimates the impact of individual-level HRSNs on health care utilization.[34]

The Screen Positive Rate for SDOH provides information on the percent of patients, 18 or older on the date of receipt of services at the HOPD, REH, or ASC, who were screened for all 5 HRSNs (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) and who screened positive for at least one of the 5 HRSNs.

Measure calculation. Hospitals and facilities would report the measure as 5 separate rates, one for each screening domain, calculated as screen-positive patients divided by screened patients.

- *Numerator*. For each HRSN, the number of patients receiving care at the HOPD, REH, or ASC (18 years or older on date of admission) who were screened for all 5 HRSNs and who screen positive for having a need in one or more of the HRSNs (calculated separately for each of the 5 HRSNs). A patient who screens positive for more than one HRSN would be included in the numerator for each of such HRSNs.
- *Denominator*. For each HRSN, the number of patients receiving care at the respective hospital or facility who are 18 years or older on date of admission and are screened for all 5 HRSNs during their care.

[32] Information on the AHC HRSN Screening Tool is available at: https://www.cms.gov/priorities/innovation/files/worksheets/ahcm-screeningtool.pdf.
[33] SIREN can be found at https://sirenetwork.ucsf.edu/tools-resources/resources/screening-tools-comparison.
[34] The measure has been adopted in other quality reporting programs. For example, the Hospital IQR program adopted the measure in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49215 through 49220).

- *Exclusion*s. Patients who opt out of screening, and patients who are unable to complete the screening themselves and lack a guardian or caregiver available do so on the patient's behalf.

Data Collection, Submission, and Reporting. CMS proposes the same data sources for this measure as described for the Screening for SDOH measure proposed in section XIV.B.2.

Even though hospitals and facilities would collect the patient-level data on their patients (enabling the hospitals and facilities to address social needs among their patient populations) for reporting purposes, CMS proposes that hospitals and facilities would submit aggregated data representing the total numerator results for each of the 5 screening areas and the total number of patients screened for all 5 of the HRSNs. Information would be submitted through a CMS-designated information system, which is currently the HQR system.

CMS proposes voluntary reporting for the 2025 reporting period followed by mandatory reporting beginning with the 2026 reporting period/2028 payment or program determination.

Pre-Rulemaking. The Hospital Recommendation Group during its January 2024 meeting did not reach a consensus for its recommendation for the measure.[35] Concerns were raised about ambiguity in the interpretation of data from the measure as well as expectations regarding health care facilities because of different ways that a high score could be interpreted. As with the Screening SDOH measure, concerns about allowing hospitals to report this measure one time each year for both the Hospital IQR and OQR programs were raised. The measure is also not CBE-endorsed. However, CMS is proposing adoption of the measure in the Hospital OQR, REHQR, and ASCQR programs as it believes adoption of the measure is important to address the health equity measurement gap and that there is no other feasible and practicable measures that are CBE-endorsed on the topic.

C. Immediate Measure Removal Policy Beginning with 2025

Under both the Hospital OQR and ASCQR programs, a measure may be immediately removed based on evidence that the continued use of the measure raises patient safety concerns.[36] In contrast, the REHQR program uses an immediate measure suspension policy under which CMS suspends a measure's use in the program until potential removal of the measure is considered under standard rulemaking if the agency believes the measure raises patient safety concerns.[37]

CMS is proposing to replace the Hospital OQR and ASCQR programs' removal policies with an immediate measure suspension policy in cases where the measure potentially raises patient safety concerns and to codify the suspension policy for the Hospital OQR and ASCQR programs at §419.46(i)(2) and §416.320(b), respectively. Specifically, in cases in which CMS determines there is evidence that the collection and reporting activities related to a quality measure raises patient

[35] A 75 percent vote is required to reach consensus.
[36] For the immediate measure removal policies see 42 CFR 419.46(i)(2) for the Hospital OQR program and 42 CFR 416.320(b) for the ASCQR program.
[37] See the 2024 OPPS/ASC final rule (88 FR 82052).

safety concerns, the agency would suspend the measure from the applicable program until the potential measure removal could be considered through the next feasible rulemaking cycle. The HOPD or ASC and the public would be notified of the suspension through standard communication channels.

XV. Hospital Outpatient Quality Reporting (OQR) Program

A. Background and Overview

CMS provides references to the legislative and regulatory histories of the Hospital OQR program.[38] 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 Hospital OQR program's measures.[39] 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.

In addition to the cross-program proposals discussed in section XIV, CMS proposes the following changes to the Hospital OQR program:

- To adopt into the Hospital OQR program measure set the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery Patient Reported Outcome-Based Performance Measure (Information Transfer Pro-PM);
- To remove from the measure set (i) the MRI Lumbar Spine for Low Back Pain measure and (ii) the Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measure;
- To require that EHR technology be certified to all eCQMs available to report and for the HQR system to be used for data submission for any PRO-PM adopted into the Hospital OQR program measure set; and
- To make available on Care Compare data for the psychiatric/mental health patients' stratification of the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients measure.

For the 2024 payment determination, of the 3,062 eligible hospitals, 117 hospitals failed to meet the reporting requirements needed to receive the full annual OPD fee schedule increase factor and an additional 58 hospitals elected not to participate.[40]

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[38] 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.

[39] Certain requirements under the Hospital OQR program are codified at 42 CFR 419.46. A detailed discussion of the statutory history of the 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).

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

CMS estimates a total information collection and reporting burden increase of 66,348,321 hours at a cost of $1,624,936,216 annually associated with the proposed OQR program policies for the 2027 reporting period/2029 payment determination and subsequent years compared to the current information burden estimates.[41]

CMS invites public comment on all proposals to the OQR program.

B. Program Measure Set Policies

CMS is not proposing any changes to its measure retention or measure adoption policies. The only change CMS is proposing to its measure removal policy is the cross-program proposal to modify the immediate removal policy under section XIV.C.[42]

C. Program Measure Proposals

1. Proposed New Measures

a. Health Equity Measures

Detailed discussions on the cross-program proposals (including for the Hospital OQR) for the adoption of the HCHE measure, the Screening for SDOH measure, and the Screen Positive Rate for SDOH measure are under sections XIV.B.1, XIV.B.2, and XIV.B.3, respectively.

b. Proposal to Adopt the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery Patient Reported Outcome-Based Performance Measure (Information Transfer Pro-PM) Beginning with Voluntary Reporting for the 2026 Reporting Period Followed by Mandatory Reporting Beginning with the 2027 Reporting Period/2029 Payment Determination

Background. CMS discusses studies indicating that outpatient settings are associated with reduced patient engagement and understanding and less complete discharge instructions when compared to inpatient settings. This can negatively affect health outcomes, including by contributing to poor adherence to treatment, decreased patient safety, and increased returns to the emergency department (ED). Therefore, the agency is proposing the adoption of a survey measure that would provide hospitals with patient reported outcome (PRO) data to assess the clarity of recovery information provided to patients.

Measure Overview. The Information Transfer PRO-PM assesses the level of clear, personalized recovery information provided to patients 18 years of age or older who had surgery or a procedure

[41] See Table 106 in the rule.
[42] Measure retention policies are under §419.46(i)(1); program policies regarding measure removal, suspension, and replacement are under §§419.46(i)(2) and (3). For a discussion of statutory requirements and agency considerations for adopting quality measures under the program, see the 2024 OPPS/ASC final rule (88 FR 81973).

in an HOPD. The measure reports the average score of a patient's survey, which consists of three domains and nine corresponding items for patients and their caregivers to rate the clarity of information received about their post-discharge recovery. The three domains are:

- Applicability to patient needs – Assesses whether recovery information considered a patient's health needs and personal circumstances.
- Medication – Examines the clarity of medication information provided (guidance on taking new medications, potential side effects, and discontinuing medication).
- Daily Activities – Assesses the clarity of guidelines provided around diet, physical activity, returning to work, and driving.

The measure would be calculated as follows:

- *Numerator.* The sum of all individual scores an HOPD receives from eligible respondents (patients or caregivers).
    - An individual score is calculated for each respondent as dividing (i) the sum of items for which the respondent gave the most positive response available ("Yes" or "Very Clear"); by (ii) the number of items applicable to the procedure (determined by subtracting the number of items for which the respondent said "Does not apply" from the total possible (9) items).
- *Denominator*. Total number of patients 18 years of age or older who had a procedure or surgery in an HOPD, left the HOPD alive, and fully completed the survey.

Data Sources, Collection, Submission and Reporting. The Information Transfer PRO-PM would be a voluntary measure for the 2026 reporting period followed by mandatory reporting beginning with the 2027 reporting period/2029 payment determination.

The measure would be calculated based on PRO data collected by HOPDs directly or through third-party vendors through a web-based survey instrument distributed to patients or their caregivers. CMS proposes that the survey be administered 2-7 days after the procedure or surgery and for there to be a 65-day window for patient response.

Pre-Rulemaking. The Hospital Recommendation Group reviewed the measure during its January 2024 meeting and recommended it with the condition that the survey be administered at the time of the surgery or procedure so there would not be any conflict with other measured pain and function outcomes in order to improve response rates. However, CMS determined that allowing time after the surgery or procedure before administration of the survey would mitigate the patient's responses being influenced by time-dependent variables related to proximity to the surgery or procedure (such as fatigue, pain, or medication that could affect understanding).

The measure is CBE-endorsed.

2. Proposed Measure Removals

a. Proposed Removal of MRI Lumbar Spine for Low Back Pain Measure Beginning with 2025 Reporting Period/2027 Payment Determination

The MRI Lumbar Spine for Low Back Pain measure is a claims-based measure that was adopted into the measure set beginning with the 2010 payment determination. It evaluates the percentage of magnetic resonance imaging (MRI) of the lumbar spine for low back pain performed in the outpatient setting without any previous conservative therapy attempted first. CMS analyses have shown that national performance on the measure has remained stable with low average volumes. The agency discusses studies showing the measure may not have any correlation with improving the appropriate use of imaging. Together, the agency believes these results indicate continued use of the measure provides limited ability to improve the quality of care for patients.

Therefore, CMS proposes to remove the measure under measure removal factor 2 (performance or improvement on a measure does not result in better patient outcomes).[43]

b. Proposed Removal of Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery Measure Beginning with 2025 Reporting Period/2027 Payment Determination

The Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measure is a claims-based measure that was adopted into the measure set beginning with the 2012 payment determination. It calculates the percentage of stress echocardiography, single photon emission computed tomography myocardial perfusion imaging (SPECT MPI), stress MRI, or computed coronary tomography angiography (CCTA) performed at each facility in the 30 days before an ambulatory non-cardiac, low-risk surgery performed at any location. CMS discusses that the range of cases per HOPD has varied greatly (from 1 to over 1,300 cases), that variation between the 10th and 25th performance percentiles has not been distinguishable, and that the average rate for the measure for the 2024 payment determination was 3.5 percent (the lower the percent the better). Together, the agency believes this shows that there are limitations for interpreting the performance trends because of the range of cases, the measure may not be providing meaningful data, and there is not room for any significant improvement in national performance in the measure.

Therefore, CMS proposes to remove the measure under measure removal factor 2 (performance or improvement on a measure does not result in better patient outcomes).

3. Summary of Proposed Program Measure Set Updates

Table 89 in the rule lists the previously finalized measure set beginning with the 2027 payment determination and Tables 90 and 91 in the rule list the proposed measure sets for 2027 and 2031 payment determinations, respectively. These tables are consolidated into the table below.

Previously Finalized and Proposed Hospital OQR Program Measure Sets for 2027 and 2031 Payment Determinations

CBE	Measure	2027	2031
	MRI Lumbar Spine for Low Back Pain +	*Proposed Removal*	
	Abdomen CT – Use of Contrast Material	X	X

[43] §419.46(i)(3)(i)(B).

CBE	Measure	2027	2031
	Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery+	*Proposed Removal*	
	Median Time from ED Arrival to ED Departure for Discharged ED Patients +	X	X
	Left Without Being Seen +	X	X
0661	ED- Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of Arrival	X	X
0658	Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients	X	X
*	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery +	Remain Voluntary	Remain Voluntary
2539	Facility Seven Day Risk Standardized Hospital Visit Rate After Outpatient Colonoscopy	X	X
3490	Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	X	X
2687	Risk-Standardized Hospital Visits 7 Days After Hospital Outpatient Surgery	X	X
**	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS-CAHPS) - About Facilities and Staff	X	X
**	OAS-CAHPS: Communication About Procedure	X	X
**	OAS-CAHPS: Preparation for Discharge and Recovery	X	X
**	OAS-CAHPS: Overall Rating of Facility	X	X
**	OAS-CAHPS: Recommendation of Facility	X	X
3636	COVID-19 Vaccination Coverage Health Care Personnel	X	X
	Breast Cancer Screening Recall Rates	X	X
	ST-Segment Elevation Myocardial Infarction (STEMI) eCQM	X	X
3663e #	Excessive Radiation eCQM	Voluntary	X
##	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)	Voluntary	X
###	*Hospital Commitment to Health Equity*	*Proposed for Adoption*	*Proposed for Adoption*
####	*Screening for Social Drivers of Health (SDOH)*	*Proposed for Adoption*	*Proposed for Adoption*
####	*Screen Positive Rate for SDOH*	*Proposed for Adoption*	*Proposed for Adoption*
4210^	*Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery PRO-PM (Information Transfer PRO-PM)*		*Proposed for Adoption*

+ CBE endorsement removed
* This measure is voluntary.
** Per the 2022 OPPS/ASC final rule (86 FR 63837-63840), mandatory reporting began with the 2024 reporting period/2026 payment determination.
# Voluntary reporting beginning for the 2025 reporting period and mandatory reporting beginning with the 2027 reporting period/2029 payment determination, as discussed in the 2024 OPPS/ASC final rule (88 FR 81988-81992).

CBE	Measure	2027	2031
## Voluntary reporting beginning for the 2025 reporting period and mandatory beginning with the 2028 reporting period/2031 payment determination, as discussed in the 2024 OPPS/ASC final rule (88 FR 81984-81986). ### Proposed in section XIV.B.1 of this rule for adoption beginning with 2025 reporting period/2027 payment determination. #### Proposed in sections XIV.B.2 and XIV.B.3 of this rule for adoption beginning with voluntary reporting for the 2025 reporting period followed by mandatory reporting beginning with the 2026 reporting period/2028 payment determination. ^ Proposed in section XV.C.1.b of the rule for voluntary reporting for the 2026 reporting period followed by mandatory reporting beginning with the 2027 reporting period/2029 payment determination.			

D. Form, Manner, and Timing of Data Submission[44]

CMS-Designated Information System and Proposal for Data Submission for HCHE, Screening for SDOH, and Screen Positive for SDOH Measures. For each of these proposed measures, the performance period (referred to as the "reporting period") would be the period beginning on January 1 and ending on December 31 of the year that is 2 years before the applicable payment determination year (i.e., 2025 if the determination year is 2027). The data submission period would be the period beginning on January 1 and ending on May 15 of the year before the applicable payment determination year (i.e., January 1-May 15, 2026 if the determination year is 2027). HOPDs would be required to submit all data required to calculate each of the 3 proposed measures annually during the submission period using a CMS-approved, web-based, data collection tool available within the HQR System. Since a review and corrections period occurs at the same time as the submission period, HOPDs would be able to enter, review, and correct data submitted during the data submission period.[45]

Electronic Clinical Quality Measures (eCQMs) and Proposal to Require EHR Technology to be Certified to All eCQMs Available to Report Beginning with 2025 Reporting Period/2027 Payment Determination. The Hospital IQR program and Medicare Promoting Interoperability Program require EHRs to be certified to all available eCQMs in the measure set of the respective program.

CMS proposes, beginning with the 2025 reporting period/2027 payment determination, the following (with corresponding revisions to regulatory text in a new section (j) added to §419.46):

- In order to meet reporting requirements, an HOPD using EHR technology certified to the ONC health IT certification criteria would be required to have the technology certified to all eCQMs that are available to report under the Hospital OQR program for the program to ensure the technology is up to date and tested on each eCQM.
- HOPDs would be required to use the most recent version of the eCQM electronic measure specifications for the reporting period available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website.

[44] General policies regarding submission of data, review and correction of submitted data, and extraordinary circumstances exception requests (ECE) for data submission can be found at §419.46(d) and the 2023 OPPS/ASC final rule (87 FR 72110-72112).
[45] The review and corrections period policy is under §419.46(d)(4).

Patient-Reported Outcome-Based Performance Measures (PRO-PMs). CMS proposes that the HQR system must be used for data submission for any PRO-PM adopted into the Hospital OQR program measure set, including the Information Transfer PRO-PM proposed in this rule.[46] Hospitals would be able to directly submit data using the HQR system or use a third-party entity to submit their data using that system.

Specifically for the proposed Information Transfer PRO-PM:

- The performance period (i.e., reporting period) would be the period beginning January 1 and ending December 31 of the year that is 2 years before the payment determination (i.e., 2027 reporting period for the 2029 payment determination).
- The submission period would begin on January 1 and end on May 15 of the year before the payment determination year (i.e., January 1-May 15, 2028 for the 2029 payment determination).
- There would be a minimum random sample size of 300 completed surveys. HOPDs that do not collect the minimum would not perform random sampling and would be required to submit data from all completed surveys.

E. Public Reporting of Measure Data

The Median Time from ED Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients) measure is a chart-abstracted measure included in the current measure set. It evaluates time from ED arrival to departure. The measure's data are stratified into 4 calculations: (i) median time for discharged ED patients—overall rate, (ii) median time for discharged ED patients—reporting measure (which excludes psychiatric/mental health and transfer patients), (iii) median time for discharged ED patients—psychiatric/mental health patients only, and (iv) median time for discharged ED patients—transfer patients only. CMS finalized in the 2024 OPPS/ASC final rule that data on each of those strata (other than the psychiatric/mental health patients only strata) be publicly reported on Care Compare (or a subsequent CMS-designated website).[47] The agency decided to take further time to consider public reporting of the psychiatric/mental health patients strata data on Care Compare. However, after consideration, CMS believes ED throughput time for this group of patients could benefit from additional improvement efforts and patients and caregivers could use the information for making informed decisions.

Therefore, CMS proposes, beginning in 2025, to make data for the psychiatric/mental health patients' stratification available on Care Compare, including data that had been previously published on data.medicare.gov but not displayed on Care Compare.

F. Payment Reduction for Hospitals that Fail to Meet Hospital OQR 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 2025

[46] This submission method is currently required for the THA/TKA PRO-PM, as finalized in the 2024 OPPS/ASC final rule (88 FR 82006).
[47] All four strata are published on data.Medicare.gov.

update factor. The resulting reduction ratio for hospitals that fail to meet OQR Program requirements, called the "reporting ratio", would be 0.9805. CMS proposes to calculate the ratio to four decimals. It is calculated by dividing the proposed reduced conversion factor of $87.636 by the proposed full conversion factor of $89.379. 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.

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. 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. Program requirements are codified at 42 CFR 419.95.

In addition to the cross-program proposals discussed in section XIV, for the REHQR program, CMS proposes to modify the reporting period for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure.

CMS estimates that for the 2025 reporting period there would be 25 REHs mandated to report under the REHQR program based on hospital conversions as of April 22, 2024. It estimates that the REHQR proposals would result in a total information collection and reporting burden of 9,747 hours at a cost of $239,076 annually for those 25 REHs beginning with the 2026 reporting period/2028 program determination, as reflected in Table 108 of the rule.

CMS invites public comment on all the proposals for the REHQR program.

B. Program Measure Set Policies

No changes are proposed to the retention, suspension, removal, modification, or adoption measure policies.[48]

C. Program Measure Proposals

1. Proposal to Adopt Health Equity Quality Measures

Detailed discussions on the cross-program proposals (including for the REHQR program) for the adoption of the HCHE measure, the Screening for SDOH measure, and the Screen Positive Rate for SDOH measure are under sections XIV.B.1, XIV.B.2, and XIV.B.3, respectively.

2. Proposal to Modify the Reporting Period for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery Measure Beginning with 2027 Program Determination

The measure is calculated from Parts A and B administrative claims data for Medicare FFS beneficiaries with an outpatient same-day surgical procedure, excluding eye surgeries and colonoscopies (other than colonoscopy with biopsy) and is intended to make unplanned hospital visits after surgery more visible through publicly reported scores. The agency does not report measures publicly unless the measure achieves sufficient case volumes. CMS has noted a limited number of current REHs are able to publicly report on the measure because of case threshold minimums.

Therefore, the agency proposes to increase the reporting period from one year to two years beginning with the 2027 program determination. The previously finalized one-year data collection period for the 2026 program determination would remain as is (encounters from January 1, 2024 through December 31, 2024). Beginning with the 2027 program determination, the reporting period would have data from the years that are 2 and 3 years before the program determination year. For example, for the 2027 program determination, the reporting period would consist of data from 2024 and 2025 (January 1, 2024 through December 31, 2025).

3. Summary of Proposed Program Measure Set Updates

Table 92 of the proposed rule shows the previously finalized measure set and initial reporting periods. The information is summarized in the below table.

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

[48] See §419.95(e) for measure retention, suspension, and removal policies. See §419.95(d) for policies on modifications to adopted measures.

* Reporting period for this measure is a three-year period, beginning 2024-2026, corresponding to an initial program determination year of 2028. The other 3 measures have an initial reporting period of January 1, 2024-December 31, 2024 and initial program determination year of 2026.

Tables 94 and 95 of the rule show the proposed updated REHR program measure set with proposed reporting period for the 2027 and 2028 program determinations, respectively. The information is consolidated in the below table.

CBE #	Measure Name	Reporting Period for Program Determination 2027	Reporting Period for Program Determination 2028
None	Abdomen Computed Tomography (CT) – Use of Contrast Material	1/1/2025-12/31/2025	1/1/2026-12/31/2026
None	Median Time from ED Arrival to ED Departure for Discharged ED Patients	1/1/2025-12/31/2025	1/1/2026-12/31/2026
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy		1/1/2024-12/31/2026
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery	1/1/2024-12/31/2025*	1/1/2025-12/31/2026
	Hospital Commitment to Health Equity (HCHE)**	1/1/2025-12/31/2025	1/1/2026-12/31/2026
	Screening for SDOH***	1/1/2025-12/31/2025	1/1/2026-12/31/2026
	Screen Positive Rate for SDOH***	1/1/2025-12/31/2025	1/1/2026-12/31/2026

* The extended reporting period proposed for this measure is discussed in section XVI.C.2 of the rule.
** This measure would be mandatory beginning with the 2025 reporting period/2027 program determination, as discussion in section XIV.B.1 of the rule
*** This measure would be voluntary for the 2025 reporting period and mandatory beginning with the 2026 reporting period/2028 program determination, as discussed in sections XIV.B.2 and XIV.B.3 of the rule.

D. Form, Manner, and Timing of Data Submission

Proposed Data Submission Policy Following Conversion to REH Status. CMS proposes to specify that when a hospital converts to REH status it must begin submitting data to the REHQR program on the first day of the quarter following the date that the hospital has been designated as converted.

Proposal for HCHE, Screening for SDOH, and Screen Positive Rate for SDOH Measures' Data Submission and Reporting Requirements. CMS proposes a web-based submission policy that aligns with the Hospital OQR and ASCQR programs for all web-based measures adopted by the REHQR program, including the three proposed in this rule. REHs would submit data for the measures once annually using a CMS-approved, web-based data collection tool available within the HQR system. Data would be submitted during the period beginning on January 1 and ending on May 15 of the year before the program determination year (i.e., for the 2025 reporting period/2027 program determination, the data submission period would be January 1, 2026 through May 15, 2026) with the review and corrections period also occurring during that same data submission period.

XVII. 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., 2025 reporting is linked to 2027 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).[49] 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.[50]

CMS states that of 5,536 ASCs billing Medicare, 4,196 were required to participate in the ASCQR program for 2024 payment determinations. Of those not required, 279 ASCs chose to participate and met full requirements. Based on the 2024 payment determination data, CMS estimates that 4,475 ASCs would submit data for the program for the 2025 reporting period.[51] The agency estimates the proposals for the ASCQR program would result in a total information collection and reporting burden increase for those ASCs of 346,349 hours at a cost of $8,551,217 annually beginning with the 2026 reporting period/2028 payment determination, as compared to the currently approved information collection burden estimates.

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

B. ASCQR Program Measure Set Policies

Details are in section XIV.C on the agency's cross-program proposal (including for the ASCQR program) to modify the immediate measure removal policy for quality measures.

C. Program Measure Proposals

1. Proposal to Adopt Health Equity Quality Measures

Detailed discussions on the cross-program proposals (including for the ASCQR program) for the adoption of the FCHE measure, the Screening for SDOH measure, and the Screen Positive Rate for SDOH measure are under sections XIV.B.1, XIV.B.2, and XIV.B.3, respectively.

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[49] 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.

[50] 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.

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

2. Summary of Proposed Program Measure Set Updates

Tables 96 and 97 in the rule list the previously finalized measure sets for the 2027 and 2031 payment determinations, respectively. Tables 98 and 99 show the proposed updated ASCQR program measure set (including the 3 proposed cross-program health equity measures) for the 2027 and 2031 payment determinations. Information from the tables are consolidated into the table below.

ASCQR Program Measures by Payment Determination Year		
	2027	**2031**
CMS WEB-BASED TOOL REPORTING		
Patient Burn +	X	X
Patient Fall +	X	X
Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant +	X	X
All-Cause Hospital Transfer/Admission +	X	X
Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (CBE #0658)	X	X
Cataracts Visual +	*V***	*V***
Normothermia Outcome	X	X
Unplanned Anterior Vitrectomy	X	X
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)**	V	X
FCHE^	Proposed Mandatory	Proposed Mandatory
Screening SDOH^^	Proposed Voluntary	Proposed Mandatory
Screen Positive for SDOH^^	Proposed Voluntary	Proposed Mandatory
CLAIMS-BASED REPORTING		
Facility 7-Day Risk Standardized Hospital Visit Rate after Outpatient Colonoscopy (CBE #2539)	X	X
Hospital Visits After Orthopedic ASC Procedure (CBE #3470)	X	X
Hospitals Visits After Urology ASC Procedure CBE #3366)	X	X
Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at an ASC (CBE #3357)	X	X
OAS CAHPS SURVEY-BASED REPORTING		
Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS-CAHPS) - 5 measures	X***	X***
CDC NHSN WEB REPORTING		

ASCQR Program Measures by Payment Determination Year		
	2027	**2031**
COVID-19 Vaccination Coverage Health Care Personnel (CBE 3636)	X	X

+ CMS notes that CBE endorsement for the measure has been allowed to lapse by the measure steward.
V** This measure is voluntary.
*X**** Reporting on a set of OAS CAHPS measures: About Facilities and Staff; Communication About Procedure; Preparation for Discharge and Recovery; Overall Rating of Facility; and Recommendation of Facility.
** This measure begins with voluntary reporting for the 2025 reporting period, followed by mandatory reporting beginning with the 2028 reporting period/ 2031 payment determination, as discussed in the 2024 OPPS/ASC final rule (88 FR 82033 through 82036).
^ Proposed as mandatory beginning with 2025 reporting period/2027 payment determination, as discussed in section XIV.B.1 of rule.
^^ Proposed with voluntary reporting for the 2025 reporting period, followed by mandatory reporting beginning with 2026 reporting period/2028 payment determination, as discussed in sections XIV.B.2 and XIV.B.3 of the rule.

D. Form, Manner and Timing of Data Submission

Data Submission and Reporting for Proposed FCHE, Screening SDOH, and Screen Positive for SDOH Measures. ASCs would submit data for the measures once annually using a CMS-approved, web-based data collection tool available within the HQR System. Data would be submitted during the period beginning on January 1 and ending on May 15 of the year before the payment determination year (i.e., for the 2025 reporting period/2027 payment determination, the data submission period would be January 1, 2026 through May 15, 2026) with the review and corrections period also occurring during that same data submission period.

E. Specialty Focused Reporting and Minimum Case Number for Required Reporting

CMS seeks comment on two potential future frameworks, (i) the Specialty Select Framework and (ii) an alternative Specialty Threshold framework, that aim to achieve the following:

- The addition of case minimums for specialty measure reporting.
- The removal of zero case attestation requirement for specialty measures to decrease burden.
- The verification of individual measure case counts using claims data to determine which specialty measures would potentially be required for reporting for individual ASCs.

CMS is considering under the alternative frameworks, whether to revise the data reporting requirements to potentially require that ASCs report only data on quality measures that are related to their medical interventions, policies, processes, procedures, or can be abstracted from claims. ASCs would continue to report measures that are generally applicable to all ASCs[52] and on relevant

[52] Currently there are 7 generally applicable measures in the measure set: (i) Patient Burn; (ii) Patient Fall; (iii) Wrong Site, Wrong Patient, Wrong Procedure, Wrong Implant; (iv) All-Cause Hospital Transfer Admission; (v) Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at Ambulatory Surgical Centers; (vi) COVID-19 Vaccination Coverage Among Health Care Personnel; and (vii) The patient experience of care survey measures (OAS-CAHPS). Plus the 3 health equity measure proposed for inclusion would also be generally applicable.

specialty-specific measures.[53]

Under the Specialty Select Framework, all ASCs would be required to report all specialty-specific claims-based measures (currently there are 4 in the measure set) plus ASCs would be required to select a specified number of the non-claims-based specialty-specific measures (currently there are 4 in the measure set) that are applicable to the ASC. CMS may use a case threshold minimum to determine if a non-claims-based specialty-specific measure is applicable to an ASC. An ASC would be able to select (for satisfying the required reporting number) any of the non-claims-based specialty-specific measures for which the ASC satisfies the case threshold minimum; if an ASC does not satisfy the threshold minimum on enough measures to meet the required number for reporting, the ASC would need to report on each measure for which it met the threshold minimum.

CMS seeks comment on: (i) the number of non-claims-based specialty-specific measures on which ASCs should be required to report, (ii) an appropriate threshold for the case threshold minimum, (iii) how the agency should determine if an ASC meets the minimum case number for a measure for allowing the ASC to choose that measure to meet reporting requirements, and (iv) specialty-specific measures recommended for development and adoption in the ASCQR program. Under the potential alternative Specialty Threshold Framework, CMS would require reporting for all non-claims-based specialty-specific measures for which an ASC meets a specified case threshold minimum. Reporting would be voluntary on a non-claims-based measure if the threshold were not met. Claims-based specialty-specific measures would remain mandatory.

Regarding both of the potential frameworks, **CMS seeks comment on**: (i) whether use of Medicare FFS claims volume would be sufficient to determine minimum case volumes; (ii) whether MA claim volume or service data should be included for determining case volume thresholds; and (iii) any recommended processes CMS could follow or analyses it should conduct to determine case minimums.

F. 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.

[53] Table 100 in the rule describes specialties that are addressed by the current measure set and the specialty-specific measures.

XVIII. Medicaid Clinic Services Four Walls Exceptions

A. Background

Clinic services are a Medicaid benefit category that states may choose to offer and are defined in statute as "furnished by or under the direction of a physician, without regard to whether the clinic itself is administered by a physician, including such services furnished outside the clinic by clinic personnel to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address" (whom CMS refers to as "individuals who are unhoused").[54]

Current regulations at 42 CFR 440.90 define clinic services as "preventive, diagnostic, therapeutic, rehabilitative, or palliative services that are furnished by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients." The regulation further states that clinic services include the following furnished to outpatients:

> (a) services furnished at the clinic by or under the direction of a physician or dentist—known as the "four walls" requirement; and
> (b) services furnished outside the clinic, by clinic personnel under the direction of a physician, to an eligible individual who is unhoused.

When CMS added §440.90(b) in 1991 in response to a statutory change, it noted that clinic services had always been limited to people who go to the clinic (or a satellite location) and get the services onsite; this statutory change for the unhoused was a sole exception.[55] CMS has reiterated this position in subsequent guidance.[56]

1. IHS/Tribal Clinics

CMS reviews various executive orders and other actions to improve healthcare access and consultation with Indian Tribes. As part of this consultation, Tribes requested a permanent exemption from the four walls requirement for IHS/Tribal clinics.

The agency also reviews the role of the Indian Health Service (IHS) and Tribal health programs, including their ability to bill Medicare and Medicaid, to improve access for American Indians and Alaska Natives (AI/ANs). The IHS delivery system includes hospitals and clinics that are owned and operated by IHS, owned by IHS and Tribally-operated as authorized by the Indian Self-Determination and Education Assistance Act (ISDEAA, P.L. 93-638), or owned and operated by Tribes and Tribal organizations as authorized by the ISDEAA. In this section's discussions of

54 Section 1905(a)(9) of the Act. These services are distinct from the federally qualified health center (FQHC) services benefit (1905(a)(2)(C)) and the Medicaid rural health clinic (RHC) services benefit (1905(a)(2)(B)), which states are required to cover.
55 CMS interprets the exception at §440.90(b) to be mandatory for the states opting to cover the clinic services benefit.
56 The agency also notes there is no federal four walls requirement for Medicaid FQHC or RHC services, although states may add their own requirement. Similarly, the optional certified community behavioral health clinic (CCBHC) services benefit, added in federal statute and effective March 9, 2024, is also distinct from the clinic services benefit and has no federal four walls requirement.

proposed amendments to §440.90, these three kinds of facilities are referred to as "IHS/Tribal facilities"; in circumstances where these facilities operate as Medicaid clinic services providers, they are referred to as "IHS/Tribal clinics."

Many IHS/Tribal facilities are covered and paid as clinic services providers in the Medicaid program. The Federal Medical Assistance Percentage (FMAP)—that is, the share of Medicaid benefit expenditures paid by the federal government—is 100 percent for Medicaid-covered services received through an IHS facility (which, again, CMS has interpreted to refer to all three kinds of IHS/Tribal facilities described above). Under CMS' longstanding interpretation of section 1905(b) of the Act, this 100 percent FMAP is available only for state expenditures on services received through an IHS/Tribal facility (such as a clinic) by AI/AN Medicaid beneficiaries; state expenditures on services furnished by an IHS/Tribal facility to other individuals are not matched by the federal government at 100 percent, but at the state's regular FMAP.

2. Behavioral Health Clinics

Medicaid plays a crucial role in financing health care for individuals with behavioral health disorders—that is, both substance use disorders and mental health disorders—and is the largest payer of behavioral health services. Approximately 16 states cover services provided by behavioral health clinics of varying types under the clinic services benefit, such as Community Mental Health Centers certified under the Medicare Conditions of Participation, substance use disorder clinics, or mental health clinics. The Center for Medicaid & CHIP Services (CMCS) published its "Mental Health and Substance Use Disorder Action Plan" in July 2023 to increase access to prevention and treatment, engagement in care, and improve quality of care for beneficiaries with behavioral health disorders.

3. Clinics in Rural Areas

In November 2022, CMS published the "CMS Framework for Advancing Health Care in Rural, Tribal, and Geographically Isolated Communities," which included priorities of expanding access to comprehensive health care coverage, benefits, and services and supports to individuals in these communities. Medicaid provides critical access to care for individuals in rural areas who are older or disabled; more than one in five residents of rural areas (approximately 22 percent) are dually enrolled in Medicaid and Medicare.

There are no federal requirements under the clinic services benefit governing how states should provide coverage of services furnished specifically by clinics located in rural areas under that benefit; the federal requirements that apply generally to that benefit, including the four walls requirement, also apply to services furnished by clinics in rural areas. A state may cover Medicaid clinic services provided by various types of clinics located in rural areas, such as primary care clinics, behavioral health clinics, and surgical clinics.[57]

57 As previously mentioned, the Medicaid RHC services benefit is different from the Medicaid clinic services benefit and does not include a four walls requirement under federal Medicaid law; thus, RHCs may provide Medicaid services under the RHC services benefit, including outside of the four walls.

4. Clinic Payments

States generally have significant latitude in setting payment methodologies and rates for Medicaid covered services. There is no specific payment methodology required for clinic services, although regulations at §447.321 require the application of upper payment limits (UPLs) for clinics that are not IHS/Tribal clinics. States usually pay for clinic services via a facility rate. For Medicaid clinic services furnished by IHS/Tribal clinics, states typically rely on the Outpatient per Visit Rate (excluding Medicare) that IHS establishes for services provided by IHS facilities to Medicaid beneficiaries. This rate, along with a set of three other rates for Medicare outpatient visits and certain inpatient services, are frequently referred to as the IHS all-inclusive rates (AIRs); in the rest of this section, this IHS Outpatient per Visit Rate (excluding Medicare) is referred to as the AIR.

5. Four Walls Waivers

CMS recognized in 2017 that IHS/Tribal clinics were providing services outside of the four walls, including those not exempt from existing requirements, with states paying for these services at the clinic services rate (nearly always the AIR). In a January 18, 2017 FAQ, CMS announced a 4-year grace period (to January 30, 2021) to allow states time to come into compliance with the four walls requirement for IHS/Tribal clinics.[58] Due to the COVID-19 Public Health Emergency (PHE), CMS issued CMCS Informational Bulletins (CIBs) extending the four walls grace period multiple times, most recently to February 11, 2025.

Throughout the grace period, Tribes, the CMS Tribal Technical Advisory Group (TTAG), and the HHS Secretary's Tribal Advisory Committee (STAC) have said that the four walls requirement will create barriers in access to care for Medicaid beneficiaries who receive care from IHS/Tribal clinics after the grace period expires and asked CMS to eliminate the four walls requirement for IHS/Tribal clinics.

CMS has also received a handful of other requests from states to allow exceptions to the four walls requirement for clinics that serve vulnerable populations—for example, a section 1115 demonstration request to cover clinic services outside of the four walls for behavioral health clinics. States have also sought to cover, under the clinic services benefit, mobile crisis services provided by behavioral health clinics to individuals experiencing a behavioral health crisis; however, CMS advised these states that it could not approve coverage of mobile crisis services under the clinic services benefit due to the four walls requirement.

B. Provisions of the Proposed Regulations

This proposed rule aims to address the concerns heard from Tribes, the TTAG, the STAC, states, and other interested parties, consistent with various executive orders, previously cited CMS reports

58 In the FAQ's answer #13, CMS said it "has no present intention to review claims by Tribal 'clinic services' providers for services furnished outside of the 'four walls' before January 30, 2021 unless there is clear evidence of bad faith efforts to engage in improper claiming procedures in violation of this guidance." To continue offering those services outside the four walls after January 30, 2021, CMS recommended those clinics change their enrollment status to FQHC.

and frameworks, etc. CMS cites its statutory authority at section 1905(a)(9) of the Act for proposing three new exceptions to the four walls requirement at §440.90, for clinic services furnished by the following:

- IHS/Tribal clinics;
- Clinics primarily organized for the care and treatment of outpatients with behavioral health disorders, including mental health and substance-use disorders; and
- Clinics located in a rural area (and that is not an RHC, which could already provide services covered under a separate Medicaid benefit).

The exception for clinic services furnished by IHS/Tribal clinics would be a mandatory component of the clinic benefit, for states opting to cover the clinic benefit. The exceptions for clinic services furnished by behavioral health clinics and clinics located in rural areas would be optional for states. CMS proposes that services subject to any of these exceptions would have to be furnished under the direction of a physician.

CMS continues to believe that the statute does not authorize broad exceptions to the four walls requirement that have no relationship to the current exception nor a complete elimination of the four walls requirement. However, it is now reinterpreting section 1905(a)(9) of the Act as permitting additional exceptions for populations with similar health care access issues to individuals who are unhoused. When Congress added that exception to the statute, it introduced the exception with the word "including" (OBRA '87, P.L. 110-203), which CMS interprets as not precluding additional exceptions, so long as any additional exception is similar to the exception for individuals who are unhoused. Had Congress wanted to limit the clinic benefit to only services provided within the four walls and services provided outside the four walls to the unhoused, it could have written a narrower exception instead of using "including" in section 1905(a)(9). As discussed in the Congressional record for OBRA '87 in H. Rept. 100-391, Congress amended section 1905(a)(9) of the Act to create an exception to the four walls requirement for individuals who are unhoused to address access concerns for a population that has unmet health needs, distrusts mainstream providers, and has difficulty accessing care when providers are unable to meet them where they are located. The agency believes adding exceptions for populations with similar needs and barriers is consistent with the statutory text and purpose of the initial exception.

CMS points to similar characteristics of the unhoused population to those targeted by this proposal—for example, 21 percent of individuals who are unhoused reported having a serious mental illness while 16 percent reported having a substance use disorder. Given those characteristics, CMS lists four criteria it used in establishing the new exceptions, which mirror the needs and barriers to access experienced by individuals who are unhoused—that is, the population experiences the following:

- High rates of behavioral health diagnoses or difficulty accessing behavioral health services;
- Issues accessing services due to lack of transportation;
- A historical mistrust of the health care system; and
- High rates of poor health outcomes and mortality.

The exceptions would authorize states to pay the facility-based clinic services payment rates (for example, the AIR for IHS/Tribal clinics) for the excepted services. Currently, states can cover and pay for services that are provided by clinic personnel outside the four walls—but that do not fit within the exception at §440.90(b)—only under Medicaid practitioner services benefits, such as physician services, rehabilitative services, or other licensed practitioner services, which are generally lower than facility-based payment rates. CMS gives examples of how higher rates could increase access for affected beneficiaries.

CMS does not anticipate that the proposal would create burdens for Medicaid clinic services providers or Medicaid beneficiaries and considered the possible burden for state Medicaid programs. **The agency invites comments on whether the proposal might create any burdens for states, beneficiaries, providers, or other interested parties.**

1. IHS/Tribal Clinics

CMS proposes to add a new paragraph (c) to §440.90 to add an exception to the four walls requirement for IHS/Tribal clinics, to authorize payment for clinic services provided outside the four walls by IHS/Tribal clinic personnel. This exception would be mandatory for all states that opt to cover the Medicaid clinic services benefit. To make clear that this exception applies only to IHS/Tribal clinics, the proposed regulation text refers to clinics that are facilities of the IHS, whether operated by IHS or by a Tribe or Tribal organization as authorized by the ISDEAA.

As discussed earlier, the FMAP is 100 percent for state expenditures for Medicaid-covered services received through an IHS facility whether operated by IHS or by a Tribe or Tribal organization (which, again, CMS has interpreted to refer to all three kinds of IHS/Tribal facilities described above). This 100 percent FMAP is available only for state expenditures on services received through an IHS/Tribal facility (such as a clinic) by AI/AN Medicaid beneficiaries. For other beneficiaries, state expenditures on services furnished by an IHS/Tribal facility are matched at the otherwise applicable FMAP; this would continue to apply for services provided outside the four walls of a clinic. In other words, although the four walls exception would apply to any Medicaid beneficiary who receives services from the IHS/Tribal clinic, the 100 percent FMAP would only be available for AI/AN Medicaid beneficiaries.

CMS is not proposing to include facilities operated by urban Indian organizations (UIOs), because many of those facilities currently participate in Medicaid as providers of the Medicaid FQHC services benefit, which is not subject to a four walls requirement. UIO facilities that provide Medicaid clinic services might qualify as behavioral health clinics or clinics in rural areas and be exempt from the four walls requirement under one of the two optional exceptions.

CMS proposes this exception based on advice and input received through Tribal consultation and because the population served by IHS/Tribal clinics, which is predominately AI/AN, tends to meet the criteria CMS has identified that warrant an exception from the four walls requirement—high rates of behavioral health needs, lack of accessible transportation, mistrust of the health care

system, and high rates of morbidity and poor health outcomes. The agency lists numerous pieces of evidence and input from Tribal consultation.

2. Behavioral Health Clinics

CMS proposes to add a new paragraph (d) to §440.90 to add an exception to the four walls requirement for clinic services provided outside the four walls by personnel of behavioral health clinics. Each state could opt whether to apply this exception to its clinic services benefit, for clinics that are primarily organized for the care and treatment of outpatients with behavioral health disorders, including mental health disorders and substance use disorders. This proposed exception would include clinic services furnished outside of the four walls by a behavioral health clinic, including non-behavioral clinic services such as physical health services.

Because states may have different types of behavioral health clinics, CMS is not proposing to limit this exception to specific types of behavioral health clinics. However, to be considered a behavioral health clinic under this exception, the clinic would have to be *primarily* organized to treat outpatients with behavioral health disorders regardless of the patient mix of the clinic. For example, if a state has established separate licensure or certification requirements for mental health clinics and primary care clinics, under which primary care clinics are licensed to treat outpatients for services beyond the treatment of behavioral health disorders, then CMS would consider a mental health clinic in that state to be primarily organized to treat outpatients with behavioral health disorders but would not consider a primary care clinic in that state to be primarily organized to treat such outpatients.

There may be other means by which a state determines that a clinic is primarily organized to treat outpatients with behavioral health disorders (that is, other than through licensure or certification), including behavioral health accreditation by accrediting organizations or based on the organizing documents of the clinic, such as a business charter. If this proposal is finalized as described, states choosing to adopt this exception would describe the types of behavioral health clinics such exception applies to in their Medicaid State plan.

Again, CMS provides evidence on how these clinics meet the previously mentioned criteria that merit an exception from the four walls requirement. However, it also acknowledges that the evidence suggests that this patient population is less likely to meet as many of the criteria as consistently nationwide as patients served by IHS/Tribal clinics. Under the proposal, a state could determine that individuals with a behavioral health disorder in that state should be engaged by behavioral health clinic personnel where they are located due to their challenges accessing services, including lack of transportation and geographic distance from services, historic mistrust and stigmatization in the health care system, and poor health outcomes.

CMS considered proposing that, to qualify for this exception, clinic services would have to be provided specifically to individuals with a behavioral health disorder, in addition to being provided by personnel of a behavioral health clinic. However, the agency believes such a requirement would be too operationally burdensome; behavioral health clinics can serve as a proxy for a population

that generally consists of individuals with a behavioral health disorder, even though there may be circumstances where a behavioral health clinic furnishes services to an individual who does not have a behavioral health disorder.

3. Clinics in Rural Areas

CMS proposes to add a new paragraph (e) to §440.90 to add an exception to the four walls requirement for clinic services provided outside the four walls by personnel of clinics located in rural areas (but that are not RHCs). Each state could opt whether to apply this exception to its clinic services benefit.

Again, CMS provides evidence on how these clinics meet its criteria as to whether an exception from the four walls requirement is merited, although this patient population is less likely to meet as many of the criteria as consistently nationwide as patients served by IHS/Tribal clinics. CMS considered proposing that, to qualify for this exception, clinic services would have to be provided specifically to individuals who reside in a rural area, in addition to being provided by personnel of a clinic located in a rural area. However, the agency believes such a requirement would be too operationally burdensome; clinics in rural areas can serve as a proxy for a population that generally consists of individuals who reside in a rural area, even though there may be circumstances where the clinic furnishes services to an individual who does not live in a rural area.

The proposed rule does not include a definition of rural, but CMS is considering defining it in the final rule and seeks comment. There are many federal and state definitions of rural for various programs; CMS proceeds to describe several and assesses some of the tradeoffs. For example, the benefits to adopting a federal definition include that the definition would be consistent for all states electing to implement the exception and all clinics located in rural areas in such states. However, then states could not consider the variation in which their rural populations under different rural definitions meet the four criteria described in this proposed rule. Moreover, CMS does not directly control any such federal definitions, so if a specific federal definition were adopted then future rulemaking might be necessary to align this rule with another federal agency's changes to that federal definition. The federal definitions it points to are from the Census Bureau, the Office of Management and Budget (OMB), HRSA's Federal Office of Rural Health Policy (FORHP).

CMS is also considering allowing states to adopt a definition of rural that has been adopted by a federal governmental agency. Under this approach, CMS would finalize in regulation text that a rural area is defined by the state based upon a reasonable definition adopted by a federal governmental agency for programmatic purposes, without specifically listing out the federal definitions of rural that CMS considers reasonable. CMS notes that definitions it considers reasonable are from Census, OMB, FORHP, and the U.S. Department of Agriculture's Economic Research Service (ERS).[59] Under this approach, states that elect this exception would identify the

59 CMS says it did not consider adopting any of the ERS definitions as one of the federal definitions it is considering because they are less commonly used on their own (that is, not in conjunction with other federal definitions) in identifying rural areas in health care. However, the ERS definitions could be used by states if states were permitted to select a federal definition. While CMS does not believe that any of the ERS definitions should be adopted for all states to follow, if states are provided with the flexibility to adopt a federal definition, CMS says it does not want to be too prescriptive.

specific federal definition of rural (that is, Census Bureau, OMB, FORHP definition, or one of the ERS definitions) they are adopting in their Medicaid state plan and attest that the selected definition best captures the population of rural individuals that meets more of the four criteria described in this proposal. Requiring states to attest that the selected federal definition best captures the population of rural individuals that meets more of the four criteria would ensure there is an explanation for any variations in the definitions selected by different states. However, CMS acknowledges that finalizing this approach could cause clinics that operate in different states to face different definitions of rule, which could be confusing or burdensome to track.

CMS could also permit states to adopt a definition of rural that is adopted by a state governmental agency with a role in setting state rural health policy (such as a state primary care office or office of rural health) and attest that the selected definition best captures the population of rural individuals that meets more of the four criteria described in this proposal. This may be a more familiar definition to providers and be easier for a state to implement. Again, however, clinics operating in multiple states, or beneficiaries moving between states, might find the different definitions confusing and burdensome.

CMS could also choose not to define rural in the final rule, so that a state that elects this exception would choose any definition of rural that can be linked to the four criteria but would not need to be identified in the state plan or submitted to CMS for review and approval. The state would be required to publish its rural definition on a web site maintained by the state that is accessible to the public. This would permit a state to adopt a definition of rural that it believes best captures the population of rural individuals that meets more of the four criteria described in this proposed rule. This approach also recognizes that states may have the best information and data to determine the definition of rural that meets their operational needs. However, CMS would not be reviewing state definitions of rural, and a state might adopt a definition of rural that is overly broad or narrow. For example, a state might adopt a definition of rural that encompasses large urban areas, such as a populous city.

CMS invites comment on which approach to defining rural it should adopt.

4. Additional Four Walls Considerations

CMS proposes that the proposed exception to the four walls requirement for IHS/Tribal clinics would be mandatory for states electing to cover the clinic services benefit. However, the proposed exceptions for behavioral health clinics and clinics located in rural areas would be applied at state option. In addition, CMS propose to codify in regulation text its longstanding interpretation (discussed in section XVIII.A) that existing §440.90(a) and (b) are mandatory components of the clinic services benefit.

The exception for IHS/Tribal clinics would be mandatory because the population served by IHS/Tribal clinics more consistently meets the four criteria described above, both within and across states, than the populations targeted by the optional exceptions, especially given the degree of state variability in whether the populations targeted by the optional exceptions meet those criteria. Further, Medicaid is the largest source of third-party payment for services billed by IHS facilities, accounting for nearly two-thirds of health coverage payments to these facilities; any reduction in the Medicaid payments IHS/Tribal clinics receive for services (such as a reduction in payment from the AIR to a professional services rate for services furnished outside the four walls by the clinic) might uniquely burden IHS/Tribal clinics.

CMS believes the exceptions for behavioral health clinics and clinics in rural areas should be optional because there may be geographic variability in which the populations served by these clinics meet the four criteria. For example, the populations served by behavioral health clinics and clinics in rural areas may not as consistently face transportation challenges nationwide, to the extent that Tribal populations do. In addition, it is CMS' understanding that Medicaid funding is less often the largest source of payment for behavioral health clinics and clinics in rural areas, compared to IHS/Tribal clinics. Thus, the agency believes it best to let each state assess the degree to which these two exceptions might be warranted based on the state's specific circumstances. In making this assessment, each state should consider the degree to which individuals located in rural areas of the state and/or individuals with behavioral health disorders meet CMS' four criteria. **CMS solicits comment on the arguments made in this proposed rule in support of the mandatory and optional exceptions, and on whether the optional exceptions should also be mandatory for states opting to cover the clinic services benefit.**

If finalized as proposed, upon the effective date of the final rule, services qualifying for the exception for IHS/Tribal clinics must be paid for as Medicaid clinic services in states that opt to cover that benefit. Accordingly, these states would be required to submit a Medicaid state plan amendment (SPA) to attest to coverage of IHS/Tribal clinic services under the exception. Services provided outside the four walls would not be eligible for federal match earlier than the effective date of a SPA implementing one or both of the optional exceptions.

CMS is not proposing any additional exceptions to the clinic services four walls requirement, as other populations are better able to access services through Medicaid benefits to which a four walls requirement does not apply—for example, FQHC services, RHC services, outpatient hospital services. As described in section XVIII.A, states have considerable discretion regarding the types of clinics they opt to cover under the clinic services benefit. There are no specific federal Medicaid credentialing requirements, such as licensure or certification, for providers of the Medicaid clinic services benefit like there are for other Medicaid facility benefits, such as hospitals and nursing facilities. This leads to considerable variability in the types of clinics providing services that a state may cover under the clinic services benefit. **CMS invites comment on whether there are additional populations that are likely to meet its four criteria and that have no alternative access to services through Medicaid benefits not subject to a four walls requirement under federal Medicaid law, and on whether there are additional types of clinics that might serve as a proxy for such a population.**

XIX. Hospital Outpatient Department (OPD) Prior Authorization Process

The CMS Interoperability and Prior Authorization final rule (89 FR 8758), published February 8, 2024, creates, improves, or shortens prior authorization timeframes for certain payers such as Medicare Advantage organizations and applicable integrated plans, CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities to respond to prior authorization requests for covered items and services, excluding drugs (89 FR 8878). The final rule requires impacted payers (excluding Qualified Health Plan issuers on the Federally-Facilitated Exchanges) to send prior authorization decisions as expeditiously as the enrollee's/beneficiary's health condition requires, but no later than 72 hours for expedited (urgent) requests and 7 days for standard (non-urgent) requests.

As part of the 2020 OPPS/ASC final rule with comment period (84 FR 61446 through 61456), CMS established a nationwide prior authorization process and requirements for certain HOPD services. HOPD providers must submit to the MAC a prior authorization request for any service on the list of outpatient department services that require prior authorization. CMS currently requires prior authorization for the following services:

- Blepharoplasty,
- Rhinoplasty,
- Botulinum toxin injections,
- Panniculectomy,
- Vein ablation,
- Cervical fusion with disc removal,
- Implanted spinal neurostimulators, and
- Facet joint interventions.

On receipt of the prior authorization request, the MAC should review it and issue a decision within specific timeframes listed in the regulation text at §419.82(d)(1)(iii) and (2), to ensure providers receive timely responses and beneficiaries get appropriate care. While Medicare FFS is not an impacted payer under the CMS Interoperability and Prior Authorization final rule, CMS proposes to align its Medicare FFS prior authorization review timeframe for standard review requests for hospital outpatient department services with the timeframe in that final rule. This change would not only streamline the prior authorization processes to be the same across payers but would also help to reduce provider burden by reducing the potential for delays in care by decreasing the time beneficiaries and providers wait for prior authorization decisions on standard requests in FFS Medicare.

CMS proposes to change in §419.82(d)(1)(iii) the current review timeframe for provisionally affirmed or non-affirmed standard review requests for these services from 10 business days to 7 calendar days. For example, if a standard request is submitted on Tuesday, June 2, under the new timeframe, a decision must be rendered by the next Monday, June 8, whereas under the old timeframe, the decision must be rendered by Monday, June 15.

CMS is still considering the impact of aligning the expedited review decision timeframe with the expedited review decision timeframe in the CMS Interoperability and Prior Authorization final rule because, depending on when the expedited request is submitted, it may take longer for an HOPD provider to receive a decision using the 72-hour timeframe than the current expedited timeframe of 2 business days. The goal of changing the standard review timeframe is not only to align the timeframe across the prior authorization programs but also to reduce the time beneficiaries wait to access the care they need. Since changing the expedited review decision timeframe from 2 business days to 72 hours would not reduce beneficiaries' wait time in all circumstances, CMS is not proposing to conform that timeframe with the one in the CMS Interoperability and Prior Authorization final rule, but the agency may address this in future rulemaking.

XX. Provisions Related to Medicaid and the Children's Health Insurance Program (CHIP)

Before January 1, 2024, states had the option to provide up to 12 months of continuous coverage to children under age 19 enrolled in Medicaid or CHIP, regardless of changes in circumstances that otherwise would impact their eligibility for these programs, per section 1902(e)(12) of the Act, federal Medicaid regulations at §435.926, and CHIP regulations at §457.342. States had the option to elect an age limit under age 19 and/or continuous eligibility (CE) periods shorter than 12 months. However, except for the limited exceptions defined in the regulations, states could not terminate the coverage of children during a CE period.

CAA, 2023 amended sections 1902(e)(12) and 2107(e)(1) of the Act to make the previously optional CE a requirement for children enrolled in Medicaid and separate CHIP, effective January 1, 2024. The three exceptions were unaffected by the CAA, 2023; states may terminate coverage for children during a CE period if:

- The child or child's representative requests a voluntary termination of eligibility;
- The agency determines that eligibility was erroneously granted at the most recent determination, redetermination, or renewal of eligibility because of agency error or fraud, abuse, or perjury attributed to the child or the child's representative; or
- The child is deceased.

Although CAA, 2023 made the CE option mandatory for state Medicaid programs, it did not foreclose these existing exceptions that CMS had already promulgated pursuant to section 1902(e)(12), which are important to maintain program integrity. CMS described its intention to retain these exceptions in CMS State Health Official (SHO) Letter #23-004, "Section 5112 Requirement for all States to Provide Continuous Eligibility to Children in Medicaid and CHIP under the Consolidated Appropriations Act, 2023," which was issued on September 29, 2023. No changes to these exceptions are proposed in this proposed rule.

CMS proposes to update the Medicaid regulations at §435.926 to conform to CAA, 2023 changes to the CE policy, incorporated by cross reference into the CHIP regulations at §457.342(a). Specifically, the agency proposes the following:

- Requiring states to provide CE for the specified period (§435.926(b));

- Removing the option at §435.926(b)(1) permitting states to limit CE to an age younger than 19;
- Removing the option at §435.926(c)(1) to limit CE to a period of time of less than 12 months; and
- Removing the option at §435.926(d)(1) to end a CE period for a person when they reach the state-specified maximum age, as now all states must provide CE to children until they reach age 19.

Prior to January 1, 2024, states also had the option under §457.342(b) to disenroll children from a separate CHIP for failure to pay required premiums or enrollment fees required under the state plan, subject to the disenrollment protections afforded under section 2103(e)(3)(C) of the Act (related to premium grace periods) and §457.570 (related to other disenrollment protections). The CAA, 2023 changed the statutory authority for the CE period in the CHIP statute, requiring that CE "shall" apply to CHIP "in the same manner" as it does to Medicaid. The Medicaid CE regulation at §435.926 never contained an exception permitting states to terminate coverage for failure to pay premiums or enrollment fees, so after the CAA, 2023, the CHIP CE period also could not contain this exception.

Therefore, CMS proposes to remove the option in §457.342(b) to disenroll children from separate CHIP coverage for failure to pay required premiums or enrollment fees during a continuous eligibility period. This change will not preclude states from disenrolling children with an unpaid premium balance at the end of their 12-month CE period, provided the state has followed the statutory premium grace period requirements, which CMS reviews.[60]

Although current paragraph (b) of §457.342, which includes a reference to enrollment fees, would be eliminated, the collection of enrollment fees, as referenced in §§457.10 and 457.510, would remain an option to states. States would maintain the option to require payment of an enrollment fee prior to initial enrollment. States will also continue to have the option to require payment of the first month's premium prior to enrolling a child who is determined eligible at application and to require payment of the first month's premium or re-enrollment fee prior to re-enrolling a child into a new CE period, if the child is determined eligible at renewal.

XXI. Health and Safety Standards for Obstetrical Services

A. Background

CMS discusses what it refers to as the United States maternal health crisis, citing several reports and studies indicating a high maternal mortality rate in the U.S., which disproportionately affects

60 The state of Florida sued in federal court to block CMS' sub-regulatory guidance—for example, in the previously mentioned SHO letter—to prevent states from disenrolling CHIP enrollees for failure to pay premiums during the CE period. The state argued that this CMS policy can only be issued through notice-and-comment rulemaking, which CMS now proposes to address in this rulemaking. On May 31, 2024, the judge denied the state's motion, saying states must "submit their CHIP plan to CMS and allow CMS to review it before seeking judicial review" (*Florida v. CMS*, 8:24-cv-00317-WFJ-AAS, p. 13). On July 8, 2024, Florida appealed to the U.S. Court of Appeals.

racial and ethnic minorities and those living in rural and frontier areas. It discusses efforts CMS has undertaken to address the issue, including launching the "Birthing Friendly" icon on the CMS Care Compare online tool; publishing a quality, safety and oversight memorandum for hospitals to elect to implement evidence-based practices for management of obstetrics emergencies; requesting information on maternal health; and conducting stakeholder listening sessions as well as a literature review that focused on obstetric (OB) services delivery, staff training, and best practices for maternal health and safety to help inform the proposals in this rule.

CMS believes the Medicare statute provides ample authority for the agency to propose new conditions of participation (CoPs) for hospitals and critical access hospitals to establish requirements that protect the health and safety of pregnant, birthing, and postpartum patients receiving obstetric services at these facilities. It cites provisions in the statute requiring hospitals and CAHs to meet such requirements as CMS finds necessary in the interest of health and safety of patients furnished services in these facilities.[61]

CMS seeks comment on all its proposals, including whether it would be appropriate to apply any of the proposed policies to rural emergency hospitals (REHs).

B. Provisions of the Proposed Regulations

1. Organization, Staffing, and Delivery of Services (§§482.59 and 485.649)

CMS proposes to add two new sections (§§482.59 and 485.649) to its CoP regulations for hospitals and CAHs offering obstetrical services outside of an emergency department. Generally, obstetrical services, if offered by the hospital or CAH, would have to be well organized and provided in accordance with nationally recognized acceptable standards of practice for the health care of pregnant, birthing, and postpartum patients. The proposal would include standards for physical and behavioral health. Additionally, outpatient obstetrical services would have to be consistent in quality with inpatient care in accordance with the complexity of services offered.

a. Standard: Organization and Staffing

The proposal would require the organization of the obstetrical services at the hospital or CAH to be appropriate to the scope of the services offered. Obstetrical services would also have to be integrated with other departments of the hospital as applicable. For example, a labor and delivery unit must ensure good communication and collaboration with laboratory services, surgical services, and anesthesia services as applicable.

Labor and delivery rooms (including rooms for operative delivery) and post-partum or recovery rooms would have to be supervised by an experienced registered nurse (RN), certified nurse midwife (CNM), nurse practitioner (NP), physician assistant (PA), or a doctor of medicine (MD) or osteopathy (DO).

61 For CAHs and hospitals, CMS cites sections 1820(e)(3) and 1861(e)(9) of the SSA, respectively, for the authority to promulgate what it describes as health and safety regulations.

Additionally, hospitals and CAHs would have to delineate obstetrical privileges for all practitioners providing obstetrical care according to the competencies of each practitioner. The obstetrical service would have to maintain a roster of practitioners that specifies the privileges of each practitioner.

CMS reminds stakeholders that existing CoPs allow for the privileging and credentialling of practitioners other than physicians, including CNMs, to admit patients to a hospital (subject to state law). CMS does not require that these practitioners be employed by, under the supervision of, or associated with an MD or DO unless required by state law, regulations, or facility policy. The agency also does not require Medicaid or other non-Medicare patients admitted to a hospital by a nurse midwife to be under the care of an MD or DO; however, in the case of CAHs, CMS may not remove the requirement for physician oversight of patients, which is imposed in statute.

Regulatory Impact. CMS assumes each facility would have to hire an individual (likely an RN) to supervise labor and delivery rooms and post-partum or recovery rooms at an average cost of $54,757. It estimates this will cost facilities $345,516,670 in the aggregate both in year 1 and over 10 years.

b. Standard: Delivery of Service

CMS proposes to require that obstetrical services furnished by the facility be consistent with the needs and resources of the facility, and that facility policies governing obstetrical care must be designed to achieve and maintain high standards of medical practice and patient care and safety. Minimum standards for equipment would be established. For example, labor and delivery room suites would have to have a call-in-system, cardiac monitor, and fetal doppler or monitor. Recognizing that facilities may offer different levels of care, CMS seeks input on an appropriate minimum set of equipment.

For obstetrical emergencies, complications, immediate post-delivery care, and other patient health and safety events, the proposed standards would require additional equipment, supplies, and medication necessary to treat emergency cases, which would have to be kept on the premises of the facility and be readily available to treat emergencies. CMS provides examples, including resuscitators, defibrillators, oxygen, IV therapy supplies, suction machines, analgesics, local anesthetics, anti-arrhythmics, antihypertensives, antiepileptics, and anticoagulants.

Regulatory Impact. CMS assumes each facility would have to purchase 3 fetal monitors or fetal dopplers at $14,247 ($4,749 × 3), 1 cardiac monitor at $5,659 ($5,659 × 1), and 4 call-in systems at $12,000 ($3,000 × 4) for an average per facility cost of $31,906. It estimates this will cost facilities a 201,326,860 over 10 years.

2. Training for Obstetrical Staff in Hospitals and CAHs (§§482.59(c) and 485.649(c))

CMS proposes standards for obstetrical staff training. It would require hospitals and CAHs to

develop policies and procedures for training on select topics in order to improve maternal care services furnished at the facilities.

Concepts addressed in the training would reflect the scope and complexity of the services furnished by the facility. This would include evidence-based best practices and protocols identified by the facility to improve the delivery of maternal care. CMS suggests that facilities may participate in local or regional perinatal quality collaboratives (PQCs) and implement patient safety bundles for safer births.[62] Additionally, hospitals and CAHs would have to use findings from their quality assessment and performance improvement (QAPI) program to inform staff training needs and any changes to training topics on an ongoing basis.

The facility's governing body would have to identify which obstetrical staff must complete the training and document that the training was successfully completed. Additionally, the hospital or CAH would have to be able to demonstrate staff knowledge on the topics for which training was provided. CMS does not propose to require a specific method for facilities to show their staff is knowledgeable and competent in improving maternal care delivery, but it notes this could be done through self-assessments, surveys, or questionnaires administered to the staff. CMS expects hospitals and CAHs to use qualified trainers. It also cautions that this new training requirement is supplemental to the education and training necessary for clinicians to administer care within the scope of their practice or for a staff member to perform their job.

Regulatory Impact. CMS assumes that 20 percent of hospital medical staff and 80 percent of medical staff in CAHs would receive training by reason of its proposals. It estimates facilities will incur annual aggregate costs $150 million, with an average per facility cost of $24,719 for hospitals and $12,601 for CAHs. The proposed requirements are estimated to take 14.2 million hours to complete and cost approximately $1.50 billion over 10 years.

3. Quality Assessment and Performance Improvement (QAPI) Program (§§482.21 and 485.641)

CMS proposes to require a hospital or CAH that offers obstetrical services to use its QAPI program to assess and improve health outcomes and disparities among obstetrical patients on an ongoing basis. At a minimum, facilities would be required to do all of the following:

- Analyze data and quality indicators collected for the QAPI program by diverse subpopulations as identified by the hospital among obstetrical patients.
- Measure, analyze, and track data, measures, and quality indicators on patient outcomes and disparities in processes of care, services and operations among obstetrical patients.
- Analyze and prioritize patient health outcomes and disparities, develop and implement actions to improve patient health outcomes and disparities, measure results, and track performance to ensure improvements are sustained among obstetrical patients.

[62] Perinatal quality collaboratives are state or multistate networks of teams that work to improve the quality of care for mothers and babies by identifying health care processes in need of improvement, and patient safety bundles are "a small, straightforward set of evidence-based best practices that, when performed collectively and reliably, have been demonstrated to improve patient outcomes."

- Conduct at least one measurable performance improvement project focused on improving health outcomes and disparities among the hospital's population(s) of obstetrical patients annually.

Under the proposal, in satisfying requirements for the analysis of data and quality indicators, facilities would determine the data analysis methodology that is most appropriate for the patient population and number of cases. CMS expects that the data analysis would be used to monitor and assess for the presence of disparities. It notes that two additional maternal health quality measures were added to the Hospital IQR program, which could be used to inform facility QAPI activities and comply with the new standard.

CMS also proposes to require the facility's obstetrical services leadership to engage in QAPI for obstetrical services, which would include participating in data collection and monitoring described above. Additionally, the facility leadership, obstetrical services leadership, or their designate(s) would have to have a process to incorporate maternal mortality review committee (MMRC) data and recommendations into the hospital QAPI program if an MMRC is available at the state or local jurisdiction where the facility is located. CMS notes that existing state statutes require facilities to report data to MMRCs, and says that a facility could comply with this proposal by participating in a PQC or pursuing a QI project based on information from a MMRC.

CMS seeks comments on the proposals as well as on other topics, including the following:

- The extent to which the proposals would achieve the agency's goal in improving the health and safety of patients receiving obstetrical care at these facilities.
- The extent to which facilities already stratify, measure, analyze, and track quality data and indicators over time by diverse subpopulations or conduct performance improvement projects focused on reducing maternal health disparities as part of their QAPI activities.
- The type(s) of data stratifications/subgroups/categories that are key to ensuring the health and safety of all pregnant, birthing, and postpartum patient subgroups.
- Whether the proposals should apply to other Medicare-participating facilities, such as REHs.

Regulatory Impact. CMS assumes that the proposals to track and implement at least one quality improvement project will require the participation of a hospital executive at $1,861.28 ($232.66 × 8 hours), an RN at $931.00 ($93.10 × 10 hours), a physician at $1,729.64 ($216.08 × 8 hours), and a data scientist at $368.96 ($92.24 × 4 hours) for a total per facility cost of $4,889.88 annually and an average hourly cost of $163. It estimates that this requirement will cost $30,855,143 annually and $308,551,428 over 10 years.

4. Emergency Services Readiness (§§482.55 and 485.618)

CMS proposes to establish a new standard for readiness to set clear expectations for facilities and their delivery of emergency services. CMS believes the proposal would improve facility readiness to care for emergency services patients, including pregnant, birthing, and postpartum patients.

However, this standard would apply to all hospitals and CAHs offering emergency services without regard to whether they also offer obstetric services. Facilities would be required to have adequate provisions and protocols to meet emergency needs of patients, which would vary depending on the complexity and scope of services offered.

Protocols would have to be consistent with nationally recognized and evidence-based guidelines for the care of patients with emergency conditions; this would include patients with obstetrical emergencies, complications, and immediate post-delivery care.

Provisions would include equipment, supplies, and medication used in treating emergency cases, which must be kept at the hospital and be readily available for treating emergency cases to meet the needs of patients. At a minimum, this would include drugs, blood and blood products, biologicals, equipment and supplies commonly used in life-saving procedures, and a call-in system for each patient in each emergency treatment area. Facilities would be expected to tailor their equipment and supplies to meet the needs of their patient populations, consistent with the needs, services, and resources of the facility.

CMS also proposes annual staff training on the protocols and provisions proposed above. Similar to the proposed training requirements for obstetric staff described above, the facility's governing body would have to identify which staff must complete the training for emergency care and document that the training was successfully completed. Additionally, the hospital or CAH would have to be able to demonstrate staff knowledge on the topics for which training was provided. Finally, CMS proposes to require hospitals and CAHs to use findings from its QAPI program on an ongoing basis to inform training needs and any changes to training topics. Comment is sought on the proposals, including whether the new standards should also apply to REHs.

Regulatory Impact. CMS assumes that 20 percent of hospital medical staff and 100 percent of medical staff in CAHs would receive 3 hours in training in emergency services protocols. It estimates aggregate costs in year 1 of $8 million for CAHs and $143 million for hospitals. For subsequent years, it anticipates that 79 percent of staff would receive one hour of refresher training and 21 percent would receive the full 3-hour training. The proposed requirements are estimated to cost approximately $72 million in each of years 2 through 10. In the aggregate over 10 years, the cost for facilities to comply with this proposal would equal $796,234,077.

With respect to proposed requirements for equipment, supplies and drugs, facilities will already satisfy many of the proposed requirements. CMS believes roughly 50 percent of facilities will have to install call-in systems in their emergency departments. Assuming that 20 percent of hospital beds are allocated for emergency services and assuming there will need to be a call-in system for each bed, this requirement would cost a total of $334,629,300 in year 1 and over 10 years.

5. Transfer Protocols

CMS states that the efficient transfer of a patient to a hospital that can treat complex conditions and provide higher levels of care is critical for patients experiencing obstetrical emergencies or

complications, or patients that require immediate post-delivery care. It believes elements of a safe transfer would include risk identification and determination of conditions necessitating consultation, referral, and transfer; mechanisms and procedures for transfer/transport to a higher-level hospital at all times; and a reliable, accurate, and comprehensive communication system between participating hospitals, hospital personnel, and transport teams.

The agency proposes to amend its discharge planning CoP regulation to impose requirements for transfer protocols. Hospitals and CAHs would be required to have written policies and procedures for the transfer of patients under their care, including hospital inpatients. The standard would apply to transfers from the emergency department to inpatient admission or transfers between inpatient units in the same hospital as well as to transfers between inpatient units at different hospitals. Hospitals and CAHs would also be required to train relevant staff on hospital policies and procedures for transferring patients under its care; the facilities would determine which staff should receive this training. CMS encourages all recipient hospitals to have policies and procedures in place for the acceptance of transfers. It also and reminds hospitals of their obligations to comply with EMTALA and Federal civil rights laws.

Comment is sought on the proposed standard as well as on how often staff should be trained in transfer protocols, whether receiving hospitals should have written policies and procedures outlining their standards and conditions for accepting transfers, and whether all hospitals (including CAHs and REHs) should be required to have a documented partnership with another hospital that both provides obstetric services and a Medical Fetal Medicine specialist available for consultations in urgent situations, if such service(s) are already offered directly by the hospital.

Regulatory Impact. CMS expects that all surgeons, physicians, physician assistants, nurse practitioners, nurse midwives, nurse anesthetists in hospitals would receive this training. However, it believes that only 5 percent of RNs nationwide would receive training and that no licensed practical nurses would receive any such training. Assuming one hour of training each year, CMS estimates that the requirement will cost $71,246,104 annually and $710,461,040 over 10 years. Tables 161 and 162 in the proposed rule provide an estimate of the total annual and 10-year financial and hourly burden for the proposed requirements related to obstetrical and emergency service. Tables 144 through 160 provide more specific information for each proposed requirement.

XXII. Hospital-Wide All-Cause Readmission and Standardized Mortality Measures

Background. Hybrid measures use more than one data source for measure calculations. The Hybrid HWR measure[63] and Hybrid HWM measure[64] are included in the Hospital IQR program measure set. Both measures use (i) core clinical data elements (CCDEs),[65] which are clinical variables derived from electronic health records (EHRs) that can be used to risk adjust hospital outcome

63 This measure is designed to capture all unplanned readmissions that arise from acute clinical events requiring urgent rehospitalization within 30 days of discharge.
64 This measure is an outcome measure that captures the hospital-level, risk-standardized mortality rate (RSMR) of unplanned, all-cause mortality within 30 days of hospital admission for any eligible condition.
65 CCDEs include vital signs and laboratory results.

measures; (ii) linking variables,[66] which are administrative data that can be used to link the CCDEs and administrative claims data for measure calculation; and (iii) claims data. Hospitals are required to submit linking variables on 95 percent of hospital discharges and CCDEs on 90 percent of discharges in a reporting period. There has initially been voluntary reporting for both measures. Data collected during the voluntary reporting periods are not publicly reported. Mandatory reporting first applies for the FY 2026 payment determination based on performance data from July 1, 2023 through June 30, 2024. Public reporting is set to begin with respect to the data collected for the FY 2026 payment determination.

Proposal to Extend Voluntary Reporting of CCDE and Linking Variable Data for the Hybrid HWR and Hybrid HWM Measures. Based on routine monitoring of hospital performance on the measures during the applicable voluntary reporting periods, during which about one-third of IPPS hospitals chose to report on the measures (mostly large, non-rural, non-critical access, and non-safety net), CMS has noted that about three-fourths of the participating hospitals would not have met the reporting thresholds for the CCDEs and linking variables and would have therefore been subject to a one quarter reduction to their annual payment update for the fiscal year. The agency believes that hospitals may need an additional year to address issues and develop experience with reporting of CCDEs and linking variables before being subject to payment consequences.

Therefore, CMS proposes that the submission of CCDEs and linking variables remains voluntary for the FY 2026 payment determination and becomes mandatory beginning with the FY 2027 payment determination. A hospital's annual payment determination for FY 2026 would not be affected by the voluntary reporting of CCDEs and linking variables, but CMS would evaluate and assess the claims data portion of the measures (and those measures would be publicly reported based on claims data). In the spring, as a preview of public reporting, hospitals would continue to receive confidential hospital-specific reports, which would reflect the CCDEs and linking variables if hospitals choose to report them.

CMS invites public comment on the proposal and requests feedback regarding difficulties hospitals have in meeting the thresholds and recommendations based on experiences reporting on hybrid measures.

XXIII. Individuals Currently or Formerly in the Custody of Penal Authorities

A. Medicare FFS No Legal Obligation Payment Exclusion and Incarceration

Payment is prohibited under Part A or Part B for any expenses incurred for items or services (other than Federally qualified health center services) for which the individual furnished those items or services has no legal obligation to pay and which no other person (by reason of such individual's membership in a prepayment plan or otherwise) has a legal obligation to provide or pay.[67] CMS refers to this prohibition as the "no legal obligation to pay" payment exclusion. As applied to

[66] Linking variables include (i) CMS Certification Number, (ii) Health and Insurance Claims Number or Medicare Beneficiary Identifier, (iii) Date of Birth, (iv) Sex, (v) Admission Date, and (vi) Discharge Date.

[67] Section 1862(a)(2) of the Act. This exclusion is implemented in 42 CFR 411.4.

individuals in custody of penal authorities, CMS' longstanding policy is that these individuals are generally considered public charges and thus have no obligation to pay for medical care. However, under certain circumstances, some Medicare-eligible prisoners may have an obligation to pay for their medical care, and Medicare may pay for that care.

Section 411.4(b) sets forth conditions to establish whether a prisoner has a legal obligation to pay for their medical care: (i) state or local law must require individuals in custody to repay the cost of the medical services they receive while in custody and (ii) the state or local government must enforce the requirement to pay by billing all such individuals. The second requirement applies whether or not the individual is covered by Medicare or any other health insurance; state and local governments must pursue collection of the amounts these individuals owe in the same way and with the same vigor that it pursues the collection of other debts.

CMS previously defined individuals who are in custody to include, but not be limited to, "individuals who are under arrest, incarcerated, imprisoned, escaped from confinement, under supervised release, on medical furlough, required to reside in mental health facilities, required to reside in halfway houses, required to live under home detention, or confined completely or partially in any way under a penal statute or rule."[68] Some stakeholders objected to the breadth of this definition. Hospitals noted that it imposed undue burdens on them because in many circumstances they had no way of identifying whether a particular individual was "in custody."

CMS notes that the no legal obligation to pay requirements for incarcerated individuals at §411.4(b) establish a rebuttable presumption. The presumption may be rebutted if (i) the state or local government requires individuals in custody to repay the cost of the medical services they receive while in custody, and (ii) the state or local government enforces the requirement to pay by billing all such individuals by pursuing collection of the amounts they owe in the same way and with the same vigor that it pursues the collection of other debts. CMS proposes a number of changes to §411.4(b), including significant restructuring of that section of the regulatory text.

B. Proposals

1. Description of "custody" (§411.4(b)(3))

CMS proposes to narrow the definition of custody by removing references to individuals who are on supervised release and home detention and to strike the phrase "completely or partially in any way under a penal statute or rule." Under the proposal, individuals lawfully released from confinement in jail, prison, penitentiary, or similar institution, or released following arrest on bail, parole, probation, or home detention would not be presumed to be in custody for purposes of the no legal obligation to pay payment exclusion, even if they are required to return to jail, prison, penitentiary, or similar institution at some later time. By contrast, individuals on "medical furlough" or similar arrangements would still be considered in custody for purposes of the exclusion. This is because they are under the control of law enforcement or penal authorities and are required to return to jail or prison after medical services have been provided. The agency seeks

[68] See §411.4(b), as added by 72 FR 47130, 47405 through 47406 (Aug. 22, 2007).

comment on the proposal, on whether the terminology in the existing description of "custody" in regulations is appropriate, and on the specific circumstances in which individuals who have been released from incarceration on bail, parole, probation, or home detention have a legal obligation to pay for some or all of the health care they receive.

The agency believes the proposal would clarify that Medicare may pay for health care items and services furnished to an individual while on bail, parole, probation, or home detention, provided the individual has a legal obligation to pay for such items or services, without having to prove that the special conditions in §411.4(b)(1) have been satisfied.

2. Halfway Houses

CMS proposes to clarify the definition of custody when applied to individuals residing at halfway houses, using the Medicaid definition as a model. Under the proposal, individuals would be considered to be in custody if they are required to reside in a halfway house under any of the following conditions:

- Halfway house residents are precluded from working outside the facility in employment that is available to individuals who are not under penal authority supervision;
- Halfway house residents may not use community resources (e.g., libraries, grocery stores, recreation, or educational institutions) at will; or
- Halfway house residents may not seek health care items and services in the broader community to the same or similar extent as individuals who are not under penal authority supervision.

The phrase "at will" would mean consistent with certain house rule restrictions and travel limitations, which aligns with the Medicaid program's interpretation of that phrase.

3. Definition of Penal Authority

CMS proposes to add a definition of the term "penal authority" to §411.4(b)(2). It would mean a police department or other law enforcement agency, a government agency operating under a penal statute, or a state, local or federal jail, prison, penitentiary, or similar institution. CMS acknowledges that private contractors operate certain penal institutions or halfway houses, and it seeks comment on whether those contractors should explicitly be included in the proposed definition of "penal authority."

4. Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals

In November 2022, CMS established a special enrollment period (SEP) for formerly incarcerated individuals who are eligible for Medicare but failed to enroll or reenroll in Parts A or B (or both) because they were in custody of penal authorities. There must be a record of release from such custody either through discharge documents or data available to the Social Security Administration (SSA). Under section 202 of the Act, the SSA determines an individual's eligibility for old age,

survivors, and disability insurance (OASDI) benefits, and for most Medicare beneficiaries, entitlement to Medicare Part A is based on entitlement to OASDI benefits. Further, SSA determines entitlement to Medicare Part A and eligibility for Part B. Under section 202(x) of the Act, payment of OASDI benefits is suspended to prisoners, certain other inmates of publicly funded institutions, fugitives, probationers, and parolees, including when an individual is confined in a jail, prison, or other penal institution or correctional facility pursuant to conviction of a criminal offense for more than 30 days.

CMS proposes to amend the SEP at §§406.27(d)(1) and 407.23(d)(1) to align the SEP triggering event more closely with the bases on which an individual's OASDI benefit is reinstated or initiated rather than using the Medicare payment exclusion in §411.4(b). Under the proposal, SSA would make a determination of an individual's eligibility to enroll using the Medicare SEP at §§406.27(d)(1) and 407.23(d)(1) based on the data SSA collects and keeps in its systems for determining OASDI benefit suspensions and any additional documentation provided by individuals to demonstrate that they have been released from incarceration. The proposed change, if finalized, would be effective beginning January 1, 2025.

The specific proposed changes to the regulations would revise the eligibility requirements for the SEP by striking the phrase "released from the "custody of penal authorities as described in §411.4(b)" and instead tying the eligibility for the SEP to whether an individual is "released from confinement in a jail, prison, or other penal institution or correctional facility," which is phrasing that is more consistent with section 202(x)(1)(A)(i) of the Act for purposes of OASDI benefits. CMS clarifies that it is not proposing that a criminal conviction or formal sentencing will be required for an individual to have been confined in a jail, prison, or other penal institution or correctional facility; this is because conviction of crime is not required for the payment exclusion in §411.4(b) to apply. However, this is different from the current requirement under section 202(x)(1)(A) of the Act, and CMS seeks comment on the types of documentation an individual could provide to demonstrate they were confined and released without conviction to determine eligibility for this SEP.

CMS also proposes a number of technical corrections to the regulatory text of the SEP at §§406.27(d)(3) and 407.23(d)(3).

XXIV. Hospital Quality Star Rating Request for Information (RFI)

A. Background

The Overall Hospital Quality Star Rating is published on the provider comparison tool on Medicare.gov. It assigns hospitals a star rating (between one and five stars) based on publicly available quality measure results reported by the hospitals through the agency's quality measurement programs. The Overall Hospital Quality Star Rating is refreshed annually, with the most current refresh planned for July 2024.

B. Current Overall Hospital Quality Star Rating Methodology

Under the current Overall Hospital Quality Star Rating methodology:

- Scoring is structured so that higher scores indicate better performance for all measures and all measure scores are standardized to a single, common scale to account for differences in score units.
- Measures are arranged into 5 measure groups (the first 4 of which include outcome measures and the 5th of which includes process measures): (1) Safety of Care, (2) Mortality, (3) Readmission, (4) Patient Experience, and (5) Timely and Effective Care.
- Measure group scores are calculated as an average of measure scores and then standardized to a common scale.
- The hospital summary score is calculated as a weighted average of measure group scores. That is, the weighted measure group scores are summated to generate the hospital summary score. Each of the groups (other than Timely and Effective Care) are weighted 22 percent. Timely and Effective Care is weighted 12 percent. In the case that a hospital has no scores in a group, the weight for that group is redistributed proportionally across the remaining groups.
- To receive a star rating, a hospital must reach the minimum reporting threshold—that is, the hospital must report at least three measures in at least three measure groups (one of which must be the Mortality or Safety of Care measure group).
- Based on the number of measure groups for which a hospital reported at least three measures, hospitals are grouped into one of the following peer groups: 3-measure peer group, 4-measure peer group, or 5-measure peer group.
- Within each peer group a clustering algorithm is applied to assign hospital summary scores to star ratings, with one star being the lowest and five stars the highest.

C. Safety of Care in Star Ratings

CMS reviews safety gaps in health care delivery, including those revealed during the COVID-19 public health emergency, and the agency's efforts to improve both patient and health care workforce safety. The agency explains that it is possible in the current Overall Star Rating methodology for a hospital to score very low in the Safety of Care measure group but still receive a high star rating by receiving high scores in the other measure groups. CMS describes an internal analysis conducted to determine correlations between the Safety of Care measure group and performance in the Overall Hospital Quality Star Rating. Results showed that hospitals that performed well in Safety of Care usually also performed well on the overall Star Rating, but there were a few that performed in the bottom quartile of the Safety and Care group that still received a 5-star rating.[69]

69 Table 101 in the rule shows the results of the analysis. Table 102 shows safety performance of hospitals in the analysis by hospital characteristics.

D. Potential Future Options to Emphasize Patient Safety in the Hospital Quality Star Rating

CMS is considering potential adjustments to the Overall Hospital Quality Star Ratings methodology that would place more emphasis on the measures within the Safety of Care measure group.[70] CMS seeks feedback on whether hospitals performing in the bottom quartile in the Safety of Care measure group should be eligible to receive a 5-star rating and specifically on the following three options for modifying the Overall Hospital Quality Star Rating methodology:

1. Reweighting the Safety of Care Measure Group – Under this option, the Safety of Care measure group's weight would be increased to 30 percent and the weights for the other groups would each be proportionally reduced (so that Mortality, Readmission, and Patient Experience would each be weighted to 19.7 percent and Timely and Effective Care at 10.8 percent). CMS' analysis shows that the reweighting of the groups would reduce the number of hospitals that both perform poorly in Safety of Care and receive a 5-star rating, but would reduce the influence of the other measure groups.
2. Policy-Based 1-Star Reduction for Poor Performance on Safety of Care – Under this option, the star rating of any hospital in the lowest quartile of Safety of Care would be reduced by 1 star. The current minimum star rating of one star would still apply so no hospital would get reduced below 1 star. Even if hospitals perform very well in all other measure groups (except Safety of Care) they would still be subject to the 1-star reduction.
3. Reweighting the Safety of Care Measure Group Combined with Policy-Based Star Rating Cap – Under this option, the Safety of Care measure group would be reweighted (same as under option 1 to 30 percent with the other groups' weights proportionally reduced) plus there would be a policy limiting hospitals in the lowest quartile of Safety of Care to a maximum of 4 stars. CMS' analysis showed this option provided a more targeted approach that restricted the 5-star rating to hospitals that achieve a minimum threshold in Safety of Care.

E. Solicitation of Public Comment

CMS seeks feedback on each of the three options described above, specifically:

- Feedback on whether interested parties: (i) support reweighting the measure groups to give greater weight to Safety of Care as described in option 1, and/or agree with the potential new weights described under such option for each measure group (as shown in Table 103 of the rule); (ii) support reducing the star rating for hospitals with a low Safety of Care score as described in option 2, and/or agree with the potential policy under such option to apply a 1-star reduction to all hospitals in the lowest Safety of Care quartile; and/or (iii) support a

[70] There are currently 8 measures in the Safety of Care measure group (6 HAI measures, 1 Complications measure after total hip or total knee replacement (Hip/Knee), and one composite adverse event measure (Patient Safety and Adverse Events Composite (PSI-90)). Any measures that are removed or suspended from one of the hospital quality programs and not published on Medicare.gov would no longer be included for the star ratings, and any measure added to the programs and published on Medicare.gov could be included in the star ratings.

combination of reweighting the Safety of Care measure group with a 4-star maximum on star ratings, as described in option 3.

- Feedback on or any preferences towards an approach of both up-scoring high performers and down-scoring poor performers as in options 1 and 3, or an approach of just down-scoring poor performers as in option 2.
- Suggestions for other methodological approaches that could be used to emphasize the Safety of Care measure group.
- Feedback on any special considerations for small, rural or safety net hospitals, including critical access hospitals.

Table 131: Estimated Impact 2025 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 *		3,511	0.0	0.1	2.7	2.3
ALL HOSPITALS		3,413	0.1	0.2	2.9	2.4
	(excludes hospitals held harmless and CMHCs)					
URBAN HOSPITALS		2,722	0.1	0.1	2.8	2.4
	LARGE URBAN	1,291	0.2	-0.3	2.4	2.2
	(GT 1 MILL.)					
	OTHER URBAN	1,431	0.0	0.4	3.1	2.5
	(LE 1 MILL.)					
RURAL HOSPITALS		691	-0.1	1.0	3.5	2.8
	SOLE COMMUNITY	356	-0.1	0.9	3.4	2.7
	OTHER RURAL	335	-0.1	1.0	3.6	3.1
BEDS (URBAN)						
	0 - 99 BEDS	920	0.3	0.4	3.3	2.8
	100-199 BEDS	763	0.2	0.2	3.0	2.5
	200-299 BEDS	423	0.2	-0.1	2.7	2.3
	300-499 BEDS	383	0.1	0.1	2.9	2.4
	500 + BEDS	233	-0.1	0.0	2.5	2.2
BEDS (RURAL)						
	0 - 49 BEDS	330	0.0	1.0	3.6	2.9
	50- 100 BEDS	203	-0.1	0.6	3.2	2.5
	101- 149 BEDS	83	-0.2	1.0	3.4	3.0
	150- 199 BEDS	44	-0.2	1.4	3.8	3.0
	200 + BEDS	31	-0.2	1.1	3.4	3.1
REGION (URBAN)						
	NEW ENGLAND	121	0.0	-1.8	0.7	0.5
	MIDDLE ATLANTIC	298	0.0	-0.6	2.0	1.8
	SOUTH ATLANTIC	445	0.1	0.3	3.0	2.7
	EAST NORTH CENT.	417	-0.1	0.4	3.0	2.7
	EAST SOUTH CENT.	166	0.0	1.7	4.3	3.9
	WEST NORTH CENT.	177	-0.1	1.6	4.1	2.8
	WEST SOUTH CENT.	453	0.4	1.6	4.7	4.3
	MOUNTAIN	210	0.1	0.0	2.7	1.8
	PACIFIC	386	0.2	-1.2	1.6	1.4
	PUERTO RICO	49	0.9	0.3	3.7	3.3
REGION (RURAL)						
	NEW ENGLAND	21	-0.2	0.8	3.2	2.9
	MIDDLE ATLANTIC	53	-0.2	0.6	3.1	2.6
	SOUTH ATLANTIC	109	-0.1	0.1	2.5	2.1
	EAST NORTH CENT.	110	-0.2	0.9	3.3	3.0

		(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**
	EAST SOUTH CENT.	132	-0.2	1.9	4.4	3.9
	WEST NORTH CENT.	79	-0.1	1.8	4.3	3.0
	WEST SOUTH CENT.	122	0.3	1.5	4.4	4.0
	MOUNTAIN	41	-0.2	1.6	4.0	1.9
	PACIFIC	24	-0.2	-1.0	1.4	1.1
TEACHING STATUS						
	NON-TEACHING	2,093	0.2	0.2	3.0	2.5
	MINOR	882	0.1	0.5	3.2	2.7
	MAJOR	438	-0.1	-0.2	2.3	2.1
DSH PATIENT PERCENT						
	0	8	1.4	-0.1	3.9	5.4
	GT 0 - 0.10	223	0.4	0.6	3.6	3.0
	0.10 - 0.16	207	0.3	0.3	3.2	2.6
	0.16 - 0.23	524	0.3	0.0	3.0	2.5
	0.23 - 0.35	1,151	0.0	0.4	3.1	2.5
	GE 0.35	905	-0.1	-0.1	2.4	2.1
	DSH NOT AVAILABLE **	395	2.6	0.0	5.2	4.9
URBAN TEACHING/DSH						
	TEACHING & DSH	1,163	0.0	0.1	2.7	2.3
	NO TEACHING/DSH	1,156	0.2	0.1	2.9	2.4
	NO TEACHING/NO DSH	8	1.4	-0.1	3.9	5.4
	DSH NOT AVAILABLE	395	2.6	0.0	5.2	4.9
TYPE OF OWNERSHIP						
	VOLUNTARY	1,967	0.0	0.1	2.7	2.3
	PROPRIETARY	1,017	0.8	0.6	4.0	3.5
	GOVERNMENT	429	-0.1	0.1	2.7	2.4
CMHCs		32	4.3	0.7	7.7	7.2

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all proposed 2025 OPPS policies and compares those to the 2024 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2025 hospital inpatient wage index. The final rural SCH adjustment would continue CMS' current policy of 7.1 percent, so the budget neutrality factor is 1. The final budget neutrality adjustment for the cancer hospital adjustment is 1.0006 because the proposed 2025 target payment-to-cost ratio is less than the 2024 PCR target.

Column (4) shows the impact of all budget neutrality adjustments and the addition of the proposed 2.6 percent OPD fee schedule update factor (3.0 percent reduced by 0.4 percentage points 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 CMS has the frontier adjustment to Column 3 in this table.

These 3,511 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.
** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.