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Medicare Program: 2025 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs Final Rule Summary

The Centers for Medicare & Medicaid Services (CMS) released the calendar year 2025[1] final rule for Medicare's hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system (CMS-1809-FC) on November 1, 2024. Policies in the final rule will generally go into effect on January 1, 2025, unless otherwise specified. The final rule was published on November 27, 2024, in the *Federal Register*.

Public comments will be accepted on the codes listed in Addendum B of the final rule with a Comment Indicator (CI) of "NI" or "NP"—codes with either an interim or proposed Ambulatory Payment Classification (APC) where CMS has not previously sought comment. **The public comment period will end on December 31, 2024.**

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

In this rule, CMS adopts a policy 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 new conditions of participation for hospitals and Critical Access Hospitals (CAHs) 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-fc.

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

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I. Overview

A. Estimated Impact on Hospitals

The increase in spending due only to changes in the 2025 OPPS final rule is estimated to be approximately $1.98 billion. Considering estimated changes in enrollment, utilization and case-mix for 2025, CMS estimates that OPPS expenditures, including beneficiary cost-sharing, will be approximately $87.7 billion, which is approximately $4.7 billion higher than estimated expenditures in 2024.

CMS estimates that the update to the conversion factor net of the productivity will increase payments 2.9 percent in 2025 (market basket of 3.4 percent less 0.5 percentage points for productivity). Including changes to outlier payments, pass-through payment and the application of the frontier state wage adjustment, CMS estimates a 3.0 percent increase in payments between 2024 and 2025.

Hospitals that satisfactorily report quality data will qualify for the full update of 2.9 percent, while hospitals that do not will be subject to an update of 0.9 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 167 hospitals will not receive the full OPPS increase factor (109 hospitals that did not meet the requirements and another 58 hospitals that chose not to participate).

CMS' impact table indicates that Medicare makes payments under the OPPS to approximately 3,562 facilities (3,460 hospitals excluding CMHCs, cancer and children's hospitals held harmless to their pre-OPPS payment to cost ratios). Table 201 in the final rule (reproduced in the Appendix to this summary) includes the estimated impact of the final rule by provider type. It shows an estimated increase in Medicare spending of 3.0 percent for all facilities and hospitals. The following table shows components of the 3.0 percent total:

	% Change All Facilities
Fee schedule increase factor	2.9
Difference in pass-through estimates for 2024 and 2025	-0.10
Difference from 2024 outlier payments (0.85% vs. 1.0%)	0.17
All changes	-2.97

For 2024, CMS estimated that pass-through will be 0.27 percent of OPPS spending. For 2025, CMS estimates that pass-through spending for drugs, biologicals and devices will be $328 million, or 0.37 percent of OPPS spending. The difference between these figures (0.27 – 0.37 = -0.10 percentage point) is the required adjustment to ensure that pass-through spending remains budget neutral from one year to the next. In addition, CMS estimates that actual outlier payments in 2024 will represent 0.83 percent of total OPPS payments compared to the 1.0 percent set aside for 2025, a 0.17 percentage point change in 2025 payments. Taken together, these factors produce the total increase in 2025 OPPS payments of 3.0 percent.

Changes to the 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 3.0 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	3.2%
All Facilities (including CMHCs and cancer and children's hospitals)	3.0%
Urban	3.2%
Large Urban	2.9%
Other Urban	3.4%
Rural	3.2%
Beds	
0-99 (Urban)	3.6%
0-49 (Rural)	3.2%
500+ (Urban)	2.9%
200+ (Rural)	3.2%
Major Teaching	2.7%
Type of ownership	
Voluntary	3.1%
Proprietary	4.9%
Government	2.6%

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, wage index changes and provider adjustments, according to table 201.

B. Estimated Impact on Beneficiaries

CMS estimates that the aggregate beneficiary coinsurance percentage will be 18.0 percent for all services paid under the OPPS in 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 June 30, 2024 (approximately 78 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 final rule payment rates, including the number of claims available at each stage of the process: https://www.cms.gov/files/document/2025-nfrm-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. By 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 final 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 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 final rule.

Effective October 1, 2024, the HCPCS workgroup created HCPCS code P9027. CMS initially assigned HCPCS code P9027 to APC 9541 with a payment rate of $252. One commenter provided cost information for the Hemanext ONE System indicating an expected average per-unit anticipated hospital cost of $510. In the final rule, CMS is changing the APC assignment for HCPCS code P9027 to APC 9541 with a payment rate of $487.10.

(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, to reflect the number, isotope, and radioactive intensity of the brachytherapy sources furnished. Since 2010, CMS has used the standard OPPS payment methodology for brachytherapy sources, with payment rates based on source-specific costs as required by statute. CMS proposed no changes to its brachytherapy policy for 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 2024, 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 proposed 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 proposed to price six low volume brachytherapy APCs under this policy (excluding those that are priced using external data). Public commenters supported CMS' proposal that it is finalizing without change.

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 2025

A C-APC is defined as a classification for a primary service and all adjunctive services provided to support its delivery. 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. A single prospective payment is made for the comprehensive service based on the costs of all reported services on the claim. A HCPCS code assigned to a C-APC has a status indicator of "J1" and is referred to as a "J1 code."

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.

Multiple commenters requested that CMS apply a complexity adjustment to additional code combinations other than those listed in Table 2 of the final rule. CMS responded that only one of requested code combinations (HCPCS code 28296 with HCPCS 28270) meets the criteria for a complexity adjustment. CMS is providing a complexity adjustment in the final rule to this additional code combination.

Public commenters made a variety of requests to CMS related to complexity adjustments:

- Not require a minimum of 25 claims.
- Allow complexity adjustments when J1 codes are billed with an add-on code.
- Allow complexity adjustments for clusters of procedures including a J1 code pair and multiple add-on codes.
- Maintain complexity adjustments for three years to improve payment stability.
- Provide additional rationale when CMS is not making requested complexity adjustments.

CMS is not making any changes in its C-APC policy in response to these comments and refers readers to earlier responses on these issues. On the last point, CMS refers readers to the Claims Accounting on CMS' website for additional explanation of why it is or is not making a requested complexity adjustment: https://www.cms.gov/files/document/2025-nfrm-opps-claims-accounting.pdf.

(i) Procedures Assigned to New Technology APCs

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.

(ii) Gene Therapies

CMS proposed to exclude specific gene therapies listed in Table 3 of the final 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 proposed 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 was made for one year only to allow CMS to gather more information from interested parties as to whether this policy appropriately captures all the unique therapies, such as the cell and gene therapies listed in Table 3 that function as primary treatments and do not support C-APC primary services. CMS indicated in the proposed rule that it 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.

Commenters were generally very supportive of the proposal and thought the agency should make the policy permanent. Other commenters suggested additional gene therapies or other classes of products to be made subject to the policy. The HOP Panel and many commenters requested that all separately payable drugs be excluded from packaged C-APC payment.

CMS is only making one change in response to these comments—it will make the policy permanent rather than temporary for one year. Based on public comments, it is adding additional gene therapies to those that may be excluded from packaging with the C-APC payment. The final list of qualifying products can be found in Table 4 of the final rule.

(iii) C-APCs for 2025

As a result of its annual review of the services and APC assignments under the OPPS, CMS did not propose 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 of the final rule. 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. Although CMS did receive several comments on the C-APC policy, it is not making any policy changes in response to them.

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 result in the provision of a complete service. Currently, CMS' composite APC policy applies only for mental health services and multiple imaging services. CMS did not propose 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 is continuing this policy.

3. Changes to Packaged Items and Services

The Consolidated 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 excluding 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.

CMS did not propose any other changes to its overall packaging policy. It did propose to continue to conditionally package the costs of selected newly identified ancillary services into payment for a primary service where it believes that the packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code. There were no public comments on the packaging of newly identified ancillary services.

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 are 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. 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 proposed 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 proposed 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 resulted in the proposed packaging threshold of $630.

CMS' 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 considered using the standard drug packaging threshold of $140 for 2025 as the threshold for separate payment for diagnostic radiopharmaceuticals. However, CMS did 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.

Selected Comments/Responses. Public comments expressed broad support for paying separately for diagnostic radiopharmaceuticals above a packaging threshold. Many commenters were supportive of the $630 packaging threshold while others suggested different, lower thresholds for various reasons. Among those suggesting lower thresholds were those favoring use of the same packaging threshold for separately payable therapeutic drugs.

CMS believes doubling the approximate payment that would typically be attributable to diagnostic radiopharmaceutical payment represents the best policy as it will identify those products that significantly exceed the amount included in the APC and is consistent with the two times rule. This rule utilizes a multiplier of two to determine 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.

With respect to using the same packaging threshold as therapeutic drugs, CMS reiterated its proposed rule rationale for rejecting this policy—diagnostic radiopharmaceuticals are unique and warrant their own specific threshold. Diagnostic radiopharmaceuticals are functioning as supplies to the nuclear medicine procedure in which they are used and are serving as an item that is integral, ancillary, supportive, dependent, or adjunctive to the primary diagnostic service. In contrast, therapeutic drugs, biologicals, and therapeutic radiopharmaceuticals are typically the only therapeutic modality provided to a patient during an encounter and may not serve as an item that is integral, ancillary, supportive, dependent, or adjunctive to the primary service.

CMS is finalizing its policy to separately pay for diagnostic radiopharmaceuticals above a packaging threshold of $630. Any diagnostic radiopharmaceutical with a per day cost at or below that threshold will continue to be policy packaged under the current policy at 42 CFR 419.2(b)(15).

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 it 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).

Like its policy for the drug packaging threshold, CMS proposed 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. CMS also proposed to use the same historical practice for packaging or paying separately for individual radiopharmaceuticals:

- 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 claims data used for the 2025 final rule, would receive separate payment in 2025.

Selected Comments/Responses. Most commenters were supportive of the methodology used to calculate the per day costs, and many commenters were able to analyze the cost data published with the proposed rule and calculate the same list of products with per day costs exceeding $630. Many commenters were concerned about per day cost fluctuations between the proposed and final rules and requested that CMS pay separately for any diagnostic radiopharmaceutical that is proposed for separate in regardless of its per day cost in the final rule.

CMS responded that the updated final rule data did not change the list of qualifying diagnostic radiopharmaceuticals with per day costs above $630 that will be separately paid in 2025. CMS is finalizing its policies described above as proposed.

d. Updating the Diagnostic Radiopharmaceutical Packaging Threshold in 2026

Starting in 2026 and subsequent years, CMS proposed to update the 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.

Selected Comments/Responses. Most commenters supported CMS' proposal for updating the diagnostic pharmaceuticals packaging threshold. A small number of commenters requested that CMS comprehensively review the appropriateness of the threshold amount yearly based on data for that year.

CMS believes it is appropriate to subject the diagnostic radiopharmaceutical packaging threshold to the same update factor that is used for the OPPS drug packaging threshold. Using the PPI for Pharmaceuticals for Human Use (Prescription) provides aggregate changes in the selling prices of

pharmaceuticals, which makes it an appropriate factor with which to update the diagnostic radiopharmaceutical packaging threshold.

CMS is finalizing its proposal to update the packaging threshold without modification. Starting in 2026 and for subsequent years, CMS will update the threshold amount of $630 by the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from IHS Global, Inc (IGI).

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. 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 that CMS would expect based on the cost and mean unit cost (MUC) data submitted by hospitals. Therefore, CMS believes a reasonable alternative for separate payment of diagnostic radiopharmaceuticals that exceed the per day cost threshold is to use MUC from claims data.

While CMS proposed 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 instances where there is more than one manufacturer of a particular diagnostic radiopharmaceutical, CMS proposed that all manufacturers submit ASP information.

CMS notes that ASP submissions for radiopharmaceutical payment under the OPPS would need to meet all 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" form 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 indicated 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 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

[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.

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 HCPCS code prior to establishing a separate payment amount based on ASP.

CMS proposed 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 proposed to make payment at 95 percent of the products' most recent AWP. Payment based on these drug pricing methodologies would be temporary until a MUC is available. For radiopharmaceuticals on pass-through, CMS raises the possibility of continuing to the use of ASP once its pass-through status has ended given that its ASP may be reliable.

The proposed rule indicated 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 can 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 noted that WAC and AWP do not capture all the pricing discounts that are reflected in ASP. If CMS were to use the 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.[3]

CMS believes diagnostic and therapeutic radiopharmaceuticals are clinically similar and use a comparable manufacturing process. It believes Medicare should use the same methodology for payment in situations where diagnostic radiopharmaceuticals are separately paid. 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 proposed 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' policy, HCPCS codes for diagnostic radiopharmaceuticals with per day costs that exceed $630 are assigned a status indicator of "K", indicating separate payment. An APC and a payment rate would be assigned as shown in Addendum B of the final rule. HCPCS codes that

[3] See prior footnote.

describe diagnostic radiopharmaceuticals with per day costs that are at or below the diagnostic radiopharmaceutical packaging threshold would continue to be assigned to a status indicator of "N", indicating packaged payment.

Selected Comments/Responses. Commenters were largely supportive of CMS' proposal to pay for diagnostic radiopharmaceuticals based on their mean unit cost for 2025 but expressed a preference for using ASP pricing long-term. Several commenters recommend CMS apply its low volume APC policy to diagnostic radiopharmaceuticals. Applying the low volume payment policy to separately paid diagnostic radiopharmaceuticals, defined as those with fewer than 100 claims, by using up to four years of claims data and basing the rate on the highest value among the arithmetic mean, geometric mean, or median will improve payment rate stability.

CMS responded that it did not propose to subject low volume diagnostic radiopharmaceutical APCs to the broader OPPS low volume policy. The current low volume APC policy does not apply to APCs to which single drugs, biologicals, or radiopharmaceuticals are assigned, even if there is a low volume of claims for these items. While CMS agrees that this suggested policy modification could result in greater payment stability, it could also result in a decrease in the overall MUC payment rate from using 4 years of cost data. CMS encourages additional engagement on this issue and may propose a different policy in the future.

One commenter indicated that it would not be necessary to update MUC quarterly like it does for ASP where drug prices are reported quarterly to CMS. CMS agrees. MUC will be calculated on an annual basis for the payment of non-pass-through diagnostic radiopharmaceuticals with per day costs exceeding $630. Because it is not adopting an ASP-based payment approach at this time, there is no need to update the payment amounts quarterly as the MUC will be set for the entire calendar year.

Some commenters requested CMS subject additional classes of drugs, such as contrast agents, to this policy. These commenters argued that the same reasoning applied to diagnostic radiopharmaceuticals would apply to other product classes. CMS responded that it will take these comments into consideration for future rulemaking.

CMS is finalizing its proposal to pay for non-pass-through, separately payable diagnostic radiopharmaceuticals using MUC, as the ASP data is not usable for the purpose of paying for diagnostic radiopharmaceuticals. The finalized list of diagnostic radiopharmaceuticals that have calculated per day costs that exceed $630, and their status indicators, can be found in Table 9 of the final rule.

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 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 payment rule year (2025). Holding all other variables constant, CMS multiplies the 2024 final relative weights and the 2025 final relative weights respectively for each APC by its associated volume from 2023. It sums the 2024 and final 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 1.4452. The unscaled proposed 2025 relative payments are multiplied by 1.4452 to determine the 2025 scaled relative weights that are shown in Addenda A and B.

Separately payable drugs and diagnostic radiopharmaceuticals above the packaging threshold 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, separately payable drugs and diagnostic radiopharmaceuticals are not affected by the budget neutrality adjustment.

B. Conversion Factor Update

The final 2025 conversion factor is $89.169 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	1.0129	$88.506
Wage Index Budget Neutrality	0.9927	$87.860	0.9927	$87.860
Cap on Wage Index Reductions	0.9995	$87.816	0.9995	$87.816
Cancer Hospital Adjustment	1.0005	$87.860	1.0005	$87.860
Rural Hospital Adjustment	1.0000	$87.860	1.0000	$87.860
Update	1.0290	$90.408	1.0090	$88.651
Pass-Through/Outlier	0.9863	$89.169	0.9863	$87.436
2025 Conversion Factor	**$89.169**	**$89.169**		**$87.436**

Note: CMS provides a similar table to this one in the final rule but only for the full update. The reduced update columns are created by HPA. CMS indicates that the CF for hospitals that do not receive the full update is $87.439 or $0.003 above HPA's calculation.

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).[4] Wage index budget neutrality is 0.9927 (-0.73 percent) for 2025. The cap on reductions to the wage index requires a budget

[4] Removing the budget neutrality adjustment from the prior year requires division so the factor equals 1.0/(1-0.01-0.0027) or 1.0127.

neutrality adjustment of 0.9995 (-0.05 percent) for 2025. The cancer hospital adjustment is 1.0005 (0.05 percent). The rural sole community hospital adjustment is 1.0000 (0.0 percent) for 2025.

The update of 1.029 (2.9 percent) equals the market basket of 3.4 percent less 0.5 percentage points for productivity for 2025. This update is the same as was included in the FY 2025 IPPS final rule and is based on the IGI second quarter 2024 forecast of the FY 2025 hospital market basket with historical data through the first quarter of 2024. The productivity estimates are from the same period.[5]

CMS estimates that pass-through spending for drugs, biologicals and devices for 2025 will be just over $328.28 million, or 0.37 percent of OPPS spending. The outlier adjustment is 0.99 (-1.0 percent). The combined adjustment for pass-through and outliers is 0.9863 (-1.37 percent).

The 2025 conversion factor for hospitals that submit quality data is $88.169. The conversion factor for hospitals that do not submit quality data is subject to all the same adjustments except the update is 1.009 (0.9 percent) instead of 1.029 (2.9 percent). The conversion factor for hospitals that do not submit quality data is $87.439 according to CMS ($0.003 higher than the amount HPA calculates in the above table).

C. Wage Index Changes

CMS proposed to continue using a labor share of 60 percent and the fiscal year IPPS post-reclassified wage index for the OPPS in 2025. The proposed rule directed readers to the IPPS rule for more details regarding specific policies affecting the 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 final rule to update labor market areas based on CBSA revisions issued by the Office of Management and Budget following the 2020 Census. These same changes adopted for the IPPS were proposed to apply to hospitals paid under the OPPS. CMS received several public comments on changes to the CBSA delineations in the 2025 OPPS proposed rule. These comments and CMS' responses are like, if not identical, to those in the FY 2025 IPPS rule and are not being repeated here.

For non-IPPS hospitals paid under the OPPS for 2025, CMS proposed to continue its past policies of assigning the wage index that would be applicable if the hospital were paid under the IPPS and allowing the hospital to qualify for the out-migration adjustment—an adjustment that a hospital may qualify for if a high proportion of its workers commute to adjacent higher wage areas. For CMHCs, CMS proposed to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. CMS notes that, consistent with its current policy, the wage index that applies to CMHCs includes the rural floor adjustment but not the out-migration adjustment, which only applies to hospitals.

[5] The final rule presents public comments and responses on the market basket and productivity adjustment that are very similar, if the not the same, as those included in the IPPS rule and are not repeated in this summary.

Low Wage Index Policy

For FY 2020, CMS adopted a low-wage index policy under the IPPS where it increased wage indexes below the 25th percentile by one-half the difference between the hospital's otherwise applicable wage index and the 25th percentile wage index value. CMS applied a budget neutrality adjustment for the low wage index policy such that increasing the wage index for the affected hospitals did not increase Medicare spending. This policy has been in place every year under the IPPS since FY 2020.

Since the IPPS wage index is also applied under the OPPS, the low-wage index policy and a budget neutrality adjustment specific to the OPPS have also applied under the OPPS since 2020. On July 23, 2024, the Court of Appeals for the D.C. Circuit held that the Secretary lacked authority under section 1886(d)(3)(E) of the Act or under the "adjustments" language of section 1886(d)(5)(I)(i) of the Act to adopt the low wage index hospital policy for FY 2020 for the IPPS, and that the policy and related budget neutrality adjustment in the IPPS must be vacated.[6] In consideration of the court decision, CMS subsequently issued an interim final rule with comment (IFC) to remove the low wage index hospital policy for FY 2025 IPPS purposes.[7]

CMS is not discontinuing the low wage index policy or its budget neutrality adjustment under the OPPS. In CMS' view, the statutory language governing the wage index under the IPPS and OPPS is different and allows for different policies under each respective payment system. Statutory language that the Court found precludes the policy under the IPPS does not apply to the OPPS, according to CMS.

Specifically, section 1886(d)(3)(E) of the Act requires that CMS base the IPPS wage index on a comparison of:

> the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level…on a survey conducted by the Secretary (and updated as appropriate) of the wages and wage–related costs of subsection (d) hospitals in the United States…

Section 1833(t)(2)(D) of the Act that requires CMS to determine an OPPS wage index does not contain the same prescriptions that apply to the IPPS in the above language. In addition, CMS has authority to apply the low wage index hospital policy to the OPPS wage index under section 1833(t)(2)(E) of the Act, which allows the Secretary to:

> establish, in a budget neutral manner, …other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals.

[6] *Bridgeport Hosp. v. Becerra*, 108 F.4th 882, 887–91 & n.6 (D.C. Cir. 2024)
[7] CMS-1808-IFC

CMS believes implementing the low wage index hospital policy is a valid exercise of the Secretary's authority to adopt "adjustments" to payments under the OPPS statute "necessary to ensure equitable payments." Further, CMS notes that the authority under which it would adopt the low-wage index hospital policy under the OPPS states explicitly that the policy must be adopted budget neutral.

CMS further adds that its policy is consistent with 42 CFR § 419.43(c), which states:

> CMS uses the hospital inpatient prospective payment system wage index established in accordance with Part 412 of this chapter to make the adjustment specified under paragraph (a) of this section.

The OPPS wage index values will match the IPPS wage index values in the FY 2025 IPPS final rule, as corrected in the FY 2025 IPPS final rule correction,[8] which were "established in accordance with Part 412". CMS states that it is merely declining to incorporate certain modifications to those values made in the IFC, which reflect extraordinary steps taken due to the timing of the court's decision in *Bridgeport Hospital*.

According to CMS, the application of the low wage-index-hospital policy under the OPPS for 2025 avoids unexpected and arguably unfair payment consequences for hospitals that were not plaintiffs in the *Bridgeport* case and so falls within its equitable adjustment authority. The final rule acknowledges the divergence between the OPPS wage index values 2025 and the ultimate, effective FY 2025 IPPS wage index values for some hospitals, but CMS continues to believe that the concerns related to the wage index that led to the application of this policy to the OPPS wage index in previous years continue to apply.

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

In cases where there is no data to calculate a hospital's CCR, CMS is continuing to use 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 uses 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 is continuing to apply 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,

[8] 89 FR 80098

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 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 estimated a PCR of 0.87 (or 87 percent) for non-cancer hospitals. After reducing this PCR by 1.0 percentage point, the proposed 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 an 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 was 0.88 and the otherwise applicable 2025 PCR without a limit would be 0.86, CMS proposed a target PCR of 0.87 that reflects a cap on the reduction of 0.01. Public commenters supported this proposal that CMS is finalizing without change.

Table 12 in the final 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 51.6 percent. CMS indicates that the reduction in the cancer hospital adjustment requires a budget neutrality adjustment of +0.05 percent.

G. Outpatient Outlier Payments

CMS makes OPPS outlier payments on a service-by-service basis when the cost of a service exceeds the outlier threshold. For 2025, CMS proposed to continue setting aside 1.0 percent of the estimated aggregate total payments for OPPS outlier payments. It proposed calculating the fixed-dollar threshold using the same methodology that was used to set the threshold for 2024 and previous years. For 2025, CMS proposed 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 proposed to set aside a portion of the 1.0 percent outlier pool—specifically, an amount equal to less than 0.01 percent of outlier payments—for CMHCs' partial hospitalization program outlier payments. If a CMHC's cost for partial hospitalization services paid using 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 using 2023 Medicare claims data to set the 2025 outlier threshold. To model hospital outlier payments and set the outlier threshold, CMS applied a charge inflation factor of 1.08406 to approximate 2025 charges from 2023 claims.

The final rule indicates that CMS is using hospital-specific overall ancillary CCRs from the July 2024 update to the Outpatient Provider-Specific File to determine the 2025 final rule outlier threshold. CMS adjusted the July 2024 CCRs by 1.015123 to approximate 2025 CCRs.

For 2025, CMS is adopting a fixed dollar threshold of $7,175 (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 0.65 percent of total OPPS payments as outliers, or 0.35 percentage points less than the 1.0 percent target. Using 2023 Medicare utilization, CMS estimates that it will pay 0.83 percent of total OPPS payments as outliers in 2024, or 0.17 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).[9] Generally, code changes

[9]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

are effective January 1, April 1, July 1, or October 1. For 2025, the interim and final status indicators, APC assignments, and payment rates can be found in Addendum B of this final rule.[10]

1. April 2024 Codes

In the April 2024 OPPS quarterly update, CMS created 73 new Level II HCPCS codes (Table 10 of the proposed rule). These codes have an interim OPPS payment status for 2024 and were subject to public comment. For those codes where there were no public comments, CMS is finalizing its proposed status indicator and APC assignments without change. These codes and their long descriptors are listed in Table 14 of the final rule. Final APC assignments and status indicators can be found in Addendum B of the final rule. Public comments on the remaining codes are presented in section III. E. of this summary.

2. July 2024 HCPCS Codes

In the July 2024 OPPS quarterly update, CMS established 130 new codes effective July (Table 11). These codes have an interim OPPS payment status for 2024 and were subject to public comment. For those codes where there were no public comments, CMS is finalizing its proposed APC assignment without change. These codes and their long descriptors are listed in Table 15 of the final rule. Final APC assignments and status indicators may be found in Addendum B of the final rule. Public comments on the remaining codes are presented in section III. E. of this summary.

3. October 2024 HCPCS Codes

In the October 2024 OPPS quarterly update, CMS established 107 new codes effective October 1 and assigned them interim OPPS status indicators and APCs. These codes are flagged with commenter indicator "NI" in Addendum B of the OPPS final rule and are currently subject to public comment. These codes and their long descriptors are listed in Table 16 of the final rule. Interim 2025 APC assignments and status indicators may be found in Addendum B of the final rule.

4. January 2025 HCPCS Codes

a. New Level II HCPCS Codes – Subject to Public Comment

CMS is soliciting comments on the new Level II HCPCS codes that will become effective January 1, 2025, in this final rule. Unlike the CPT codes that are effective January 1, 2025, and made subject to comment in the proposed rule and except for new C-codes and G-codes listed in Addendum O of the 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.

procedures and services not described by CPT codes).

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

New Level II HCPCS codes that will be effective January 1, 2025, are flagged with comment indicator "NI" in Addendum B, indicating that the codes have an interim OPPS payment status for 2025 and are subject to public comments. Comments may be made on the interim 2025 status indicators, APC assignments, and payment rates. CMS will finalize these determinations in the 2026 OPPS/ASC final rule.

b. CPT Codes – Subject to Public Comment

For 2025, CMS received CPT codes that are effective January 1, 2025, in time to be included in the proposed rule. CMS requested comments on the proposed APC assignment, payment rates and status indicators. The status indicators and APC assignments for these codes are final in this rule.

Table 17 (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 Two Times Rule

In accordance with section 1833(t)(2) of the Act, CMS annually reviews the items and services within an APC group to determine, with respect to resource comparability, if the highest cost item or service within an APC group is more than two times greater than the lowest cost item or service within that same group. In making this determination, CMS considers 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) made recommendations for specific services for the 2025 OPPS. CMS' responses to HOP Panel recommendations are discussed throughout section II.E or where applicable in this summary.

2. APC Exceptions to the Two Times Rule

CMS may make exceptions to the two 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 make exceptions to the two times rule:

- Resource homogeneity.
- Clinical homogeneity.
- Hospital outpatient setting utilization.
- Frequency of service (volume).
- Opportunity for upcoding and code fragments.

In the proposed rule, CMS identified 23 APCs with a violation of the two times rule. All 23 of those met the requirements for an exception. There were no public comments on CMS' proposal to except all 23 APCs from the two times rule. In the final rule, CMS identified another five APCs with a two times violation (28 in total including the 23 from the proposed ruled). These additional five APCs also met the criteria for the exception of the two times rules. CMS is finalizing its proposal to except 23 APCs from the two times rule and also except another five APCs in the final rule. Table 18 of the final rule lists all APCs where there was a two times rule violation where CMS is making an exception.

CMS notes that in cases in which a recommendation by the Panel appears to result in a violation of the two 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.

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 midpoint of the APC's assigned cost band. The payment rates for New Technology APCs are included in Addendum A of the final 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 two times rule.

In the 2019 OPPS/ASC final rule, CMS finalized a payment methodology for low-volume services assigned to a New Technology APC.[11] 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 four years of claim data.

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

Public commenters were generally in agreement with CMS' proposal but recommended that the threshold for being exempt from the universal low-volume APC policy be increased from 10 to 25 claims. CMS responded that it would finalize its proposal without change because at 10 claims a rough standard distribution begins to appear.

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 two years if sufficient claims data are available and also to retain a service in a New Technology APC for more than two years if there is not sufficient claims data for basing a reassignment.

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

2025 New Technology APC and Status Indicator Assignments				
HCPCS	**Long Descriptor**	**2025 SI**	**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 34 claims over 4 years. CMS will assign code to APC

[11] 83 FR 58892-58893

2025 New Technology APC and Status Indicator Assignments				
HCPCS	**Long Descriptor**	**2025 SI**	**2025 APC**	**Notes**
				1563 based on universal low volume APC methodology.
G0562	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 is maintaining 2024 interim assignment. Code G0562 is a replacement for C9794.
G0563	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 is maintaining 2024 interim assignment. Code G0563 is a replacement for C9795.
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 is 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 is maintaining current APC assignment.
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 assign the code to APC 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	1520	Using 4 years of claims data including additional claims in the final rule, proposed assignment being changed from APC 1521 to APC 1520.
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	S	1521	Sufficient 2023 claims data to assign code to APC 1522 in the proposed rule. Change to geometric mean costs in final

2025 New Technology APC and Status Indicator Assignments				
HCPCS	**Long Descriptor**	**2025 SI**	**2025 APC**	**Notes**
	(e.g., myocardial viability); with concurrently acquired computed tomography transmission scan			rule results in assignment to APC 1521.
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 is 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 suggest a cost of $498 which is below the current APC payment. CMS is maintaining 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	No claims for this procedure. CMS is 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 is maintaining current APC assignment.
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 is 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	S	1579	APC assignment based on the low volume methodology. Assignment changed from 1578 to 1579 in the proposed rule and finalized without change.

2025 New Technology APC and Status Indicator Assignments				
HCPCS	**Long Descriptor**	**2025 SI**	**2025 APC**	**Notes**
	catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed			
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 is 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	1511	Proposed APC assignment based on the low volume methodology. Assignment changed from 1511 to 1504. Proposal not finalized. CMS maintaining assignment to 1511 agreeing with commenters that low volume of claims does not justify reassignment.
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	1511	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 is 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 is 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., organ, gland, tissue, target structure) during the same session; multiple organs	S	1511	Proposed APC assignment based on the low volume methodology. Assignment changed from 1511 to 1509. Proposal not finalized. CMS maintaining assignment to 1511 agreeing with commenters that low volume of claims does not justify reassignment.

2025 New Technology APC and Status Indicator Assignments				
HCPCS	**Long Descriptor**	**2025 SI**	**2025 APC**	**Notes**
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	1511	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 is 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	Add-on code to 0723T assigned to the same APC.
0662T	Scalp cooling, mechanical; initial measurement and calibration of cap	S	1519	Proposed APC assignment based on the low volume methodology to 1515. Additional data in the final rule results in assignment to APC 1519.
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	1513	Sufficient claims to determine a geometric mean cost. Proposed APC assignment to 1512 in 2025 from 1513. Changed to 1513 based on additional data in final rule. CMS considering assigning to a clinical APC for 2026.
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	1516	Sufficient claims to determine a geometric mean cost. Proposed APC assignment to 1518 in 2025 from 1520. Changed to 1516 based on data in the final rule. CMS considering assigning to a clinical APC for 2026.
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 is maintaining the current APC assignment

2025 New Technology APC and Status Indicator Assignments				
HCPCS	**Long Descriptor**	**2025 SI**	**2025 APC**	**Notes**
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 anesthesia in an approved investigational device exemption (IDE) study	S	1537	Code effective October 1, 2023. No claims. CMS is maintaining the 2024 APC assignment for 2025.
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 is maintaining the 2024 APC assignment for 2025.
0889T	Personalized target development for accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation derived from a structural and resting-state functional MRI, including data preparation and transmission, generation of the target, motor threshold–starting location, neuronavigation files and target report, review and interpretation	S	1511	Code not effective until July 1, 2024. No claims. CMS assigning to APC 1511 based on expected resource utilization.
0890T	Accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation, including target assessment, initial motor threshold determination, neuronavigation, delivery and management, initial treatment day	S	1525	Code not effective until July 1, 2024. No claims. CMS proposed assignment to APC 1522 but changing to 1525 based on public comments.
0891T	Accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent treatment day	S	1525	Code not effective until July 1, 2024. No claims. CMS proposed assignment to APC 1522 but changing to 1525 based on public comments.
0892T	Accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent motor threshold redetermination with delivery and management, per treatment day	S	1525	Code not effective until July 1, 2024. No claims. CMS proposed assignment to APC 1522 but changing to 1525 in the final rule. Public commenters requested 1528.

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 APCs 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 proposed 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 relative weights. See Table 64 of the final rule for the APCs (other than New Technology APCs listed above) where CMS is using the low-volume rate setting methodology.

E. APC-Specific Policies

This section describes areas where CMS discussed APC-specific policies in the proposed rule or where there was no proposed rule discussion but there were comments based on status indicator and APC assignments in the proposed rule addenda. There may have been placeholder codes for these codes in the proposed rule that have now been made final. The below uses the final rule codes, not their placeholder codes. All payment amounts are from the proposed rule Addenda unless otherwise indicated.

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 requested comments in the proposed rule 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 stated in the proposed rule that it will decide whether to revise the payment methodology for 2025 using a simulated geometric mean cost based on the study it conducted.

Public commenters indicated that cardiac CT services involve resources across both the cardiology and radiology departments. Commenters described cardiac CT services as resource intensive, stating that the cross-department coordination between cardiology and radiology, the skill level of staff (technicians, nurses, and physicians), the expense of up-to-date CT equipment, and the amount of testing time involved is comparable to other more expensive and invasive cardiac tests.

There were additional comments indicating barriers to reporting costs and charges in a cardiac cost center despite the removal of the CMS edit, due to third-party edits (billing and payer) in place from clearinghouses, billing companies, or billing software companies. There were also public comments requesting CMS do further provider education instructing hospitals that they may bill for cardiac CT services using a cardiology cost and revenue center.

CMS acknowledged that, even with the revenue code edit removed for 2024, there remain procedural and logistical hurdles to providers billing with the cardiology revenue codes in 2024. While CMS has consistently stated that hospital outpatient facilities must determine the most appropriate cost center and revenue code for the cardiac CT codes, it will be providing further public education and instruction through the CMS Medicare Learning Network.

In the final rule, CMS is using its equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the payment for the cardiac CT services in 2025 using an alternative to its traditional methodology for calculating APC relative weights. CMS is finalizing a temporary reassignment of the cardiac CT codes (CPT code 75572 through 75574) to APC 5572 (Level 2 Imaging with Contrast).

Based on comments received on the proposed rule, CMS anticipates that it may take 3 to 4 years to see an impact from changes in billing practices that will result in common use of the cardiology cost center for cardiac CT services. For this reason, CMS will leave in place its policy of assigning cardiac CT codes to APC 5572 beyond 2025 for "several years." The final rule does not specify how many years this policy will stay in place but states "if we do not see a significant change in the geometric mean costs after several years, [CMS] would revert payment for these services to the standard OPPS payment methodology and assign the cardiac CT codes to appropriate APCs based on their geometric mean costs."

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 five level APC structure for these APCs, it did propose to reassign HCPCS codes 0266T and 33276 from New Technology APC 1580 to Level 5 neurostimulator APC 5465. CMS

also requested public comments on whether to adopt a 6-level structure for these APCs even though it has rejected those comments in the past.

The HOP Panel and several commenters requested that CMS either create a new Level 6 Neurostimulator and Related Procedures APC where CPT codes 33276, 64568, and 0266T could be assigned, or alternatively, assign these three codes to New Technology APC 1580. CPT codes 33276 and 0266T are currently assigned to New Technology APC 1580 (New Technology—Level 43 ($40,001– $50,000)). CPT code 64568 is currently assigned to APC 5465 (Level 5 Neurostimulator and Related Procedures).

CMS believes that the 5 level APC structure for neurostimulator and related procedures remains appropriate. However, CMS recognizes the concerns regarding reassigning HCPCS codes 0266T and 33276 from New Technology APC 1580 to APC 5465. CMS will retain these codes in New Technology APC 1580 in the final rule.

For HCPCS code 64568, CMS believes its current assignment to APC 5465 (Level 5 Neurostimulator and Related Procedures) remains appropriate. The code has been assigned to this APC series for many years. There is sufficient claims volume to assign HCPCS code 64568 to a clinical APC based on its geometric means costs rather than a New Technology APC that is for low volume services with insufficient claims volume to be assigned to a clinical APC.

3. Focal Laser Ablation (APC 5374)

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 proposed 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 for 2025. One commenter supported CMS' proposal that it is finalizing without change.

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.

For 2025, CMS proposed 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 proposed 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. CMS is finalizing these proposals without change.

5. 3D Contour Simulation, CPT Code 0944T (APC 5523)

The AMA CPT Editorial Panel established CPT code 0944T effective January 1, 2025. CMS proposed to assign 0944T to status indicator "E1" to indicate that the code is not payable by Medicare when submitted on outpatient claims because the service had not received FDA clearance at the time of the proposed rule.

The CAS-One® IR has since received FDA clearance and will be assigned status indicator "Q1" indicating a conditionally packaged procedure. CPT code 0944T will be packaged when it is provided with a significant procedure but will be separately paid when the service appears on the claim without a significant procedure. CMS is assigning CPT code 0944T to APC 5523 (Level 3 Imaging without Contrast) with a final payment rate of approximately $240.00.

6. Administration of Lacrimal Ophthalmic Insert into Lacrimal Canaliculus, CPT code 68841 (APC 5503)

Dextenza is a drug indicated for treatment of ocular inflammation and pain. CPT code 68841 is used to code the insertion of the drug in a natural opening in the eyelid (called the punctum) and deliver a tapered dose of dexamethasone to the ocular surface for up to 30 days. This CPT code has an OPPS status indicator of "Q1" indicating that it is conditionally packaged. The code is only paid when performed by itself and not with a significant procedure. Under the ASC payment system, CPT code 68841 would be packaged, as it would always be performed with a surgical procedure on the covered ASC list. For 2025, CMS proposed to continue assigning status indicator Q1 to CPT code 68841 stating the assignment remains applicable because the procedure is performed 98 percent of the time with another surgical procedure.

Public commenters requested that CMS change the status indicator for CPT code 68841 so that it is always separately paid. These commenters provided examples of other procedures that are performed independently at a frequency of 2 percent or a lower percentage that are assigned a separately payable status indicator. They also believe CPT code 68841 is like other procedures for introducing a product to the eye, such as CPT code 66020 (Injection, anterior chamber of eye (separate procedure); air or liquid) that do not have a conditional payment status indicator.

CMS disagreed stating it has long maintained that Dextenza is a drug that functions as a surgical supply and should be conditionally packaged under the OPPS and ASC payment systems. Historically, CMS has stated that it considers all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management

drugs, to be part of the surgery for purposes of its drug and biological surgical supply packaging policy (79 FR 66875).

CMS further added that its policy is not hindering utilization of Dextenza as billing increased from approximately 260,000 to 320,000 units between 2022 and 2023. While CMS is not changing the payment status indicator for CPT code 68841, it notes that Dextenza will be eligible for separate payment as non-opioid drug that manages pain for three years under its implementation of section 4135 of the CAA, 2023. This policy is discussed further in section XIII.F. of this summary.

7. Application of Rigid Total Contact Leg Cast, CPT Code 29445 (APC 5102)

The HOP Panel and several commenters requested that CMS consider HCPCS code 29445 a separately payable code when performed concurrently on the same date of service as several other codes such as a debridement or graft procedure. The commenters indicated a National Correct Coding Initiative edit precludes billing the two procedures on the same date. CMS will take commenters' suggestions into consideration for future rulemaking.

8. Aquabeam Waterjet Ablation Procedure, CPT Code 0421T (APC 5376)

CMS proposed to assign CPT code 0421T to APC 5376 (Level 6 Urology and Related Services) with a geometric mean cost of $9,356. One public commenter supported this proposal that CMS is finalizing without change.

9. Aqueous Shunt to Extraocular Plate Reservoir Procedure, CPT Code 66180 (APC 5493)

For 2025, CMS proposed to maintain the APC assignment of CPT code 66180 to APC 5492 (Level 2 Intraocular Procedures) with a payment rate of $3,873. Two commenters requested CMS reassign CPT code 66180 to APC 5493 (Level 3 Intraocular Procedures) due to the code's similarity to CPT code 66179 (Aqueous shunt to extraocular equatorial plate reservoir, external approach; without graft) which CMS proposed to assign to APC 5493 for 2025. The commenters further indicated that the cost data is more consistent with CPT code 66180 being assigned to APC 5493. CMS agreed with the commenters and finalized an assignment of CPT code 66180 to APC 5493.

10. Arteriovenous Fistula (AVF) Creation Procedures, CPT Codes 36836 and 36837 (APC 5194)

For 2025, CMS proposed to continue assigning CPT codes 36836 and 36837 to APC 5194 (Level 4 Endovascular Procedures) with a payment rate of $17,956. There were comments supporting CMS' proposal and others that indicated CPT code 36836 should be assigned to a lower paying APC than 5194 where the commenters believe it is overpaid. CMS responded that it continues to believe that CPT code 36836 is more similar clinically to services in APC 5194, which includes more complex endovascular procedures, than those in APC 5193, which primarily contains less complex revascularization and embolization procedures. CMS further believes additional claims and clinical data would be useful before moving this code to a different APC.

11. Arthroscopic Subacromial Balloon Implant, HCPCS Code C9781 (APC 5115)

CMS proposed to continue assigning HCPCS code C9781 to APC 5115 (Level 5 Musculoskeletal Procedures) with a payment rate of $12,755.58. Public commenters supported CMS' proposal that it is finalizing without change.

12. Artificial Iris Insertion Procedures, CPT Code 66683 (APC 5496)

CMS proposed to assign the placeholder code 66683 to APC 5496 (Level 6 Intraocular Procedures) with a payment rate of around $16,416. Commenters supported CMS' proposal that it is finalizing without change.

13. Bronchoscopy with Needle Biopsy, CPT Code 31629 (APC 5154)

CMS proposed to continue assigning CPT code 31629 to APC 5154 (Level 4 Airway Endoscopy) with a payment rate of $3,681.38. One commenter stated that CPT code 31629 is the highest cost significant procedure in APC 5154 with a geometric mean cost of $5,123.33 that exceeds the geometric mean cost of the lowest cost significant procedure in APC 5155.

CMS responded that the geometric mean cost of the CPT code 31629 is $1,974 lower than the geometric mean cost of APC 5155 and does not violate the two times rule in APC 5154. Further, CMS finds CPT code 31629 is more clinically and resource similar with other procedures in the APC where it is currently assigned. CMS is finalizing its proposal without modification.

14. CADScor System, CPT Code 0716T (APC 5733)

For 2025, CMS proposed to assign CPT 0716T to APC 5733 (Level 3 Minor Procedures) with a payment rate of $59.07 and a status indicator of "Q1" (conditionally packaged). Public commenters disagree with the conditional packaging status indicator and believe the service should always be paid separately. With conditional packaging, the service will always be packaged as it is furnished in conjunction with an emergency department visit. Commenters also believe CPT code 0716T should be assigned to APC 5722 based on clinical and resource homogeneity with other services assigned to that APC.

CMS responded that it has no claims data for this procedure and will maintain its current APC assignment until it has claims data to support a different APC assignment. However, CMS agrees with commenters that CPT code 0716T should not be conditionally packaged as it is unlikely the service would be furnished without an emergency department visit. CMS is revising the status indicator for the code from "Q1" (conditionally packaged) to "S" (Procedure or Service, Not Discounted When Multiple) to indicate that the service is paid separately.

15. Cardiac Magnetic Resonance Imaging, CPT Codes 75561 and 75563 (APCs 5572 and 5573)

CMS proposed to maintain the APC assignments for CPT code 75561 to APC 5572 and CPT code 75563 to APC 5573. A public commenter requested CMS reassign of one or both procedures to a higher paying APC based clinical or resource homogeneity. However, CMS reviewed its data and believes the high volume of claims and the geometric means support the proposed assignments.

16. CardioMEMS, HCPCS Code G0555, CPT Code 93264 (APCs 5724 and 5741)

The CardioMEMS Heart Failure System (CPT code 33289) enables patients to transmit critical heart failure status information to clinicians regularly, potentially eliminating the need for frequent clinic or hospital visits. Interested parties have requested that CMS establish coding for clinical scenarios when crucial components of the system require replacement.

CMS proposed such a code (G0555) in the 2025 physician fee schedule proposed rule. While this code was not discussed in the OPPS proposed rule, it was included in Addendum B with an assignment to APC 5741 (Level 1 Electronic Analysis of Devices) with a payment rate of $36.90 and a conditionally packaged status indicator of Q1. CPT Code 93264 is for remote monitoring of a wireless pulmonary artery pressure sensor by a physician or other qualified health care professional that has a status indicator of "M" to indicate that this code is not payable under the OPPS.

Commenters requested changes to proposed code G0555 to clarify that it is for the replacement patient electronics system (PES) and does not include "reporting of test results to physician or qualified health care professional". Commenters requested that the revised code be assigned to APC 1528 (New Technology - Level 28 ($5001-$5500)), which they believe is reflective of the cost of the replacement PES.

CMS agrees that the proposed APC assignment does not represent the costs of the replacement PES. For 2025, CMS is revising the assignment for HCPCS code G0555 to APC 5724 (Level 4 Diagnostic Tests and Related Services) with a separately payable status indicator of "S" instead of a conditionally packaged status indicator and a payment rate of $1,017.

Commenters also requested that CMS change the status indicator for CPT 93264 to separately payable like CMS' treatment of similar monitoring procedures (e.g., CPT codes 93297 and 93298) under the OPPS. CMS agreed and will provide CPT code 93264 with a conditional packaging status indicator of Q1 and assign it to APC 5741 (Level 1 Electronic Analysis of Devices), the same status indicator and APC assignment as CPT codes 93297 and 93298.

17. Caregiver Training Services, HCPCS Codes GCTD1, GCTD2, and GCTD3 (APC 5731)

CMS proposed to establish new coding and payment for caregiver training for direct care services and support in the 2025 PFS rule. The topics of training could include techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control. Unlike other caregiver training codes that are currently paid under the PFS, the caregiver training codes for direct care services and supports focus on specific clinical skills aimed at the caregiver effectuating hands-on

treatment, reducing complications, and monitoring the patient when the patient is not capable to do so themselves.

CMS did not propose an APC assignment or status indicator for these G codes in the 2025 OPPS proposed rule. Public commenters requested that CMS give these codes a payable status indicator under the OPPS to recognize the different types of hospital staff that can render appropriate care training services. CMS is giving these codes an interim status indicator "A" under the OPPS to indicate that these codes are payable under a fee schedule or payment system other than the OPPS. Because CMS did not propose APC and status indicator assignments in the OPPS proposed rule, the status indicator is interim and subject to public comment.

18. Chimeric Antigen Receptor Therapy (CAR T), CPT Codes 0537T, 0538T, 0539T, and 0540T (APC 5694)

Chimeric Antigen Receptor T-Cell (CAR T-cell) therapy is a cell-based gene therapy in which T-cells are collected and genetically engineered to express a chimeric antigen receptor that will bind to a certain protein on a patient's cancerous cells. The CAR T-cells are then administered to the patient to attack certain cancerous cells, and the individual is observed for potential serious side effects that would require medical intervention. Even though the harvesting of the cells and the cell processing (leukopheresis) is performed by hospitals at a different point in time than the administration, CMS does not allow separate or packaged payment for these services. The codes have a non-payable status indicator.

The AMA created four new Category I CPT codes to replace the Category III codes that were established in 2019. CMS proposed to continue the prior status indicators for these new codes as the codes they are replacing, indicating that these codes describe the various steps required to collect and prepare the genetically modified T-cells, and Medicare does not generally pay separately for each step used to manufacture a drug or biological. Public commenters raised the following issues:

- Program Integrity: CMS' policy to consider the dose collection and preparation services performed by hospitals to be part of the manufacturing process of the drug raises significant program integrity concerns. If these services are part of the manufacturing process, commenters indicate that hospitals must seek payment of their costs from the drug manufacturer that raises potential violations of anti-kickback statutes.
- Unrecognized Hospital Costs: Cell collection and leukapheresis services are costly and labor-intensive. If the hospital provides these services and does not provide the administration—either because the patient receives the administration elsewhere or is unable to receive the administration due to illness or death—the hospital receives no compensation for reasonable services. The commenters indicated that in 10 to 15 percent of the cases, a hospital does cell collection and leukapheresis services but does not administer the product.
- Inconsistency with PFS Proposed Rule: CMS is seeking comment on the direct practice expenses associated with cell collection and leukapheresis services in the 2025 PFS rule,

suggesting that these services will be paid separately under the PFS when performed in a physician office but not under the OPPS.[12]

- Improper Coding Policy: Under the Health Information Portability and Accountability Act that governs medical code sets, the HCPCS Workgroup describes HCPCS Level II as "…a standardized coding system that is used primarily to identify drugs, biologicals and non-drug and nonbiological items, supplies, and services not included in the CPT code set."[13] CMS needs to revise the product specific Q-codes to remove "leukapheresis and dose preparation procedures" as these services can be described by Level I HCPCS codes.
- Inconsistency with Other Services: CMS' policy for CAR T is consistent with other drug services that use similar processes for cell collection and leukapheresis (J3394 and J3393) (Injection, betibeglogene autotemcel, per treatment), which in a commenter's view is like CAR T-cell therapy and requires similar dose preparation procedures.
- HOP Panel: Commenters supported the HOP Panel's recommendation to give these codes a status indicator of S and place the code in APC 5242, Level 2 Blood Product Exchange and Related Services.

CMS continues to believe that these codes describe the various steps required to collect and prepare the genetically modified T-cells, and Medicare does not generally pay separately for each step used to manufacture a drug or biological product. Therefore, CMS does not believe that separate or packaged payment under the OPPS is necessary for the procedures described by CPT codes 38225, 38226, and 38227 for 2025. Payment for these services is incorporated into the drug codes.

With respect to the inclusion of cell collection and leukapheresis in the product specific Q codes for CAR T, CMS is not revising its descriptors or its guidance that Medicare payment for the various steps required to collect and prepare CAR-T is included in payment for the biological. CMS states:

> We thank commenters for their feedback and for raising concerns related to our guidance contained in MLN Matters Article SE19009. We are not revising this document at this time as we believe these instructions are consistent with our longstanding policies, but we understand the feedback provided.

19. Complex Bunion Correction Procedure CPT Code 28297 (APC 5115)

CMS proposed to move CPT code 28297 from APC 5114 (Level 4 Musculoskeletal Procedures) to APC 5115 (Level 5 Musculoskeletal Procedures) with a payment rate of $12,755.58. Public commenters supported CMS' proposal that it is finalizing without change.

20. Computational Electrocardiogram (ECG) Analysis System (vMap), CPT Code 0897T (APC 5724)

[12] While CMS does not address this issue in the OPPS rule, CMS adopted a bundled status indicator for these services under the PFS. Nevertheless, there remains an inconsistency between the PFS and OPPS as the services are bundled under the PFS and non-payable under the OPPS.

[13] CMS, Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures, Baltimore (MD): CMS, December 2022, pg. 1. Healthcare Common Procedure Coding System Level II Coding Procedures (cms.gov).

Effective July 1, 2024, CMS recognized CPT code 0897T that utilizes ECG data to identify potential arrhythmia focal points for patients. CMS assigned this code to APC 5724 (Level 4 Diagnostic Tests and Related Services) for 2024 and proposed to continue this assignment for 2025. Public commenters supported CMS' proposal that it is finalizing without change.

21. Computed Tomographic Colonography, CPT Code 74263 (APC 5523)

CPT code 74263 is for screening CT Colonography—a service that has been non-covered to date. However, CMS is expanding coverage under the colon cancer screening benefit to include CT colonography. CMS proposed to assign CPT code 74263 to APC 5522 (Level 2 Imaging without Contrast) with a separately payable status indicator based on its similarity to CPT code 74261 for diagnostic colonography.

One commenter requested assigning CPT code 74263 to APC 5571 (Level 1 Imaging with Contrast) on the basis that the proposed APC assignment will result in payment insufficient to cover the costs of providing the service. CMS disagrees with this comment as CPT code 74263 is completed without contrast. CMS is finalizing the proposed assignment of CPT code 74263 to APC 5522.[14]

22. Concurrent Optical and Magnetic Stimulation (COMS) Therapy, CPT Codes 0906T (APC 5051)

On June 20, 2023, CMS approved for Medicare coverage the Category B Investigational Device Exemption (IDE) study associated with COMS. Effective July 1, 2024, CPT code 0906T was assigned to APC 5051 (Level 1 Skin Procedures) with a payment of $201.14. CMS proposed to continue this APC assignment for 2025.

The manufacturer of COMS commented that hospitals incur costs greater than the payment in APC 5051 due to the extensive wound examination, wound bed preparation, and dressing management required with the use of COMS. The commenter requested an assignment to APC 5053 (Level 3 Skin Procedures) with a payment rate of $619.13. Absent any cost data from claims for this procedure, CMS is maintaining the assignment of CPT code 0906T to APC 5051 based on its similarity to CPT code 0521T (Extracorporeal shock wave for integumentary wound healing) and CPT code 97610 (Low frequency, non-contact, non-thermal ultrasound).

23. Cystourethroscopy with Temporarily Implanted Nitinol Device Procedure, HCPCS code C9769 (APC 5376)

[14] CT colonography is also discussed in section X.D of this summary as well as on page 182 of the unpublished version of the 2025 PFS final rule. CMS received detailed comments on technical issues with cost to charge ratios for the MRI and CT cost centers and their effect of the OPPS payment and, in turn, the PFS payment due to the PFS payment being capped at the OPPS rate. These comments are not presented in the OPPS rule and only briefly presented in the 2025 PFS final rule.

For 2025, CMS proposed to continue to assign HCPCS code C9769 to APC 5376 (Level 6 Urology and Related Services) with a proposed payment rate of approximately $9,209. One commenter indicated that the new CPT code 53865 will replace HCPCS code C9769 effective January 1, 2025. CMS acknowledged the comment and will assign CPT code 53865 to APC 5376 for 2025.

24. Dental Alveoloplasty and Exostosis Removal Procedures, CDT codes D7320, D7321, and D7471 (APCs 5163, 5164)

Effective January 1, 2024, CMS made 229 additional dental codes payable under the OPPS when payment and coverage requirements are met. A public commenter requested that CMS make CDT codes D7320, D7321, and D7471 payable under the OPPS as these procedures are often necessary for medically compromised patients undergoing tooth removal prior to radiation treatment consistent with CMS' coverage policy on payment for dental services. CMS agreed with this comment and is assigning CDT codes D7320 and D7321 to APC 5163 (Level 3 ENT Procedures) and CDT code D7471 to APC 5164 (Level 4 ENT Procedures) based on clinical and resource similarities to other alveoloplasty codes currently assigned to the same clinical APCs.

25. Digital Mental Health Treatment Devices, HCPCS Codes G02552 and G0553 (APC 5012)

In the 2025 PFS proposed rule (89 FR 61956), CMS proposed to create three new HCPCS codes for the supply of a Digital Mental Health Treatment Devices (DHMT) and monthly management of the patient. CMS did not address the status indicators or APC assignments for these three codes.

In the final rule, CMS is assigning HCPCS codes G0552 and G0553 a separately payable status indicator and to APC 5012 (Clinic Visits and Related Services). CMS is assigning HCPCS code G0554 a packaged status indicator as it is an add-on code always packaged with the primary service. These assignments are interim and subject to public comment as they were not previously presented in the 2025 OPPS proposed rule.

26. Drug-Coated Balloon for Esophageal and Bowel Strictures, CPT codes 0884T, 0885T, and 0886T (APC 5331)

The first of the above three codes is applicable to the esophagus and the second two to the lower GI tract using the ProTract technology. CMS proposed to assign the first code to APC 5303 (Level 3 Upper GI procedures) with a payment rate of $3,805 and the other two codes to APC 5313 (Level 3 Lower GI Procedures) with a payment rate of $2,742.

The manufacturer of ProTract provided a detailed analysis showing the cost of CPT code 0884T is $6,081, CPT code 0885T is $5,568, and CPT code 0886T is $5,424. The commenter requested that

CMS assign all these of these codes to APC 5331 with a payment rate of $5,953. CMS agreed and is assigning these codes to APC 5331.

27. EchoGo Echocardiography Image Processing Service, HCPCS Code C9786 (APC 5743)

For 2025, CMS is deleting HCPCS code C9786 because the CPT Editorial Panel established Category III CPT code 0932T that describes the same service. CMS proposed to assign this code to APC 5743 (Level 3 Electronic Analysis of Devices), the same APC to which HCPCS code C9786 is assigned. One public commenter supported CMS' proposal that it is finalizing without change.

28. Endoscopic Submucosal Dissection (ESD) Procedure, HCPCS Code C9779 (APC 5303)

CMS established HCPCS code C9779 effective October 1, 2021. This code is currently assigned to APC 5303 (Level 3 Upper GI Procedures). One commenter requested CMS assign the HCPCS code C9779 to APC 5361 (Level 1 Laparoscopy and Related Procedures) on the basis that its geometric mean costs are higher than four procedures with significant volume assigned to APC 5361. CMS responded that endoscopic submucosal dissection is not a laparoscopic procedure that should be assigned to a laparoscopic APC family. CMS is retaining the APC assignment of HCPCS code C9779 in APC 5303.

29. Esophageal Balloon Distention Study, CPT Code 91040 (APC 5723)

For 2025, CMS proposed to assign CPT code 91040 to APC 5723 (Level 3 Diagnostic Tests and Related Services) with a proposed payment rate of around $530. One public comment requested this procedure be reassigned to APC 5724 (Level 4 Diagnostic Tests and Related Services) on the basis that its geometric mean cost is approximately around $1,500 compared to an APC payment of $537.

CMS responded that approximately 70 percent of the costs for this procedure are made up of higher cost items (equipment, drugs, and supplies) that are packaged and only 2.7 percent (approximately 95) of claims were billed with only CPT code 91040. Other procedures that are performed with CPT code 91040 are increasing the geometric mean cost of CPT code 91040. CMS will continue to assign CPT code 91040 to APC 5723.

30. Esophagogastroduodenoscopy with Optical Endomicroscopy, CPT Code 43252 (APC 5302)

CMS proposed to continue to assign CPT code 43252 to APC 5302 with a proposed payment rate of $1,884.11. Two public commenters said a prior reassignment of this code from APC 5303 to 5302 resulted in a significant payment reduction that could be impeding access. Both commenters requested CMS reassign CPT code 43252 to APC 5303 based on its similarity to another CPT code (0654T). CMS responded that the geometric mean cost of approximately $1,839.38 for CPT code

43252 is consistent with its assignment to APC 5302 that has a payment rate of $1,920. CMS finalizing its proposal without change.

31. Extracorporeal Shock Wave Lithotripsy (SWL), CPT Code 50590 (APC 5374)

CMS proposed to maintain the assignment of CPT code 50590 in APC 5374 based on a total of 26,669 single frequency claims and a geometric mean cost of approximately $3,536. One commenter requested that CMS reassign CPT code 50590 to APC 5375 (Level 5 Urology and Related Services) because of its similarity to two other codes (CPT codes 52353 and 52356) that are assigned to the higher paying APC. The commenter stated that higher payment for the latter two CPT codes 52353 and 52356 has driven service volume toward those codes and away from CPT code 50590.

In the final rule, CMS is making no changes to the APC assignment for CPT code 50590. CMS indicates that the code's geometric mean cost closely aligns to the APC where it is assigned and well below that of APC 5375.

32. Female Intraurethral Valve-Pump, Insertion and Replacement, CPT Codes 0596T and 0597T (APC 5372)

CMS proposed to assign CPT codes 0596T and 0597T to APC 5372 (Level 2 Urology and Related Services) with a payment rate of $675.64. There were comments in support of this proposal and other comments that stated the assignment to APC 5372 does not sufficiently consider the targeted device cost of $1,885. The commenters requested reassignment of CPT code 0596T to APC 5373 (Level 3 Urology and Related Services) with a payment rate of $2,074.53. CMS responded that it has no claims data yet for CPT code 0596T and continues to believe that CPT code 0596T shares similar clinical characteristics and resource costs to services assigned to APC 5372.

33. Fractional Flow Reserve (FFR) with 3D Coronary Mapping, CPT Code 0523T

CPT Code 0523T is an add-on code where payment is always packaged with the primary service with which it is performed. One commenter requested that the packaging exemption for Software as a Service (SaaS) add-on codes policy should be applied to CPT code 0523T. The SaaS exemption is for SaaS add-on codes for which a standalone, identical SaaS code that is performed without concurrent imaging is separately payable under the OPPS. CMS' response is not explicit but suggests that CPT 0523T does not meet the criteria for the SaaS exemption. The proposed packaged payment under CMS' policy for add-on codes is being finalized without change.

34. Fractional Flow Reserve Derived from Computed Tomography (FFRCT), CPT Code 75580 (APC 5724)

CPT code 75580 is used to bill for HeartFlow®. Commenters indicated that several Medicare Administrative Contractors have an edit in place that prohibits using cardiology revenue code (0480) when billing CPT code 75580. CMS responded that it has identified and removed the

outdated edit. Facilities may use CPT 75580 with any appropriate revenue code. Further public education and instruction will be provided through the CMS Medicare Learning Network.

35. Gastric Electrophysiology Mapping with Simultaneously Validated Patient System Profiling (GEMS) Service, CPT Code 0868T (APC 5723)

Effective July 1, 2023, CMS established HCPCS code C9787 for GEMS and assigned it to APC 5723 (Level 3 Diagnostic Tests and Related Services). Effective July 1, 2024, CPT code 0868T replaced HCPCS code C9787 and was also assigned to APC 5723. For 2025, CMS proposed to continue to assign CPT code 0868T to APC 5723 with a payment rate of $527.44.

Public commenters requested that CMS assign CPT code 0868T to either:

- New technology APC 1520 New Technology - Level 20 ($1801-$1900),
- APC 5724 (Level 4 Diagnostic Tests and Related Services), with a payment rate of $1,017, or
- APC 5302 (Level 2 Upper GI Procedures), with a payment rate of $1,897.

Commenters believe the assignment to APC 5723 will result in payment that is insufficient relative to the procedure's costs.

CMS' analysis of the available claims data demonstrates that the geometric mean cost for HCPCS code C9787 is approximately $310 based on 5 single frequency claims. Based on the resource and clinical similarities to other services assigned to APC 5723, CMS believes that its proposed APC assignment is appropriate for 2025. It is finalizing its proposal without change.

36. Hernia Repair Procedures, CPT Codes 49593, 49595, and 49615 (APCs 5342 and 5361)

Effective January 1, 2023, the AMA created these new abdominal hernia repair CPT codes. For 2023, CMS assigned these codes to APC 5341 (Level 1 Abdominal/Peritoneal/Biliary and Related Procedures). For 2025, CMS proposed to reassign these codes to APC 5342 (Level 2 Abdominal/Peritoneal/Biliary and Related Procedures). Public commenters supported this proposal that CMS is finalizing without change.

37. Imaging of Retina for Detection or Monitoring of Disease, CPT Code 92229 (APC 5733)

CMS proposed maintaining CPT code 92229 in APC 5733 (Level 3 Minor Procedures) pending more claims data before reassessing an APC reassignment. Public commenters supported this proposal. CMS is finalizing its proposal without change.

38. Implantable Cardiac Alert System, CPT Codes 0525T and 0527T (APCs 5224 and 5222)

CMS proposed to assign CPT code 0525T to Level 3 Pacemaker and Similar Procedures (APC 5223) and CPT code 0527T to Level 2 Pacemaker and Similar Procedures (APC 5222). Public

commenters indicated that the APC assignment for CPT code 0525T did not account for the cost of the medical device that is receiving pass-through payment through December 31, 2024. CMS agreed and is finalizing an assignment for CPT code 0525T to APC 5224 (Level 4 Pacemaker and Similar Procedures). It is finalizing its proposal to assign CPT code 0527T to APC 5222 (Level 2 Pacemaker and Similar Procedures).

39. Implantable Glucose Monitoring System, CPT Codes 0446T and 0448T (APC 5054)

For 2025, CMS proposed to maintain both CPT codes in APC 5054 (Level 4 Skin Procedures) with a payment amount of $1,829. The manufacturer requested the codes be reassigned to APC 1531 (New Technology - Level 31 ($6501-$7000)) with a payment of $6,750.50 to reflect the increased expense of the implantable sensor that has quadrupled the life of the 90-day sensor. CMS is creating two new HCPCS G codes effective January 1, 2025, to describe the implantable interstitial glucose sensor with a 365-day battery life. CMS is assigning HCPCS codes G0564 and G0565 to APC 1561 (New Technology - Level 24 ($3001-$3500)) with a payment rate of $3,250.50.

40. Integrated Sacral Neurostimulators, CPT Code 0786T

CMS proposed to assign CPT code 0786T to APC 5463 (Level 3 Neurostimulator and Related Procedures) with a proposed payment rate of $13,029.81. Based on public comments indicating that the Neuspera integrated sacral nerve stimulation system has not yet received FDA approval, CMS is assigning CPT code 0786T a non-payable status indicator.

41. Laparoscopic Appendectomy, CPT Code 44970 (APC 5361)

CMS proposed to continue assigning CPT code 44970 to APC 5361 (Level 1 Laparoscopy and Related Services) based on 2023 Medicare claims data. One commenter requested the procedure be assigned to APC 5342 (Level 2 Abdominal/Peritoneal/Biliary and Related Procedures) based on clinical homogeneity and resource utilization like CPT code 44950 (Appendectomy). CMS continues to believe CPT code 44970 is appropriately assigned to the Laparoscopy and Related Procedures family and is finalizing its proposal without change.

42. Litholapaxy Procedure, CPT code 52318 (APC 5374)

For 2025, CMS proposed to continue assigning CPT code 52318 to APC 5374 (Level 4 Urology and Related Services) with a proposed payment rate of $3,438. One commenter requested assigning CPT code 52318 to APC 5375 (Level 5 Urology and Related Services) on the basis that the procedure is comparable in complexity and resources required for CPT code 52318. Based on the

claims data, CMS believes that CPT code 52318 is appropriately assigned to APC 5374. CMS is finalizing its proposal without change.

43. LIXELLE® Apheresis

There are currently no specific HCPCS or CPT codes that represent the LIXELLE® apheresis service. One commenter provided four different options under which this service could be paid under the OPPS. CMS is not adopting any of these options but indicates that this complex, ongoing issue is still under consideration and continues to merit a thorough evaluation to ensure an appropriate Medicare benefit category and payment pathway for the service is determined.

44. Low Ejection Fraction AI-ECG Service, CPT codes 0764T and 0765T (APC 5734)

For 2025, CMS proposed that CPT codes 0764T and 0765T continue to be assigned a non-payable status indicator as the technology is not FDA approved. However, public commenters provided documentation of the procedure's FDA approval. CPT code 0764T will be separately payable for 2025 and assigned to APC 5734 (Level 4 Minor Procedures) with a final rule payment rate of $128.90 while CPT 0764T is an add-on code and will be unconditionally packaged (at least according to the preamble of the final rule). The final rule shows a separately payable status indicator for CPT code 0765T and an assignment to APC 5734).

45. Lower Esophageal Myotomy (POEM), CPT 43497 (APC 5331)

CMS proposed to assign CPT code 43497 to APC 5331 (Complex GI Procedures) with a payment rate of $5,838. One commenter requested reassigning this procedure code to APC 5361 (Level 1 Laparoscopy and Related Services) with a payment of $5,798 on the basis that the procedure utilizes techniques that are surgical in nature. Based on its understanding of the service, CMS does not agree that CPT code 43497 has clinical and resource homogeneity to other services in APC 5361. It is finalizing its proposal without change.

46. Magnetic Resonance Exam Safety Procedures, CPT Codes 76014 through 76019 (APCs 5521, 5523, 5731, 5733, and 5742)

The AMA CPT Editorial Panel created six codes to report magnetic resonance (MR) examination safety procedures effective January 1, 2025. Table 96 shows CMS' proposed status indicators and APC assignments for these six new codes for 2025. Based on public comments, CMS is changing the final rule APC assignment for two of these codes and maintaining the proposed assignment for the remaining four codes.

47. MindMotion GO Neurorehabilitative Remote Therapy Service, CPT code 0733T (APC 1505)

CMS proposed to assign CPT code 0733T to APC 5741 (Level 1 Electronic Analysis of Devices) with a proposed payment rate of $36.90. One comment requested that CMS reassign CPT code 0733T to APC 1510 (New Technology - Level 10 ($801-$900)) based on its expected resource

costs once it comes on the market. CMS agreed that its proposed APC assignment would result in a payment that is too low for CPT code 0733T. In the final rule, CMS is assigning CPT code 0733T to APC 1505 (New Technology - Level 5 ($301-$400)).

48. Musculoskeletal Procedures (APCs 5111 through 5116)

CMS did not propose any changes to the six level APC structure for musculoskeletal procedures. Nevertheless, there were comments suggesting that CMS create an additional APC level. CMS is not making any changes in response to these comments but will consider them for future rulemaking.

49. Noncontact Near-infrared (NIR) Spectroscopy, CPT 0640T (APC 5732)

For 2025, CMS proposed to assign CPT code 0640T to APC 5732 (Level 2 Minor Procedures) and separately payable status indicator "S" with a $39 payment rate. One commenter requested CMS reassign 0640T to APC 5722 (Level 2 Imaging without contrast) with a proposed payment rate of approximately $310 for 2025 based on a crosswalk to CPT code 0598T. CMS disagreed stating the resource cost associated with noncontact real-time fluorescence imaging (CPT code 0598T) is significantly higher compared to NIR spectroscopy (CPT code 0640T/0641T). CMS is finalizing its proposal without change.

50. Percutaneous Coronary Revascularization Services by Intracoronary Antiproliferative Drug Delivery, CPT Codes 0913T and 0914T (APC 5192)

For 2025, CMS proposed to assign CPT code 0913T to APC 5192 (Level 2 Endovascular Procedures) with a geometric mean cost of $5,771.29 based on clinical and resource similarity to other percutaneous coronary intervention procedures. CMS proposed to unconditionally package CPT 0914T as it is an add-on code.

The HOP Panel recommended reassigning CPT 0913T to APC 5193 (Level 3 Endovascular Procedures) as did several commenters based on a cost analysis provided with their comments. CMS responded that it believes that CPT code 0913T describes a service like other codes in APC 5192. CMS is finalizing its proposal without change.

51. Potential Two-Times Rule Violations (APCs 5302, 5415, 5092, and 5114)

Endoscopic Esophageal Procedures

Public commenters indicated that the following CPT codes had a two times rule violation with an assignment APC 5302: 43254, 43270 and 43275. CMS indicated that CPT code 0653T, the comparator code provided by the commenters, has fewer than 100 claims and does not meet the significance threshold for the two times rule evaluation.

Vaginal Hysterectomy Procedures

Public commenters indicated that the following CPT codes had a two times rule violation with an assignment APC 5415: 58260 and 58262. CMS indicated that CPT code 38555, the comparator code provided by the commenters, has fewer than 100 claims and does not meet the significance threshold for the two times rule evaluation.

Mastectomy Procedures

Public commenters indicated that the following CPT codes had a two times rule violation with an assignment to APC 5092: 19303 and 19307. CMS indicated that CPT code 57550, the comparator code provided by the commenters, has fewer than 100 claims and does not meet the significance threshold for the two times rule evaluation.

Arthrodesis Procedure

A public commenter indicated that CPT code 28740 has a geometric mean cost of $11,058, which is more than two times the geometric mean cost of CPT code 27385 of $5,616. Based on final rule data, CMS found that the geometric mean cost for CPT code 28740 is $11,074 which is less than two times the updated cost of $5,616 for CPT code 27385.

52. Prostate Laser Enucleation Procedure, CPT Code 52649 (APC 5375)

For 2025, CMS proposed to continue assigning CPT code 52649 to APC 5375 (Level 5 Urology and Related Services) with a payment rate of approximately $5,057. One commenter requested it be assigned to APC 5376 (Level 6 Urology and Related Services) based on clinical similarity with other procedures in that APC. CMS is not changing the proposed APC assignment as the claims data supports the proposed APC assignment.

53. Remote Uroflowmetry Service, CPT Code 0812T (APC 5721)

For 2025, CMS proposed to assign CPT code 0812T to APC 5741 (Level 1 Electronic Analysis of Devices). One commenter disagreed with this APC assignment citing resource similarity to CPT code 51741 (Complex uroflowmetry (e.g., calibrated electronic equipment)). CMS responded that CPT code 51741 is a more complex procedure than CPT code 0812T. However, CMS believes

CPT code 0812T is resource like CPT code 51703 and is reassigning it to APC 5721 (Level 1 Diagnostic Tests and Related Services).

54. Skin Cell Suspension Autograft (SCSA) Procedures, CPT Codes 15011 through 15018 (APCs 5051, 5054, and 1567)

Effective January 1, 2025, there will be eight new Category 1 CPT codes to describe SCSA procedures, four of which are add-ons that CMS proposed a packaged status indicator. For the other four codes, CMS proposed an assignment to either level 1 or level 4 skin procedures.

Two commenters requested that CMS reassign CPT code 15013 from APC 5051 (Level 1 Skin Procedures) with a payment rate of $199 to APC 1575 (New Technology - Level 38 ($10,001- $15,000)). CMS acknowledged arguments made by the commenters that CMS' proposed assignment for CPT 15013 would result in a payment that would be too low. In the final rule, CMS is assigning CPT code 15013 to APC 1567 (New Technology - Level 30 ($6001- $6500)).

55. Surgical Pathology Examination, CPT Code 88309 (APC 5674)

For 2025, CMS proposed to reassign CPT code 88309 from APC 5674 (Level 4 Pathology) to APC 5673 (Level 3 Pathology) with a proposed payment rate of $356.00. Three commenters requested that CMS maintain the current APC assignment based on concerns that the 25 percent reduction in payment would not reflect the actual costs of performing the test. CMS responded that it based the proposed reassignment on claims that are an accurate reflection of the service's changing costs. However, CMS is also concerned about the large reduction in payment and will use its equitable adjustment authority to maintain the assignment of CPT code 88309 in APC 5674 for 2025.

56. Therapeutic Ultrafiltration, CPT 0692T (APC 5242)

For 2025, CMS proposed to continue assigning CPT code 0692T (Therapeutic ultrafiltration) to APC 5241 (Level 1 Blood Product Exchange and Related Services) with a payment rate of $431.37. Several comments requested CMS reassign CPT code 0692T from APC 5241 (Level 1 Blood Product Exchange and Related Services) to APC 5242 (Level 2 Blood Product Exchange and Related Services). Based on the code's clinical similarity and expected resource cost similarity to CPT code 36514, CMS agrees with the commenters and assigned CPT 0692T to APC 5242 for 2025.

57. Thyroid Ablation, CPT Codes 60660 and 60661 (APC 5072)

For 2025, CMS proposed to assign CPT code 60660 to APC 5072 (Level 2 Excision/ Biopsy/ Incision and Drainage) and package 60661 as an add-on code. Two commenters suggested different

APC assignments, but CMS continues to believe CPT code 60660 is appropriately assigned to APC 5072.

58. Thyroid Removal, CPT Code 60240 (APC 5361)

For 2025, CMS proposed to assign CPT code 60240 to APC 5361 (Level 1 Laparoscopy and Related Services) with a proposed APC payment rate of $5,798.13. One commenter requested CMS reassign CPT code 60240 to APC 5362 (Level 2 Laparoscopy and Related Services) with a payment rate of $10,378.45 on the basis that the current assignment creates a two times violation. However, CMS found that the comparator code raised by the comment has insufficient claims volume to be used to evaluate the two times rule.

59. Trabecular Bypass Procedures, CPT codes 66989, 66991, 0660T, 0661T, and 0671T (APCs 5492 and 5493)

For 2025, CMS proposed to assign these CPT codes 66989, 66991 and 0671T to APC 5493 (Level 3 Intraocular Procedures) with a proposed payment rate of $5,160 and CPT codes 0660T and 0661T to APC 5492 (Level 2 Intraocular Procedures) with a payment rate of $4,023. Public commenters supported these proposals that CMS is finalizing without change.

60. Transcutaneous Magnetic Peripheral Nerve Stimulation CPT codes 0766T and 0767T (APC 5722)

For 2025, CMS proposed to continue assigning CPT code 0766T to APC 5721 (Level 1 Diagnostic Tests and Related Services). CPT code 0767T is an add-on code that is unconditionally packaged. After further evaluation, CMS is assigning CPT code 0676T to APC 5722 (Level 2 Diagnostic Tests and Related Services). CMS is also changing its status indicator from C-APC to a standalone service that can be billed in addition to other services furnished in the same hospital outpatient encounter.

61. Transurethral Ultrasound Ablation (TULSA) Procedure, HCPCS code C9734 and CPT code 55882 (APC 5377)

For 2025, CMS proposed to continue assigning HCPCS code C9734 to APC 5115 (Level 5 Musculoskeletal Procedures) with a payment rate of approximately $12,756. CPT code 55882 will replace HCPCS code C9734 effective January 1, 2025. CMS agreed with the commenters that the TULSA procedure should be assigned to the urology procedures APC series. For 2025, CMS is

assigning CPT 5882 to APC 5377 (Level 7 Urology and Related Services) with a final rule payment of $12.992.

62. Unfold AI Service, CPT code 0898T (APC 5724)

CMS proposed to assign new CPT code 0898T to APC 5724 (Level 4 Diagnostic Tests and Related Services), a proposal supported by commenters that CMS is finalizing without change.

63. Ureteroscopy, HCPCS code C9761 (APC 5376)

For 2025, CMS proposed to continue assigning HCPCS code C9761 to APC 5376 (Level 6 Urology and Related Services) with a payment rate of approximately $9,208. CMS received one out-of-scope comment on this code. It is finalizing its proposal without change.

64. V-LAP System Left Atrial Pressure Monitoring Procedure, CPT Code 0933T (APC 5191)

For 2025, CMS proposed to assign CPT code 0933T to APC 5191 (Level 1 Endovascular Procedures) and pay the service through a C-APC with a payment of $3,210. CMS disagreed with the one comment it received. CMS proposal is being finalized without change.

65. Vagal Nerve Neurostimulator System, CPT codes 0908T through 0912T

CMS proposed payable status indicators and APC assignments for each of these codes in the proposed rule. However, because the technologies associated with these codes are not FDA approved, CMS is assigning these codes a non-payable status indicator in the final rule.

66. VisONE® Synchronized Diaphragmatic Stimulation™ (SDS®) System CPT codes 0674T through 0685T

The VisONE® Synchronized Diaphragmatic Stimulation™ (SDS®) System was not FDA approved at the time of the proposed rule. CMS proposed assigning these CPT codes a non-payable status indicator. The manufacturer of the SDS® System updated CMS on FDA approval of a Category B Investigational Device Exemption trial for this system and requested clinical APC assignments for 9 of the 12 CPT codes and packaged status for the remaining three add-on CPT codes. CMS agreed with the commenters recommended APC assignments and status indicators and provides the status indicators and APC assignments for each of these CPT codes in table G81 of the final rule (an atypical table number as the prior table is numbered 111 and the subsequent table is numbered 112).

67. Xenograft Implantation into the Articular Surface, CPT code 0737T (APC 5115)

For 2025, CMS proposed to continue to assign CPT code 0737T to APC 5115. Commenters supported this proposal that CMS is finalizing without change.

68. OPPS Payment for Software as a Service

CMS refers to algorithm-driven services that assist practitioners in making clinical assessments, and that providers pay for either on a subscription or per-use basis, as Software as a Service (SaaS). The proliferation of SaaS procedures approved by the FDA and their subsequent assignment of CPT codes by the AMA has led the agency to seek a workable SaaS payment strategy. CMS did not make a proposal on this issue but solicited comments in the final rule on the following issues:

- Identifying a payment strategy that is applicable across settings of care (for example, physician offices).
- Identifying the fair costs associated for SaaS services.
- Distinguishing services that should be paid separately versus services that should be packaged under a prospective payment system.
- Identifying a payment strategy for SaaS services that are part of other medical devices versus those that are distinct services.

CMS will consider input from the public comments for any future SaaS payment policy.

69. APC and Status Indicator Review Process

Each year, CMS receives a high volume of requests to make changes to the APC and status indicator assignments of new or revised codes. These changes were not necessarily discussed in the proposed rule but are subject to comment and reflected in the various addenda to the proposed and final OPPS payment rules. One commenter requested that all APC assignment requests be included in the OPPS proposed rule and that CMS follow a process like the IPPS. For the IPPS, there is an annual deadline provided in each year's final rule for when MS-DRG requests must be made to be included in the following year's proposed rule.

CMS will consider this comment for future rulemaking.

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 until the device costs are incorporated into the APC payment.[15] CMS follows the statutory requirements that a category of devices is eligible for transitional pass-through payments for at least two but not more than three years. To allow a pass-through payment period that is as close to a full three years as possible, CMS finalized a quarterly expiration of pass-through payments status for devices in the 2017 OPPS final rule. Except for brachytherapy sources,

[15] 87 FR 72032-72033

CMS packages the costs of the devices into its associated procedure payment when pass-through payment expires. Beginning March 1, 2023, CMS publicly posts OPPS device pass-through applications online.

Table 112 lists 13 device categories currently receiving pass-through payment.

Table 112 Devices with Pass-Through Status Expiring in 2024, 2025 or 2026

HCPCS Codes	Long Descriptor	Effective Date	Pass-Through Expiration Date
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
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
C8000	Support device, extravascular, for arteriovenous fistula (implantable)	10/01/2024	09/30/2027

2. New Device Pass-Through Applications for 2025

a. Background

For a device to be eligible for transitional pass-through payment, 42 CFR §419.66(b)(1) through (b)(3) specify the device must meet be:

1. Approved by the FDA (if required) and the pass-through application submitted within 3 years of the date of FDA approval 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. Be reasonable and necessary for the diagnosis or treatment of an illness or injury to improve the functioning of a malformed body part.
3. Be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically implanted or inserted (either permanently or temporarily) or applied in or on a wound or other skin lesion.

In addition, a device is not eligible for device pass-through payment under 42 CFR §419.66(b)(4) 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).

Further, under 42 CFR §419.66(c), a new device category may only be established if the device:

2. Is 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.

3. Substantially improves the diagnosis or treatment of an illness or injury or improves 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, the device has received marketing authorization for the indication covered by the FDA through its Breakthrough Device designation program.

4. 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 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.
    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 (except for brachytherapy and temperature-monitored cryoablation, exempted from the cost requirements at §419.66(c)(3) and §419.66(e)).

Once a device has been approved for pass-through payment, the pass-through payment for a device is the hospital's charge adjusted to cost minus the amount included in the APC payment amount for the device—known as the device offset amount.

An issue that has been raised to CMS is that the device offset amount is the entire device related portion of the APC even if the pass-through device is only replacing a fraction of the device related portion. The issue is addressed in section IV.B of the final rule.

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 preliminarily 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.[16] 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 the 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 March 1, 2024, the last deadline in time for applications to be included in the 2025 rulemaking cycle. CMS preliminarily approved the following applications:

1. The DETOUR™ System: Effective January 1, 2024.

[16] 84 FR 61295

2. AVEIR™ DR Dual Chamber Leadless Pacemaker System: Effective July 1, 2024.
3. EndoSound Vision System® (EVS): Effective July 1, 2024.

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

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 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 indicated 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 did not agree with the applicant that C2623 is limited to use with femoral or popliteal revascularization procedures. The proposed rule cited 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 indicated that upon becoming packaged, C2623 effectively became reportable with other transluminal angioplasty including percutaneous procedures and related coronary procedures.

Public comments on this issue indicated that AGENT™ is not used to perform transluminal angioplasties. AGENT™ is used to deliver its drug to a lesion after the vessel wall has been prepared. CMS responded that the FDA Breakthrough Device designation for AGENT™ appears

to be consistent with the applicant's and commenters' assertions. After consideration of the public comments, CMS has determined that the AGENT™ Paclitaxel-Coated Balloon Catheter meets the eligibility criterion at §419.66(c)(1).

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: AGENT Paclitaxel-Coated Balloon Catheter meets the three tests to determine cost significance.

Final Decision: CMS approved AGENT™ for transitional pass-through payment effective January 1, 2025.

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 an 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 indicated that Aveir DR System meets the three tests to determine cost significance.

Final Decision: The Aveir™ DR System pass-through application was preliminarily approved for transitional pass-through payment effective July 1, 2024.

3. 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 indicated the DETOUR System meets the three tests to determine cost significance.

Final Decision: The DETOUR™ System pass-through application was preliminarily approved for transitional pass-through payment effective January 1, 2024.

4. 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 concern 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 indicated that EVS meets the three tests to determine cost significance.

Final Decision: The UDK-T component of the EVS pass-through application was preliminarily approved for transitional pass-through payment effective July 1, 2024. The applicant asked that CMS include two additional CPT codes (43240 and 43253) that may be billed with the pass-through device (HCPCS C1606). CMS is evaluating this request.

5. 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 because 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) ("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.").

The applicant commented that the iFuse Bedrock Granite Implant System technology, including the associated instrument sets is integral to the service furnished, is single use, permanently implanted, and surgically inserted into the patient, aligning fully with §419.66(b)(3). CMS agreed and determined that the iFuse Bedrock Granite™ Implant System meets the criterion at §419.66(b)(3).

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.

The applicant and others commented that unlike devices described by C1713, the iFuse Bedrock Granite Implant System's intended use is not to anchor bone to bone, or soft tissue, tendons, or ligaments to bone, but to promote simultaneous pelvic stabilization and fusion across the SI joint space. Based on these and other points, CMS agreed that C1713 is not applicable to the iFuse Bedrock Granite Implant System.

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 indicated the iFuse Bedrock Granite Implant System meets the first of three tests of cost significance. It must meet all three tests to be approved for pass-through payment.

The applicant and another commenter indicated that CMS should evaluate whether the iFuse Bedrock Granite Implant System meets the cost criterion using HCPCS code 22612 rather than HCPCS code 27279. CMS agreed with the detailed clinical arguments made by these commenters. Evaluating whether the iFuse Bedrock Granite Implant System meets the cost criterion relative to HCPCS code 22612 results in the product meeting all three tests of cost significance.

Final Decision: CMS approves the iFuse Bedrock Granite Implant System for transitional pass-through payment status effective January 1, 2025.

The applicant further commented that the costs of the iFuse Bedrock Granite™ Implant System are additive for hospitals currently performing lumbar spinal fusion procedures and requested that

CMS set the device offset to $0. CMS agreed and will not apply a device offset when the iFuse Bedrock Granite Implant System is paid on a transitional pass-through basis.

6. 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 indicated that the Paradise Ultrasound RDN System meets the three tests to determine cost significance.

Final Decision: CMS approves the applicable components of the Paradise® Ultrasound RDN System for transitional pass-through payment effective January 1, 2025.

7. 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: CMS raised concerns about whether Precision GI is integral to the service furnished, used for one patient only, comes in contact with human tissue, and is surgically inserted or implanted, or applied in or on a wound or other skin lesion. While the needle does come into contact with human tissue and is surgically inserted, the motorized mechanism of the Precision GI device itself may not come in contact with human tissue and may not be surgically implanted or inserted (either permanently or temporarily).

In response to CMS' concerns, the applicant indicated that the Precision GI device is an endoscopic ultrasound-guided fine needle biopsy (EUS-FNB) medical device that is essential to obtain and remove cancerous tissue. Precision GI comes in contact with human tissue when the device enters the patient and extracts suspected tumor tissue from the body. It is surgically inserted through the patient's mouth. CMS agrees that Precision GI is integral to the services with which it is performed, comes in contact with human tissue, and is surgically inserted and used for one patient only.

Based on the description of the product 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. The applicant commented that Precision GI is used to capture and extract a diagnostically relevant portion of the tumor. Further, the applicant distinguished Precision GI from a generic biopsy device because it is used for tissue removal. Unlike HCPCS code C1782 which also removes tissue and is not a biopsy device, Precision GI is endoscopically inserted while HCPCS code C1782 is for tissue removal through laparoscopy. Based on the additional information provided in the comments, CMS agrees that Precision GI is not equipment, an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered as depreciation assets, or a material or supply furnished incident to a service.

One commenter indicated that CMS' discussion of Precision GI raises an important policy question about the definition of a biopsy apparatus. Technological advances in needle shapes have resulted in devices that should not be classified along with biopsy forceps or aspiration needles. The commenter requested that CMS reconsider the definition of a supply and consider re-classification of mechanical tissue extraction apparatuses such as Precision GI into a new category of devices outside of the existing definition. CMS will consider this issue in future rulemaking.

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.

Final Decision: CMS approves Precision GI for transitional pass-through payment effective January 1, 2025.

8. 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 indicated that the Symplicity Spyral Catheter meets the three tests to determine cost significance.

Final Decision: CMS approved the Symplicity Spyral Catheter for transitional pass-through payment effective January 1, 2025.

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.
- Both 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 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 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.

While CMS raises issues and questions regarding whether one or two category descriptors are necessary for each of these technologies, it did not make a proposal. Rather, it requested public comments 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.

Comments/Responses: Below is a brief summary of some of the major comments that were presented on this issue. See final rule for more details.

General Overview: The applicant for the Paradise® Ultrasound RDN System stated that two device categories are needed to recognize documented procedural differences between the two treatment modalities and CMS's previous creation of separate and distinct device categories for similar technologies. The Symplicity Spyral RDN System applicant emphasized the similarities between the two devices and procedures, opinions from the physician community, existing policy and coding standards, and potential future consequences of this determination.

Clinical Differences: Commenters presented detailed clinical differences between the two procedures including procedure time, cost differences, clinical effectiveness, outcomes, etc. CMS did not evaluate these arguments or make a judgment on whether these factors were relevant to a determination of creating one or two categories.

Pricing: Pricing of each product was also a subject of the comments. The Paradise® Ultrasound RDN System applicant stated that having two distinct device categories would allow hospitals to set charges that accurately reflect the cost of each procedure enabling CMS to more accurately calculate the costs of each procedure. The Symplicity Spyral RDN System applicant commented that when the pass-through period expires, packaged payment will be packaged into the payment for the same CPT code, whether these costs are similar or not. The Symplicity Spyral RDN System applicant, therefore, questioned the utility of using separate device categories for cost tracking.

Precedent: The Paradise® Ultrasound RDN System applicant asserted that CMS has previously created separate and distinct device categories for similar technologies. They provided several

examples of these precedents. The applicant for the Symplicity Spyral RDN System argued that pass-through device categories are not established for the purpose of describing specific devices; rather, device categories are intended to encompass all devices that can be appropriately described by a category (89 FR 59316)

CMS responded that it is establishing two pass-through payment device categories for the following reasons:

- Procedural differences and resource requirements between the two treatment modalities that warrant separate device categories.
- The circumstances presented by the nominated devices are sufficiently like the previous scenarios in which CMS established device category codes to differentiate similar devices with different modalities.

While CMS is establishing two device categories, it disagrees with a suggestion in the comments that device category codes should be specific to the physical device characteristics rather than modality-specific device categories. CMS is finalizing two modality-specific pass-through payment device categories for RDN devices: radiofrequency and ultrasound.

Traditional Device Pass-Through Applications

1. Ambu® aScope™ Gastro

Summary: The Ambu® aScopeGastro 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® aScopeGastro 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).

The applicant clarified that the Ambu® aScope Gastro is not a material or supply furnished incident to the service and meets the eligibility criterion at §419.66(b)(4) because it must be purchased for each patient and is a device that is integral to the procedure. The applicant reiterated that as a single-use scope, it is not subject to capital equipment depreciation schedules. CMS agrees that Ambu® aScope™ Gastro is not a material or supply furnished incident to the service.

CMS did not identify an existing pass-through payment category that describes the Ambu® aScope Gastro. However, a few commenters stated that they believed that the existing code C1748 appropriately describes the Ambu® aScope Gastro technology. CMS disagreed stating no current category appropriately describes a single use, transoral gastroscope with illumination and imaging intended for use in the upper GI anatomy.

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.
- 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 different 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.

The applicant submitted comments and a multitude of studies to address CMS' concerns. However, CMS continued to have concerns about the studies and evidence submitted, as most of these are

background articles that do not directly assess, evaluate, or review Ambu® aScope Gastro relative to products on the market. CMS does not believe that the documents provided by the applicant and commenters demonstrate any clinical improvements that result from the use of the Ambu® aScope Gastro when compared to available reusable or single-use devices. CMS has determined that the Ambu® aScope Gastro does not meet the substantial clinical improvement criterion at §419.66(c)(2).

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

Final Decision: CMS does not approve the Ambu® aScope Gastro for transitional pass-through payment status because the product does not meet the substantial clinical improvement criterion at § 419.66(c)(2).

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 raised concern whether OCM is an integral part of the service being furnished. OCM does not appear to be necessary to furnish or deliver the primary procedure with which it is used, specifically debridement. The applicant responded to this concern by citing CMS' 2014 OPPS rule that indicated that skin substitutes are integral to, dependent on, and supportive to the surgical procedures in which they are used.[17] While OCM is not a skin substitute, it meets the integral service criterion for wound management, as outlined in the 2014 OPPS final rule, given that OCM not only matches but also exceeds the clinical utility of skin substitutes as an advanced wound therapy. CMS agreed with this comment and found that OCM is an integral part of the service being furnished.

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).

[17] 78 FR 74932

The applicant stated that OCM does not fit the classification of an incident to supply, defined as a material or supply furnished incident to a service because it aids in the management of wounds by supplementing the missing necessary components for the natural function of healing to occur; and is necessary to the wound care procedure itself when debridement alone is insufficient. CMS agreed stating OCM is necessary to the wound care procedure itself when debridement alone is insufficient and is, therefore, not a material or supply furnished incident to a service.

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.

The applicant responded to the second point above by stating at the time of the initial application, none of the studies had been submitted for peer-review or published in indexed journals. The clinical evidence previously referenced has now been published, is in press for an indexed journal, or has been submitted for review at an indexed journal and is publicly available on a preprint server. CMS indicated that the applicant has addressed its concerns about the lack of peer-reviewed and published studies.

However, CMS continues to believe the information submitted by the applicant does not address CMS' other two concerns. The submitted evidence does not demonstrate OCM's substantial clinical improvement in product safety in comparison to similar products. While the applicant has shown that OCM is safe, CMS continues to believe that the applicant has not shown that the product demonstrates substantial clinical improvement in comparison to currently available therapies.

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

Final Decision: CMS does not approve OCM for transitional pass-through payment status because the product does not meet the substantial clinical improvement criterion at §419.66(c)(2).

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 existing code for the product.

One commenter stated that OPN NC is similar in purpose and function to other devices under C1725; however, the double-layer construction is unique in the coronary space, and enables the high-pressure inflation needed for angioplasty of resistant lesions. The product has unique functionality of using pressure to dilate lesions and stents that would otherwise be resistant to dilatation.

CMS disagreed stating C1725 is used for devices that rely on inflation of a balloon to directly apply pressure to plaque in a vessel during an angioplasty procedure. While OPN NC may vary in construction from other devices described by C1725, CMS continues to believe that OPN NC may be coded with C1725. CMS has determined that OPN NC does not meet the device category eligibility criterion at §419.66(c)(1) because it is appropriately described by an existing category or a category previously in effect.

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.

Several commenters supported the approval of OPN NC based on personal experience with the product and opinions on the clinical benefit of utilizing OPN NC but did not provide data or studies to demonstrate that the product is a substantial clinical improvement. The applicant did not provide any comment. As CMS did not receive any information or evidence to address its concerns in the proposed rule, CMS found OPN NC does not meet the substantial clinical improvement criteria.

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

Final Decision: CMS does not approve OPN NC for transitional pass-through payment status because the product does not meet the device category eligibility criterion at §419.66(c)(1) or the substantial clinical improvement criterion at §419.66(c)(2).

8. 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 indicated in the proposed rule 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 in the proposed rule is that the technology is described by a prior category that would make OSCAR ineligible for pass through as there is an existing code for the product.

The applicant commented on this concern stating that C1725 describes non-laser catheters used for transluminal angioplasty, which may include guidance, infusion, or perfusion capability but OSCAR® facilitates the steps of percutaneous transluminal angioplasty (PTA) procedures through lesion access, lesion crossing, and lesions of different length treatment, achieved using only a single device for the entire procedure. OSCAR also provides features that are not available with other devices, such as user-adjustable guidewire support for accessing and crossing lesions and a length-adjustable balloon for lesion-specific angioplasty.

CMS responded that it continues to believe that C1725 appropriately describes OSCAR because, as described by the applicant, 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 function of devices that may appropriately be described by C1725. While CMS acknowledges OSCAR's additional features and functionality, it remains unclear whether some of these additional items are incidental to the service. CMS has determined that OSCAR does not meet the device category eligibility criterion at §419.66(c)(1) because it is appropriately described by an existing category or a category previously in effect.

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 raised the following concerns in the proposed rule 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 relied 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 like six device types including those using workhorse guidewires and premium guidewires. CMS does not believe OSCAR is like 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.

The applicant responded to CMS' concerns about the lack of sufficient peer-reviewed or published evidence stating internal benchmark tests and a real-world user evaluation demonstrate substantial clinical improvement. CMS acknowledged that data sources other than peer-reviewed or published studies may support substantial clinical improvement, but the predominance of the data submitted by the commenter appears to be opinion-based survey questions asked of physicians for marketing purposes.

On CMS' second concern, the applicant asserted that, in its 510(k) approval summary, FDA stated that OSCAR is comparable to the predicate device rather than equivalent. CMS responded that the FDA found OSCAR to be substantially equivalent to a legally marketed device, the INFINITY Angioplasty Balloon Catheter, which received 510(k) clearance on May 20, 2020. CMS maintains its concern that OSCAR does not demonstrate a substantial clinical improvement compared to the predicate device, INFINITY Angioplasty Balloon Catheter

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

Final Decision: CMS does not approve OSCAR for transitional pass-through payment status because the product does not meet the device category eligibility criterion at §419.66(c)(1) or the substantial clinical improvement criterion at §419.66(c)(2).

B. Device-Intensive Procedures

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

For 2019 and subsequent years, CMS finalized that device-intensive procedures would be subject to the following criteria:

- All procedures must involve implantable devices assigned to a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device-offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost. [18]

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 satisfies all the following:

- 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).
- Is not 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).

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. The device offset is used when CMS offsets the cost of the device from its payment such as when the hospital receives a device at no cost because the new device replaces a recalled device. CMS will continue temporarily assigning a

[18] 83 FR 58944-58948

higher offset percentage if warranted by additional information such as pricing data from a device manufacturer although CMS indicates this would happen very rarely.[19]

Once claims data are available for a new procedure requiring the implantation of a medical device, device-intensive status is applied to the code if the HCPCS code-level device offset is greater than 30 percent. 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 proposed 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. This policy would apply to both the OPPS and ASC payment systems beginning January 1, 2025.

Below is a summary of the major comments CMS received on this proposal:

Apply the Policy only Under the ASC System: Many commenters recommended that CMS delay implementing the proposed change under the OPPS because of a concern about inflating the transitional pass-through cost significance tests.

CMS Response: The purpose of the proposal was to improve the accuracy of the device percentage for device-intensive procedures in the absence of claims data. CMS believes this improvement in accuracy should be applied both for the ASC and OPPS. It is not delaying the policy for the OPPS or applying the policy only under the ASC payment system.

Incorrect Device Offset Percentages: There were also comments that the device offset percentage for specific codes was incorrect because of the lack of a device charge on the claim from the commenters. The comments suggested that CMS only determine the device percentage using claims where there was a device charge.

CMS Response: CMS agreed and will only calculate a device percentage based on hospital claims that reported a device code.

Do Not Apply Device Offset Percentages to Code Not Covered by Medicare: Some commenters indicated that CMS provided a device percentage for services that are not covered by Medicare. These commenters indicated that the device percentage is likely to be incorrect and requested that CMS not assign a device percentage to non-covered procedure codes.

[19] Additional information for consideration of an offset percentage higher than the default can be submitted to outpatientpps@cms.hhs.gov. Additional information can be submitted prior to the issuance of an OPPS/ASC proposed rule or as a public comment to a proposed rule.

CMS Response: CMS agrees with this comment and will not assign a device percentage to status indicator "E" codes that are not covered by Medicare.

Update Device Offset Percentages Annually for Predecessor Codes: One commenter recommended that CMS update the device offset percentages from predecessor codes annually rather than just in the first year it calculates the device offset percentage from the predecessor code.

CMS Response: CMS agreed with the commenter and will refine the process for applying device offset percentages to use available claims data from predecessor codes annually rather than just in the first year.

Final Decision: CMS is finalizing its proposed policy with the modifications above in response to comments. The full listing of 2025 device-intensive procedures is provided in Addendum P.

2. Device Edit Policy

Going back to 2015, CMS has had device to procedure edits that require a device charge on a claim for device-intensive procedures. 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 newly defined device-intensive procedures. In addition, CMS created HCPCS code C1889 to recognize devices 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.

CMS did not propose any changes to its device edit policy but did receive comments requesting additional device to procedure edits for specific HCPCS codes. One comment indicated that if the device percentage for a procedure is over 30 percent but declines to below 30 percent, the device to procedure edit no longer applies. This could result in a device related procedure not having a device charge and not being subject to a device to procedure edit.

In response to this comment, CMS is adopting a policy that will apply the device edit policy permanently once a procedure is designated as a device-intensive procedure in a year. CMS indicates that this policy will retain CMS' ability to properly set payment rates and determine appropriate device offset percentages for device-intensive procedures

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

CMS currently pays for drugs, biologicals, and radiopharmaceuticals in one of three ways: packaged (either policy packaged or threshold packaged); separately paid above a cost threshold; or transitional pass-through payments. When a drug, biological or radiopharmaceutical is packaged into the payment for the associated service, hospitals do not receive 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 ($140 drugs and biologicals other than radiopharmaceuticals 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

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. Transitional pass-through drugs and biologicals for 2025 and their designated APCs are assigned status indicator "G" in Addenda A and B of the final rule. For 2025, CMS is continuing to use ASP+6 percent as payment for transitional pass-through drugs and biologicals. CMS will be paying 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 130 of the final rule lists 25 drugs and biologicals where CMS will be expiring transitional pass-through payment by 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 131 of the final rule lists 28 drugs where CMS will end transitional pass-through payment status in 2025. Table 132 of the final rule lists 80 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 proposed 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 policy-packaged and not paid separately except when receiving transitional pass-through payments. Beginning with 2025, CMS is packaging diagnostic radiopharmaceuticals with per-day costs equal to or below $630 and paying separately for diagnostic radiopharmaceuticals with per-day costs above $630.

The packaging threshold was initially set at $50 in 2005 for drugs, biologicals and therapeutic radiopharmaceuticals. To calculate the 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 proposed to use the same methodology to update the diagnostic radiopharmaceutical packaging threshold beginning in 2026.

CMS proposed 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 (except for those drugs and biologicals with multiple HCPCS codes that include different dosages as described below). Using 2023 claims data processed through June 30, 2024, 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 final rule, CMS used ASP+6 percent for each HCPCS code with manufacturer-submitted ASP data from the 2nd quarter of 2024 (data that was used to pay for drugs and biologicals in physicians' offices effective October 1, 2024). For products that do not have an ASP, other than diagnostic and therapeutic radiopharmaceuticals, CMS uses wholesale acquisition cost (WAC) or average wholesale price (AWP) pricing to determine the per-day cost. If neither of these is available, CMS uses 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 is using mean unit cost derived from the 2023 hospital claims data to determine their per-day cost. CMS does not use 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 proposed 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.

Final Decision: CMS did not receive any comments and is finalizing the proposed update to the drug packaging threshold without change.

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.
- 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
- 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 proposed to continue its policy of making an annual packaging determination for a HCPCS code in the OPPS final rule and not updating that code's packaging status during the year. Only HCPCS codes that are identified as separately payable in the 2025 final rule will be subject to quarterly updates.

As in past years, CMS proposed 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 indicates 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.

Final Decision: CMS addressed comments on the radiopharmaceutical packaging threshold earlier in the final rule (section II.A of this summary). Otherwise, these policies represent routine annual updates that CMS is finalizing without change.

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

For 2025, CMS is continuing 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 133 of the final rule.

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

As indicated above, CMS proposed to pay for separately payable drugs and biologicals at ASP+6 percent in 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 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 physicians' offices when hospital acquisition costs are unavailable.

The payment rates shown for drugs and biologicals in Addenda A and B of the final rule are not the payment rates that Medicare will pay on January 1, 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 final rule for which there was no ASP information available for the 4th quarter of 2023 (used for payment in physicians' offices for the 2nd quarter of 2024) are based on 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 is 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 the ASP of their reference product. These biosimilars will be paid at 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

134 of the final 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, proposed to allow payment based on invoice cost consistent with how these products are paid in physician offices. CMS is adopting this policy beginning in 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.

Some commenters were concerned about the operational burden of using acquisition cost minus any rebates, chargebacks, or post-sale concessions because rebates are often made months after sale. Other commenters were concerned with participating 340B providers' disclosure of their 340B drug acquisition cost which is proprietary data.

CMS responded that this policy has been in effect under the PFS and there is no evidence that health care professionals paid under the PFS forgo reimbursement for drugs paid at invoice prices because of administrative burden. In response to the 340B concern, CMS indicated that it does not disclose proprietary data.

Final Decision: CMS is finalizing its proposal without modification for 2026 to allow MACs to use the provider invoice amount to set a payment rate for a separately payable drug, biological, or radiopharmaceutical until its payment amount becomes available and CMS provides a payment rate.

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 will pay separately for diagnostic radiopharmaceuticals with a per-day cost above $630. CMS is basing 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 will use WAC. If WAC also is unavailable, CMS will base payment on 95 percent of AWP.

6. Payment for Blood Clotting Factors

CMS will 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 continuing 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 one day in the hospital outpatient setting. CMS applies ASP+6 percent (or WAC or AWP as applicable) to determine their 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 policies related to this provision in the 2025 PFS rule. Readers are referred to the 2025 PFS rule for a full description of the policy including any comments and responses.

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 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 in 2022, these HCPCS codes are assigned to APCs as follows in 2024:

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

For 2025, CMS proposed to continue the following policies:

- Skin substitutes with transitional pass-through payment status will be assigned to the high-cost category.
- Skin substitutes with pricing information but without claims data will be assigned to either the high- or low-cost categories based on the product's ASP+6 percent payment rate (WAC+3 percent if ASP is unavailable, or 95 percent of AWP if neither ASP nor WAC is available) as compared to the MUC threshold.
- Any skin substitute product 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.

Even though these policies are consistent with those that CMS has adopted in prior years, there were several public comments. The HOP Panel and other commenters requested that CMS discontinue its packaging policy for skin substitutes on the basis that it discourages treating larger wounds in the hospital setting. These cases are shifting to the physician office setting where skin substitutes are paid based on the amount of product being used, according to the commenters. CMS disagreed, stating that the average cost of the product being used will be reflected in the overall cost of the application procedure and such a policy is consistent with the principles of a prospective payment system. In some cases, payment will exceed provider costs, and, in other cases, it will be less than provider costs.

The HOP Panel and several commenters also requested that the payment rate for graft skin substitute procedures be the same no matter where on the body the graft skin substitute product is applied to the patient. CMS responded that there are different CPT codes for applying graft skin substitutes to the trunk, arms, and legs as compared to the face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, fingers, and toes in explaining why its payments may differ in circumstances where the codes are assigned to different APCs based on costs.

Several comments, including from the HOP Panel, requested that all new graft skin substitute products be assigned to the low-cost group whether they have a Q- code or an A-code until cost data becomes available for the product. CMS explained that its policy on this issue was a result of including HCPCS code C1849 in the high-cost group. Assigning the successor products' A codes

or other new products with A codes avoids having products with less than two years of claims data that were originally in the high-cost group being reassigned to the low-cost group simply because of a lack of available data.[20]

CMS added that skin substitute products may contain both biological and synthetic elements. Having products with both biological and synthetic elements leads to difficulty defining which of the products assigned to the A2XXX series would be considered ‘‘synthetic’’ and described by HCPCS code C1849. By giving the broadest definition of products that could have been described by HCPCS code C1849 ensures that none of those graft skin substitute products would be assigned to the low-cost group until CMS receives cost data for them.[21]

One commenter requested that CMS realign products in the high- and low-cost groups based on their ASP that is are now required to be reported by skin substitute manufacturers.[22] CMS disagrees arguing that such an approach would not be feasible as it would involve extracting the units of graft skin substitute product used on a particular packaged service and then multiplying by an ASP to revise the cost of packaged procedure.[23]

There was one public comment requesting that CMS not package skin substitute products that have been approved by the FDA through the premarket approval (PMA), biological license application (BLA) or new drug application (NDA) processes as these are more rigorous approval processes than others that skin substitutes may undergo. CMS referred the commenter to its response to a similar comment in the 2014 OPPS final rule (78 FR 74931). In that rule, commenters asserted skin substitutes approved under the PMA, BLA or NDA processes are “specified covered outpatient drugs” and must be paid separately under section 1834(t)(14) of the Act. CMS disagrees that skin substitutes are “drugs” and not supplies even though they are treated as drugs for purposes of payment outside of the hospital outpatient department.

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[20] While CMS’ policy explains why codes previously coded with C1849 are assigned to the high-cost group, its policy remains different for new A codes relative to new Q codes. A new A code with no prior assignment to either the high or low-cost group is assigned to the high-cost group even though there is no pricing data while a new Q code without pricing data is assigned to the low-cost group until there is pricing data.

[21] This discussion suggests that once CMS has cost data for an A code, the code would be assigned to the high- or low-cost group based on the products MUC or PDC. However, CMS also has a policy that once a product is included in the high-cost group, it will remain in the high-cost group and not be reassigned to the low-cost group—two policies that appear to be in conflict. The final rule preamble has indicated for several years that skin substitutes assigned A codes are always assigned to the high-cost group meaning these products will be paid a higher amount irrespective of the MUC or PDC.

[22] This commenter is referring to 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.

[23] This issue may involve a misunderstanding between CMS and the commenter. The commenter is saying that CMS should use the ASP as the per unit cost for purposes of assigning a skin substitute product to the high- or low-cost group. CMS’ response suggests that it would not know how to calculate the geometric mean cost for the application procedure using ASP. These are distinct issues. CMS could calculate the geometric mean cost the same way it does currently and still assign a skin substitute product to the high- or low-cost group based on its ASP much as it does with products that do not have an MUC in the cost data CMS uses to set the relative weights.

Final Decision: CMS is finalizing all its policies as proposed and is not making any changes in response to these commenters. Table 135 of the final 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) produced without the use of HEU available to meet the needs of patients in the United States.[24]

In the 2023 rulemaking cycle, CMS indicated that the Department of Energy (DOE) 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 policy packaged into the diagnostic imaging with which they are used, 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 through the end of 2025.

While CMS anticipated ending this additional $10 payment for non-HEU-sourced Tc-99m beginning in 2025, the DOE 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.

[24] Mo-99 is source material for the radioisotope Technetium-99 (Tc-99m).

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 proposed 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.

Multiple commenters encouraged CMS to work with interested parties to determine a different payment amount that would adequately cover the cost difference between domestically produced Tc-99m radiopharmaceuticals and foreign produced Tc-99m radiopharmaceuticals. There were also comments stating that the add-on payment for Tc-99m radiopharmaceuticals produced from non-HEU sources has not substantially influenced the types of Tc-99m radiopharmaceuticals purchased by outpatient hospitals. Commenters were also concerned about to define a Tc-99m radiopharmaceutical as a domestically produced product.

One commenter opposed this proposal on administrative grounds that a provider purchasing Tc-99m will not be able to track or document information on the production source of the Tc-99m generators they purchase. Further, this commenter argued that a domestic producer will charge the same price as a foreign producer to Tc-99m to remain competitive.

CMS responded that DOE recommends maintaining the $10 value as the add-on payment transitions from a non-HEU payment to a domestically sourced Tc-99m payment. If commenters have data showing that the price differential between domestically produced and foreign produced Mo-99 will be significantly more or less than $10, they may provide that data to CMS to be considered for the 2026 OPPS rulemaking. With respect to the determination that a Tc-99m radiopharmaceutical is domestically produced, DOE is establishing those criteria that CMS will include in the 2026 OPPS rule.

Final Decision: CMS is finalizing its proposal without change 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. As established in the 2024 OPPS/ASC final rule, 2025 will be the final year of the $10 add-on payment for TC-99m derived from non-HEU sources.

VI. Estimate of Transitional Pass-Through Spending

CMS estimates 2025 final rule transitional pass-through payments of approximately $88.7 million, or 0.37 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 $318.28 million in 2025 for devices—$91 million for those recently eligible for transitional pass-through payments that will continue for 2025 and $227.1 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 did not propose any changes to the current clinic and emergency department hospital outpatient visits payment policies or to the payment policy for critical care services when these services are provided on the campus of a hospital for 2025. It also did propose 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[25] 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 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.[26] 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 for IOP services furnished in CMHCs. Of note, the outpatient mental health treatment limitation does not apply to IOP services.

[25] See section 1833(t)(2)(E) of the Act.
[26] The 2025 payment policies for IOP services furnished by FQHCs and RHCs are established in the 2025 Physician Fee Schedule final rule.

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 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.[27] 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 did 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.

Selected Comments/Responses. Some commenters advocated for including caregiver training services and PIN services in determining payment for the number of PHP or IOP services per day; others suggested including discharge support and peer services as applicable for PHP and IOP. CMS does not adopt any of these suggestions, citing inadequate utilization data among other rationales. Other commenters urged CMS to allow PHP and IOP services to be furnished remotely, but the agency notes that the flexibility under the COVID-19 PHE to provide PHP services remotely to a beneficiary in their home ended with the expiration of the PHE on May 11, 2023. The same applies to the remote provision of IOP services. However, CMS reminds readers that none of the PHP regulations would preclude a patient that is under a PHP plan of care from receiving other reasonable and medically necessary non-PHP services from a hospital, which means patients could receive mental health services provided outside of the PHP by the same or another hospital when such services are reasonable and medically necessary. The IOP regulations afford the same flexibility.

[27] 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.

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

2. 2025 Payment Rate Methodology for PHP and IOP

CMS finalizes its proposed policies for the 2025 payment rate methodology for PHP and IOP services without modification. It uses 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 calculates 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 are 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 sets 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 2025 geometric mean per diem costs and payment rates are as follows:

2025 APC	Group Title	PHP and IOP APC Geometric Mean Per Diem Costs*	Payment Rates**
5851	Intensive Outpatient (3 services per day) for CMHCs	$112.59	$111.24
5852	Intensive Outpatient (4 or more services per day) for CMHCs	$170.37	$168.32
5853	Partial Hospitalization (3 services per day) for CMHCs	$112.59	$111.24
5854	Partial Hospitalization (4 or more services per day) for CMHCs	$170.37	$168.32
5861	Intensive Outpatient (3 services per day) for hospital-based IOPs	$272.46	$269.19
5862	Intensive Outpatient (4 or more services per day) for hospital-based IOPs	$413.50	$408.55
5863	Partial Hospitalization (3 per day) for hospital-based PHPs	$272.46	$269.19
5864	Partial Hospitalization (4 or more services per day) for hospital-based PHPs	$413.50	$408.55

* Table 136 of the final rule shows the proposed 2025 PHP and IOP APC geometric mean per diem costs.
** The 2025 payment rates are from Addendum A to the final rule.

D. Outlier Policy for CMHCs

For 2025, CMS updates 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 is calculated using the existing methodology and will 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 designates less than 0.01 percent of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHC outliers.

CMS sets 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 apply to intensive outpatient services paid under the CMHC IOP APCs.

For 2025, CMS uses 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 applies that policy 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 continues this policy for 2025 and applies 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 continues this policy for 2025 and to apply it to both PHP and IOP APCs.

E. Regulatory Impact

CMS estimates that payments to 35 CMHCs for PHP services will increase by 11.9 percent in 2025 relative to their 2024 payments. The 2023 claims data used for rate-setting in the 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 require intensive or extensive postoperative care.

CMS has historically worked with interested stakeholders, including professional societies, hospitals, surgeons, hospital associations, and beneficiary advocacy groups, to evaluate the IPO list and determine whether services should be added or removed. Stakeholders are encouraged to request reviews for a particular code or group of codes. CMS has asked that requests include

evidence that demonstrates that the procedure can be performed on an outpatient basis in a safe and appropriate manner in a variety of different types of hospitals.

Prior to 2021, CMS traditionally used the following five criteria to determine whether a procedure should be removed from the IPO list. It incorporated these criteria into the regulations beginning in 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 services that could be removed from the IPO list. Using the five criteria listed above, CMS did not find sufficient evidence that these services met the criteria for being removed from the IPO list for 2025. CMS did 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).

Public commenters supported CMS' proposal to add CPT codes 0894T, 0895T, and 0896T to the IPO list for 2025.

The HOP Panel and one commenter requested that CMS remove CPT code 22848 on the basis that procedure meets criteria 1 – 4 listed above. CMS agrees with this comment. Further, CPT 22848 is

an add-on code and the primary procedure with which it is billed is not on the IPO list.

- 22848 - Pelvic fixation (attachment of caudal end of instrumentation to pelvic bony structures) other than sacrum (List separately in addition to code for primary procedure)

Final Decision: CMS is finalizing the addition of CPT codes 0894T, 0895T and 0896T to the IPO list. In addition, it is removing CPT 22848 from the IPO list.

X. Nonrecurring Policy Changes

A. Remote Services

1. Payment for Outpatient Therapy Services, Diabetes Self-Management Training (DSMT), and Medical Nutrition Therapy (MNT) When Furnished by Institutional Staff to Beneficiaries in Their Homes Through Communications Technology

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.[28]

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. In the 2024 Physician Fee Schedule (PFS) final rule, CMS sought comment on current practice for these services when billed, including how and to what degree they continue to be provided remotely to beneficiaries in their homes. CMS also sought comment as to whether these services may fall within the scope of Medicare telehealth at section 1834(m) of the Act or if

[28] 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*.

there were other relevant authorities the agency might consider in future rulemaking.

In the 2025 OPPS proposed rule, CMS noted that if the telehealth waivers were to be extended, the agency expected 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. **However, without additional legislation, Medicare will no longer pay for outpatient therapy DSMT, and MNT services when furnished remotely by hospital staff to beneficiaries in their homes beginning January 1, 2025**.

2. Periodic In-Person Visits for Mental Health Services Furnished Remotely 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 until January 1, 2025, 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.

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. Again, in the 2025 OPPS proposed rule, CMS anticipated aligning its policies that apply to hospitals with the statutory extension.

In this final rule, however, **CMS affirms that the in-person visit requirement for professionals billing for mental health services via Medicare telehealth will apply again beginning January 1, 2025, and accordingly, the in-person visit requirements will also apply for mental health services furnished remotely by hospital staff to beneficiaries in their homes through communications technology beginning January 1, 2025**.

3. 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 proposed not to pay for these codes under the PFS because the agency believed they would be duplicative of office E/M codes already paid for under the telehealth benefit established under section 1834(m) of the Act.

Under the OPPS, CMS does not recognize the CPT E/M codes and instead uses HCPCS code 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 proposed not to recognize the telemedicine E/M code set under OPPS.

However, CMS sought 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. CMS also sought comment on whether to develop separate coding for telemedicine hospital E/M services.

In this final rule, CMS is finalizing its proposal not to recognize the telemedicine E/M code set under the OPPS.

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 proposed 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 proposed 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.

CMS indicates that all comments on this proposal supported CMS making conforming revisions to §§410.27 and 410.28 to allow for the direct supervision of CR, ICR, PR services and diagnostic services via audio-video real-time communications technology (excluding audio-only) through December 31, 2025, with some commenters suggesting that the proposed changes to direct supervision be made permanent.[29]

In this final rule, CMS is finalizing, without modification, its proposal to revise §§410.27(a)(1)(iv)(B)(*1*) and 410.28(e)(2)(iii) to allow for the direct supervision of CR, ICR, PR services and diagnostic services via audio-video real-time communications technology (excluding audio-only) through December 31, 2025.

[29] One commenter, however, opposed making this change permanent, arguing that it would increase "incident to" billing, which would obscure the extent to which physician assistants and nurse practitioners were actually performing the services.

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.[30] For 2024, the AIR is $667 for the lower 48 states and $961 for Alaska. The AIR is intended to cover the cost of hospital outpatient services, including 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. Public commenters on this issue in the 2024 OPPS rule expressed universal support for establishing a policy that would allow IHS and tribal health care facilities to receive separate payment for drugs that cost more than the AIR.

In the 2025 OPPS/ASC proposed rule, CMS proposed to separately pay IHS and tribal hospitals for drugs furnished in hospital outpatient departments with per day costs that exceed twice the AIR in the lower 48 states ($1,334 in 2024) through an add-on payment to the AIR beginning January 1, 2025. CMS proposed only paying separately when a drug's cost exceeds two times the rate applicable to the lower 48 states' AIR to ensure that the add-on payment only applies to drugs whose costs significantly exceed the AIR.[31] CMS sought 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.

CMS proposed to pay for drugs with costs above the $1,334 threshold at the drugs' average sales price (ASP) without the 6 percent add-on that is included in other Medicare payments for Part B drugs. The justification for not paying the add-on was that IHS and tribal facilities, unlike hospitals paid under the OPPS, primarily obtain their drugs through the federal supply schedule, at costs that are significantly lower than ASP. This approach is also consistent with paying ASP without the add-on to certain Opioid Treatment Program drugs.

In the event ASP pricing information was not available for a particular drug, CMS proposed to pay wholesale acquisition cost (WAC) without an add-on. If WAC pricing information was not available, CMS proposed to pay 89.6 percent of average wholesale price (AWP) (the effective equivalent of 95 percent of AWP absent a 6 percent add-on, *e.g.*, 100/106 x 95 = 89.6). CMS proposed to follow its existing methodology to calculate per-day costs that it uses for OPPS drugs to determine whether an OPPS drug's cost 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.

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[30] Sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248(a), 249(b)), 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.

[31] This cost-multiplier approach is consistent other OPPS thresholds for making additional payment such as outliers payments when 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 indicates that *all* commenters on the proposed policy supported separately paying IHS and tribal hospitals for all high-cost drugs (not just oncology drugs) furnished in hospital outpatient departments through the establishment of an add-on payment to the AIR using the authority under which the annual AIR is calculated. **CMS is finalizing this policy as proposed. Medicare will pay IHS and Tribal facilities an amount equal to ASP (without a 6 percent add-on) for Part B drugs whose costs exceed two times the lower 48 AIR ($1,334 in 2024). Medicare will also make this add-on payment for biosimilars whose per-day costs do not exceed the 2x lower 48 AIR threshold, but whose reference biologics costs do exceed the threshold.**

Request for Information - Paying all IHS and Tribally Operated Clinics the IHS Medicare 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 IHS Medicare outpatient per visit rate/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 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 proposed rule (86 FR39240). In response, CMS did not receive specific information on costs or specific types of clinics but expressed an interest in continuing a 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, in the 2025 OPPS/ASC proposed rule (89 FR 59394) CMS requested the same information from the public that it requested in the 2022 rulemaking including:

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

CMS indicates it received "a few comments" in response to the 2025 RFI. The agency discusses these comments, but none resulted in any action by CMS in response.

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

In the 2025 PFS proposed rule, CMS proposed to modify its policies on payment for CRC screening services (§410.37) 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 proposed to make the following OPPS changes for 2025:

- Delete screening barium enema HCPCS codes G0106, G0120 (which will no longer be necessary), and G0122 (which is already non-covered);
- 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.

After consideration of the public comments received, CMS is finalizing the proposals made in the CY 2025 OPPS/ASC proposed rule affecting CRC Screening Services with one modification. **CMS is finalizing the deletion of HCPCS codes G0106 and G0120 (screening barium enema) effective December 31, 2024, and is finalizing the reassignment of CPT code 74263's status indicator as proposed from status indicator "E1" (not covered/not payable) to "S" to indicate that the code is separately payable. The modification relative to the proposed rule is that CMS is reassigning CPT code 74263 to APC 5523 (Level 3 Imaging Without Contrast) in this final rule**.

E. 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.[32] HHS has conducted stakeholder outreach to understand barriers to awareness and uptake and to seek feedback on potential modifications that could increase effectiveness.

In the proposed version of this rule, CMS sought comment on domestically produced PPE, specifically addressing questions it raised regarding (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.

Selected Comments. Several commenters supported modifying the payment adjustment to provide a national standard unit cost differential, which would minimize reporting burden and ensure payments to hospitals are equitable. One stated the national differential should be set at $0.50. Others encouraged CMS to work with external partners and resources to determine the national standard unit cost differential.

Several offered suggestions to CMS for additional support for hospitals to purchase domestic-made surgical N95 respirators, such as:

- Work with Congress to give CMS authority to apply this payment policy in a non-budget neutral manner under the OPPS.
- Work with Congress to give CMS authority to offset all the marginal costs incurred by the hospital in procuring domestically made surgical N95 respirators, rather than just the Medicare-share of these costs.

[32] 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).

- Reimburse hospitals 5 times the differential between the acquisition cost of domestic surgical N95 respirators and non-domestic surgical N95 respirators.
- Increase education and communication of the payment adjustment to hospital purchasing decision-makers within the healthcare system.

Regarding why use of the payment adjustments has been limited, a few said some providers may still have stockpiles of surgical N95 respirators purchased during the pandemic. Other explanations included:

- The current supply and production capacity of wholly domestically made surgical N95 respirators is still insufficient.
- The payment adjustment does not result in a significant decrease in cost for providers.
- Hospitals primarily buy surgical N95 respirators through distributors who are not incentivized to purchase and make available to hospitals more expensive domestically produced surgical N95 respirators, raising the issue of payment adjustment eligibility, discussed in the following section.

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 CY 2023 OPPS/ASC final rule 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.

Selected Comments. In response to several questions posed by CMS in the proposed version of this rule, commenters generally expressed support for making publicly available a list of products eligible for the payment adjustment, since hospitals have had difficulty ascertaining which products meet the definition of domestic and obtaining written statements from manufacturers. If such a list were made available, commenters said CMS should modify the payment adjustment so that hospitals attesting to purchasing wholly domestically made surgical N95 models from such a list do not need to obtain a written statement from the manufacturer. Some commenters stated that if such a list were established, products not on the list should still be eligible for the payment adjustment if the product could be verified as domestic by some other means, such as through a written statement from the manufacturer.

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 health care 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).

Selected Comments. In response to several questions posed by CMS in the proposed version of this rule, commenters were supportive of expanding the payment adjustment to include non-surgical N95 respirators. A few indicated that non-surgical N95 respirators represent most of the N95 respirators purchased by health care providers and that including them in the payment adjustment would lead to greater utilization of the payment adjustment by hospitals.

3. Potential Modifications to Include Nitrile Gloves

CMS lists several 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. Prior to 2020, more than 95 percent of nitrile gloves sold in the U.S. came from other countries. 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 of 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 but that U.S. manufacturers 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. 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.

Selected Comments. In response to several questions posed by CMS in the proposed version of this rule, commenters were generally supportive of modifying the payment adjustment to include nitrile gloves, citing several reasons, including quality concerns. Some indicated that certain domestic nitrile glove manufacturers have ceased operations due to their higher prices; reducing or eliminating the price difference would increase utilization of domestic nitrile gloves. However, commenters differed in their assessment of the magnitude of the actual price differential.

A few commenters supported applying the Make PPE in America Act requirements when defining domestic nitrile gloves and that there should be a temporary exception for NBR that could be eliminated when domestic supply of NBR is sufficient to support domestic demand. Another commenter expressed concerns that neither the Berry Amendment nor the Make PPE in America Act requirements are commonly used by hospitals and health systems and therefore urged CMS to consider using another standard.

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. In the proposed version of this rule, CMS sought comment on other PPE types and medical devices that could be appropriate for a similar payment adjustment.

Selected Comments/Responses. Several commenters urged CMS to expand the payment adjustment to include other PPE types and medical devices such as gowns, hair nets, beard covers, bouffant caps, shoe covers, face shields, ASTM level II and III surgical masks, powered air purifying respirators, elastomeric respirators, syringes, needles, catheters, and wound care dressings. Commenters indicated many of these products are currently being purchased from non-domestic manufacturers and have been prone to shortages and quality issues, and that expanding the payment adjustment to more products would increase uptake of the payment adjustment by hospitals, strengthen the existing U.S. manufacturing base, incentivize other manufacturers to prioritize domestic production, and protect access to high-quality products.

CMS thanked commenters for all the comments on payment adjustments under the IPPS and OPPS for domestic personal protective equipment, etc., and agrees with the calls for improvements to and expansion of these payment adjustments. In 2026 rulemaking, CMS intends to:

- Propose a new payment methodology, such as one that no longer relies exclusively on hospital-specific data;
- Propose expansion of the payment adjustments to domestic non-surgical N95 respirators and domestic nitrile gloves;
- Continue to explore expanding the payment adjustments to include other types of domestically made PPE and other medical products; and
- Explore the feasibility of creating a list of qualifying surgical N95 respirators that are domestically made PPE.

F. 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.

On September 30, 2024, the final NCD decision memo was issued and made effective. Thus, all components are covered as an additional preventive service without Part B cost sharing (i.e., deductibles or co-pays).

Table 142 (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

CMS proposed to pay for HIV PrEP drugs and related services as additional preventive services under the OPPS beginning in 2025. Since the resource costs for these codes would be similar across different settings of care, including the HOPD and physician office, CMS proposed that payment amounts for these services in the 2025 PFS proposed rule would be appropriate for use under the OPPS, as well. CMS proposed 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.[33] For the drugs themselves (J0739, J0750 and J0751), CMS proposed that the payment amount utilize the ASP methodology under section 1847A of the Act, when ASP data is available, which is preferable to CMS 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,[34] etc., to 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 proposed 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 proposed 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 notes that the PFS proposal also included a final step of invoice pricing not available under the OPPS and thus not proposed here, but addressed in section V.B.2.d—Invoice Drug Pricing for 2026. Because invoice pricing is not available in the OPPS, CMS proposed 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 (DCAPS).

If the HIV PrEP drugs are covered as additional preventive services in accordance with the proposed (at the time) NCD, CMS proposed 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).

[33] CMS did not propose to pay for HIV PrEP counseling performed by physicians under the OPPS as this is a physician-only service.
[34] 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.

For HCPCS code J0799 (an HIV PrEP drug that is FDA approved but does not yet have a HCPCS code), CMS proposed 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 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.

Final Action. Given the final decision memorandum for the NCD effective September 30, 2024, CMS will pay for PrEP for HIV drugs under the OPPS, generally based on the ASP methodology, for the interim period of September 30 through December 31, 2024. Beginning January 1, 2025, CMS is finalizing in this rule its payment approach for determining a payment limit for DCAPS drugs, which will apply to PrEP for HIV, as described in greater detail below.[35]

The finalized policy reflects some modifications from the proposal. In the proposed rule, when using NADAC pricing to determine a payment rate, all NDCs (generic and brand) were to be averaged together to determine the payment amount. Similarly, when using the FSS, CMS proposed calculating the average price per billing unit for all NDCs listed for a drug. In this final rule, to maintain consistency with the PFS finalized policy, CMS is finalizing a policy to treat drugs as in the Medicare Claims Processing Manual, Chapter 17, sections 20.1.3 and 20.4—that is, when calculating the price for multiple-source DCAPS drugs using NADAC or FSS pricing, use the lesser price of (1) the median of all generic forms of the drug; or (2) the lowest brand name product.

CMS finalizes the following payment approach for drugs covered as additional preventive services (DCAPS) and paid under the OPPS:

- If ASP data is available, the payment limit will be determined based on the methodology under section 1847A(b) of the Act (usually 106 percent of ASP);
- If ASP data is not available, the payment limit will be calculated using NADAC prices for the drug;
- If ASP data and NADAC prices are not available, the payment limit will be calculated using the FSS[36] prices for the drug; and

[35] The agency directs interested parties to https://www.cms.gov/medicare/coverage/prep for more information on the final NCD and the transition of PrEP for HIV coverage and payment from Part D to Part B. The payment assignments for the interim period (that is, September 30 to December 31, 2024) are in Table 143 for the final rule, listing the HCPCS codes, long descriptor, status indicator, and APC. For 2025, PrEP for HIV will be paid in accordance with the payment approach finalized for all DCAPS drugs, with the APC assignments shown in Table 144 of the final rule.
[36] CMS also clarifies that the FSS price is the "other government agencies" price.

- If ASP data, NADAC prices, and FSS prices are not available, payment will be WAC plus 6 percent, or 3 percent if in an initial sales period, consistent with payment for separately payable drugs paid under the OPPS.

Because invoice pricing is not currently available in the OPPS, if ASP, NADAC and FSS pricing are not available for a DCAPS drug, CMS will use WAC plus 6 percent, or 3 percent if in an initial sales period—but only for 2025. As discussed in section V.B.2.d (Invoice Drug Pricing for 2026), CMS is finalizing a policy to begin to price certain drugs based on their invoices starting in 2026 and is making a conforming change that, starting in 2026, if ASP data, NADAC prices and FSS prices are not available, the payment rate will be based on the invoice price.

For additional clarification, CMS is adding conforming regulation text in a new paragraph (j) in §419.41, which details the payment amounts for drugs covered as additional preventive services under the OPPS and includes the finalized payment methodology hierarchy as described above.

Selected Comments/Responses. Several commenters were supportive of the proposed payment policies and encouraged CMS to use its authority to pay for PrEP for HIV drugs and services as additional preventive services.

Several commenters supported the proposal to use ASP plus 6 percent as the basis of payment, except when ASP is unavailable, in which case CMS should base payment on WAC plus 3 or 6 percent, rather than NADAC or FSS pricing. Commenters expressed concern that pricing under NADAC and FSS would be inadequate. CMS believes that NADAC and FSS pricing are appropriate for determining a payment limit under the OPPS for DCAPS drugs when ASP data is not available and reiterates why.

A few commenters stated that Medicare payments for these services should take into account the site of service since, in their view, hospital outpatient departments are more likely to care for patients who are more medically and socially complex than those cared for in physicians' offices. However, CMS continues to believe that the additional preventive services in this section generally should have resource costs that align between care settings, such as the HOPD and the physician's office, and thus is adopting a similar payment approach under the fee schedule for DCAPS drugs in the physician office setting.

For the PrEP for HIV counseling services performed by hospital staff (HCPCS code G0013), CMS finalizes its proposal to assign this service to a clinical APC with a payment rate that approximates the payment rate in the physician office setting (APC 5821—*Level 1 Health and Behavior Services*). For the administration of the drug, however, CMS finalizes its proposed assignment of HCPCS code G0012 (*Injection of pre-exposure prophylaxis (prep) drug for hiv prevention, under skin or into muscle*) to APC 5692 (*Level 2 Drug Administration*) based on the OPPS specific crosswalk to HCPCS code 96372 (*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*). Since there is an existing crosswalk code under the OPPS on which to base payment for HCPCS code G0012, CMS believes it is appropriate to finalize the assignment of that code to APC 5692, rather than the PFS payment rate.

A commenter strongly opposed use of FSS pricing to pay for PrEP for HIV drugs but asked that CMS confirm it will utilize the Other Government Agency (OGA) FSS price if it proceeds with finalizing the use of the FSS price when ASP and NADAC pricing data are not available. The commenter stated that basing payment on the OGA FSS price would better support patient access to PrEP for HIV drugs compared to the Big 4 FSS price (VA, DoD, the Public Health Service, and the Coast Guard) that reflects substantial statutory discounts that do not apply to Medicare Part B providers, which could lead to significant underpayment for PrEP for HIV drugs. CMS confirms that the FSS pricing data used will be the OGA prices.

G. Clinical Trials and 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 proposed to use its authority under section 1833(w) of the Act to expand the policy to national coverage determinations (NCDs) that provide Medicare coverage for drugs using CED. Under the proposed policy, CMS would create a new HCPCS code, or revise an existing HCPCS code, to describe a study under CED. The HCPCS code would 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).[37] The HCPCS code would be billed for both patients in the experimental arm and the

[37] Under CMS' proposal, 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). The payment amount for the study drug, or active comparator drug, would be based on ASP+6 percent if ASP data is available. If ASP data is not available, CMS would base the payment on WAC+3 percent during the initial sales period, and WAC+6 percent if ASP remained unavailable two calendar quarters after the drug is first used. If WAC is not available, CMS proposed to pay 95 percent of AWP.

control. CMS proposed to assign 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,[38] or comparator drug, is used.

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.

Comments on the CMS proposal were decidedly mixed. Many spoke in opposition to the proposal, arguing that a single blended payment rate would lower payments and disincentivize provider participation in clinical trials, particularly safety net providers serving disadvantaged populations. Others opposed the proposal asserting that it is unethical to require Medicare beneficiaries to participate in a study in order to obtain access to an already FDA-approved drug, or that it is unethical to require patient cost sharing for a placebo when an FDA-approved treatment is available. Others argued that CMS should not apply a CED designation to drugs and biologics that are already approved by the FDA. Several commenters supported the CMS proposal, but asked for additional information and guidance.

In light of public comments, **CMS is not finalizing this proposal, noting that upon consideration, the proposal raises broader policy and ethical implications. CMS is not revising the regulation text at §419.47 to include a payment methodology for CED drugs and devices. The agency is finalizing its proposal to codify its coding and payment policy for Category B IDE clinical trials with control arms through revisions to §419.47(a) to specify that CMS' policy applies only to IDE studies with a control arm and where a payment adjustment is necessary to preserve the scientific validity of such a study.**

XI. 2025 OPPS Payment Status and Comment Indicators

2025 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.
For 2025 and subsequent years, CMS proposed to create two new status indicators:

Proposed (and Finalized) Status Indicator	Proposed (and Finalized) Descriptor	Proposed (and Finalized) 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.

[38] CMS asserts that while the 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, these items and services can be necessary in order to conduct a scientifically valid clinical study. As such, these items can be covered under section 1862(a)(1)(E) of the Act when furnished in the context of a qualifying clinical study.

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

CMS indicates that the comments it received regarding the new "K1" and "H1" status indicators were supportive and that the agency received no comments responding to its proposal to modify the descriptor of status indicator "K." Therefore, **CMS is finalizing these proposals without modification.**[39] The 2025 payment status indicator assignments for APCs and HCPCS codes are listed in Addenda A and B respectively. The complete list of 2025 payment status indicators and their definitions are in Addendum D1 of this final rule.

2025 Comment Indicator Definitions

For 2025, CMS proposed to continue 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

[39] CMS is also modifying status indicator "A" to include HCPCS code C9399 to conform with its policy being finalized in section X.F of this final rule, and it is revising the descriptors of the "J1" and "J2" status indicators for C-APCs to exclude certain items and services from C-APC packaging.

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.

CMS received no comments in response to this proposal and thus is finalizing the continued use of these comment indicator definitions for 2025 without modification.

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.

CMS notes that it is updating the OPPS payment rates by the amount specified in current law (the agency has no discretion to do otherwise). Other OPPS-related MedPAC comments are discussed elsewhere in this final rule.

Medicare Safety Net Index: In its March 2023 "Report to Congress: Medicare Payment Policy," MedPAC stated that its 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.

CMS indicates that it looks forward to working with Congress on the issues implicated in MedPAC's Medicare Safety Net Index recommendation. (Again, any CMS action would require statutory authorization.)

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.

CMS indicates that in the 2025 OPPS/ASC proposed rule, it did not propose cost reporting requirements for ASCs. Given the administrative burden of such reporting, but CMS did solicit comments on ways that reporting burden could be mitigated. **CMS indicates it received comments from an ASC trade group and that it will consider these comments in future rulemaking.**

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	0.9969	
2025 Update		
Hospital market basket update	3.4%	
Productivity adjustment	-0.5%	
Net MFP adjusted update	2.9%	
Penalty for not reporting quality data	0.0%	-2.0%
Net MFP and quality adjusted update	2.9%	0.9%
2025 ASC Conversion Factor	$54.895	$53.828

The ASC update is based on the IPPS hospital market basket and is estimated to be 2.9 percent with a reduction 2.0 percentage points for ASCs that do not submit quality data. CMS estimates that under this final rule, total ASC Medicare payments for 2025 will be approximately $7.1 billion, an increase of $206 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, or not require an overnight stay or active medical monitoring and care at midnight following the procedure. Payment for ancillary items and services (with some exceptions) is 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 lists proposals for new codes in two categories:

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

Table 150 in the final rule (shown below) provides the process and timeline for ASC list updates.

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

April and July 2024 Codes

For the April 2024 ASC quarterly update, there were no new CPT codes, but several new Level II HCPCS codes. Table 147 in this final rule displays the codes and descriptors implemented April 1, 2024 in the April 2024 quarterly update (Transmittal 12559, March 28, 2024, CR 13577). **CMS received no public comments on the proposed April payment indicators and new codes, and thus is finalizing them in this final rule.**[40]

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. **CMS received no public comments on the proposed July payment indicators and new codes, and**

[40] The list of codes in Table 147 includes permanent drug HCPCS J-codes that replaced temporary codes listed in the April update.

thus is finalizing them in this final rule with comment period. The Level II HCPCS codes are listed in Table 148 of this final rule; they are also available at the CMS website in Addenda AA and BB of the 2025 OPPS/ASC final rule.[41]

October 2024 HCPCS Codes Final Rule Comment Solicitation

CMS proposed in the 2025 OPPS/ASC proposed rule (89 FR 59410) 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. Subsequent to the proposed rule, in the October 2024 ASC quarterly update, CMS added several separately payable Level II HCPCS codes to the list of covered surgical procedures and covered ancillary services. Table 149 of this final rule lists the full set of codes in the October 2024 update. **CMS invites comments in this 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.**

January 2025 HCPCS Codes

New Level II HCPCS Codes Final Rule Comment Solicitation

CMS is listing new Level II HCPCS codes with a comment indicator "NI" in ASC addenda AA and BB, and solicits comment on their inclusion in the ASC payment system. (These codes are released in November and were not available for publication in the 2025 OPPS/ASC proposed rule.) These codes will be effective January 1, 2025. **CMS invites public comments on these codes and the payment indicator assignments, which would then be finalized in the 2026 OPPS/ASC proposed rule**.

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

For the 2025 ASC update, CMS received the CPT codes that will be effective January 1, 2025, from the AMA in time to be included in the 2025 OPPS/ASC proposed rule. These codes are listed in ASC Addendum AA and Addendum BB to the 2024 OPPS/ASC proposed rule. CMS notes that the new and revised CPT codes are assigned to comment indicator ''NP'' in ASC Addendum AA and Addendum BB of the 2025 OPPS/ASC proposed rule to indicate that the code is new for the next calendar year, or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year with a proposed payment indicator assignment.

CMS did not receive any comments on the proposed ASC payment indicators for the new CPT codes effective January 1, 2025, so the agency is finalizing these codes as proposed.

[41] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1809-fc*

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, in the 2025 OPPS/ASC proposed rule, CMS proposed several new and revised Category I and Category III CPT codes and revised Level II HCPCS codes. CMS also proposed 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. **CMS did not receive any public comments on the proposal to modify the L6 payment indicator descriptor and is finalizing this change as proposed**.

C. Payment Policies Under the ASC Payment System

Final ASC Payment for Covered Surgical Procedures

In the July proposed rule CMS proposed 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. CMS proposed that payment for office-based procedures (payment indicators "P2," "P3," and "R2") would 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 (payment indicator "J8") 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.

CMS received minimal comments on these proposals and is thus finalizing them without modification to calculate the 2025 payment rates for ASC covered surgical procedures according to Medicare's established rate calculation methodologies under §416.171 and its device-intensive methodology as discussed in section XIII.C.1.b. of this 2025 OPPS/ASC final rule with comment period.

Final 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 ("J1") 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 proposed 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. The full list of the proposed ASC complexity adjustment codes for 2025 can be found in the ASC addendum J.[42]

CMS is finalizing the ASC special payment policy for OPPS complexity-adjusted C-APCs, as proposed. The final ASC complexity adjustment codes, based on the most recent data available for this 2025 OPPS/ASC final rule with comment period, can be found on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical- center-asc/annual-policy-files*. Existing ASC complexity adjustment codes that do not meet the criteria for separate payment for 2025 because the code combination is not eligible for a complexity adjustment under the OPPS for 2025 will be non-payable and assigned a status indicator of "B5" – "Alternative code may be available; no payment made" – for 2025. Additionally, proposed ASC complexity adjustment codes that met the criteria based on data available for the 2025 OPPS/ASC proposed rule but do not meet criteria based on claims data available for this final rule with comment period will be deleted and assigned a payment indicator of "D5" – "Deleted/discontinued code; no payment made."

[42] *https://www.cms.gov/medicare/payment/prospective-payment- systems/hospital-outpatient/regulations-notices*

Final Low-Volume APCs and Limit on ASC Payment Rates for Procedures Assigned to Low Volume APCs

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.

In the July 2025 OPPS/ASC NPRM, based on its analysis of claims data, CMS proposed to designate six brachytherapy APCs and four clinical APCs as Low-Volume APCs under the ASC payment system (89 FR 59414). 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 151 in this final rule lists the number of 2023 claims used to set payment rates for these 10 APCs. **CMS indicates that comments were supportive of its proposals to so designate these APCs, and the agency is finalizing its proposal in this final rule with comment period.**

Final Payment for Covered Ancillary Services for 2025

In July, CMS proposed 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 proposed 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 final rule (available on the CMS website).

CMS is finalizing its proposal to update the ASC payment rates and to make changes to ASC payment indicators, as necessary, to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the final 2025 OPPS and ASC payment rates and subsequent years' payment rates. CMS did not receive any public comments on, and thus is also finalizing without modification, its proposal to continue to set the 2025 ASC payment rates and subsequent years' payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for 2025 and subsequent years' payment rates.

Covered Surgical Procedures Designated as Office-Based Procedures

In the 2025 OPPS/ASC proposed rule, CMS proposed 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[43] that it proposed to permanently designate as office-based for 2025. 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.

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 the proposed rule for 2025, CMS determined that one additional procedure (67516)[44] is predominantly office-based and proposed 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).

CMS indicates it did not receive any public comments on its proposed permanent office-based designations and therefore, **the agency is finalizing its proposal to designate the procedures in Table 152 (reproduced below) as permanently office-based beginning in 2025.** With respect to its proposal to designate nine surgical procedures as temporarily office-based, **CMS is finalizing its proposal with modification – CPT code 0910T ((placeholder code XX34T) (Removal of integrated neurostimulation system, vagus nerve)), will not be so designated**.[45] **Nor is CMS designating CPT code 65785 (Implantation of intrastromal corneal ring segments) as temporarily office-based, as this code meets the agency's criteria to be designated as device-intensive for 2025 and CMS is finalizing that designation for this CPT code.**

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[43] 0447T (Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision) and CPT code 21127 (Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft).

[44] 67516 - Suprachoroidal space injection of pharmacologic agent (separate procedure).

[45] As discussed in section III.E of this final rule with comment period, since the vagal nerve neurostimulation system has not yet received FDA approval, CMS is finalizing an OPPS status indicator "E1" to indicate that the code is not payable by Medicare when submitted on outpatient claims (any outpatient bill type).

TABLE 152: ASC COVERED SURGICAL PROCEDURES TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR 2025

CY 2025 CPT/HCPCS Code	Long Descriptor	Final 2024 ASC Payment Indicator	Final 2025 ASC Payment Indicator*
0447T	Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision	G2	P3*
21127	Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft)	G2	P2*
67516	Suprachoroidal space injection of pharmacologic agent (separate procedure)	P3	P3*

* Payment indicators were based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the 2025 PFS final rates.

Device-Intensive ASC-Covered Surgical Procedures

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

For 2022 and subsequent years, CMS modified its approach to assigning device-intensive status to surgical procedures under the ASC payment system. First, it assigns device-intensive status to procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures if their device offset percentage exceeds 30 percent under the ASC standard 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 proposed 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 proposed 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.

CMS indicates that commenters "strongly supported" its proposed change to the device offset policy for 2025 and subsequent years under the ASC payment system (although several commenters asked CMS to reevaluate its data in making determinations of eligibility for device-intensive status for specific codes). **The agency is finalizing its proposal (without modification) to apply the greater of the APC-wide device offset percentage or 31 percent for new HCPCS codes that do not have claims data or any predecessor code as described by CPT coding guidance**.

In addition, **CMS is finalizing a modification to its device edits policy which reinstates device edits for device-intensive procedures created on or after January 1, 2017. Such device edits will be permanent and will apply regardless of the procedure's device offset percentage.** In conjunction with the modification to CMS's device edits policy for 2025, CMS is relying only on claims from hospitals that reported a device code for determining device offset percentages under the OPPS and ASC payment systems. As part of this policy, CMS is also allowing the device-intensive policy applicable to current CPT codes to apply to specific instances of the code's predecessor codes.[46]

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

In July 2024, CMS proposed 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 an "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.

[46] *E.g.*, the device-intensive policy applicable to CPT code 53685 (Cystourethroscopy with insertion of temporary device for ischemic remodeling (*i.e.*, pressure necrosis) of bladder neck and prostate) in 2025 could also include its predecessor HCPCS code C9769.

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 did not propose any changes to policies related to no cost/full credit or partial credit devices for 2025, nor did the agency receive any comments on this topic. **Therefore, the agency is finalizing the continuation of its existing policies for 2025 without modification.**

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 included proposals to operationalize section 90004 of the Infrastructure Act, including a proposal that impacts HOPDs and ASCs. ASCs and other interested stakeholders are directed to the HPA summary of the 2025 PFS final rule for more information.

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 Medicare 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 covered procedures list (CPL), CMS proposed in the July proposed rule to update the ASC CPL by adding 20 medical and dental (of the 20 procedures, 16 are dental) surgical procedures to the list for 2025 (shown in Table 82 in the proposed rule). CMS stated that it will continue to gradually expand the ASC CPL as medical practice and technology continue to evolve and advance in future years.

CMS indicates that "multiple commenters" supported the addition of the 20 procedures to the ASC CPL, although one commenter urged that CMS not add two leadless pacemaker procedures (CPT codes 0795T and 0801T); CMS agreed with this commenter and will not add these two procedures. In addition, commenters recommended adding 74 additional procedures to the ASC CPL. Upon review of evidence, literature, and other data, in response to this input CMS is adding:

- D7320 (Alveoloplasty not in conjunction with extractions - four or more teeth or tooth spaces, per quadrant),
- D7321 (Alveoloplasty not in conjunction with extractions - one to three teeth or tooth spaces, per quadrant), and
- D7471 (Removal of lateral exostosis (maxilla or mandible)).

CMS provides an extensive rationale for its decision not to add 71 other procedures suggested by public commenters, and provides the final list of procedures added (19 dental procedures and two surgical procedures) for 2025 in Table 154 of this final rule.

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 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 provided in section XIII.B of this final rule, and are also included in Addendum BB (available on the CMS website). **Noteworthy**

changes relative to the 2025 OPPS/ASC proposed rule include CMS's decision not to add HCPCS code C1605 and CPT code 93355 to the list of covered ancillary services.

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. **CMS maintains this policy in the 2025 OPPS/ASC final rule**.

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 106 percent of average sales price (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. 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 "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, in the July proposed rule for the 2025 OPPS/ASC payment systems, CMS encouraged 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.

CMS proposed 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. Based on the comments received, **CMS is finalizing its proposal that drugs and biologicals that meet the definition of a**

non-opioid treatment for pain relief for purposes of section 4135 that are currently subject to the ASC policy for non-opioid treatments authorized by section 6082 of the SUPPORT Act, would instead receive separate payments, subject to the payment limitation, for the duration of the payment period for section 4135.[47]

For a drug or biological that qualifies for separate payment, the statute sets payment using the methodology 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 *did not* propose to apply a payment offset for non-opioid products paid separately in 2025 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 indicates it received substantial support for its proposal not to offset the costs of non-opioid products paid separately in 2025. **CMS is finalizing its policies regarding separate payments for non-opioid post-surgical pain management drugs and devices as proposed**.

CMS proposed 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 proposed 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. After consideration of public comments received, **the agency is finalizing its policy to base the 18 percent payment limitation on the volume weighted average of the 2025 payment rates of the top five primary procedures by volume into which a non-opioid treatment for pain relief would have their payment packaged, absent this policy. CMS is also finalizing that it will apply the 18 percent payment limitation per date of service billed. Lastly, CMS is finalizing its proposed policy to create new OPPS status indicators for non-opioid drugs and devices to implement this payment limitation for 2025**.

In addition, CMS reviews several non-opioid products that public commenters submitted to CMS for consideration for separate payment under the ASC payment system. The criteria that CMS uses to assess eligibility for separate payment under the statute include: use to reduce postoperative or

[47] Note that CMS is codifying the exact language in the statute as the definition of non-opioid treatment for pain relief. In doing so, the agency asserts that only non-opioid analgesics specifically approved by the FDA for post-surgical or post-operative pain relief will qualify, *not* products approved for pain relief generally. CMS denied a commenter's request for the agency to consider separate payments for Caldolor, Dexycu, and Ofirmev on this basis.

post-surgical pain, FDA clearance and supporting literature that demonstrates the product is able to substitute for opioid use, and whether the device or product is not currently receiving transitional passthrough status and would otherwise be packaged into the payment for a covered OPD/ASC service. On this basis, CMS in this rule approved for separate payment: the SPRINT peripheral nerve stimulator system, Cryo Nerve Block Therapy, ambIT electronic fusion pump, and the Iovera system.[48]

CMS provides the final list of qualifying non-opioid drugs and devices for 2025 in Table 156 of this final rule, reproduced here:

TABLE 158: FINALIZED QUALIFYING PRODUCTS FOR SEPARATE PAYMENT UNDER SECTION 4135 OF THE CAA, 2023 FOR 2025

Brand Name	HCPCS Code	Long Descriptor	Meets Requirements
Exparel	C9290	Injection, bupivacaine liposome, 1mg	Yes
Omidria	J1097	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml	Yes
Dextenza	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	Yes
Xaracoll	C9089	Bupivacaine, collagen-matrix implant, 1 mg	Yes
Zynrelef	C9088	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg	Yes, effective April 1, 2025
Ketorolac tromethamine Injection	J1885	Injection, ketorolac tromethamine, per 15 mg	Yes
ON-Q Pump	C98X4 / C9804	Elastomeric infusion pump (e.g., ON-Q* Pump with Bolus), including catheter and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)	Yes
SPRINT Peripheral Nerve Stimulator System	(C9807)	Nerve stimulator, percutaneous, peripheral (e.g., SPRINT Peripheral Nerve Stimulation System), including electrode and all disposable system components, non- opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)	Yes
Cryo Nerve Block Therapy	(C9808)	Nerve cryoablation probe (e.g., cryoICE, cryoSPHERE, cryoSPHERE MAX, cryoICE cryoSPHERE, cryoICE Cryo2), including probe and all disposable system components,	Yes

[48] CMS considered, but after reviewing the products in light of the statutory criteria, did not approve for separate payment, the IceMan Motorized Cold Therapy Device, the CryoCuff Motorized Cold Therapy Device, the Thermazone Thermal Therapy Device, the SimplFusor Elastomeric Pump, and several other candidate devices.

		non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post- surgical pain relief in accordance with Section 4135 of the CAA, 2023)	
ambIT Electronic Infusion Pump	(C9806)	Rotary peristaltic infusion pump (e.g., ambIT Pump), including catheter and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)	Yes
Iovera System	(C9809)	Cryoablation needle (e.g., iovera System), including needle/tip and all disposable system components, non- opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)	Yes

CMS did not receive any public comments on the corresponding proposed regulation text and the agency is finalizing as proposed with slight changes to one provision. In particular, CMS is clarifying the description of the payment limitation at §§416.174(c)(3) and 419.43(k)(3)(iii) to state that the volume-weighted average for the payment limitation will be based on the most frequent 5 OPD primary procedures into which a non-opioid treatment for pain relief would be packaged.

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 did not propose to revise the current payment adjustment ($50 per lens) for NTIOLs in the July OPPS/ASC payment system NPRM for 2025. While some commenters suggested increasing the NTIOL payment adjustment for 2025, **in this final rule CMS is making no change to the current payment adjustment amount**.

H. ASC Payment Rates and ASC Conversion Factor

In the July NPRM, CMS proposed 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[49], CMS computes the ratio of:

[49] 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.

- 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, was the proposed weight scalar for 2025. The scalar 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 scalar would not apply to ASC payments for separately payable covered ancillary services that have a predetermined national payment amount and are not based on OPPS relative payment weights (*e.g.*, drugs and biologicals that are separately paid and services that are contractor-priced or paid at reasonable cost in ASCs).

After consideration of the public comments received, **CMS is finalizing its proposal to use the ratio of 2024 to 2025 total payments (the weight scalar) to scale the ASC relative payment weights for 2025.** CMS estimates that there will not be an additional increase in ASC spending related to the final ASC complexity adjustment codes for 2025. Based on the revised payment limitations from data available for this final rule with comment period, the agency estimates that the implementation of section 4135 of the CAA, 2023 will decrease ASC spending by $5.5 million for 2025 as a result of the payment limitation to currently separately payable drugs qualifying non-opioid products. Therefore, CMS reduced estimated 2025 total payments by $5.5 million in its weight scalar calculation. **The final 2025 ASC weight scalar is 0.872, representing a 1.9 percent decrease from the final 2024 ASC weight scalar**.

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)[50] 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 scalar, CMS computes the ratio of:

[50] Consistent with CMS's proposed changes to other FY and CY 2025 fee-for-service payment systems, CMS proposed 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 proposed to limit reductions in the wage index values to 5 percent. All of these changes would be implemented in a budget-neutral manner. The agency is finalizing its proposals for the ASC payment system in this final rule.

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

The resulting ratio, 0.9958, was the proposed wage index budget neutrality adjustment to the conversion factor for 2025 in the July notice of proposed rulemaking.

To update ASC rates, CMS proposed to 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 proposed to 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.

CMS is finalizing its update to the 2025 ASC conversion factor using its proposed (established) methodology, but using the most current estimates of the hospital market basket update (3.4 percent) and productivity adjustment (0.5 percentage point), resulting in an adjusted market basket update of 2.9 percent for ASCs meeting quality reporting requirements. The resulting proposed 2025 ASC conversion factor is $54.895 for ASCs reporting quality data, and $53.828 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 0.9969	
Net MFP-adjusted update	x 1.029	x 1.009
2024 Proposed ASC conversion factor	$54.895	$53.828

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 (Table 202 of the final rule, reproduced below). The eye surgical specialty group remains the largest source of payments, with a 3 percent increase in payments attributable to the changes proposed for 2025.

Table 202: Estimated Impact of the 2025 Update to the ASC Payment System on Aggregate 2024 Medicare Program Payments by Surgical Specialty or Ancillary Items and Services Group		
Surgical Specialty Group	Estimated 2024 ASC Payments (in Millions)	Estimated 2025 Percent Change
Total	**$6,864**	**3%**
Eye	$2,019	3%
Musculoskeletal	$1,319	3%
Nervous system	$1,242	3%
Gastrointestinal	$1,015	5%
Cardiovascular	$335	3%
Genitourinary	$262	3%

CMS provides estimated increases for 30 selected procedures in Table 203 in this final rule; the top 10 procedures are replicated below. CPT code 66984 (Cataract surgery with intraocular lens, 1 stage) is the largest aggregate payment procedure by far and is estimated to have a 3 percent increase in payment. The second largest aggregate payment procedure, CPT code 27447 (total knee arthroplasty), is also expected to see a 3 percent increase.

Excerpt from Table 203: Estimated Impact of the Final 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	$1,339	3
27447	Total knee arthroplasty	$336	3
45380	Colonoscopy and biopsy	$259	4
45385	Colonoscopy w/lesion removal	$244	4
63685	Ins/rplc spi npg/rcvr pocket	$216	5
63650	Implant neuroelectrodes	$184	3
43239	Egd biopsy single/multiple	$180	7
27130	Total hip arthroplasty	$168	3
66991	Xcapsl ctrc rmvl cplx insj 1+	$128	1
64483	Njx aa&/strd tfrm epi l/s 1	$108	1

As noted at the beginning of this ASC section, Addenda tables available only on the website provide additional details; they are at https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and/cms-1809-fc. 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
- A – OPPS APCs 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 finalizes its proposals for 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 finalizes its proposal 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.

1. Adoption of 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

CMS finalizes, as proposed, adoption of the HCHE measure for the Hospital OQR and REHQR programs and of the FCHE measure for the ASCQR program.

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.

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 159 and Table 160, respectively, in section XIV of the rule.

There are two differences between the HCHE and FCHE measure specifications (as seen in Tables 159 and 160 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).

Data Submission Requirements. Hospitals and ASCs will 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.

Selected Comments/Responses. Many commenters supported the adoption of the HCHE and FCHE measures in part because the measures would align quality measurement across quality reporting programs and would reduce health disparities. In response to some concerns raised regarding the accuracy of self-reported data, CMS notes it has provided an Attestation Guidance document and a FAQ document for the HCHE measure in the Hospital IQR program and intends to provide guidance for the Hospital OQR, REHQR, and ASCQR programs, which will clearly define what constitutes an affirmative attestation and provide answers to FAQs.[51]

In response to several commenters suggesting CMS consider alternative approaches to address health equity, the agency believes that adoption of these measures will lay the groundwork for a more comprehensive suite of measures to assess providing high-quality health care to all. Some commenters were concerned that these measures would penalize facilities rather than incentivize them to comply with ways to advance health equity. In response, CMS commented that the Hospital OQR and ASCQR programs are pay-for-reporting programs, meaning that participants are penalized only if they fail to submit required data and their performance on the measures would not affect their payments. Also, the REHQR program does not include any financial incentive or penalty for REHs. Further, the measures are not meant for facility or hospital comparison with one another, but to help facilities and hospitals identify where structural gaps need to be addressed.

Other commenters did not support adoption of the measures for reasons including the measures were not endorsed by a consensus-based entity (CBE endorsed) and the measures are not tailored to the specific setting; they also had concerns about the one-size fits all approach. The agency, however, believes these measures and their implementation in the inpatient hospital, PPS-Exempt cancer hospital, and dialysis facility settings have demonstrated their broad applicability.[52]

Other commenters who did not support adoption of the measure expressed concerns that the attestation domains for assessment could be misleading to the public, believing that a holistic view of organizational culture, internal policies, and other factors is needed to accurately and fairly evaluate facilities and hospitals. The agency believes that public reporting of the measures will improve health equity and it intends to provide educational materials to promote understanding and interpretation of the data.

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[51] 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.

[52] 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.

Several commenters raised concerns specific to the HCHE measure, including duplicative reporting of attestations for the measure in the Hospital OQR and IQR programs. CMS responds that hospital inpatient departments treat different patient populations than outpatient departments and employ different staff, which is why the agency is requiring the separate data submissions.

Several other commenters raised concerns specific to the FCHE measure for the ASCQR program, including that there are differences between an ASC's operational infrastructure and a hospital's operational infrastructure, which make the measure infeasible to implement in the ASC setting. However, the agency believes the measure specifications and current application in different settings, as well as its goals to identify equity gaps, implement plans to address the gaps, and promote leadership commitment to health equity, demonstrate the measure's broad application to care settings. Other concerns included that many ASCs do not have electronic health records (EHRs) and therefore would not be able to attest "yes" to Domain 2, and that these facilities do not have the technological tools needed to identify priority populations who experience health disparities within their communities. CMS acknowledges these challenges but since the ASQR program is a pay-for-reporting program, ASCs that do not have EHR technology will be able to attest they satisfy the other domains, as applicable, and would have no financial penalty for not satisfying all domains. The agency recognizes that EHR adoption is initially costly but believes that over time EHRs may save money for ASCs by streamlining documentation of patient information and encourages the facilities to adopt the technology.

2. Adoption of the SDOH Measure for the Hospital OQR, REHQR, and ASCQR Programs

CMS finalizes, as proposed, adoption of the Screening for SDOH measure in 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. 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 to 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 health care costs, utilization, and outcomes. The 5 core domains[53] to screen for HRSNs that were applied in the AHC Model are used in the Screening for SDOH measure finalized for adoption in this section and the Screen Positive Rate for SDOH measure finalized for adoption in section XIV.B.3. The Screening for SDOH and Screen Positive Rate for SDOH measures have been adopted in other

[53] The 5 domains are described in detail in Table 161 of the rule.

quality reporting programs, including in the Hospital IQR program in the FY 2023 IPPS/LTCH PPS final rule.[54]

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.

The measure is not CBE-endorsed, but the agency will consider submitting it to the CBE for endorsement in the future.[55]

Data Sources, Submission and Reporting. Hospitals and other facilities will use a self-selected screening tool to collect data on the measure. CMS points to the AHC HRSN Screening Tool[56] as an example as well as the Social Interventions Research and Evaluation Network (SIREN) website for information on HRSN screening tools.[57]

There will initially be a voluntary reporting period for the measure during the 2025 reporting period, during which facilities may choose to submit aggregate data for the measure, and then required reporting will begin with the 2026 reporting period/2028 payment or program determination. Hospitals and other facilities will not be required to submit patient-level data, but will instead aggregate data they collect for the numerator and denominator. Hospitals and other facilities will 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.

Consistent with the Hospital IQR program, HOPDs, REHs, and ASCs will be able to 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

[54] FY 2023 IPPS/LTCH PPS final rule (87 FR 49191 through 49220).
[55] 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.
[56] Information on the AHC HRSN Screening Tool is available at: https://www.cms.gov/priorities/innovation/files/worksheets/ahcm-screeningtool.pdf.
[57] SIREN can be found at https://sirenetwork.ucsf.edu/tools-resources/resources/screening-tools-comparison.

information is in the EHR in another health setting during the same reporting period, the HOPD, REH, or ASC could use that information to report the measure instead of screening the patient.

Selected Comments/Responses. Many commenters supported adoption of the measure and the agency's commitment to improving health equity, specifically supporting that the measure facilitates appropriate referrals and access to needed and timely interventions across outpatient settings, enables hospitals to use SDOH screening information recorded in the EHR in another setting during the same reporting period to report data on the measures, and provides flexibility to use a facility's preferred screening tool. Some commenters suggested that the agency include a method to confirm that referrals resulted in actual service delivery. In response to commenters' questions on the measure's technical specifications, CMS clarifies that patients receiving services that are limited to specific medical tests are not included in the denominator. Specifically, these services include imaging, laboratory, and pharmacy services that are typically types of auxiliary services to more comprehensive care, where the screenings are to be provided.

Several commenters provided recommendations for various screening approaches, alternative measures, and additional social drivers of health, and CMS responds the agency will consider these recommendations in future rulemaking. In response to concerns about protected health information (PHI), the agency clarifies that the SDOH measure does not require facilities to disclose any PHI or individually identifiable health information to CMS, and that as covered entities under the HIPAA Privacy Rule, facilities must ensure the confidentiality of all electronic PHI.[58]

Some commenters raised questions about the frequency of screening and potential duplication with the Hospital IQR program. CMS clarifies that outpatient settings will not be required to rescreen patients in the same reporting period if the data are already in the EHR. After an initial screening, during subsequent visits within the period the patient's provider could confirm the accuracy of the previously reported screening result but does not need to rescreen. Also, facilities could confirm the status of any previously reported HRSNs in another care setting instead of rescreening a patient for all HRSN domains in the reporting period. Because patient populations for the Hospital IQR program are different from those for the Hospital OQR program, and because separate Compare tool data for inpatient and outpatient departments could be useful for patients, CMS is requiring separate data submission for each of the Hospital IQR and OQR programs. The agency also refers to its Hospital IQR Program's FAQ document on the measure and notes that it will develop a similar document for the Hospital OQR, REHQR, and ASCQR programs, which will be provided through routine communications.[59]

Some commenters expressed concern about increased burden, especially to ASCs that do not have sufficient resources to implement the measure without additional funding. CMS believes the benefits of screening patients for SDOH outweigh the burden of collecting information. Other commenters expressed concern that the measure was not tested in these specific outpatient settings. CMS responds that even though the measure was initially developed for the acute care setting, the

[58] 45 CFR 164.306.
[59] The Hospital IQR Program's FAQ is available at https://www.qualityreportingcenter.com/globalassets/2024/04/iqr/17.-sdoh-measure--faqs_april-2024_vfinal508.pdf.

measure underwent assessment of its appropriateness for the outpatient setting through the Pre-Rulemaking Measure Review (PRMR) process and the agency will continue to monitor and test the performance of the measure in the HOPS, ASC, and REH settings throughout the voluntary reporting period.

In response to recommendations to provide more timely actionable data, the agency responds that it intends to publicly display data for the measure on the first available refresh of Care Compare, which typically would occur in October of the year following data submission. As an example, for the 2026 reporting period/2028 payment determination (or program) year, the data is to be displayed on Care Compare in October 2027, which CMS describes is as soon as technically feasible for data collected during the 2026 performance period and submitted between January 1 and May 15, 2027.

3. Adoption of the Screen Positive Rate for SDOH Measure for the Hospital OQR, REHQR, and ASCQR Programs

CMS finalizes, as proposed, adoption of 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 finalized for adoption 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.[60]

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. The measure is not intended for comparing screen positive rates of HRSNs across facilities but is instead intended to provide actionable information to facilities on the unmet needs among their patients.

Measure calculation. Hospitals and facilities will 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.

[60] 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).

- *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.
- *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. The data sources for this measure are the same data sources described for the Screening for SDOH measure in section XIV.B.2.

Even though hospitals and facilities will collect the patient-level data on their patients (enabling the hospitals and facilities to address social needs among their patient populations) for reporting purposes, hospitals and facilities will 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 will be submitted through a CMS-designated information system, which is currently the HQR system.

Selected Comments/Responses. Many commenters supported adoption of the measure as a step towards facilities developing action plans to address identified risk factors as well as for supporting the focus on unmet needs. Some commenters did not support the measure because the Hospital Recommendation Group during the PRMR process in its January 2024 meeting did not reach a consensus for its recommendation for the measure,[61] the measure is not CBE-endorsed, and concerns about increased burden, including regarding training staff to appropriately screen and collect data. However, CMS believes that adoption of the measure in the Hospital OQR, REHQR, and ASCQR programs is important to address the health equity measurement gap, that there are no other feasible and practicable measures that are CBE-endorsed on the topic, and that the voluntary reporting period will provide time for training.

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.[62] 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.[63]

CMS finalizes, as proposed, 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

[61] A 75 percent vote is required to reach consensus.
[62] 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.
[63] See the 2024 OPPS/ASC final rule (88 FR 82052).

is evidence that the collection and reporting activities related to a quality measure raises patient safety concerns, the agency will suspend the measure from the applicable program until the potential measure removal could be considered through the next feasible rulemaking cycle. HOPDs or ASCs, as applicable, and the public will be notified of the suspension through standard communication channels. In response to comments, the agency clarifies that once a measure is suspended, data collection and reporting for that measure would stop until permanent action is taken in a subsequent rulemaking cycle. Entities will not be penalized for non-compliance with a suspended measure.

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.[64] 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.[65] CMS will 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 final reporting factor of 0.9806 (as opposed to the proposed 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 finalized 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.

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[64] 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.

[65] 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).

B. Program Measure Set Policies

CMS did not propose any changes to its measure retention or measure adoption policies. The only change CMS proposed (and is finalizing) to its measure removal policy is the cross-program proposal to modify the immediate removal policy under section XIV.C.[66]

C. Program Measure Updates

1. Adoption of New Measures

a. Health Equity Measures

Detailed discussions on the finalized 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, and are described above.

b. Adoption of 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)

CMS is finalizing, as proposed, adoption of the Information Transfer Pro-PM in the Hospital OQR measure set 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). The agency believes this can be addressed by the adoption of a survey measure that provides hospitals with patient reported outcome (PRO) data to assess the clarity of recovery information provided to patients.

Measure Overview.[67] 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 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:

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[66] 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).

[67] CMS refers readers to the technical specification manuals for further information: https://qualitynet.cms.gov/outpatient/specifications-manuals.

- 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 is 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.

The measure is CBE-endorsed.

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

The measure will 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. The survey is to be administered 2-7 days after the procedure or surgery and there is to be a 65-day window for patient response.

Selected Comments/Responses. Many commenters supported adoption of the measure for reasons including that the measure is an effective means to collect patient experience data, the importance of patients receiving clear and personalized recovery information, the potential for the measure in increasing patient satisfaction and trust in their care providers, and that the measure will provide valuable feedback to clinicians. Other commenters expressed concerns about time, resource, and financial burden to HOPDs as well as burden to patients (including survey fatigue). CMS responds that it is not requiring HOPDs to collect data in a standardized way and is providing flexibility for them to use a variety of data collection, storage, and submission approaches so that HOPDs can use the method that best suits them.

Several commenters noted that the minimum sample size stated in the proposed rule was inconsistent with the minimum sample size in the measure specifications. CMS responds that it intends to update the measure specification manual to reflect the minimum sample size of 300 completed surveys. The agency also notes that all questions on the survey must be completed for the survey to count toward that minimum.

2. Measure Removals

a. 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.

CMS is finalizing its proposal to remove the measure under measure removal factor 2 (performance or improvement on a measure does not result in better patient outcomes) beginning with the 2025 reporting period/2027 payment determination.[68]

b. 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.

CMS is finalizing its proposal to remove the measure under measure removal factor 2 (performance or improvement on a measure does not result in better patient outcomes) beginning with the 2025 reporting period/2027 payment determination.

3. Summary of Finalized Program Measure Set Updates

Table 162 in the rule lists the previously finalized measure set beginning with the 2027 payment determination and Tables 163 and 164 in the rule list the newly finalized measure sets for 2027 and 2031 payment determinations, respectively. These tables are consolidated into the table below.

[68] §419.46(i)(3)(i)(B).

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

CBE	Measure	2027	2031
	MRI Lumbar Spine for Low Back Pain +	*Removal Finalized in Rule*	
	Abdomen CT – Use of Contrast Material	X	X
	Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery +	*Removal Finalized in Rule*	
	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*	*Finalized Adoption*	*X*
####	*Screening for Social Drivers of Health (SDOH)*	*Finalized Adoption*	*X*
####	*Screen Positive Rate for SDOH*	*Finalized Adoption*	*X*
4210^	*Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery PRO-PM (Information Transfer PRO-PM)*		*Finalized Adoption*
+ CBE endorsement removed.			

CBE	Measure	2027	2031
* 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). ## 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). ### Finalized in section XIV.B.1 of this rule for adoption beginning with 2025 reporting period/2027 payment determination. #### Finalized 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. ^ Finalized 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[69]

CMS-Designated Information System and Data Submission for HCHE, Screening for SDOH, and Screen Positive for SDOH Measures. For each of these three measures, the performance period (referred to as the "reporting period") will 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 will 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 will be required to submit all data required to calculate each of the 3 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 will be able to enter, review, and correct data submitted during the data submission period.[70]

Electronic Clinical Quality Measures (eCQMs) and the Requirement that EHR Technology 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 finalizes, 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 Office of the National Coordinator (ONC) health IT certification criteria will be required to have the technology certified to all eCQMs that are available to report under the Hospital

[69] 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).
[70] The review and corrections period policy is under §419.46(d)(4).

OQR program for the program to ensure the technology is up to date and tested on each eCQM.
- HOPDs will 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.

The agency is also codifying the requirement for hospitals to use certified technology updated consistent with the ONC health information technology (IT) certification criteria at §419.46(j)(1).

Patient-Reported Outcome-Based Performance Measures (PRO-PMs). CMS finalizes its proposal 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 adopted in this rule.[71] Hospitals will 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 newly finalized Information Transfer PRO-PM:
- The performance period (i.e., reporting period) will 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 will 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 will be a minimum random sample size of 300 completed surveys. HOPDs that do not collect the minimum will not perform random sampling and will 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. Data for the measure for each stratum are currently collected and submitted by participating hospitals and are accessible in downloadable files from CMS' Provider Data Catalog available at data.cms.gov. CMS finalized in the 2024 OPPS/ASC final rule that data on each of those strata (other than the psychiatric/mental health patients only stratum) be publicly reported on Care Compare (or a subsequent CMS-designated website).[72] The agency decided to take further time to consider public reporting of the

[71] This submission method is currently required for the THA/TKA PRO-PM, as finalized in the 2024 OPPS/ASC final rule (88 FR 82006).
[72] The rule notes that all four strata are published on data.medicare.gov. However, data.medicare.gov redirects to data.cms.gov.

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. Since the data are already being collected from hospitals, this would not result in any additional reporting burden.

CMS finalizes, as proposed, 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[73] but not displayed on Care Compare.

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

CMS finalizes its proposal 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 update factor. The reduction ratio for hospitals that fail to meet OQR program requirements is called the "reporting ratio". CMS will calculate the ratio to four decimals. Continuing previous policies, the reporting ratio will be applied to all services calculated using the OPPS conversion factor and applied to all HCPCS codes to which CMS has 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 will continue to be applied to the national unadjusted payment rates and minimum unadjusted and national unadjusted copayment rates of all applicable services for hospitals that fail to meet the OQR program's reporting requirements. All other applicable standard adjustments to the OPPS national unadjusted payment rates also will continue to apply, and OPPS outlier eligibility and outlier payments also would be based on the reduced payment rates.

In the proposed rule, for 2025, CMS proposed a reporting ratio of 0.9805, which, when multiplied by the proposed full conversion factor of $89.379, results in a proposed reduced conversion factor of $87.636 for hospitals that fail to meet OQR program requirements.

As finalized, for 2025, the final reporting ratio is 0.9806, which, when multiplied by the final full conversion factor of $89.169 results in a final reduced conversion factor of $87.439 for hospitals that fail to meet OQR program requirements.

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

[73] The rule states the data are on data.Medicare.gov. However, data.medicare.gov redirects to data.cms.gov.

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 is there a 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 finalizes its proposal to modify the reporting period for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure.

B. Program Measure Set Policies

No changes were proposed to the retention, suspension, removal, modification, or adoption measure policies.[74]

C. Program Measure Updates

1. Adoption of 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 above under sections XIV.B.1, XIV.B.2, and XIV.B.3, respectively.

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

The Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery 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 a REHQR program measure 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.

CMS finalizes its proposal 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 will remain as is (encounters from January 1, 2024 through December 31, 2024). Beginning with the 2027 program determination, the reporting period will have data from the years that are 2 and 3 years before the program determination year. For

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

example, for the 2027 program determination, the reporting period will consist of data from 2024 and 2025 (January 1, 2024 through December 31, 2025). Since the measure is calculated from administrative Medicare information, REHs would not have any additional reporting burden.

3. Summary of Finalized Program Measure Set Updates

Table 165 of the final 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
* 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 167 and 168 of the rule show the newly finalized updated REHQR program measure set with 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 finalized for this measure is discussed in section XVI.C.2 of the rule. ** This measure will be mandatory beginning with the 2025 reporting period/2027 program determination, as finalized in section XIV.B.1 of the rule *** This measure will be voluntary for the 2025 reporting period and mandatory beginning with the 2026 reporting period/2028 program determination, as finalized in sections XIV.B.2 and XIV.B.3 of the rule.			

D. Form, Manner, and Timing of Data Submission

Data Submission Policy Following Conversion to REH Status. CMS finalizes its proposal 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.

HCHE, Screening for SDOH, and Screen Positive Rate for SDOH Measures' Data Submission and Reporting Requirements. CMS finalizes its proposal for 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 finalized in this rule. REHs will submit data for the measures once annually using a CMS-approved, web-based data collection tool available within the HQR system. Data will 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 will 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).[75] 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.[76]

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.[77]

B. ASCQR Program Measure Set Policies

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

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[75] 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.

[76] 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.

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

C. Program Measure Updates

1. Adoption of Health Equity Quality Measures

Detailed discussions on the finalized cross-program adoption (including for the ASCQR program) 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.

2. Summary of Finalized Program Measure Set Updates

Tables 169 and 170 in the rule list the previously finalized measure sets for the 2027 and 2031 payment determinations, respectively. Tables 171 and 172 show the newly finalized updated ASCQR program measure set (including the 3 finalized cross-program health equity measures) for the 2027 and 2031 payment determinations. Information from the tables is 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^	Finalized Mandatory	Finalized Mandatory
Screening SDOH^^	Finalized Voluntary	Finalized Mandatory
Screen Positive for SDOH^^	Finalized Voluntary	Finalized 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

ASCQR Program Measures by Payment Determination Year		
	2027	**2031**
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		
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).
^ Finalized as mandatory beginning with 2025 reporting period/2027 payment determination, as discussed in section XIV.B.1 of rule.
^^ Finalized 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 FCHE, Screening SDOH, and Screen Positive for SDOH Measures. CMS finalizes that ASCs will submit data for the measures once annually using a CMS-approved, web-based data collection tool available within the HQR System. Data will 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 will be January 1, 2026 through May 15, 2026) with the review and corrections period also occurring during that same data submission period.

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

In the proposed rule, CMS sought comment on two potential future frameworks under the ASCQR program, (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[78] and on relevant specialty-specific measures.[79]

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.

Selected Comments. Several commenters supported either of the described frameworks because they would decrease ASC reporting burden and ensure ASCs report on the most applicable measures. Some commenters suggested that CMS use only FFS data for determining the applicable case volume thresholds, with concern raised that inclusion of MA claim volume could result in misrepresentation of services most commonly provided in an ASC. Several commenters recommended measure additions and modifications to support a specialty-focused framework.

A few commenters raised concerns about the specialty-focused frameworks, including that, because of the limited number of measures in the ASCQR measure set, the frameworks may inhibit patients' ability to compare ASCs, as well as that there could be increased burden for multi-specialty ASCs that would be required to report on more specialty measures than single-specialty ASCs.

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

CMS finalizes, as proposed, the continuation of its 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

[78] 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 measures finalized for inclusion would also be generally applicable.

[79] Table 173 in the rule describes specialties that are addressed by the current measure set and the specialty-specific measures.

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.

XVIII. Medicaid Clinic Services Four Walls Exceptions

A. Background

Clinic services are a Medicaid benefit category that states may choose to offer (optional benefit) 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"[80] (whom CMS refers to as "individuals who are unhoused").

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.[81] CMS has reiterated this position in subsequent guidance.[82]

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

[80] 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 (mandatory benefits).
[81] CMS interprets the exception at §440.90(b) to be mandatory for the states opting to cover the clinic services benefit.
[82] 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.

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 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.

3. Clinics in Rural Areas

Medicaid provides critical access to care for individuals in rural areas who are older or disabled. For example, 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.[83]

[83] 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 to individuals 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.[84] 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) said that after the grace period expires, the four walls requirement would create barriers in access to care for Medicaid beneficiaries who receive care from IHS/Tribal clinics 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.

[84] 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.

B. Proposed Provisions, Public Comments and Responses

The proposed rule aimed to address the concerns heard from Tribes, the TTAG, the STAC, states, and other interested parties, consistent with various executive orders as well as CMS reports and frameworks, etc. CMS cites its statutory authority under 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 are not an RHC, which could already provide services covered under a separate Medicaid benefit).

For states opting to cover the clinic benefit, the four wall exception for clinic services furnished by IHS/Tribal clinics would be a mandatory component of 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 proposed 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 said it did not anticipate that the policy would create burdens for Medicaid clinic services providers or Medicaid beneficiaries and considered the possible burden for state Medicaid programs, inviting comment. In response, the agency received 96 public comments.

Final Action. CMS finalizes its proposals at §440.90 that the exception to the four walls requirement for IHS/Tribal clinics would be a mandatory component of the clinic services benefit for states electing to cover that benefit, and that the exceptions for behavioral health clinics and clinics located in rural areas would be optional for states covering that benefit.

1. General Comments

One commenter recommended including a severability provision so that if any other provision in the OPPS/ASC final rule is held to be invalid or unenforceable it would not apply to the Medicaid clinic services benefit four walls exceptions. CMS agrees and adds relevant language in the supplementary information section of the final rule.

Many commenters supported CMS' clarifications and effort to mitigate operational burdens—for example, by not proposing to require behavioral health clinics to verify that an individual has a behavioral health diagnosis or that clinics located in rural areas verify that an individual lives in a rural area.

Two supportive commenters expressed concern about the federal and state budgetary impacts, given that the policies may increase provider payment rates. CMS acknowledges this possibility, pointing to its estimate of total impact over five years, which is $1.18 billion—$1.15 billion federal and $30 million state.[85] However, CMS says the changes are expected to benefit Medicaid beneficiaries, Tribes, and states by improving access to care for the populations served by IHS/Tribal clinics, behavioral health clinics, and clinics in rural areas. The agency reminds states of the importance of meeting requirements for actuarially sound capitation rates in Medicaid managed care. Specifically, states and their actuaries should assess if these changes would materially impact

[85] This high federal share indicates that CMS expects much of the new Medicaid spending to be for services received through an IHS/Tribal clinic by AI/AN Medicaid beneficiaries.

actuarially sound capitation rates, and if so the state and its actuary should account for this in developing capitation rates in accordance with 42 CFR 438.4 and 438.5.

2. Justification and Criteria for Additional Medicaid Clinic Services Four Walls Exceptions

Many commenters agreed that it is within CMS's authority under section 1905(a)(9) of the Act to institute the four walls exceptions and that the generally higher facility-based clinic services payment rates would help incentivize providers to furnish these services, thereby helping ensure access to care. Some recommended that CMS consider eliminating the four walls requirement completely, but CMS says it does not interpret the statute as authorizing it to completely eliminate the four walls requirement.

In response to a request for clarification regarding telehealth, CMS said it will take this into consideration as it contemplates issuing sub-regulatory guidance regarding how the four walls requirement applies when Medicaid clinic services are delivered via telehealth. However, the agency provides additional clarification below, in response to comments in the section on behavioral health clinics.

3. IHS/Tribal Clinics

CMS finalized without modification its proposal 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 is 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 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 will continue to apply for services provided outside the four walls of a clinic. In other words, although the four walls exception will apply to any Medicaid beneficiary who receives services from the IHS/Tribal clinic, the 100 percent FMAP will only be available for AI/AN Medicaid beneficiaries.

Selected Comments/Responses. Most commenters expressed support for the proposed exception at §440.90(c) to the Medicaid clinic services benefit four walls requirement for IHS/Tribal clinics, particularly given substantial practitioner shortages currently experienced at IHS/Tribal clinics.

4. Behavioral Health Clinics

CMS proposed 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—finalized without modification—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 did not 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. States choosing to adopt this exception would describe the types of behavioral health clinics such exception applies to in their Medicaid State plan.

Selected Comments/Responses. Most commenters expressed support for the four walls exception at §440.90(d) for behavioral health clinics. Several expressed that telehealth flexibilities adopted by states under section 1135 waivers during the PHE to allow coverage of Medicaid clinic services outside of the four walls (when neither the clinic practitioner nor beneficiary was present at the clinic) increased access to services furnished by behavioral health clinics, and that a permanent exception to the four walls requirement for behavioral health clinics would increase access to care.

Many indicated that the agency's current interpretation of how the four walls requirement applies when Medicaid clinic services are furnished via telehealth—under which clinic services furnished via telehealth are covered only when either the clinic practitioner or the beneficiary is physically onsite at the clinic facility—is burdensome for behavioral health clinics. In response, CMS noted that upon the effective date of this rule, if a state adopts exceptions to the four walls requirement for behavioral health clinics and/or clinics located in rural areas, then neither the beneficiary nor the clinic practitioner would need to be present in such a clinic for services to be delivered via telehealth. In addition, IHS/Tribal clinic services can be delivered via telehealth without the beneficiary or clinic practitioner present in the clinic upon the effective date of this final rule.

While many commenters expressed support for including in the four walls exception those behavioral health clinic types that are recognized nationally, such as Community Mental Health Centers (CMHCs), CMS reminds them that the states implementing this exception will determine

which clinics are subject to it. Having said that, CMS expects all states that opt to implement this exception to include behavioral health clinic types that are recognized nationally.

5. Clinics in Rural Areas

CMS proposed adding a new paragraph (e) to §440.90 to extend 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 did not include a required definition of rural, leaving it to states to determine. However, CMS had listed specific potential federal definitions (not described here) and sought comment on whether it should adopt any in the final rule.

Selected Comments/Responses. Most commenters expressed support for the proposed exception at §440.90(e) to the four walls requirement for clinics located in rural areas.

Many commenters recommended that CMS not adopt a definition of rural at §440.90(e). However, many others recommended that CMS allow states to choose any state or federal definition of rural, believing that states are best equipped to determine the extent to which a specific definition best captures the rural population that meet the four criteria and recognizing each states' unique geographic needs. Three others recommended that CMS define rural with a definition that is adopted and used by a federal governmental agency.

CMS notes that the overwhelming majority of commenters recommended that it either not adopt a definition of rural or allow states to choose either a state or federal definition of rural that best captures the rural population that meets the four criteria described earlier. CMS finalizes this exception with a modification that the best approach is to permit states to choose either a state or federal definition of rural that best captures the state's rural population meeting the four criteria. States implementing the exception must include in their Medicaid State plans a definition of rural area. This definition must be either a definition adopted and used by a federal governmental agency for programmatic purposes, or a definition adopted by a state governmental agency with a role in setting state rural health policy.

As part of their Medicaid State plan submission, states will need to attest that the selected definition falls into one of the two described categories and that it best captures the population of rural individuals that meets more of the four criteria. Because the definition will be identified in the Medicaid State plan, it will be changed through the State Plan Amendment (SPA) process, which gives CMS and the public notice of the change.

6. Additional Four Walls Considerations

CMS proposed—and finalizes without modification—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, while the proposed exceptions for behavioral health clinics and clinics located in rural areas would be applied at state option. In addition, CMS proposed to codify in regulation text its longstanding interpretation that existing §440.90(a) and (b), described at the beginning of this section, 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, both within and across states, than the populations targeted by the optional exceptions. 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.

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 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 the exception(s).

Selected Comments/Responses. Most commenters expressed support for the proposal to make the IHS/Tribal clinic four walls exception mandatory for states that cover the clinic services benefit. Many also supported making the exception optional for behavioral health clinics and clinics located in rural areas. However, many others also urged CMS to make the exception for behavioral health clinics mandatory for states that cover the clinic services benefit, in order to make services more accessible, strengthen states' behavioral health workforces, and more effectively enable providers to meet individuals where they are in need.

CMS reiterates that its proposal to make the IHS/Tribal clinic four walls exception mandatory and the exceptions for behavioral health clinics and clinics located in rural areas optional was based on the population served by IHS/Tribal clinics more consistently meeting the four criteria described earlier. While it appreciates the evidence and information provided, the agency does not believe that the evidence or information included in some public comments contradicts its assumptions. Therefore, it finalizes its proposal at §440.90 to make the IHS/Tribal clinic four walls exception

mandatory and the exceptions for behavioral health clinics and clinics located in rural areas at state option, for states that cover the clinic services benefit.

Many commenters recommended additional exceptions to the four walls requirement—for example, for underserved and high-risk populations including racial and ethnic minorities, individuals with disabilities, LGBTQ+ individuals, low-income individuals, women, and individuals who are elderly. A few other commenters suggested exceptions for additional types of services (for example, maternity care) or additional types of clinics (for example, those provided school-based services). CMS finalizes its proposal but said it will take these recommendations into consideration when determining if possible future rulemaking on additional exceptions is warranted.

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). It requires impacted payers (excluding Qualified Health Plan issuers on the Federally-Facilitated Exchanges) to send prior authorization decisions as expeditiously as the individual'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 (84 FR 61446 through 61456), CMS established a nationwide prior authorization process and requirements for certain HOPD services under Medicare FFS. 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 proposed 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 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 proposed 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 that 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. Thus, CMS did not propose to conform that timeframe with the one in the CMS Interoperability and Prior Authorization final rule.

Final Action. CMS is finalizing its proposal to change the current review timeframe for provisionally affirmed or non-affirmed standard review requests for covered OPD services subject to prior authorization from 10 business days to 7 calendar days (§419.82(d)(1)(iii)).

Selected Comments/Responses. Some commenters supported the change. Others requested it be even shorter than proposed, but CMS responds that it believes the 7-day timeframe (in alignment with the Interoperability and Prior Authorization final rule) is reasonable.

Several commenters suggested that "gold carding" be approved for providers with a history of prior authorization approval. Also, mental health organizations commented that their comprehensive treatment plan is more restrictive and complex compared to the assessment for medical-surgical health care services and suggested updating comprehensive treatment plans that would help to improve beneficiary access to services. CMS responds that under 42 CFR 419.83(c), it may already elect to exempt a provider from the prior authorization process upon the providers' demonstration of compliance with Medicare coverage, coding, and payment rules. This exemption would remain in effect until withdrawn by CMS, and providers who are exempt do not need to submit prior authorization requests. In addition, mental health and substance use services do not require prior authorization under Medicare FFS.

Some commenters suggested removing implanted spinal neurostimulators and facet joint interventions from HOPD prior authorization, to promote non-opioid alternatives to pain management. One commenter stated that trends showed that utilization for facet joint interventions was decreasing without need for prior authorization requirements. While CMS says it is committed to adjusting guidelines and acknowledges the benefits of implanted spinal neurostimulators and facet joint intervention services for chronic pain, they are non-emergency procedures that first require the beneficiary to undergo conservative treatment. The agency points to the 2021 and 2023

OPPS/ASC final rules for its rationale on requiring prior authorization for facet joint interventions and implanted spinal neurostimulators.

Some commenters suggested that CMS eliminate outpatient hospital services prior authorization requirements. In response, the agency says it remains fully committed to reducing unnecessary burdens while protecting its programs' sustainability by serving as a responsible steward of public funds. CMS believes it has structured the prior authorization processes to effectively account for concerns associated with processing timeframes, patient care, and other administrative concerns.

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.[86] 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 were proposed.

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

[86] Per section 1902(e)(12) of the Act, federal Medicaid regulations at §435.926, and CHIP regulations at §457.342.

§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 proposed 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.

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.

Final Action. CMS finalizes updating 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, without modification to its proposal, the agency finalizes 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;
- 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; and
- Removing 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.

Selected Comments/Responses. The vast majority of commenters were supportive of the Medicaid and CHIP Continuous Eligibility proposal, citing a number of reasons.

One commenter suggested that CMS track rates of churn for children to help evaluate the effectiveness of the continuous eligibility policy. CMS said it uses data from the Transformed Medicaid Statistical Information System (T-MSIS) Analytic Files (TAF) to monitor churn across several eligibility groups and will continue to monitor churn to inform the impact of this policy.

A few commenters suggested that CMS extend the continuous eligibility requirements to additional populations—for example, patients undergoing active treatment for serious illnesses, pregnant women, or adults with disabilities. Another suggested expanding continuous eligibility to all adults and children covered under any Medicaid eligibility category. At this time, CMS is only codifying

the requirements of the CAA, 2023 related to children up to age 19 in Medicaid and CHIP. However, the agency points out other relevant requirements and state options in existing statute and regulations. For example, section 1902(e)(7) of the Act and §435.172 currently protect children enrolled in the mandatory Medicaid eligibility group for infants and children under age 19 who are receiving inpatient services when they age out of coverage in their eligibility group and would otherwise remain eligible for coverage. This provision requires that these children continue eligibility, despite exceeding the maximum age for the group, until the end of their inpatient stay.

For a number of reasons, the majority of commenters also supported removing nonpayment of premiums as an optional exception to continuous eligibility in CHIP, which CMS finalizes as proposed. In response to commenter concerns that states may institute other measures in response (for example, implementing higher premiums to make up for lost revenue), CMS notes that under section 2105(d)(3) of the Act, states shall not have in effect eligibility standards, methodologies, or procedures under a CHIP State plan or waiver of a CHIP State plan that are more restrictive than the eligibility standards, methodologies, or procedures as in effect on March 23, 2010.[87] In prior guidance, CMS clarified that, for CHIP, this applies to increases to existing premiums above certain inflation-related adjustments and to the imposition of new premiums to existing eligibility groups.

CMS notes that all states will be required to submit a CHIP SPA to demonstrate compliance with the provision of this final rule regarding removing nonpayment of premiums as an exception to continuous eligibility in CHIP. Most states are already in compliance with this provision and have submitted SPAs.

Two commenters opposed removing nonpayment of premiums as an optional exception to continuous eligibility in CHIP. They requested clarity regarding the authority under which CMS can remove this previously optional exception and cited concerns regarding the potential increased costs to states or health plans if premiums are unpaid. In response, CMS provides a lengthy review of the statutory and regulatory history in Medicaid and CHIP of continuous eligibility for children and related exceptions.

XXI. Health and Safety Standards for Obstetrical Services

A. Background

CMS discusses what it describes 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 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

[87] This requirement applies to children in families whose income does not exceed 300 percent of the Federal poverty level (FPL) and remains in effect through September 30, 2029. The same requirement applies to state Medicaid agencies (1902(a)(74) and (gg)(2) of the Act).

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 policies finalized in this rule.

CMS believes the Medicare statute provides ample authority for the agency to establish 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.[88]

Selected Comments/Responses. Reactions to the proposed standards were mixed. Those in favor of new conditions of participation for hospitals and CAHs for obstetrical services describe the new standards as essential to address maternal health disparities and as being more responsive to the peri-natal needs of high-risk patients and communities. They also encouraged CMS to strengthen or reinforce the Emergency Medical Treatment and Labor Act (EMTALA) protections for patients experiencing pregnancy-related emergencies to reduce maternal morbidity and mortality. The agency notes in response that EMTALA requirements are separate from those it proposed here, but it had nonetheless taken steps to support hospitals in complying with federal requirements under EMTALA.[89]

Other commenters believed the agency should have first collaborated with hospitals and CAHs in developing the policy and urged the agency to withdraw the proposals; they believe amending the CoPs was not the appropriate mechanism to achieve change. They also believe the potential loss of Medicare certification was too punitive a measure. These commenters were also concerned about the additional burden the proposals would occasion, especially the staffing requirements. Others observed that the proposed standards do not address the underlying issues that prevent access to high quality maternal and neo-natal care. Concern that the proposed requirements duplicated existing requirements was also expressed. CMS does not agree with these commenters. The agency says that it conducted extensive outreach and believes its approach is necessary as part of its multi-pronged approach to address the maternal health crisis. The additional efforts the agency has undertaken, including new quality measures, to address the crisis is discussed at length in the preamble. Noting that there are currently no minimum care standards that hospitals and CAHs must comply with pertaining to emergency readiness, transfer protocols, organization, staffing, and delivery of services for maternity care, CMS believes the new CoPs will advance patient health and safety and complement the activities of other agencies on this issue. It also notes that there are no CoPs specifically addressing organization, staffing, and delivery of OB services.

The agency finalizes its proposals with modifications described below, which are generally effective January 1, 2026. However, the agency also finalizes a phased-in implementation for

[88] 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.
[89] https://www.hhs.gov/about/news/2024/07/02/biden-harris-administration-reaffirms-commitment-emtalaenforcement.html

hospitals and CAHs in 3 phases, over a 2-year period. Table 174 in the final rule (reproduced below) shows the implementation timeline.

TABLE 174: IMPLEMENTATION TIMEFRAME FOR HOSPITALS AND CAHS

Regulatory Section	Implementation Date
• Emergency Services Readiness for Hospitals (§482.55) and CAHs (§ 485.618) • Transfer Protocols for Hospitals (§482.43)	6 months after the effective date of the final rule
Organization, Staffing, and Delivery of Services for Hospitals (§482.59(a) and (b)) and CAHs (§485.649(a) and (b)	1 year after the effective date of the final rule
•Training for OB Staff in Hospitals (§482.59(c)) and CAHs (§485.649(c) • QAPI Program for OB Services in Hospitals (§482.21) and CAHs (§485.641)	2 years after the effective date of the final rule

B. Provisions of the Regulations

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

CMS adds 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, must be well organized and provided in accordance with nationally recognized acceptable standards of practice for the health care of pregnant, birthing, and postpartum patients. Standards for physical and behavioral health are included. Additionally, outpatient obstetrical services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

a. Standard: Organization and Staffing

If the hospital offers obstetrical services, the services must be well organized and furnished in accordance with nationally recognized acceptable standards of practice for the health care of pregnant, birthing, and postpartum patients. The organization of the obstetrical services at the hospital or CAH must be appropriate to the scope of the services offered. Obstetrical services must 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 must 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).

Additionally, hospitals and CAHs must delineate obstetrical privileges for all practitioners providing obstetrical care according to the competencies of each practitioner. One modification in the final rule is to require that practitioner competencies are established in accordance with the medical staff bylaws of the hospital or, in the case of CAHs, agreements for credentialing and quality assurance for CAHs. The obstetrical service will 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 $269,842,496 in the aggregate both in year 1 and over 10 years.

b. Standard: Delivery of Service

Obstetrical services furnished by the facility must 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 are established. One modification in the final rule is that the regulations (§§482.59(b)(1) and 485.649(b)(1)) require that certain basic equipment (i.e., call-in-system, cardiac monitor, and fetal doppler or monitor) be kept at the hospital or CAH and be readily available for treating obstetrical cases to meet the needs of patients in accordance with the scope, volume, and complexity of services offered. This means a large-volume high-acuity OB unit may have this equipment in every labor and delivery room, while a rural hospital with a low-volume of births may have this equipment readily available within the hospital.

For obstetrical emergencies, complications, immediate post-delivery care, and other patient health and safety events, the standards require additional equipment, supplies, and medication necessary to treat emergency cases, which must be kept on the premises of the facility and be readily available to treat emergencies. Examples include 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 $157,232,768 in year 1. CMS also expects the equipment will need to be replaced in 5 years; thus, the 10-year cost of this requirement is estimated to be $314,465,536.

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

CMS finalizes standards for obstetrical staff training. Effective January 1, 2027, hospitals and CAHs must 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 must reflect the scope and complexity of the services furnished by the facility. This includes 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 and implement patient safety bundles for safer births.[90] Additionally, hospitals and CAHs must 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. Another modification in the final rule is a new requirement for hospitals and CAHs to provide relevant new staff with initial training.

The facility's governing body must identify which obstetrical staff must complete the training; this includes initial training discussed above and subsequent biannual training. The governing body must document that the training was successfully completed. Additionally, the hospital or CAH must be able to demonstrate staff knowledge on the topics for which training was provided. No particular method for facilities to show their staff is knowledgeable and competent in improving maternal care delivery is required, but CMS 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 new requirements. It estimates facilities will have an average annual cost of approximately $85 million, with a total cost of $849,937,432 over 10 years to comply with these requirements. Over 10 years, the requirements are estimated to take 7,875,903 million hours to complete.

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

[90] 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."

CMS finalizes its proposals, without modification, 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 must 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.
- 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.

To satisfy requirements for the analysis of data and quality indicators, facilities must 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.

The facility's obstetrical services leadership must engage in QAPI for obstetrical services, which includes participating in the data collection and monitoring described above. Additionally, the facility leadership, obstetrical services leadership, or their designate(s) must 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 standard by participating in a perinatal quality collaborative or pursuing a QI project based on information from a MMRC. In response to a comment, the agency clarifies that it is not requiring the facilities to report data to MMRCs.

CMS sought comment on whether the proposed standards should apply to other Medicare-participating facilities, such as REHs. Based on feedback received, CMS is not extending the new QAPI standards to REHs at this time.

Regulatory Impact. CMS assumes that the requirements 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 if the requirement went into effect in year 1.However, CMS assumes no burden for year 1 because the requirement does not go into effect until year 2. It estimates that this requirement will cost an average of $22,170,365 annually and $221,703,645 over 10 years.

Additionally, for maternal health QAPI activities, CMS estimates an average annual cost of $5,607,200 and a 10-year total cost of $56,071,996.

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

CMS finalizes its proposals, without modification, to establish a new standard for readiness to set clear expectations for facilities and their delivery of emergency services. CMS believes the standard will improve facility readiness to care for emergency services patients, including pregnant, birthing, and postpartum patients. However, this standard applies to all hospitals and CAHs offering emergency services without regard to whether they also offer obstetric services. Facilities must have adequate provisions and protocols to meet emergency needs of patients, which would vary depending on the complexity and scope of services offered.

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

Provisions 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 includes 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 are 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.

Annual staff training on the protocols and provisions described above is required. Similar to the training requirements for obstetric staff described above, the facility's governing body must identify which staff must complete the training for emergency care and document that the training was successfully completed. Additionally, the hospital or CAH must be able to demonstrate staff knowledge on the topics for which training was provided. Finally, CMS hospitals and CAHs must use findings from their QAPI programs on an ongoing basis to inform training needs and any changes to training topics.

CMS sought comment on whether the proposed standard should apply to other Medicare-participating facilities, such as REHs. Based on feedback received, CMS is not extending the new emergency services standards to REHs at this time.

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 $9.8 million for CAHs and $173.4 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, which results in an estimate of $796,234,077 for years 2 through 10. In the aggregate over 10 years, the cost for facilities to comply with this requirement would equal $842,377,531.

With respect to requirements for equipment, supplies and drugs, facilities will already satisfy many of the 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. CMS expects that under normal use, call-in systems will need to be replaced in five years, so it estimates a total cost of $669,384,600 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 proposed amending its discharge planning CoP regulations to impose requirements for transfer protocols under which 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. CMS finalizes the requirements for the standard for acute care hospitals *but not for CAHs or REHs*.

A hospital must train relevant staff on hospital policies and procedures for transferring patients under its care; each hospital 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.

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 an average of $87,934,883 annually and $879,348,830 over 10 years.

Tables 231 and 232 in the final rule provide an estimate of the total annual and 10-year financial and hourly burden for the requirements related to obstetrical and emergency service. Tables 215 through 229 provide more specific information for each proposed requirement. These estimates exclude the cost for collection of information requirements shown in Tables 199 and 200, which

are estimated to cost $129,748,120 million over 10 years and take 1,038,698 hours to complete. Overall, the estimated total financial cost of the requirements will be approximately $4.10 billion and take 22.4 million hours to complete over 10 years.

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[91] and Hybrid HWM measure[92] are included in the Hospital IQR program measure set. Both measures use (i) core clinical data elements (CCDEs),[93] which are clinical variables derived from electronic health records (EHRs) that can be used to risk adjust hospital outcome measures; (ii) linking variables,[94] 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.

Extension of 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.

CMS had proposed to continue voluntary reporting of the CCDEs and linking variables or both measures for the performance period of July 1, 2023, through June 30, 2024, which would extend voluntary reporting for the FY 2026 payment determination and start mandatory reporting beginning with the FY 2027 payment determination.

Based on comments (described further below) regarding the need for additional time, in addition to finalizing its proposal that the submission of CCDEs and linking variables will remain voluntary for the FY 2026 payment determination, CMS is further extending voluntary reporting of CCDEs and linking variables for the FY 2027 payment determination as well (performance period of July

[91] This measure is designed to capture all unplanned readmissions that arise from acute clinical events requiring urgent rehospitalization within 30 days of discharge.
[92] 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.
[93] CCDEs include vital signs and laboratory results.
[94] 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.

1, 2024, through June 30, 2025). A hospital's annual payment determination for FY 2026 and FY 2027 will not be affected by the voluntary reporting of CCDEs and linking variables, but CMS will evaluate and assess the claims data portion of the measures (and those measures will be publicly reported based on claims data). In the applicable spring, as a preview of public reporting for each of those payment determinations, hospitals will continue to receive confidential hospital-specific reports, which will reflect the CCDEs and linking variables if hospitals choose to report them. CMS says it intends to make additional changes to the measures, including lowering the reporting thresholds, and will propose any substantive changes in future rulemaking.

Selected Comments/Responses. Many commenters supported the extension of voluntary reporting of CCDEs and linking variables for the FY 2026 payment determination. Commenters also requested the voluntary reporting be extended beyond the FY 2026 payment determination because of many challenges identified with the current measure reporting requirements. Some of the challenges mentioned include challenges with the 24-hour timeframe specified by the measure due to changes in patient status from observation to inpatient, data inconsistences with patient transfers, labs collected prior to the timeframe, and extended emergency department stays; challenges with reporting CCDE required laboratory results; the lack of a standard unit of measurement for required CCDE data elements; and the need to address clinical workflow and improve data collection processes.

The agency describes several upcoming measure specification changes, which will address some of the challenges raised, including:

- In the eCQM Annual Update that will be posted in Spring 2025 (which impacts the July 1, 2026, through June 30, 2027, performance period and FY 2029 payment determination), the agency will extend the anchor timestamp requirement for CCDEs from the first CCDE beginning 24 hours before to 24 hours after the start of the inpatient admission for laboratory results and 24 hours before to 2 hours after the start of the inpatient admission for vital signs (except weight), to the first CCDE resulted after the start of the hospital encounter.
- Beginning with July 1, 2023, through June 20, 2024, performance period data, which is associated with the FY 2026 payment determination, platelet laboratory test values with the unit of Femtoliter (fL) will be accepted. This means that reported fL values will no longer be set to missing.

In addition, commenters described challenges meeting the 90 percent thresholds for CCDEs and 95 percent thresholds for linking variables. CMS responds that the agency will continue to monitor hospital performance and intends to propose to lower the thresholds in the upcoming FY 2026 IPPS/LTCH PPS proposed rule.

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

A. Medicare FFS No Legal Obligation Payment Exclusion and Incarceration

1. Background

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.[95] CMS refers to this prohibition as the "no legal obligation to pay" payment exclusion. As applied to 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."[96] 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 and 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 proposed a number of changes to §411.4(b), including significant restructuring of that section of the regulatory text.

[95] Section 1862(a)(2) of the Act. This exclusion is implemented in 42 CFR 411.4.
[96] See §411.4(b), as added by 72 FR 47130, 47405 through 47406 (Aug. 22, 2007).

2. Description of Proposals

Description of "custody" (§411.4(b)(3)). CMS proposed to narrow the description of custody by removing references to individuals who are on supervised release and home detention and striking the phrase "completely or partially in any way under a penal statute or rule." 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 believes this change 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. Although CMS proposed to narrow the description of "custody" to no longer include individuals on bail, parole, probation, or home detention (and as discussed below, individuals required to reside in halfway houses), the agency emphasizes that the no legal obligation to pay payment exclusion in §411.4(a) would remain the general rule that is applicable to *all* health care items or services (except FQHC services and as provided in §411.8(b)) received by *any* Medicare beneficiary.

Halfway Houses. CMS proposed 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.

Definition of Penal Authority. CMS proposed 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 sought comment on whether those contractors should explicitly be included in the proposed definition of "penal authority."

3. Final Action

CMS finalizes its proposal to narrow the description of custody with one modification to strike the term "under arrest." The agency is also finalizing an illustrative list of individuals who are not considered to be in custody (as described further below). In addition, CMS finalizes excluding halfway house residents from the description of custody (and, unlike its proposal, is not incorporating the Medicaid guidelines). Individuals required to live in a halfway house or other community-based transitional facility will not be considered to be in custody for purposes of the no legal obligation to pay payment exclusion. Also, CMS finalizes the definition of "penal authority" as proposed. In addition, the agency finalizes its proposed non-substantive edits to §411.4(a) and proposed reorganization of §411.4(b).

4. Select Comments/Responses

All but one of the 67 comments received supported the proposal to narrow the description of "custody". Most commenters agreed that individuals on supervised release are typically responsible for their own health care costs and believed that the narrowed description of "custody" would promote successful reentry and community integration, as well as improve access to Medicare, including by individuals who are also eligible for Medicaid.

Many commenters requested CMS to explicitly state that individuals on bail, parole, probation, or home confinement are not considered to be in custody to provide further clarity to individuals, providers, and advocates as well as to reassure providers that services provided to such individuals will be reimbursed by Medicare. In response, CMS is including in the regulatory text at §411.4(b)(3)(ii) an illustrative list (which is not exhaustive) of individuals who are not considered to be in custody under the no legal obligation to pay payment exclusion. As finalized, that regulatory text provides that "individuals who are not considered to be in custody under the payment exclusion include, but are not limited to, those individuals who are released to the community pending trial (including those in pretrial community supervision and those released pursuant to cash bail), on parole, on probation, on home detention or home confinement, or required to live in a halfway house or other community-based transition facility."

Also, in response to comments concerned that the phrase "under arrest" is imprecise and overly broad, CMS is removing the term from the description of "custody" under §411.4(b)(3)(i). The agency is also, in response to comments raising that the term "bail" is too narrow, changing the reference to "bail" in its proposal to "released to the community pending trial (including those in pretrial community supervision and those released pursuant to cash bail)."

Commenters also supported narrowing "custody" to exclude individuals who are required to reside in halfway houses, providing feedback that typically these individuals are responsible for paying for their own health care. In response to comments, CMS is not including individuals who are required to live in halfway houses in the description of custody. The agency is using the phrase "community-based transitional facility" in the regulatory text instead of halfway house. The agency reiterates, as with any individual, if an individual who is required to live in a halfway house has no

legal obligation to pay for a health care item or service, the general no legal obligation to pay payment exclusion continues to prohibit Medicare from paying for such item or service, regardless of the scope of the description of custody.

Many commenters suggested that CMS exclude from the rebuttable presumption any items or services furnished by a third party not under arrangement or contract with the penal authority. CMS is not limiting the scope of the rebuttable presumption to only those items or services that are furnished by the penal authority or by a third party that has an arrangement with the penal authority to provide such items or services because the agency is concerned that such a limitation may lead to improper payments and believes it is reasonable to prevent those improper payments by requiring the penal authority overcome the rebuttable presumption.

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

1. Background

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 Part 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.

2. Proposals

CMS proposed 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. CMS proposed the change 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 was 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.

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

3. Final Action

CMS is finalizing its proposals with modifications (in response to comments discussed below) to (i) explicitly state that individuals released from incarceration or confinement and transitioning to residence in a halfway house are not considered incarcerated or in confinement for purposes of the SEP; and (ii) replace the term "discharge documents" with "documentation of discharge."

4. Select Comments/Responses

Commenters unanimously supported the proposal to revise the eligibility requirements for the SEP for formerly incarcerated individuals. Commenters supported the extension of the SEP to individuals residing in halfway houses. In response to comments, the agency is revising its proposal to allow for individuals who have been recently released from incarceration or confinement and residing in halfway houses to be eligible for the SEP. Some commenters suggested that CMS revise "discharge documents" in proposed §§406.27(d)(2)(i) and 407.23(d)(2)(i) to a term that would allow flexibility in the types of documentation accepted. In response, CMS revises the proposed regulatory language to replace the term "discharge documents" with "documentation of discharge" in order to allow individuals who may not have specific discharge documents, but have other proof of their discharge, the ability to use the SEP.

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 in 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 summed 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.[97]

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

In the proposed rule, CMS stated it is considering potential adjustments to the Overall Hospital Quality Star Ratings methodology that would place more emphasis on the measures within the

[97] Table 175 in the rule shows the results of the analysis. Table 176 shows safety performance of hospitals in the analysis by hospital characteristics.

Safety of Care measure group.[98] CMS sought 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. Select Comments Received

Several commenters supported option 1 to reweight the Overall Hospital Quality Star Rating measure groups to give greater weight to Safety of Care. Other commenters expressed concern that option 1 would detract from the importance of the other measure groups and that not all hospitals report on the same measures with the Safety of Care measure group or may not have data to report on the required number of safety measures.

A few commenters agreed with option 2 to lower by 1 star the star rating of hospitals in the lowest quartile of Safety of Care. A few other commenters raised concerns with this approach believing it to be unfair and to lead to hospitals receiving a double penalty, as well as raising concerns that the approach would undermine fair comparisons between hospitals receiving 4 stars for performing well across all measure sets and hospitals receiving that score for not performing well on the Safety of Care measure group.

[98] 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.

Several commenters supported option 3 to reweight the Safety of Care measure group and cap poor performers within the group at 4 stars. Commenters believed this approach would incentivize hospitals to invest in safety and that it is misleading if a hospital performing in the lowest quartile of the measure group could receive 5 stars. Other commenters thought the approach would confuse consumers who would not understand why a hospital did not receive 5 stars.

Other commenters suggested alternative approaches including uniform application of a Star Rating cap across all measure groups so that poor performance in any group would preclude a hospital from receiving 5 stars, a simpler weighting system, and delaying the proposal until more recent non-COVID affected data are available.

Table 131: Estimated Impact 2025 OPPS FINAL 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 *	3,562	0.0	0.1	3.0	3.0
ALL HOSPITALS (excludes hospitals held harmless and CMHCs)	3,460	0.1	0.2	3.2	3.2
URBAN HOSPITALS	2,775	0.1	0.1	3.2	3.2
LARGE URBAN (>1 Million)	1,311	0.2	-0.4	2.7	2.9
OTHER URBAN (<1 Million	1,464	0.1	0.5	3.5	3.4
RURAL HOSPITALS	685	-0.4	0.9	3.3	3.2
SOLE COMMUNITY	350	-0.4	0.8	3.3	3.0
OTHER RURAL	335	-0.4	1.0	3.5	3.4
BEDS (URBAN)					
0 - 99 BEDS	972	0.4	0.4	3.7	3.6
100-199 BEDS	761	0.2	0.4	3.5	3.4
200-299 BEDS	424	0.3	0.0	3.1	3.2
300-499 BEDS	384	0.2	0.2	3.3	3.3
500 + BEDS	234	-0.1	-0.1	2.7	2.9
BEDS (Rural)					
0 - 49 BEDS	327	-0.4	0.9	3.4	3.2
50- 100 BEDS	201	-0.4	0.9	3.4	3.1
101- 149 BEDS	85	-0.6	0.4	2.7	2.7
150- 199 BEDS	42	-0.4	1.4	4.0	3.7
200 + BEDS	30	-0.4	0.6	3.1	3.2
REGION (URBAN)					
NEW ENGLAND	124	-0.2	1.0	3.7	3.8
MIDDLE ATLANTIC	298	0.0	-1.3	1.6	1.8
SOUTH ATLANTIC	452	0.2	0.9	4.1	4.2

		(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 NORTH CENT.	418	0.0	1.4	4.3	4.4
	EAST SOUTH CENT.	169	0.1	1.3	4.4	4.4
	WEST NORTH CENT.	186	0.1	0.5	3.5	2.7
	WEST SOUTH CENT.	471	0.6	0.8	4.3	4.4
	MOUNTAIN	221	0.3	0.3	3.5	3.0
	PACIFIC	387	0.3	-2.5	0.6	0.9
	PUERTO RICO	49	0.7	-0.3	3.4	3.5
REGION (RURAL)						
	NEW ENGLAND	21	-0.6	0.5	2.8	2.9
	MIDDLE ATLANTIC	52	-0.6	1.5	3.8	3.9
	SOUTH ATLANTIC	110	-0.4	-0.1	2.4	2.4
	EAST NORTH CENT.	110	-0.4	2.3	4.9	5.0
	EAST SOUTH CENT.	130	-0.4	1.3	3.8	3.9
	WEST NORTH CENT.	77	-0.4	0.6	3.1	2.4
	WEST SOUTH CENT.	119	-0.2	1.2	3.9	4.0
	MOUNTAIN	42	-0.5	1.3	3.8	2.0
	PACIFIC	24	-0.7	-2.3	-0.2	-0.1
TEACHING STATUS						
	NON-TEACHING	2,125	0.1	0.3	3.3	3.3
	MINOR	893	0.2	0.5	3.7	3.5
	MAJOR	442	-0.1	-0.3	2.5	2.7
DSH PATIENT PERCENT						
	0	11	0.0	1.4	4.4	4.6
	GT 0 - 0.10	218	0.8	0.8	4.6	4.3
	0.10 - 0.16	211	0.4	0.4	3.8	3.6
	0.16 - 0.23	529	0.5	0.4	3.8	3.8
	0.23 - 0.35	1,132	0.0	0.5	3.4	3.3
	GE 0.35	918	-0.2	-0.4	2.3	2.5
	DSH NOT AVAILABLE**	441	2.3	-0.1	5.2	5.3
URBAN TEACHING/DSH						
	TEACHING & DSH	1,176	0.1	0.1	3.1	3.1
	NO TEACHING/DSH	1,147	0.3	0.2	3.4	3.3
	NO TEACHING/NO DSH	11	0.0	1.4	4.4	4.6
	DSH NOT AVAILABLE[2]	441	2.3	-0.1	5.2	5.3
TYPE OF OWNERSHIP						
	VOLUNTARY	1,975	0.0	0.2	3.1	3.1
	PROPRIETARY	1,059	1.0	1.0	4.9	4.9
	GOVERNMENT	426	-0.1	-0.3	2.5	2.6
CMHCs		35	9.1	0.0	12.2	11.9
Column (1) shows total hospitals and/or CMHCs.						

		(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**
Column (2) includes all final CY 2025 OPPS policies and compares those to the CY 2024 OPPS.						
Column (3) shows the budget neutral impact of updating the wage index by applying the FY 2025 hospital inpatient wage index, including the low wage index hospital policy. The rural SCH adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The final budget neutrality adjustment for the cancer hospital adjustment is 1.0005 because the final CY 2025 target payment-to-cost ratio is less than the CY 2024 PCR target.						
Column (4) shows the impact of all budget neutrality adjustments and the addition of the final 2.9 percent OPD fee schedule update factor (3.4 percent reduced by 0.5 percentage point for the productivity adjustment).						
Column (5) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate and adding estimated outlier payments. Note that previous years included the frontier adjustment in this column, but we have included the frontier adjustment to Column 3 in this table.						
* These 3,562 providers include children's and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs. ** Complete DSH numbers are unavailable for rehabilitation, psychiatric, and long-term care hospitals.						