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Medicare Program: 2027 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 2027[1] final rule for Medicare's hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system (CMS-1850-FC) on November 4, 2026. Policies in the final rule will generally go into effect on January 1, 2026, unless otherwise specified. The final rule was published on November 6, 2026, 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 Ambulatory Payment Classification (APC) or where CMS has not previously sought comment. **The public comment period will close on January 4, 2027.**

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, cancer hospitals and 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, the ASC Quality Reporting (ASCQR) Program and Rural Emergency Hospital Quality Reporting (REHQR) Program.

Among other provisions, CMS finalized the following policies:

- To reduce the otherwise applicable update for non-drug OPPS services by 2 percent as part of recouping additional spending resulting from adverse litigation against the Secretary for 340B acquired drugs.
- To change the payment for 340B acquired drugs from ASP+6 percent to ASP-28.0 percent based on a drug cost survey done earlier this year. This reduction in payments is estimated to be $4.65 billion 2027 for 340B acquired drugs that will be completely offset by a 7.5 percent increase to non-drug OPPS services.
- To reduce payments for imaging services without contrast furnished in off-campus provider-based departments to a physician equivalent rate.
- To continue elimination of the inpatient only (IPO) list by pricing 637 additional procedures under the OPPS.

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-1850-fc.

[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 2027 OPPS final rule is estimated to be approximately $1.78 billion. Considering estimated changes in enrollment, utilization and case-mix for 2027, CMS estimates that OPPS expenditures, including beneficiary cost-sharing, will be approximately $114.4 billion, which is approximately $10.7 billion higher than estimated expenditures in 2026. CMS estimates a 2.0 percentage point reduction to the OPPS payment update—the 340B recoupment payment adjustment—for non-drug OPPS services for most hospitals will reduce OPPS payments by $1.6 billion in 2027.

The reduction in payment for imaging without contrast in off-campus provider-based department will reduce payment $260 million ($190 million in Medicare spending and $70 million in reduced beneficiary copayments). CMS presents this savings as a one year only without assuming any change in provider behavior. The 10-year impact is a savings of $9.3 billion although it is unclear from the final rule whether this impact assume provider behavior changes.

CMS estimates that the update to the conversion factor net of the productivity will increase payments 2.3 percent in 2027 (market basket of 3.2 percent less 0.9 percentage points for productivity). Including this update, all budget neutral changes, changes to outlier payment, application of the frontier State wage adjustment, the payment adjustment for imaging without contrast and the reduction to the quality update for hospitals that do not meet the HOQRP requirements to receive the full update, CMS estimates a 1.7 percent increase in payments between 2026 and 2027 before application of the 2.0 percent reduction in payment for non-drug OPPS services for recoupment of past additional spending for 340B acquired drugs.

Hospitals that satisfactorily report quality data will qualify for the full update of 2.3 percent update (before application of the 340B recoupment payment adjustment) while hospitals that do not will be subject to a 2.0 percentage point reduction in the applicable update or 0.3 percent. All other adjustments are the same for the two sets of hospitals. An additional 2.0 percentage points will reduce these updates to 0.3 percent and -2.3 percent respectively. Of the 3,620 hospitals included in modeling the payment impacts, CMS determined that 66 hospitals will not receive the full OPPS increase factor for failing to meet the HOQRP requirements.

CMS' impact table indicates that Medicare makes payments under the OPPS to approximately 3,620 facilities (3,502 hospitals excluding CMHCs, cancer and children's hospitals held harmless to their pre-OPPS payment-to-cost ratios). Table 112 of the final rule (reproduced in the Appendix to this summary) includes the estimated impact of the final rule by provider type. It shows a 1.7 percent increase in Medicare spending for all facilities and all hospitals after accounting for all factors excluding the 340B recoupment adjustment. The table shows an additional reduction of -2.0 percent across all facilities and hospitals. The following table shows components of the payment change:

	% Change All Facilities
Fee schedule increase factor, Wage and Provider Adjustments	2.30
Imaging without Contrast Reduction	-0.40
Difference from 2026 outlier payments (1.21% vs. 1.0%)	-0.21
Difference in Pass-Through Payments	+0.07
Subtotal	1.76
340B Acquired Drugs Recoupment Adjustment	-2.00
All changes	-0.24

For 2026, CMS estimated that pass-through will be 0.30 percent of OPPS spending. For 2027, CMS estimates that pass-through spending for drugs, biologicals and devices will be $260.4 million, or 0.23 percent of OPPS spending. The difference between these figures ((0.30 – 0.23) =0.07 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 2026 will represent 1.21 percent of total OPPS payments compared to the 1.0 percent set aside for 2027, a -0.21 percentage point change in 2027 payments. Taken together, these factors produce a total change in 2027 OPPS payments of approximately -0.24 percentage points.

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 decrease of 0.3 percent for all facilities, the rule's impacts vary depending on the type of facility. Impacts will differ for each hospital category based on the mix of services provided, location and other factors. Impacts for selected categories of hospitals are shown in the table below:

Facility Type	2027 Impact
All Hospitals	-0.3
All Facilities (including CMHCs and cancer and children's hospitals)	-0.3
Urban	-0.7
Large Urban	-1.2
Other Urban	-1.3
Rural	3.3
Beds	
0-99 (Urban)	5.3
0-49 (Rural)	4.9
500+ (Urban)	-5.7
200+ (Rural)	2.4
Major Teaching	-0.7
Type of ownership	
Voluntary	-0.6
Proprietary	8.2
Government	-3.7

An increase or decrease larger than the average will be accounted for by CMS' policy to pay for 340B acquired drugs at ASP-28.0 percent and apply a budget neutrality adjustment to non-drug OPPS services of 7.5 percent. The resulting impacts are large reductions in payment for 340B hospitals and large increases for hospitals that do not acquire drugs through the 340B program.

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 2027. 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 ($1,736 in 2026 and not yet announced for 2027), which accounts for the aggregate coinsurance percentage being less than 20 percent.

II. Updates Affecting OPPS Payments

A. Ambulatory Payment Classification (APC) Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

For 2027, CMS is using 2025 hospital final action claims for services furnished from January 1, 2025, through December 31, 2025, processed through the Common Working File as of June 30, 2026 (approximately 83 million claims). CMS is using Medicare cost reports beginning in 2024 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/2027-fr-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 2027 final rule, CMS is bypassing the 177 HCPCS codes identified in Addendum N. There are 2 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 2025 but were deleted for 2026.

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 2027, 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 furnished service billed under the OPPS. CMS proposed to continue following this basic process for 2027. CMS eliminates 2025 claims from off-campus provider-based departments (PBDs) 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 proposed to continue determining 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 proposed to continue including blood and blood products in the comprehensive APCs, which provide all-inclusive payments covering all services on the claim. HCPCS codes and their associated APCs for blood and blood products are identified with a status indicator of "R" (Blood and Blood Products) in Addendum B of the final rule. CMS received one comment supporting its proposals that it is finalizing without change.

(ii) Brachytherapy sources

The statute requires the Secretary 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 2027.

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 2026, 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 2025 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 2027 for HCPCS code C2645.

Similarly, there were no 2025 claims available for HCPCS A9527 (Iodine i-125, sodium iodide solution, therapeutic, per millicurie) or HCPCS code C2636 (Brachytherapy linear source, non-stranded, palladium-103, per 1 mm). These codes are assigned to APCs 2632 and 2636, respectively. Four years of claims data only yielded 2 claims for each APC which CMS believes is insufficient for rate setting. Using its equitable adjustment authority, CMS proposed for 2027 to maintain the 2026 payment rates for APC 2632 and APC 2636 at $396.32 per millicurie for APC 2632 and $89.40 per 1 mm for APC 2636.

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 2027, CMS proposed to price five low volume brachytherapy APCs under this policy (excluding those that are priced using external data).

Recommendations for HCPCS codes that describe new brachytherapy sources should be directed to: outpatientpps@cms.hhs.gov. 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 2027

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 a new APC for claims with a geometric mean cost that is higher than the highest cost C-APC in a clinical family just to accommodate potential complexity adjustments. CMS did not propose any changes to its criteria for making a complexity adjustment but requested public comment on these and other issues.

Multiple commenters requested that CMS apply a complexity adjustment to additional code combinations listed in Table 1 of the final rule. CMS is applying a complexity adjustment to one additional code combination: HCPCS code 37187 with HCPCS code 37248. The final rule states the additional code combinations requested by the commenters did not meet CMS' criteria for a complexity adjustment.

CMS further summarized comments requesting additional changes to the complexity adjustment criteria, many of which repeated comments in response to a prior comment solicitation. The response indicated that CMS will further consider these comments in future rulemaking.

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 assigned to the "Comprehensive Observation Services" C-APC. CMS proposed to continue this policy without change.

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 (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 consistent with section 1833(t)(15) of the Act.

Beginning with 2025, CMS excluded specific gene therapies listed in Table 3 of the final rule from the C-APC policy. Based on a public comment, CMS added HCPCS codes J1413, J3401 and J929 to the list of gene therapy products excluded from C-APC packaging effective January 1, 2027 once transitional pass-through for these products ends.

If HCPCS codes for cell and gene therapies appear on the same claim as a HCPCS code that is subject to the C-APC policy, CMS' policy is to pay separately for the cell and gene therapy and not package payment into the C-APC. The rationale underlying CMS' policy 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. CMS adopted this policy on a permanent basis in 2025 and did not propose any changes for 2027.

Several commenters recommended that CMS expand the C-APC exclusion policy beyond cell and gene therapies to include other drugs and biologicals that constitute the primary treatment furnished during an outpatient encounter. The associated procedure or observation service facilitates the administration or monitoring of the drug, while the drug or biological itself is the primary therapeutic intervention. Once transitional pass-through expires for these products, packaging the costs into a C-APC will result in inadequate payment

There were other comments that stated the costs of relatively low-volume, high-cost therapies may not be adequately reflected in C-APC rates. These commenters requested that CMS exclude therapies from C-APC packaging that are directly administered oncology therapies furnished via a procedure. CMS acknowledged that certain other drugs and biologicals may similarly represent the primary therapeutic intervention in an outpatient encounter but does not believe that alone provides sufficient basis to establish a categorical exclusion from the C-APC packaging policy. Additional consideration and data would be necessary to determine when additional exclusions from C-APC packaging beyond cell and gene therapy are warranted. CMS will take commenters' feedback and recommendations into consideration as it continues to evaluate the C-APC methodology in future rulemaking.

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. However, some commenters expressed concerns that the C-APC methodology lacks appropriate charge capture mechanisms to accurately reflect the services associated with the C-APC. CMS responded that it will consider providing additional provider education regarding the reporting of these services.

The full list of C-APCs, the data CMS used to evaluate creating a C-APC, and C-APC complexity adjustments are found in Table 4 of the final rule and Addendum J with a status indicator of "J1" or "J2" (only for the Comprehensive Observation Services C-APC).

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 for mental health services and multiple imaging services. CMS did propose any changes to its composite APC policies for 2027.

For the mental health composite APC 8010, CMS does not believe the mental health composite APC payment should be higher than the highest partial hospitalization payment. APC 5864 is the highest paid partial hospitalization APC 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 2027, CMS proposed to continue this policy.

One commenter expressed concern that the policy may discourage hospitals from furnishing multiple clinically appropriate mental health services on the same date of service, including for beneficiaries in rural areas who may travel significant distances for care and for whom

consolidation of services may be appropriate. Another commenter requested that CMS evaluate whether APC 8010 appropriately recognizes and pays for hospital outpatient services furnished to beneficiaries with substance use disorder (SUD).

CMS replied that it will examine how frequently payment through APC 8010 occurs and the combinations of services to which it applies. Based on what the available data show about same-day care for beneficiaries in rural areas and the treatment of services furnished to beneficiaries with SUD, CMS will consider whether policy changes to the mental health composite are warranted.

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 excludes non-opioid treatments for pain relief that meet the criteria for separate payment from APCs. This policy is discussed in more detail in section XIV.E of this summary.

CMS did not propose any other changes to its overall packaging policy. Nevertheless, as in past rules, CMS received comments to unpackage specific services. No change are being made in response to these comments and CMS' packaging policy is being finalized unchanged from prior years.

4. Separate OPPS Payment for Diagnostic Radiopharmaceuticals

Beginning with 2025, CMS adopted a policy to pay separately for diagnostic radiopharmaceuticals with per days costs above $630. Below this threshold, diagnostic radiopharmaceuticals remain packaged. Starting in 2026, CMS adopted a policy to update the $630 threshold amount 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 uses the most recently available four-quarter moving average PPI levels to trend the 2025 threshold forward from the third quarter of 2025 to the third quarter of 2027 and rounds the resulting dollar amount to the nearest $5 increment. Based on this methodology, CMS determined an updated threshold of $634.80 rounded to the nearest $5 increment or $635 per day for 2027 (which is $30 below the amount proposed for 2027 but not further explained).

While CMS would ordinarily use the average sales price (ASP) methodology to pay for separately payable diagnostic radiopharmaceuticals, it has continued to find that the ASP data is not usable for payment purposes. CMS continues to believe a reasonable alternative for separate payment of diagnostic radiopharmaceuticals that exceed the per day cost threshold is to use mean unit cost (MUC) from claims data.

CMS encourages manufacturers to begin or continue reporting ASP data for potential future use. To facilitate potential future payment of diagnostic radiopharmaceuticals using ASP, CMS

sought comment on this guidance in the 2026 OPPS rule: *Submission of OPPS ASP Data for Nonpass-Through Separately Payable Therapeutic Radiopharmaceuticals and Radiopharmaceuticals with Pass-Through Status*.

CMS proposed to base the initial payment for new diagnostic radiopharmaceuticals with HCPCS codes that do not have pass-through status and are without claims data on ASP or wholesale acquisition cost (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.

Many commenters expressed concerns about payment based on MUC rather than ASP. These concerns included differential reporting practices from hospitals including variable cost-to-charge ratios and revenue codes, charge compression, and other issues that may inappropriately lower a diagnostic radiopharmaceutical's MUC. CMS responded that based on the claims data and claims volume for these diagnostic radiopharmaceuticals, CMS believes extremely high ASPs appear to be erroneously reported. For this reason, CMS will continue to use MUC as an appropriate proxy for the average cost of a diagnostic radiopharmaceutical.

Many commenters requested that CMS release the *ASP Reporting Framework for Diagnostic Radiopharmaceuticals* referred to in prior rulemaking. CMS responded that it will continue to consider additional ASP reporting guidance for diagnostic radiopharmaceuticals and welcomes input from interested parties on the framework's content.

The HCPCS codes for diagnostic radiopharmaceuticals that will be paid separately appear in Addendum B with status indicator "K." Packaged diagnostic radiopharmaceuticals are assigned status indicator "N." The list of diagnostic radiopharmaceuticals that CMS will pay separately in 2027 are listed in Table 7 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 PBD 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 (2025) to determine budget neutrality for changes in the OPPS relative weights for the payment rule year (2027). Holding all other variables constant, CMS multiplies the 2026 final relative weights and the 2027 final relative weights respectively for each APC by its associated volume from 2025. It sums the 2026 final relative weights and the 2027 relative weights respectively and divides the 2026 aggregate relative weights by the 2027 aggregate unscaled relative weights to determine the weight scaler. Using this process, CMS is applying a weight scaler of 1.4614. The unscaled 2027

relative payments are multiplied by 1.4614 to determine the 2027 scaled relative weights that are shown in Addenda A and B of the final rule. There were no public comments on this process.

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 2026 and 2027 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 2027 conversion factor will be $98.011 for most hospitals—that is, hospitals receiving the full update for outpatient quality reporting that are subject to the 340B recoupment adjustment. Hospitals first receiving payments under the OPPS after January 1, 2018 are not subject to the 340B recoupment adjustment and will receive payment based on a conversion factor of $99.970. The components of the update are shown below:

	Full Update	
2026 Conversion Factor (CF)	**$91.415**	**Resulting CF**
Remove pass-through & outliers from prior year CF	1.0133	$92.628
Wage Index Budget Neutrality	0.9952	$92.184
Cap on Wage Index Reductions	0.9996	$92.147
COLA for Alaska and Hawaii	0.9992	$92.073
Cancer Hospital Adjustment	0.9996	$92.036
Rural Hospital Adjustment	1.0000	$92.036
340B Adjustment	1.0750	$98.939
Update	1.0230	$101.215
Pass-Through/Outlier	0.9877	$99.970
2027 Conversion Factor (Pre 340B Recoup)	**$99.9700**	**$99.9700**
340B Recoupment Adjustment	**0.9804**	**$98.0110**

CMS removes the prior year's pass-through (0.0031) and outlier adjustment (0.0100) from the 2026 conversion factor, which equals 1.0133 (1.33 percent).[2] Wage index budget neutrality is 0.9952 (-0.48 percent). The cap on reductions to the wage index requires a budget neutrality adjustment of 0.9996 (-0.04 percent). The budget neutrality adjustment for the Alaska and Hawaii cost of living allowance (COLA) is 0.9992 (-0.08 percent). The cancer hospital adjustment is 0.9996 (-0.04 percent). The rural sole community hospital adjustment is 1.0000 (0.0 percent).

The update of 1.023 (2.3 percent) equals the market basket of 3.2 percent less 0.9 percentage points for productivity for 2027. This update is the same as was included in the FY 2027 IPPS final rule and is based on the IGI second quarter 2026 forecast of the FY 2027 hospital market basket with historical data through the first quarter of 2026. The productivity estimates are from the same period.

[2] Removing the budget neutrality adjustment from the prior year requires division so the factor equals 1.0/(1-0.01-0.0031) or 1.33 percent.

CMS estimates that pass-through spending for drugs, biologicals and devices for 2027 will be $260.4 million, or 0.23 percent of OPPS spending. The outlier adjustment is 0.99 (-1.0 percent). The combined adjustment for pass-through and outliers is 0.9877 (-1.23 percent).

The 2027 conversion factor for hospitals that submit quality data before application of the 340B recoupment adjustment will be $99.9700. CMS will apply a 340B recoupment adjustment of 0.9804 (-1.96 percent that is the equivalent of reducing the applicable update from 2.4 percent by 2.0 percentage points) that would equal a conversion factor of $98.011.

The conversion factor for hospitals that do not submit quality data is subject to all the same adjustments except the update is 1.003 (0.3 percent) instead of 1.023 (2.3 percent). CMS applies this reduction by applying a "reporting ratio" of 0.9804 (-1.96 percent which is the equivalent of reducing the applicable update of 2.3 percent by 2.0 percentage points). The resulting conversion factor would be $98.011. Applying the 340B adjustment of 0.9804 (-1.96 percent) would further reduce this conversion factor to $96.090.

C. Wage Index Changes

CMS proposed to continue using a labor share of 60 percent, the fiscal year (FY) 2027 IPPS post-reclassified wage index and all the other adjustments that apply to IPPS hospitals for hospitals paid under the OPPS in 2027. These other adjustments include the rural floor, imputed floor, occupational mix adjustment, adjustment based on commuting patterns of employees, and a 5 percent cap on a decrease to hospital's wage index.

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 was in place every year under the IPPS from FY 2020 through FY 2024.

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 applied from 2020 through 2025. CMS discontinued the low wage index policy under the IPPS for FY 2025 in response to adverse litigation against the Secretary and under the OPPS beginning in 2026. The elimination of the low-wage index policy has led CMS to establish a transition policy to phase out the adjustment over multiple years on a budget neutral basis such that these hospitals would not experience more than a 5 percent reduction to their wage index in any single year.

Under the transition policy, CMS compares the hospital's wage index for FY 2027 to its wage index under the low-wage index policy in FY 2024 under the IPPS. If the hospital's wage index decreases by more than 5 percent annually (or 14.26 percent over three years),[3] the hospital would be eligible for the transitional policy. The limit on the reduction in the wage index would

[3] Over a 3-year period if its wage index were decreasing by more than 5 percent each year, this would mean a hospital's wage index for a FY cannot be lower than 0.95*0.95*0.95 of its wage index from three years earlier or 0.857357 which would be a reduction of 14.2625 percent.

be 5 percent from the otherwise applicable policy that would apply in FY 2027 if the low-wage index policy continued. As CMS proposed to align the 2027 OPPS wage index with the FY 2027 IPPS wage index, it proposed to apply this same transition policy to 2027 OPPS wage indexes.

For non-IPPS hospitals paid under the OPPS for 2027, 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 Core Based Statistical Area (CBSA) where the CMHC is located. CMS notes that, consistent with its current policy, the wage index that applies to CMHCs includes the rural floor adjustment but not the out-migration adjustment, which only applies to hospitals.

CMS received comments either supporting its policies or requesting that it not discontinue the low-wage index policy. As in past years, commenters requested CMS not apply budget neutrality for the transitional low-wage index policy or only apply it to non-low wage index hospitals. CMS responded that it does not have the statutory authority to continue the low-wage index policy which was struck down by a Federal Court. Under section 1833(t)(2)(E) of the Act, CMS must apply the wage index budget neutral. CMS disagreed with applying budget neutrality only to hospitals that are not low wage index hospitals as it would mean the wage indexes would differ between the IPPS and OPPS.

CMS is finalizing all its proposed wage index policies without modification.

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 (those that are new Medicare as well as 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 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. CMS indicates that the table of statewide average CCRs can be found at: https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/annual-policy-files/2027.

E. Rural Sole Community Hospital (SCH) Adjustment

For 2027, 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, devices paid on transitional pass-through, and items paid at charges reduced to costs. The adjustment is budget neutral and is applied before calculating outliers and copayments.

Several commenters requested that CMS expand the rural SCH adjustment to urban SCHs, Medicare Dependent Hospitals (MDHs) and rural hospitals that are not SCHs. CMS responded that its authority under the statute for the study of costs relative to other hospitals that is the basis for the adjustment only applies to rural SCHs.

F. Cancer Hospital Adjustment

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

To calculate the 2027 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 2027 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 2024 and 2025. CMS estimated a PCR of 0.89 (or 89 percent) for non-cancer hospitals. After reducing this PCR by 1.0 percentage point, the target PCR would be 0.88 (or 88 percent).

Table 10 in the final rule shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals, with increases in OPPS payments for 2027 ranging from 5.3 percent to 52.9 percent. Other information in the final rule indicates the cancer hospital adjustment requires a budget neutrality adjustment of -0.04 percent to the OPPS conversion factor.

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 2027, 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 2026 and previous years. For 2027, 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 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 satisfactorily report outpatient quality data 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 used 2025 Medicare claims data to set the 2027 outlier threshold. To model hospital outlier payments and set the outlier threshold, CMS applied a charge inflation factor of 1.15064 to approximate 2027 charges from 2025 claims.

The final rule indicates that CMS is using hospital-specific overall ancillary CCRs from the July 2026 update to the Outpatient Provider-Specific File to determine the 2027 final rule outlier threshold. CMS adjusted the July 2026 CCRs by 0.971037 to approximate the 2027 CCRs.

For 2027, CMS is adopting a fixed dollar threshold of $7,150 (compared to $6,225 in 2026 and $7,100 in the proposed rule). 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 2025, CMS estimates that it paid 0.88 percent of total OPPS payments as outliers, or 0.12 percentage points less than the 1.0 percent target. Using 2025 Medicare utilization, CMS estimates that it will pay 1.21 percent of total OPPS payments as outliers in 2026, or 0.21 percentage points more than the 1.0 percent target. CMS does not make any revisions to past or future payments if the amount paid as outliers differs from the 1.0 percent of payment set aside to fund outliers.

III. APC Group Policies

A. Treatment of New and Revised HCPCS Codes

Payments for OPPS procedures, services, and items are generally based on medical billing codes, specifically, Healthcare Common Procedure Coding System (HCPCS) codes, that are reported on hospital outpatient department (HOPD) claims. Code changes that affect the OPPS are published through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). Generally, these code changes are effective January 1, April 1, July 1, or October 1. CMS assigns the new codes to interim status indicators (SIs) and APCs and annually finalizes these interim assignments in the OPPS/ASC final rule. Addendum B (OPPS payment file by HCPCS code), Addendum D1 (OPPS Status Indicators), and Addendum D2 (OPPS Comment Indicators) are available on the CMS 2027 OPPS final rule website.

1. April 2026 HCPCS Codes Proposed Rule Comment Solicitation

For the April 2026 update, CMS established 61 new HCPCS codes that became effective on April 1, 2026. CMS sought comment on the proposed APC and status indicator assignments for the codes listed in Table 12 (New HCPCS Codes Effective April 1, 2026) in the final rule. The

comments are addressed in relevant sections of the final rule, including sections III.C. (New Technology APCs), III.E. (OPPS APC-Specific Policies), and IV. (OPPS Payment for Devices).

2. July 2026 HCPCS Codes Proposed Rule Comment Solicitation

For the July 2026 update, CMS established 98 new HCPCS codes that became effective July 1, 2026. CMS sought comment on the proposed APC and status indicator assignments for the codes listed in Table 13 (New HCPCS Codes Effective July 1, 2026) in the final rule. The comments are addressed in relevant sections of the final rule, including sections III.C. (New Technology APCs), III.E. (OPPS APC-Specific Policies), and IV. (OPPS Payment for Devices).

3. October 2026 HCPCS Codes Final Rule Comment Solicitation

For the October 2026 update, 144 codes were established and made effective October 1, 2026 and assigned appropriate interim OPPS status indicators and to APCs. CMS notes that due to a change in the AMA's release date for Category III CPT codes, there were a number of Category III codes that became effective October 1, 2026 instead of January 1, 2027, as CMS had proposed. Table 14 lists the codes that were effective October 1, 2026. Several of the temporary C-codes have been replaced with permanent J-codes effective January 1, 2027. CMS invites public comments on the interim payment indicators, which will be finalized in the 2028 OPPS final rule. CMS notes that proposed APC assignments and status indicators for these same codes will be subject to comment in the 2028 OPPS proposed rule and will be finalized in the 2028 OPPS final rule.

4. January 2027 HCPCS Codes

a. New Level II HCPCS Codes Final Rule Comment Solicitation

CMS is soliciting comments on the new Level II HCPCS codes that will be effective January 1, 2027. To indicate these codes are subject to public comment, CMS has assigned interim SI "N1" to them in final rule Addendum B. The interim final APC assignments and status indicators for these new Level II HCPCS codes that will be effective January 1, 2027, will be subject to comment in the 2028 OPPS proposed rule, and will be finalized in the 2028 OPPS final rule.

b. New CPT Codes Proposed Rule Comment Solicitation

In this section of the final rule preamble, CMS describes its policies for addressing timely and untimely receipt of new/revised CPT codes from the AMA's CPT Editorial Panel.

In the proposed rule, CMS solicited public comments on the proposed 2027 status indicators and APC assignments for the new and revised CPT codes that would be effective January 1, 2027. The CPT codes were listed in Addendum B in the proposed rule with short descriptors only; long descriptors were included in Addendum O in the proposed rule. Proposed status indicator and APC assignments for these codes were included in Addendum B in the proposed rule. CMS responds to comments received in sections III.C., III.E., and IV. of the final rule preamble. The final SIs, APC assignments, and payment rates for the new CPT codes that are effective January

1, 2027, can be found in final rule Addendum B. In addition, the SI definitions can be found in final rule Addendum D1.

Table 15 (reproduced below) summarizes CMS' current process for updating codes through the OPPS quarterly update CRs, seeking public comments, and finalizing the treatment of these codes under the OPPS.

Table 11: Comment and Finalization Timeframes for New or Revised HCPCS codes				
OPPS Quarterly Update CR	**Type of Code**	**Effective Date**	**Comments Sought**	**When Finalized**
April 2026	HCPCS (CPT and Level II Codes)	April 1, 2026	2027 OPPS/ASC proposed rule	2027 OPPS/ASC final rule with comment period
July 2026	HCPCS (CPT and Level II Codes)	July 1, 2026	2027 OPPS/ASC proposed rule	2027 OPPS/ASC final rule with comment period
October 2026	HCPCS (CPT and Level II Codes)	October 1, 2026	2027 OPPS/ASC final rule with comment period	2028 OPPS/ASC final rule with comment period
January 2027	CPT Codes	January 1, 2027	2027 OPPS/ASC proposed rule	2027 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2027	2027 OPPS/ASC final rule with comment period	2028 OPPS/ASC final rule with comment period

B. OPPS Changes – Variations Within APCs

1. Background

In accordance with statute,[4] CMS developed a grouping classification system referred to as Ambulatory Payment Classifications (APCs) which is codified at 42 CFR 419.31. CMS uses Level I and Level II HCPCS codes to identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, CMS has established distinct groups of similar services. CMS has also developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices that are not packaged into the payment for the procedure. Payment for each procedure or service within an APC group includes packaged costs associated with those items and services that are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support.

Under the OPPS, CMS generally pays for covered hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. For 2027, CMS proposed that each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in APC 5012 (Clinic Visits and Related Services). The APC relative payment weights are scaled to APC 5012 because it is the hospital clinic visit APC and clinic visits are among the most frequently furnished services in the hospital outpatient setting.

4 Sections 1833(t)(2)(A) and (B) of the Act.

2. Application of the 2 Times Rule

In accordance with statute,[5] 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 2 times greater than the lowest cost item or service within that same group (the "2 times rule"). In making this determination, CMS considers only those HCPCS codes that are significant based on the number of claims. Specifically, CMS considers significant only those HCPCS codes that either (i) have more than 1,000 single major claims or (ii) 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. For 2027, CMS proposed to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as for certain low-volume items and services.

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) provides recommendations for specific services for the 2027 OPPS and CMS' responses are discussed in relevant sections in the 2027 OPPS final rule.

For 2027, CMS identified APCs with violations of the 2 times rule and proposed changes to the procedure codes assigned to these APCs in Addendum B (identified with comment indicator "CH") other than those for which CMS proposed an exception to the 2 times rule. CMS noted that in many cases, the proposed procedure code reassignments and associated APC configurations for 2027 are related to changes in costs of services that were observed in the 2025 claims data.

3. APC Exceptions to the 2 Times Rule

CMS used the following criteria to decide whether to propose exceptions to the 2 times rule for affected APCs:

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

Based on claims data available for the proposed rule, CMS proposed to except 27 APCs with violations of the 2 times rule because all of them met criteria for an exception to the 2 times rule. CMS is finalizing its proposal with modification, based on an analysis of updated claims data available for the final rule. Table 16 (reproduced below from the final rule, modified to emphasize changes) lists the 28 APCs that CMS is excepting from the 2 times rule for 2027 based on the criteria cited above and claims data submitted between January 1, 2025, and

5 Section 1833(t)(9)(A) of the Act.

December 31, 2025, and processed on or before June 30, 2026, and updated CCRs, if available. Comments on the APCs identified in the proposed rule are addressed in section III.E.

Table 16: Final 2027 APC Exceptions to the 2 Times Rule			
APC	**Proposed**	**Final**	**APC Group Title**
5012	Y	Y	Clinic Visits and Related Services
5024	N	Y	Level 4 Type A ED Visits
5051	N	Y	Level 1 Skin Procedures
5054	Y	Y	Level 4 Skin Procedures
5071	Y	Y	Level 1 Excision/Biopsy/Incision and Drainage
5301	Y	Y	Level 1 Upper GI Procedures
5521	Y	Y	Level 1 Imaging without Contrast
5522	Y	Y	Level 2 Imaging without Contrast
5523	Y	Y	Level 3 Imaging without Contrast
5524	Y	Y	Level 4 Imaging without Contrast
5572	Y	Y	Level 2 Imaging with Contrast
5573	Y	Y	Level 3 Imaging with Contrast
5611	Y	Y	Level 1 Therapeutic Radiation Treatment Preparation
5612	Y	Y	Level 2 Therapeutic Radiation Treatment Preparation
5613	Y	N	Level 3 Therapeutic Radiation Treatment Preparation
5671	Y	Y	Level 1 Pathology
5672	N	Y	Level 2 Pathology
5674	Y	Y	Level 4 Pathology
5691	Y	Y	Level 1 Drug Administration
5692	Y	Y	Level 2 Drug Administration
5722	Y	Y	Level 2 Diagnostic Tests and Related Services
5731	Y	Y	Level 1 Minor Procedures
5734	Y	Y	Level 4 Minor Procedures
5735	Y	N	Level 5 Minor Procedures
5741	Y	Y	Level 1 Electronic Analysis of Devices
5742	Y	Y	Level 2 Electronic Analysis of Devices
5791	Y	Y	Pulmonary Treatment
5821	Y	Y	Level 1 Health and Behavior Services
5822	Y	Y	Level 2 Health and Behavior Services
5823	Y	Y	Level 3 Health and Behavior Services

C. New Technology APCs

1. Background

CMS retains services within New Technology APC groups until it can gather sufficient claims data to enable assignment of the service to an appropriate clinical APC. This policy allows CMS to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows CMS to retain a service in a New Technology APC for more than 2 years if sufficient data for reassignment have not been collected.

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

- The service cannot be reported by an existing HCPCS code assigned to a clinical APC and does not appropriately fit within an existing clinical APC;

- The service is not eligible for transitional pass-through payment; and
- The service falls within the scope of Medicare benefits and is reasonable and necessary.

For 2026, there were 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)).

CMS discusses its goals for making payments that are appropriate for the services under the OPPS and some of the challenges in setting payment for emerging technologies. CMS does not (and believes Medicare should not) assume responsibility for more than its share of the costs of procedures. CMS relies on hospitals to make informed business decisions regarding the acquisition of high-cost capital equipment.

Some services assigned to New Technology APCs have low annual volume, which CMS considers to be fewer than 100 claims in the year of claims data used for ratesetting. CMS describes the various methods it has used to address this issue. In 2022, CMS replaced its low volume policy with a universal low volume policy that applies to clinical APCs and brachytherapy APCs, in addition to procedures assigned to New Technology APCs, and uses the highest of the geometric mean, arithmetic mean, or median based on up to 4 years of claims data to set the payment rate for the APC. Because low volume issues have persisted, beginning in 2025, CMS finalized a policy to exempt services assigned to New Technology APCs with fewer than 10 claims over the 4-year lookback period used for the universal low volume policy. Instead of assigning these services to a different New Technology APC based on the very few claims available, CMS maintains the New Technology APC assignment for each service from the prior year.

Finally, CMS explains it has been the agency's policy to maintain the New Technology APC assignment for services with zero claims in the claims year used for rulemaking. For 2027, if a service has no 2025 claims, CMS proposed to maintain the same New Technology APC assignment for 2027. The proposed payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 were included in Addendum A of the proposed rule.

2. Services in New Technology APCs with Zero Claims for the Rulemaking Period or Under 10 Claims in the 4-year Lookback Period

For 2027, CMS identified several services that had either zero claims (based on 2025 claims) or fewer than 10 claims in the previous 4-year lookback period for which CMS proposed to maintain the New Technology APC assignments. Based on updated data, these services are displayed in Table 17 (reproduced from the final rule).

TABLE 17: SERVICES WITH FEWER THAN 10 CLAIMS IN THE LOOKBACK PERIOD OR ZERO CLAIMS FOR CY 2027 RATESETTING					
Name of Service	**HCPCS Code**	**# of Single Frequency Claims Over Previous 4 years**	**Final CY 2026 OPPS FR APC & SI Assignments**	**Proposed CY 2027 OPPS NPRM APC & SI Assignments**	**Final CY 2027 OPPS FR APC & SI Assignments**
Blinded Procedure for NYHA Class III/IV Heart Failure	C9758	9 claims	1590, T	1590, T	1590, T
CardiAMP	C9782	3 claims	1590, T	1590, T	1590, T
Corvia Medical Interatrial Shunt	C9760	3 claims	1592, T	1592, T	1592, T
DARI Motion Procedure	0693T	0 claims	1505, S	1505, S	1505, S
Magnetic Resonance Imaging With Inhaled Hyperpolarized Xenon-129 Contrast Agent	C9791	6 claims	1551, T	1551, T	1551, T
Surfacer Inside-Out Access Catheter	C9780	7 claims	1534, S	1534, S	1534, S
Transcatheter Atrial Shunt System (TASS)	C9792	2 claims	1537, S	1537, S	1537, S

CMS did not receive any public comments on these proposals, therefore, CMS finalizes its proposal to exempt services assigned to New Technology APCs with fewer than 10 claims over the 4-year lookback period from the universal low volume policy.

3. Procedures Assigned to New Technology APC Groups for CY 2027

For 2027, consistent with CMS' current policy, CMS proposed to retain services within New Technology APC groups until the agency obtains sufficient claims data to justify reassignment of the service to an appropriate clinical APC. The flexibility associated with this policy allows CMS to reassign a service from a New Technology APC in less than 2 years if sufficient claims data has been obtained or more than 2 years if not. The following table has been created to summarize CMS' proposed and final New Technology APC assignments for 2027. CMS evaluates each code using updated claims available for the final rule to determine ratesetting and final APC assignment, except when using its equitable adjustment authority under section 1833(t)(2)(E).

Proposed and Final 2027 New Technology APC and Status Indicator Assignments				
HCPCS	**Long Descriptor**	**Proposed 2027 APC,SI**	**Final 2027 APC,SI**	**Notes and Proposals**
0810T	Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies	1564,T	1563,T	No comments received. 12 claims found; final assignment based on universal low volume APC policy
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)	1518,S	1517,S	No comments received. 29 claims; final assignment based universal low volume APC policy

Proposed and Final 2027 New Technology APC and Status Indicator Assignments				
HCPCS	**Long Descriptor**	**Proposed 2027 APC,SI**	**Final 2027 APC,SI**	**Notes and Proposals**
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	1523,S	1524,S	No comments received. 89 claims; final assignment based on universal low volume APC policy.
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	1594,S	1594,S	Supportive comments received. Finalizing assignment from new technology APCs to clinical APC based on geometric mean costs of restructured APCs 5591-5594 (see section III.E).
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)	1594,S	1594,S	Supportive comments received. Finalizing assignment from new technology APCs to clinical APC based on geometric mean costs of restructured APCs 5591-5594 (see section III.E).
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability); with concurrently acquired computed tomography transmission scan	1594,S	1594,S	Supportive comments received. Finalizing assignment from new technology APCs to clinical APC based on geometric mean costs of restructured APCs 5591-5594 (see section III.E).
C9789	Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed	1550,T	1548,T	Clarifications provided in response to comment. 316 claims; final reassignment based on geometric mean cost.
0620T	Endovascular venous arterialization, tibial or peroneal vein, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed	1581,S	1580,S	Supportive comments received. 31 claims; final assignment based on universal low volume APC policy.
0686T	Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance	1575,S	1575,S	Commenter requests declined. 184 claims; final assignment based on geometric mean cost.
G2082	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	1513,S	1513,S	Supportive comments. CMS declines to establish a new clinical APC series. Finalizing assignment based on geometric mean.

Proposed and Final 2027 New Technology APC and Status Indicator Assignments				
HCPCS	**Long Descriptor**	**Proposed 2027 APC,SI**	**Final 2027 APC,SI**	**Notes and Proposals**
	professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation			
G2083	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	1518,S	1517,S	Supportive comments. CMS declines to establish a new clinical APC series. Acknowledges proposed rule Table 19 discrepancy. Finalizing assignment based on geometric mean.
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	1511,S	1511,S	89 claims found. Finalizing assignment based on equitable adjustment authority under section 1833(t)(2)(E) to maintain current assignment based on comments and HOP Panel recommendation.
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	1521,S	1525,S	88 claims. Finalizing assignment based on equitable adjustment authority under section 1833(t)(2)(E) to maintain current assignment based on comments and HOP Panel recommendation.
0891T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent treatment day	1520,S	1525,S	Greater than 100 claims. Finalizing assignment based on equitable adjustment authority under section 1833(t)(2)(E) to maintain current assignment based on comments and HOP Panel recommendation.
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	1523,S	1525,S	19 claims. Finalizing assignment based on equitable adjustment authority under section 1833(t)(2)(E) to maintain current assignment based on comments and HOP Panel recommendation.
15006 (Placeholder 15X19)	Skin cell suspension autograft (SCSA), trunk, arms, and/or legs; first 100 sq cm or less, or 1% of body area of infants and children	1575,S	1575,S	In light of recent coding changes, CMS finalizes proposal to maintain overall payment rates for the SCSA procedure and to delete HCPCS code C8002. Commenters support.
15007 (Placeholder 15X20)	each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)	N/A,N	N/A,N	In light of recent coding changes, CMS finalizes proposal to maintain overall payment rates for the SCSA procedure and to delete HCPCS code C8002. Commenters support.
15008 (Placeholder 15X21)	Skin cell suspension autograft (SCSA), face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits;	1575,S	1575,S	In light of recent coding changes, CMS finalizes proposal to maintain overall payment rates for the SCSA

Proposed and Final 2027 New Technology APC and Status Indicator Assignments				
HCPCS	**Long Descriptor**	**Proposed 2027 APC,SI**	**Final 2027 APC,SI**	**Notes and Proposals**
	first 100 sq cm or less, or 1% of body area of infants and children			procedure and to delete HCPCS code C8002. Commenters support.
15009 (Placeholder 15X22)	Skin cell suspension autograft (SCSA), face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)	N/A,N	N/A,N	In light of recent coding changes, CMS finalizes proposal to maintain overall payment rates for the SCSA procedure and to delete HCPCS code C8002. Commenters support.
0888T	Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including image guidance	1534,S	1575,S	18 claims; final assignment based on universal low volume APC policy.

4. Final CY 2027 Policy for SaMS Procedures Currently Assigned to New Technology APCs

CMS refers readers to Section X.B. (corresponding to section XI.B. in this summary) for the final 2027 policy and payment rates for SaMS procedures assigned to New Technology APCs.

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

For 2027, CMS proposed to designate five brachytherapy APCs and four clinical APCs as low volume APCs: APCs 2635, 2642, 2643, 2645, 2647, 5244, 5495, 5496, and 5881. CMS received comments in support for continuing its low volume APC policy for 2027. CMS is therefore finalizing this policy as proposed. There were no changes to the proposed APCs based on updated claims data for the final rule.

E. APC-Specific Policies

This section addresses 2027 final rule APC policies and APC-specific assignments. CMS notes that the final 2027 payment rates for these codes and status indicator definitions can be found in final rule Addenda B and D1, respectively, on the CMS 2027 OPPS final rule website.

1. Creation and/or Revisions of Clinical APCs

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

In the 2027 proposed rule, Medicare declined previous stakeholder requests to create a Level 6 Neurostimulator APC, maintaining its existing five level structure because it provides for an appropriate distribution of clinical and cost similarity at the different APC levels.

Selected Comments/Responses: Some commenters supported CMS' assignment proposals while others requested creation of a Level 6 APC or changes to the APC assignments for various CPT codes. Some commenters noted that restructuring and creation of new clinical APCs would allow for efficient payment for services being phased out of the IPO list. For example, commenters requested that the customary methodology be applied when evaluating CPT code 64568 and that

CMS remove hypoglossal nerve stimulation claims for the treatment of obstructive sleep apnea from the determination of its geometric mean cost. In response, CMS agrees that the claims were restricted to only allow specific procedure-device combinations under the device dependent APC methodology for CPT code 64568, however, those procedure-device combinations are no longer restricted. With the assignment of CPT code 64568 to New Tech APC 1580, and the future availability of 2026 claims that would separate those hypoglossal nerve stimulation services based on distinct C codes, CMS does not believe it is necessary to update the final rule claims data and associated cost files to assume which claims describe each type of service. CMS notes that note that the agency is not removing any codes from the IPO list to the Neurostimulator and Related Procedures APC series for 2027.

Final Action: CMS is finalizing the proposed assignments of CPT codes 33276 and 64568 to New Technology APC 1580, finalizing the proposed assignment of 61885 to APC 5465, and maintaining the 5-level APC structure for the Neurostimulator and Related Procedures APC series for 2027.

b. Laparoscopy and Related Services (APCs 5361 Through 5362)

As part of the 2016 OPPS APC restructuring process, the four level APC series for Laparoscopy and Related Services was consolidated into a 2-level APC series (80 FR 70379). Since that time, CMS has maintained a 2-level structure.

Selected Comments/Responses: A commenter requested that CMS consider whether a higher level Laparoscopy and Related Services APC is needed to establish appropriate payment for high cost services (CPT codes 32663, 32666 and 32669) that are being removed from the IPO list and proposed to be assigned to Level 2 Laparaoscopy and Related Services APC. In response, CMS recognizes the commenter's concern but declines to modify its proposal, noting that the geometric mean costs for CPT codes 32666 and 32669 fall well within the range of significant costs for the APC, and that all three codes have limited outpatient claims volume.

Final Action: CMS is finalizing its proposal to maintain the 2-level APC structure for the Laparoscopy and Related Services APC series for 2027.

c. Nuclear Medicine and Related Services APC Series (APC 5591 Through 5594)

Beginning in 2016, CMS finalized a four-level APC structure for the Nuclear Medicine and Related Services series. CPT code 61885 is currently assigned to APC 5464 (Level 4 Neurostimulator and Related Procedures). Beginning in 2025, CMS began paying separately for certain diagnostic radiopharmaceuticals (89 FR 93948 through 93963) and no longer packaged their costs. As a result, CMS observed impacts on the estimated cost of services assigned to the Nuclear Medicine and Related Services APC series such that the range of cost significant codes across the various APC levels became less distinct, in particular between Levels 3 and 4.

In the proposed rule, CMS indicated its belief that, given the relative proximity of the APC geometric mean costs and the clinical and cost similarities of the services between the APCs in the Nuclear Medicine and Related Services series, it would be appropriate to reorganize the

Nuclear Medicine and Related Services APC series for 2027 and reassign a number of services to revised levels. CMS referred readers to proposed rule Addendum B to view the Nuclear Medicine APC CMS proposed to assign each HCPCS code in the series. Additionally, CMS proposed to assign PET/CT procedures (CPT codes 78431, 78432, and 78433) to APC 5594 for 2027 because these codes had sufficient 2025 claims data available to be appropriately assigned to clinical APCs for 2027 OPPS ratesetting.

Selected Comments/Responses: Commenters expressed various concerns related to assignment of CPT codes 78830, 78075, 78454, 7881, and 78831 to APC 5592 and requested reassignment to APC 5593. However, CMS continues to believe that these codes are more appropriately placed based on their estimated costs in APC 5592 rather than Level 3 APC 5593.

Final Action: CMS is finalizing the HCPCS assignments for CPT codes 78075, 78454, 78811, 78830, and 78831 to APC 5592, as proposed. CMS is also finalizing the assignment of CPT codes 78431, 78432, and 78433 to APC 5594 as discussed in section III.C. (New Technology APCs).

2. Audiology and Otolaryngology: Cochlear Infusion of a Pharmacologic Agent, CPT Code 1056T (APC 5165)

For 2027, the AMA CPT Editorial Board created a new Category I CPT code 1056T (Placeholder code X565T) to describe a cochlear infusion procedure required for the administration of OTARMENI™ which is the first FDA-approved gene therapy for genetic hearing loss. Later, the AMA CPT Editorial Board changed the effective date from January 1, 2027, to October 1, 2026. In the 2027 proposed rule, CMS proposed to assign CPT code 1056T to APC 5163 (Level 3 ENT Procedures) and SI "J1" with a proposed payment rate of $1,755.96.

Selected Comments/Responses: Commenters requested reassigning CPT code 1056T to Level 5 ENT Procedures (APC 5165) arguing it is a complex, open surgical approach requiring significantly more facility resources, specialized training, and operative expertise than the minimally invasive Level 3 transcanal procedure described by CPT code 69801 that CMS used as a comparison. CMS agrees.

Final Action: CMS is not finalizing its proposal. Instead, CMS is assigning CPT code 1056T to APC 5165 (Level 5 ENT Procedures) and SI "J1" for 2027.

3. Audiology and Otolaryngology: Vestibular Testing Codes, CPT codes 92513, 92514, and 92527 (APC 5721)

For 2027, the AMA CPT Editorial Board created 4 New Category I CPT codes 92513, 92514, 92527 and 92528 (placeholder CPT codes 92X10, 92X11, 92XX5, and 92XX6). These new codes reflect advances in vestibular testing and provide greater specificity for reporting services used by audiologists to evaluate vestibular function. CMS proposed to assign CPT codes 92513, 92514, and 92527 to APC 5721 (Level 1 Diagnostic Tests and Related Services) with SI "S". CMS also proposed to assign status indicator "N" to CPT code 92528.

Selected Comments/Responses: A commenter supported assignment of CPT codes 92513, 92514, and 92527 to APC 5721 for 2027; however, they were concerned regarding assignment of status indicator "N" to CPT code 92528 which would package payment for VST into payment for the base rotational vestibular assessment service (CPT code 92527) and requested CMS reconsider. The commenter stated that VST requires significantly more provider time, work intensity, and resource costs than the base sinusoidal harmonic acceleration (SHA) testing service (CPT code 92527). In response, CMS concluded the proposal is consistent with the agency's packaging policy outlined at 42 CFR 419.2(b), which lists the types of items and services for which payment is packaged under the OPPS, including add-on codes.

Final Action: CMS is finalizing its proposal without modification.

4. Cardiac Magnetic Resonance (CMR) Imaging, CPT Codes 75557, 75559, 75561, 75563 (APCs 5523, 5524, 5572, and 5573)

Selected Comments/Responses: Citing concerns with payment disparities between clinically comparable advanced cardiac imaging services, a commenter requested that CMS reassign CPT code 75561 to APC 5593 and reassign CPT code 75563 to APC 5594. The commenter also requested that CMS evaluate the appropriate placement of CPT code 75557 which is currently assigned to APC 5523 and CPT code 75559 which is currently assigned to APC 5524. In response, CMS notes that the proposals were proposed based on available 2025 claims data. The agency does not agree with the commenter's position that cardiac MRI with stress imaging is very similar to myocardial perfusion imaging just because both tests are performed under a stress protocol. CMS continues affirm its longstanding position MRI services should not be assigned to the nuclear medicine APCs.

Final Action. For 2027, CMS proposed and is finalizing, without modification, the assignments for CPT codes 75557, 75559, 75561, 75563 as indicated in the following chart:

HCPCS Code	Long Descriptor	Proposed 2027 Assignment	Final 2027 Assignment
75557	Cardiac magnetic resonance imaging for morphology and function without contrast material	APC 5523	APC 5523
75559	Cardiac magnetic resonance imaging for morphology and function without contrast material; with stress imaging	APC 5524	APC 5524
75561	Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences	APC 5572	APC 5572
75563	Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences; with stress imaging	APC 5573	APC 5573

5. Cardiac CT Services, CPT Codes 75572, 75573, and 75574 (APC 5572)

For 2027, CMS proposed to maintain CPT Codes 75572, 75573, and 75574 in APC 5572 (Level 2 Imaging with Contrast) with a payment rate of around $400 based on 2025 claims data. CMS reviews the history of the codes assignment in relationship to the hospital's potential selection of revenue codes. CMS notes that in December, 2024, CMS removed an edit that was prohibiting

hospitals from reporting these codes with a cardiology revenue code (048X) which maps to the cardiology cost center (03140). With the edit no longer in place, hospitals are able to bill for cardiac CT services with whichever revenue code they believe is appropriate for these services, including cardiology revenue code 048X.

Selected Comments/Responses: Numerous commenters supported CMS' proposal to maintain the current APC assignment for 2027, but noted continued hesitancy on the part of providers to select appropriate revenue codes due to "CT" being in the CPT code descriptors. Commenters requested that CMS issue subregulatory guidance to confirm that hospitals should report these procedures under cardiology revenue codes (048x). In response, CMS reaffirms its policy not to provide specific coding guidance, referring to section 20.5 in Chapter 4 (Part B Hospital) of the Medicare Claims Processing Manual.

Final Action: CMS is finalizing its proposal without modification and assigning CT codes 75572, 75573, and 75574 to APC 5572 (Level 2 Imaging with Contrast).

6. Cardiac Leadless Pacemaker Procedures, CPT Codes 0823T, 0796T, 0795T, 0801T, 0802T, and 0825T (APCs 5231 and 5232)

CPT codes 0823T and 0796T describe the insertion of a permanent single-chamber leadless pacemaker and the insertion of a permanent dual-chamber leadless pacemaker when a right ventricular single leadless pacemaker already exists; these codes are currently receiving device pass-through payments when coded with C1605. When pass-through payment expires at the end of 2026, the device costs will be packaged into the current APC payment. CMS proposed to assign: CPT codes 0823T and 0796T to APC 5231, SI "J1"; CPT codes 0795T and 0801T to APC 5232, SI "J1"; and CPT codes 0802T and 0825T to APC 5224, SI "J1".

Selected Comments/Responses: Numerous commenters supported CMS' proposals. A couple of commenters requested that CMS also reassign CPT codes 0802T and 0825T from APC 5224 to APC 5231 to establish cost-reflective payment across the full set of leadless pacemaker procedures. In response, after analyzing the request, CMS agrees that CPT codes 0802T and 0825T be reassigned to APC 5231 based on clinical and resource coherence with the other leadless pacemaker codes.

Final Action: For 2027, CMS is finalizing, with modification, assignments for CPT codes 0823T, 0796T, 0795T, 0801T, 0802T, and 0825T as follows:

- CPT codes 0823T and 0796T to APC 5231, SI "J1" as proposed.
- CPT codes 0795T and 0801T to APC 5232, SI "J1" as proposed.
- Modify assignment of CPT codes 0802T and 0825T to APC 5231, SI "J1".

7. C-Codes Describing Percutaneous Coronary Intervention With Drug-Eluting Stents

Effective January 1, 2013, CMS created several HCPCS C-codes to describe certain percutaneous coronary intervention (PCI) procedures utilizing drug eluting stents to mirror PCI CPT codes that do not utilize drug eluting stents. The AMA CPT Editorial Board deleted several of those CPT codes effective January 1, 2026. For 2027, CMS proposed to delete the C-codes

that mirrored the deleted CPT codes, specifically revising the status indicators for C9601, C9603, C9605, and C9608 to "D" (Discontinued Codes) indicating that they are no longer active codes.

Selected Comments/Responses: Commenters supported the deletion of these C-codes but a couple of commenters requested that CMS create a new C-code to mirror CPT code 92930 to avoid a CPT/HCPCS mismatch. In response, CMS disagrees with the request to create a new C-code, explaining that when the deleted C-codes were created, CMS needed a mechanism to capture their high costs. However, these C-codes are no longer needed because the gap between the costs of drug-eluting stents and bare metal stents are not as significant as they were over ten years ago when the codes were created.

Final Action: CMS is finalizing its proposal without modification to delete the previous HCPCS C-codes and declined to create a C-code at this time to mirror CPT code 92930.

8. Chimeric Antigen Receptor (CAR-T) Administration, CPT Code 38228 (APC 5694)

CMS previously finalized that the CAR T-cell therapy procedures described by CPT code 0540T would be assigned SI "S" (Procedure or Service, Not Discounted when Multiple) and APC 5694 (Level 4 Drug Administration) from 2019 through 2024 and did not propose to change the APC assignment for 2025 when CPT code 0540T was replaced by CPT code 38228. For 2027, CMS proposed to maintain CPT code 38228 to APC 5694 and SI "S".

Selected Comments/Response: A commenter requested that CMS reassign code to APC 5242, citing closer clinical alignment with CPT code 38241 (Hematopoietic progenitor cell (HPC); autologous transplantation) than with the other services currently assigned to APC 5694. In response, CMS reviewed the claims data and CMS' initial comparison in 2019 to CPT code 96413 (Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug). CMS concludes that CPT code 96413 continues to be a clinically similar HCPCS code and the claims data for CPT code 38228 are reasonably in range with its current APC placement.

Final Action: CMS is finalizing its policy as proposed.

9. Syn-One Test®

The Syn-One Test® detects phosphorylated synuclein to aid clinicians in the diagnosis of a synucleinopathy based on a skin biopsy. According to CMS, hospitals do not perform any of the testing. Syn-One bills with established pathology CPT codes from the PFS, including CPT codes 88305, 88314, 88346, 88350, and 88356.

Selected Comments/Response: A commenter requested a limited exception to the laboratory date of service (DOS) policy and CMS' packaging rules as well as a G-code and an appropriate status indicator to identify the specialized pathology services that are not subject to the DOS policy. In response, CMS welcomes the commenter to apply for a HCPCS code to describe the Syn-One Test® through MEARIS on the CMS website.

Final Action: CMS declines to make any changes to DOS policy in the final rule, but may consider this issue in future rulemaking.

10. Transdermal Glomerular Filtration Rate (TGFR) System CPT Codes 0602T and 0603T (APC 5721)

The CPT Editorial Panel created CPT code 0602T and 0603T which became effective July 1, 2020, and describes a transdermal glomerular filtration rate measurement device called the TGFR system. For 2027, CMS proposed to maintain the status indicator assignments for CPT codes 0602T and 0603T of "Q4" (Conditionally Packaged Laboratory Tests; Paid under OPPS or CLFS). CMS did not identify any claims data for ratesetting purposes.

Selected Comments/Response: Several commenters requested that CMS provide clarification on its proposal and one commenter noted that being assigned a status indicator of "Q4" suggests that CPT codes 0602T and 0603T are associated with a clinical laboratory test, which is not the case. After further evaluation, CMS is persuaded that it is appropriate for the procedure described by CPT codes 0602T and 0603T to be paid separately.

Final Action: CMS is finalizing assignment for CPT codes 0602T and 0603T to APC 5721 (Level 1 Diagnostic Tests and Services). CMS is revising the status indicator to "S" indicating that these services are separately payable.

11. Dialysis-Related Amyloidosis (DRA) Treatment with LIXELLE® Apheresis Columns and Dialysis Technologies

For 2027, there are currently no specific HCPCS or CPT codes that represent the service performed with the LIXELLE® apheresis device which is intended for use in hemodialysis sessions.

Selected Comments/Responses: A commenter urged CMS to clarify coverage for LIXELLE® in the OPPS final rule for the benefit of the small number of patients with DRA. The commenter raised a number of challenges CMS continues to evaluate, including ensuring appropriate payment pathways for innovative treatments that may be administered during dialysis but fall outside the definition of a renal dialysis service under §413.171 and thus are not paid for under the ESRD PPS. Commenters supported the payment of such technologies through the OPPS. In response, while CMS recognizes the challenges raised, CMS reminds commenters that routine outpatient maintenance dialysis for End-Stage Renal Disease (ESRD) is not paid under the OPPS and because the treatment with Lixelle is used at each hemodialysis session (e.g., routine maintenance dialysis).

Final Action: CMS does not believe that the OPPS is a viable option for payment for the DRA treatment with LIXELLE® at this time.

12. Esophagogastroduodenoscopy, Flexible, Transoral; with Optical Endomicroscopy, CPT Code 43252 (APC 5302)

CPT code 43252 describes an upper gastrointestinal endoscopy that includes real-time, microscopic tissue analysis using optical endomicroscopy. For 2027 OPPS/ASC, CMS proposed to continue assigning CPT code 43252 to APC 5302 (Level 2 Upper GI Procedures) with status indicator "J1".

Selected Comments/Responses: The manufacturer requested that CMS use its equitable adjustment authority under section 1833(t)(2)(E) of the Act to reassign CPT 43252 to APC 5303 or assign CPT 43252 to an appropriate New Technology APC to stabilize payment while representative cost data accumulate. The commenter also described an ongoing underreporting issue and requested that CMS issue guidance on reporting per-use costs for reposable devices.

Final Action: CMS is finalizing its proposal, without modification.

13. Endoscopic Submucosal Dissection, CPT 43498 and 45991 (APC 5303 and 5313)

Effective January 1, 2027, the AMA CPT Editorial Panel created CPT codes 43498 and 45991 previously described by placeholder CPT codes 4XX01 and 4XX02 respectively. For 2027, CMS proposed to assign CPT codes 43498 to APC 5303 and CPT code 45991 to APC 5313. Additionally, CMS proposed to delete HCPCS code C9779 which served as the predecessor code for the CPT codes.

Selected Comments/Responses: Six commenters requested that CMS reassign CPT codes 43498 and 45991 to APC 5331 (Complex GI Procedures), stating that the procedures described by these codes are clinically similar to the POEM procedure described by CPT code 43497. In response, and after further review, CMS agrees. Additionally, CMS' updated claims data shows that the cost of the procedure may be higher than the payment for its previously assigned APC.

Final Action: CMS is finalizing its proposal with modification to assign both CPT codes 43498 and 45991 to APC 5331 (Complex GI Procedures) with SI "J1".

14. Permanent Placement of Common Carotid Artery Filters, CPT Code 1091T (APC 1576)

To cover Javelin Medical's Category B IDE clinical study on bilateral permanent carotid artery filters, Medicare created HCPCS code C8010 in April 2026 and soon after raised its payment rate to $17,500.50 (New Technology APC 1576) in July 2026 after stakeholder feedback showed the initial rate did not cover implant costs. Because the AMA has established permanent code 1091T to describe bilateral filters, CMS deleted the predecessor code and assigned new CPT code 1091T to APC 1576 with SI "S", effective October 1, 2026. For 2027, CMS proposed to maintain the deletion and ACP assignment for the new CPT code.

Selected Comments/Responses: CMS received a request to finalize the APC assignment for the placement of the permanent carotid filters under the auspices of the new Category III CPT code.

Final Action: CMS is finalizing its proposal to delete HCPCS C8010 and assign CPT code 1091T to APC 1576 (New Technology - Level 39 ($15,001-$20,000)).

15. Venous Mechanical Thrombectomy, CPT code 37187 (APC 5193)

Since 2018, CPT code 37187 has been assigned to the Endovascular Procedures APC series. Since 2021, it has been assigned to APC 5193. CMS proposed to maintain this code's assignment for 2027.

Selected Comments/Responses: A commenter argued that the current rate fails to account for claim-level cost variations, patient complexity, and growing outpatient utilization. In response, CMS explains that the noted variations simply reflect normal practice patterns and that nearly all available claims are already captured in ratesetting.

Final Action: CMS is finalizing the assignment of CPT code 37187 to APC 5193.

16. Simulation Angiogram for Radioembolization of Tumors, HCPCS Code C8004 (APC 5194)

HCPCS code C9797 describes a vascular embolization or occlusion procedure with use of a pressure-generating catheter. It became effective April 1, 2024 and was assigned it to APC 5194 (Level 4 Endovascular Procedures) and a status indicator of "J1". CMS then created HCPCS C8004 to describe the simulation angiogram service using a pressure-generating catheter effective April 1, 2025 and assigned it to APC 5193 (Level 3 Endovascular Procedures) and status indicator "J1". For 2027, CMS proposed to maintain the payment assignments for these HCPCS codes.

Selected Comments/Responses: CMS received one request to reassign HCPCS code C8004 to APC 5194 (Level 4 Endovascular Procedures) because of the clinical and resource similarities between C8004 and C9797. Following analysis and review, CMS agrees with the commenter and believe that APC 5194 is a more appropriate assignment for C8004 based on clinical and resource homogeneity.

Final Action: CMS is modifying its proposal and finalizing assignment of HCPCS code C8004 to APC 5194 (Level 4 Endovascular Procedures). CMS plans to review the coding descriptors for these codes, including related G-code G0577, for the January 2027 quarterly update to determine if further coding/descriptor refinements are necessary.

17. Colorectal Anastomosis (Colovac), CPT Code 0967T

The CPT Editorial Panel created CPT code 0967T which became effective July 1, 2025, and describes the insertion of a device called the Colovac. For 2027, CMS proposed to maintain the APC assignment to 5312 (Level 2 Lower GI Procedures) and status indicator "T". CMS notes there are zero claims for ratesetting purposes.

Selected Comments/Responses: Several commenters, including the manufacturer, requested that CMS reassign CPT code 0967T to a status indicator of "E1" while the Colovac device is still

investigational. Commenters also requested removal of CPT code 0967T from the ASC Covered Procedures List. In response, because CMS is unable to verify marketing authorization for Colovac, the status indicator "E1" is appropriate. CMS looks forward to hearing from the manufacturer when FDA marketing authorization has been obtained.

Final Action: CMS is finalizing its proposal with modification. CMS is assigning status indicator "E1" to CPT code 0967T and removing this code from the ASC Covered Procedures List.

18. Gastrointestinal Myoelectrical Activity Study (Stomach Through Colon), CPT Code 0779T (APC 5723)

Since CPT code 0779T became effective January 1, 2023, CMS has had no claims and therefore the agency has maintained its initial APC assignment to APC 5723 (Level 3 Diagnostic Tests and Related Services). For 2027, no claims were identified and CMS proposed to maintain assignment to APC 5723.

Selected Comments/Responses: A commenter requested reassignment of 0779T from APC 5723 (Level 3 Diagnostic Tests and Related Services) to APC 5724 (Level 4 Diagnostic Tests and Related Services) citing acquisition costs. The commenter claimed clinical and resource coherence to CPT code 91035 as a multi-day, multi-organ ambulatory diagnostic. In response, upon further review, CMS continues to believe that assigning CPT code 0779T to APC 5723 is supported. More specifically, CMS believes CPT code 0779T shares more clinical and resource similarities with the services assigned to APC 5723 than those assigned to APC 5724, which are generally more complicated and invasive services. Further, CMS believes the invasiveness of the upper endoscopy included in CPT code 91035 requires more resources than an external wearable patch system described by CPT code 0779T.

Final Action: CMS is finalizing its proposal without modification to continue to assign CPT code 0779T to APC 5723 for 2027.

19. Gastric Electrophysiology Mapping With Simultaneously Validated Patient System Profiling (GEMS) Service, CPT Code 0868T (APC 5724)

For 2027 ratesetting, there are 37 single frequency claims available for CPT code 0868T, with a geometric mean cost of $2,497.78. The manufacturer of the GEMS service presented at the August 2026 meeting of the HOP Panel, resulting in a HOP Panel recommendation to reassign CPT code 0868T to APC 5724 (Level 4 Diagnostic Tests and Related Services) for 2027.

Selected Comments/Responses: Several commenters requested that CMS reassign CPT code 0868T from APC 5723 to APC 5724 consistent with the HOP Panel's August 2026 recommendation. Commenters pointed to the cost disparity between CPT code 0868T's geometric mean cost and APC 5723's proposed payment rate. In response, CMS agrees that the proposed APC assignment for CPT code 0868T is inappropriate at this time based on a review of the available claims data.

Final Action: CMS is not finalizing the APC assignment for CPT code 0868T as proposed. For 2027, CMS is finalizing assigning CPT code 0868T to APC 5724 (Level 4 Diagnostic Tests and Related Services).

20. Duplex Scan of Hemodialysis Fistula, CPT Code 0876T SI "S", APC 5724

The AMA CPT Editorial Panel established CPT code 0876T effective July 1, 2024, and CMS assigned status indicator "E1" based on the agency's belief that the implantable marker used with this procedure did not have FDA marketing authorization. Because CMS has not been notified that FDA marketing authorization status has changed, for 2026, CMS proposed to continue the code's assignment to E1.

Selected Comments/Responses: One commenter requested that CMS assign CPT code 0876T to an APC and a payable SI. However, CMS is unable to determine that all devices in this category have received marketing authorization from the FDA.

Final Action: CMS is finalizing the status indicator "E1" assignment for CPT code 0876T without modification.

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

For 2027, CMS proposed to continue to assign CPT code 74263 to APC 5523 (Level 3 Imaging without Contrast) and a status indicator of "S" (Procedure or Service, Not Discounted When Multiple; Paid under OPPS).

Selected Comments/Responses: A commenter requested that CMS reassign CPT code 74263 to APC 5524 (Level 4 Imaging without Contrast) arguing that CTC requires significant radiologist and technologist involvement, as well as increased resource costs. In response, CMS reviewed its claims data and continues to believe the code is more appropriately placed based on its estimated costs in APC 5523 rather than Level 4 APC 5524.

Final Action: CMS is finalizing its proposal without modification.

22. Breast Imaging Service Performed with QT Scanner, CPT Code 1079T (APC 5522)
Effective October 1, 2026, CPT code 1079T (placeholder code X579T) describes the breast imaging service performed with QT Scanner. The device is "not intended to be used as a replacement for screening mammography." For 2027, CMS proposed to assign CPT code 1079T status indicator "E1" because the agency did not believe the QT Scanner service would fall under an existing benefit category.

Selected Comments/Responses: The manufacturer of the QT Scanner asked CMS to change CPT code 1079T from status indicator "E1" (not payable by Medicare) to "S" (separately payable) and place it in a New Technology APC, arguing that its FDA-cleared diagnostic use falls under NCD 220.5 for ultrasound diagnostic procedures. In response, CMS partially agrees, but believes that the appropriate APC assignment for CPT code 1079T is APC 5522 (Level 2 Imaging without

Contrast) with SI "S", based on similar codes in that APC series, for example CPT code 76641 (Ultrasound, breast, unilateral or bilateral, real-time with image documentation, complete). CMS emphasizes that routine breast cancer screening in asymptomatic patients is not covered, noting that neither statutory authority nor a qualifying United States Preventive Services Task Force (USPSTF) recommendation exists for screening breast ultrasonography.

Final Action: CMS is modifying its proposal and finalizing assignment of CPT code 1079T to APC 5522 (Level 2 Imaging without Contrast) with SI "S".

23. Maternity Care Services, CPT Codes 59081 – 59083, 59431, 59432, 59502 - 59504 (APCs 5414 through 5416)

Effective January 1, 2027, the AMA created several new codes describing maternity care provided during the antepartum, labor management, and postpartum periods. For 2027, CMS proposed to assign the following CPT codes to APC 5414: 59081 (59XX2), 59082 (59XX3), 59083 (59XX4), 59431 (59XX5), and 59432 (59XX6). CMS proposed to assign the following CPT codes to APC 5416: 59502 (59XX7), 59503 (59XX8), and 59504 (59XX9).

Selected Comments/Responses: Commenters requested higher-level APC assignments for obstetric services to better reflect their clinical complexity and resource requirements, specifically recommending APC 5415 for complex labor management, APC 5416 for vaginal deliveries, APC 5342 or 5361 for cesarean deliveries, and a separate, higher payment level for cesarean hysterectomies rather than grouping them with standard cesarean sections. In response, after further review, CMS believes that CPT code 59432 (59XX6) shares greater resource cohesion with several services and procedures included in APC 5415. However, the agency continues to believe that CPT codes 59081, 59082, 59083, 59431, 59502, 59503, and 59504 are appropriately assigned.

Final Action: CMS finalizes the maternity care service codes as proposed, with the modification of assigning CPT code 59432 to APC 5415.

24. Transcutaneous Magnetic Peripheral Nerve Stimulation CPT Codes 0766T and 0767T (APC 5722)

For 2027, CMS proposed to maintain assignment of CPT code 0766T to SI "S", APC 5722. CMS notes that there are no claims available for CPT code 0766T in 2025. CMS also proposed to continue SI "N" (packaged) for related add-on CPT code 0767T. CMS notes that a presentation was made at the August 24, 2026 HOP Panel Meeting requesting (1) the reassignment of 0766T from APC 5722 to APC 5724 (Level 4 Diagnostic Tests and Related Services) and (2) reassignment of the status indicator for 0767T from "N" to "S". The Panel made no recommendations on these requests.

Selected Comments/Responses: All commenters reiterated HOP Panel Meeting requests, claiming that CPT code 0766T is not clinically similar and does not use comparable resources to other services in APC 5722 and the additional nerve stimulations described by CPT code 0767T require additional physician work. However, CMS continues to believe CPT code 0766T is more

comparable, both clinically and from a resource cost perspective, to CPT codes 90867 and 90868 which are assigned to APC 5722 because these services share similar magnetic stimulation and nerve localization processes. Because CPT code 0767T is an add-on code, its payment is packaged into payment for the primary code.

Final Action: CMS finalizes the proposed APC assignment and status indicators for CPT codes 0766T and 0767T without modification.

25. BioWavePENS, CPT 1088T (APC 5721)

Effective October 1, 2026, the AMA CPT Editorial Panel created CPT code 1088T to describe the procedure for percutaneous electrical nerve stimulation using microneedle electrode arrays for the treatment of pain. Beginning on October 1, 2026, CMS assigned CPT code 1088T to APC 5721 (Level 1 Diagnostic Tests and Related Services).

Selected Comments/Responses: A commenter requested that CMS assign CPT code 1088T to APC 5443 (Level 3 Nerve Injections) due to clinical similarity to other percutaneous nerve interventions in APC 5443. In response, CMS believes the code is appropriately assigned which noting that since the code is new, the agency does currently have any claims data for this procedure.

Final Action: CMS is finalizing its proposal to assign CPT code 1088T to APC 5721 (Level 1 Diagnostic Tests and Related Services).

26. Hypoglossal Nerve Neurostimulator (HGNS) Procedures, C8007-C8009 and C8011-C8013, (APCs 5465, 5463, and 5432)

Effective January 1, 2022, the AMA's CPT Editorial Panel created three new codes to describe the open implantation of hypoglossal nerve neurostimulator (HGNS) array, including CPT codes 64582, 64583, and 64584. Because the HGNS CPT codes do not accurately describe newer hypoglossal nerve neurostimulators that are on the market, CMS created six new C-codes that describe the implantation, revision or replacement, and removal of hypoglossal nerve neurostimulators that do not contain a separate implantable respiratory sensor electrode or electrode array, and systems that do not contain an implanted battery or pulse generator. CMS used the current HGNS CPT codes as the crosswalk codes for the new C-codes. These new HCPCS codes and their APC and status indicator assignments were published in the April 2026 quarterly update CR and are retroactive to January 1, 2026. CMS proposed APC and status indicator assignments for HCPCS codes C8007 – C8009 and C8011 – C8013. Specifically, CMS proposed to assign: C8007 and C8011 to APC 5465 with SI "J1"; C8008 and C8012 to APC 5463 with SI "J1"; C8009 and C8013 to APC 5432 with SI "Q2".

Selected Comments/Responses: Two commenters supported the creation of the C-codes and their APC assignments. One commenter requested delay because the AMA CPT Editorial Panel may be creating new HGNS codes. Another requested that C8011 be reassigned to New Technology APC 5465 (Level 5 Neurostimulator and Related Procedures). CMS responds that if new CPT codes are created that describe these newer HGNS procedures, CMS will review the new codes

and determine if maintaining the HCPCS C-codes are necessary. CMS does not believe that it is appropriate to assign C8011 to a New Technology APC at this time without having adequate claims data to support the reassignment.

Final Action: CMS is finalizing the proposed APC assignments for the C-codes noted previously without modification.

27. IB-Stim, CPT Code 64567 (APC 5301)

Effective January 1, 2026, the AMA CPT Editorial Panel created CPT code 64567 to describe a neuromodulation therapy for the treatment of functional gastrointestinal disorders. CPT code 64567 replaced the predecessor CPT code 0720T. For 2027, CMS proposed to continue to assign CPT code 64567 to APC 5301 (Level 1 Upper GI Procedures).

Selected Comments/Responses: A commenter requested that CMS reassign CPT code 64567 to APC 5312 (Level 2 Lower GI Procedures) to better align payment with the clinical and resource cost of CPT code 64567. CMS notes that the agency will not have claims data for this code until 2028 rulemaking and there were no claims data for the predecessor code, however, based on the commenter's request, CMS will reassign CPT code 64567 to APC 5311 (Level 1 Lower GI Procedures) to better align the procedure clinically.

Final Action: CMS is finalizing its proposal with modification to reassign CPT code 64567 to APC 5311.

28. ReneuRX™ System, CPT Code 1096T (APC 5442)

Effective October 1, 2026, the AMA CPT Editorial Panel created CPT code 1096T. Because the technology associated with the procedure had not received FDA marketing authorization at the time of its assignment, CMS assigned CPT code 1096T status indicator "E1".

Selected Comments/Responses: A commenter stated that this device received FDA approval on August 21, 2026 and requested that CMS reassign CPT code 1096T to APC 5431 (Level 1 Nerve Procedures) due to the clinical similarity to other procedures in this APC. CMS agrees that CPT code 1096T should be reassigned to a clinical APC, however, CMS believes that this procedure has similar clinical and resource utilization to procedures in APC 5442 (Level 2 Nerve Injections).

Final Action: CMS finalizes its proposal with modification to assign CPT code 1096T to APC 5442 (Level 2 Nerve Injections) retroactive to October 1, 2026.

29. Radiation Oncology Treatment Delivery, CPT Codes 77402, 77407, 77412 (APCs 5621 and 5623)

At the September 2024 CPT Editorial Panel meeting, the Panel approved the revision of radiation therapy CPT codes 77402, 77407 and 77412 to establish a technique-agnostic family of codes and bundle imaging into the three CPT codes. In addition, Intensity Modulated Radiation

Therapy (IMRT) treatment delivery codes 77385 and 77386 and CT guidance code 77014 were deleted and consolidated into the new code structure. CMS describes the crosswalking methodology it used to impute claims for the codes and assign them to APCs. For 2027 CMS proposed to continue to assign CPT code 77402 to APC 5621 (Level 1 Radiation Therapy), status indicator "S", CPT code 77407 to APC 5622 (Level 2 Radiation Therapy), status indicator "S", and CPT code 77412 to APC 5623 (Level 3 Radiation Therapy), status indicator "S".

Selected Comments/Responses: Many commenters expressed concern that CMS' proposed APC assignments for these codes do not adequately reflect the procedures described by the revised codes and does not provide sufficient payment and recommended assignment to higher APC levels. A number of commenters asked CMS to update the methodology used by the agency to crosswalk historical claims data to the revised CPT codes to reflect real world data. In response, CMS is unpersuaded, stating that the impact of its crosswalking methodology using 2025 claims data for ratesetting will not be evident until the 2028 rule. Based on an analysis of the claims data and the costs of the codes, CMS agrees that it would be appropriate to reassign CPT code 77407 to APC 5623 (Level 3 Radiation Therapy) since the revised CPT code 77407 includes the deleted IMRT services.

Final Action: CMS is finalizing its proposal to assign CPT code 77402 and 77412 to APC 5621 and 5623, respectively, with SI "S". CMS is finalizing with modification its proposal to assign CPT code 77407 to APC 5623 (Level 3 Radiation Therapy) with SI "S".

30. Radiation Treatment Planning Software (MAXPOINT), CPT Code 1025T (APC 5612)

Effective January 1, 2026, CPT code 1025T describes a 3D treatment planning software that is used to aid in electrode placement for Tumor Treatment Fields (TTFields) therapy utilization called MAXPOINT. For 2027, CMS proposed to assign CPT code 1025T to APC 5611 (Level 1 Therapeutic Radiation and Treatment Preparation). Since the code was made effective in 2026, CMS does not currently have available claims data to use for ratesetting. Following MAXPOINT's presentation to the HOP Panel at the August 2026 meeting, the Panel recommended reassignment of CPT code 1025T to APC 5612 (Level 2 Therapeutic Radiation and Treatment Preparation).

Selected Comments/Responses: Commenters asked CMS to reconsider the proposed assignment, stating that the proposed APC assignment for CPT code 1025T does not accurately describe the MAXPOINT technology and that the planning software's mechanism of action involves advanced computational analysis, which is similar to other codes assigned to APC 5613. In response, the agency agrees that APC 5611 may not be an appropriate APC assignment for CPT code 1025T at this time due to similarities between the code and other more complex services in APC 5612.

Final Action: CMS is modifying its proposal and is finalizing an APC assignment for CPT code 1025T to APC 5612 in line with the HOP Panel's recommendation.

31. Scalp Cooling Preparation and Pre-Cooling Service, CPT 97007 - 97009 (APC 1494)

Effective January 1, 2026, the scalp cooling service is described by CPT codes 97007, 97008, and 97009. For 2026, CMS assigned CPT code 97007, to APC 1516 with SI "S", and assigned SI "N" to CPT codes 97008 and 97009, explaining the agency's belief that the costs associated with the scalp cooling service are appropriately captured within the packaged payment for chemotherapy treatment. However, for 2027, CMS acknowledged that the resources required to furnish CPT code 97008 may not be fully captured when packaged. Using chemotherapy infusion services (including CPT code 96415 as a comparator), CMS proposed to assign CPT code 97008 to APC 1495 (New Technology – Level 1D ($31-$40)), SI "S".

Selected Comments/Responses: Commenters stated that the proposed APC assignment for CPT code 97008 does not fully capture the costs of the preparation and pre-cooling portion of the scalp cooling service, estimating the costs to be higher. However, CMS disagrees stating that the resources described by commenters are consistent in clinical intensity with other short-duration, nursing-supported services paid for under the OPPS.

Final Action: CMS is finalizing the APC and SI assignments for CPT code 97008 as proposed.

32. Administration of Lacrimal Ophthalmic Insert Into Lacrimal Canaliculus, CPT Code 68841 (APC 5503)

HCPCS code J1096 describes the drug Dextenza, which is a drug indicated for "the treatment of ocular inflammation and pain following ophthalmic surgery" and for "the treatment of ocular itching associated with allergic conjunctivitis." CPT code 68841 describes the insertion of the implant to administer Dextenza. For 2027, CMS proposed to continue to assign CPT code 68841 to APC 5503 (Level 3 Extraocular, Repair, and Plastic Eye Procedures) and status indicator "Q1" (STV-Packaged Codes; Paid under OPPS).

Selected Comments/Responses: Several commenters urged CMS to change the status indicator for Dextenza insertion (CPT code 68841) under APC 5503 from "Q1" to "J1" so that the procedure is separately payable in Ambulatory Surgical Centers (ASCs), arguing that a lack of payment discourages facilities from offering an alternative to self-administered eye drops that are difficult for older patients to use. Commenters also argued that having a low rate of standalone claims does not justify packaging the procedure under a "Q1" status indicator, pointing out that CMS grants separate ASC payment via "J1" or "T" status indicators to roughly 75 comparable low-standalone-frequency procedures. In response, CMS notes that CPT code 68841 does not have any single frequency claims out of the 4,619 total frequency claims. Thus, CMS believes that these data, combined with the clinical nature of this procedure, reinforces the agency's assignment as a packaged procedure.

Final Action: CMS finalizes its proposal without modification to assign CPT code 68841 to APC 5503 (Level 3 Extraocular, Repair, and Plastic Eye Procedures) and "Q1". In addition, based on the OPPS assignments, CMS is finalizing an ASC payment indicator of "N1" (Packaged service/item; no separate payment made) for CPT code 68841 for 2027.

33. Implantation of Drug-Releasing Device, CPT Codes 0660T, 0661T (APC 5492)

CPT codes 0660T and 0661T describe the implantation of a device that releases a drug into the eye. These codes became payable in OPPS in 2024 after the implantable articles used in each procedure received FDA marketing authorization. For 2027, CMS proposed to maintain their current payment assignments to APC 5492 (Level 2 Intraocular Procedures) and status indicator of "J1".

Selected Comments/Responses: A commenter supported the proposed APC assignment but requested revision of the SI to "S" for both codes, noting that the drug used with this procedure (iDose TR® (travoprost intracameral implant)) will be coming off of pass-through July 1, 2027 and packaged with the procedure. Based on its claims analysis, CMS concludes that this procedure is often done with another ophthalmic procedure and therefore does not believe that the SI should be revised.

Final Action: CMS finalizes its proposal, without modification.

34. Implantation of Scaffolding Allograft, CPT 1084T

The AMA CPT Editorial created CPT code 1084T (Implantation of scaffolding allograft to reinforce the suprachoroidal space) to replace CPT X588T which was initially going to become effective January 1, 2027. However, the AMA revised its "release and effective date" schedule for Category III CPT codes, and the new effective date is October 1, 2026. For 2027, CMS proposed to assign 1084T to APC 5492 (Level 2 Intraocular Procedures) and status indicator "J1".

Selected Comments/Responses: The manufacturer requested reassignment of CPT code 1084T to APC 5493 (Level 3 Intraocular Procedures) using CPT codes 0671T and 0449T as crosswalk codes. In response, CMS believes that CPT code 1084T is more similar clinically and in terms of resource requirements and procedure costs to the procedures assigned to APC 5492 (Level 2 Intraocular Procedures).

Final Action: CMS is finalizing its proposal without modification.

35. Patient-Initiated Remote Retinal Optical Coherence Tomography (OCT) Scans, CPT Codes 0604T – 0606T

CPT codes 0604T-0606T describe patient-initiated remote retinal optical coherence tomography (OCT) scans. For 2027, CMS proposed to continue to assign status indicator "E1" to CPT codes 0604T-0606T.

Selected Comments/Responses: A commenter requested that CMS change the 2027 status indicators for each of these codes from "E1" to "B" because these procedures are furnished exclusively in independent diagnostic testing facilities or physician offices rather than hospital outpatient departments, and the "E1" indicator has caused some Medicare Administrative Contractors (MACs) to mistakenly deny payment across all outpatient sites of service. In

response, CMS agrees with the commenter and is changing the status indicator for CPT codes 0604T, 0605T and 0606T to "B" in the October 2026 update of the Integrated Outpatient Coding Editor (I/OCE) and in the October 2026 Update of the Addendum B that was posted to the CMS website.

Final Action: CMS is finalizing its proposal with modification and is assigning SI "B" to CPT codes 0604T, 0605T and 0606T.

36. Evacuation of Meibomian Glands, Using Heat Delivered Through Wearable, Open-Eye Eyelid Treatment Devices and Manual Gland Expression, Bilateral CPT 0563T (APC 5501)

CPT code 0563T describes evacuation of meibomian glands, using heat delivered through wearable, open-eye eyelid treatment devices and manual gland expression, bilateral. For 2027, CMS proposed to continue to assign CPT code 0563T to APC 5733 (Level 3 Minor Procedures) and SI "Q1".

Selected Comments/Responses: Commenters asked CMS to reassign CPT code 0563T from APC 5733 to APC 5503 (Level 3 Extraocular, Repair and Plastic Eye Procedures) with SI "J1", arguing that the specialized equipment, components, and clinical labor costs exceed the current payment and that limited hospital outpatient claims are unrepresentative because the procedure is mostly performed in physician offices. In response, CMS agreed that the Extraocular Procedures APC family is more clinically appropriate, but declined to increase payment due to a lack of supporting claims data.

Final Action: CMS is not adopting its proposal. Instead, CMS finalizes assignment of CPT code 0563T to APC 5501 (Level 1 Extraocular, Repair and Plastic Eye Procedures) and SI "T".

37. Application of Rigid Total Contact Leg Cast, CPT Code 29445 (APC 5102) 5501, T

CPT code 29445 describes a procedure of applying a Total Contact Leg Cast. For 2027, CMS proposed to continue to assign CPT code 29445 to APC 5102 (Level 2 Strapping and Cast Application) with status indicator "T" (Procedure or service, multiple procedure reduction applies; with a separate APC payment under OPPS). At the August 24, 2026, HOP Panel Meeting, a presenter requested reassignment of this code to SI "S" (Procedure or Service, Not Discounted When Multiple; with a separate APC payment under OPPS). Based on the information presented at the meeting, the Panel recommended that CMS make that reassignment.

Selected Comments/Responses: A commenter requested reassignment of this code to SI "S" rather than packaging it with same-day wound debridement or cellular and/or tissue-based product applications, arguing that total contact casting is a labor-intensive, costly therapeutic cast rather than a routine wound dressing. CMS declined the request, explaining that comparable leg ulcer casting procedures, such as short leg casts (CPT code 29405) and Unna boots (CPT code 29580), are similarly assigned status indicator "T."

Final Action: CMS is maintaining the status indicator assignment as proposed for 2027.

38. Arthrocentesis, Aspiration, and/or Injection of Joint, CPT Codes 20604 and 20611 (APC 5441)

CPT codes 20604, 20606, and 20611 describe arthrocentesis, aspiration, and/or injections of small, intermediate, or major joints with ultrasound guidance. For 2027, CMS proposed to maintain their assignments as follows: CPT codes 20604 and 20611 to APC 5441 (Level 1 Nerve Injections), SI "T"; and CPT code 20606 to APC 5442 (Level 2 Nerve Injections), SI "T".

Selected Comments/Responses: A commenter requested CMS reassign ultrasound-guided joint injection CPT codes 20604 and 20611 to APC 5442 (Level 2 Nerve Injections) to match sister code 20606. However, based on an analysis of the geometric mean costs, CMS concludes that the current assignments remain appropriate.

Final Action: CMS is finalizing its proposal without modification.

39. Arthroscopy, Knee, Surgical; with Meniscus Repair (Medial or Lateral), CPT Code 29882 (APC 5113)

CPT code 29882 describes an arthroscopic surgical procedure of the knee used to repair a torn meniscus in either the medial (inner) or lateral (outer) compartment. For 2027, CMS proposed to continue to assign CPT code 29882 to APC 5113 (Level 3 Musculoskeletal Procedures), SI "J1".

Selected Comments/Responses: Commenters recommended moving CPT code 29882 to APC 5114, as this would be a better fit for this arthroscopic meniscal repair procedure, separating these repairs from less costly debridement or meniscectomy procedures grouped in APC 5113. CMS disagrees because it would be difficult to rely on the claims data to determine the APC assignment for this code, given that claims data used for 2027 ratesetting would be from before the service was payable in the OPPS. Thus, CMS continues to believe that CPT code 29882 is appropriately assigned to APC 5113 based on clinical and resource similarity with other codes in that APC.

Final Action: CMS finalizes its proposal without modification.

40. Fusion of Foot Bones, CPT Code 28740 (APC 5114)

CPT code 28740 describes the fusion of foot bones. For 2027, CMS proposed to continue to assign this code to APC 5114 (Level 4 Musculoskeletal Procedures), SI "J1".

Selected Comments/Responses: A commenter raised concerns that assignment of CPT code 28740 to APC 5114 may violate the 2 times rule, which may impede access to care for beneficiaries. The commenter recommended reassignment to APC 5115 (Level 5 Musculoskeletal Procedures). In response, CMS analyzed claims data according to its established methodology but did not identify a violation of the two-times rule for APC 5114.

Final Action: CMS is finalizing its proposal without modification.

41. Hip Arthroplasty Revision Procedures, CPT Codes 27134, 27137, and 27138 (APC 5115)

For 2026, CMS removed the revision of hip arthroplasty procedures described by CPT codes 27134, 27137, and 27138 from the IPO list as part of the first phase of the elimination of the list and assigned them to APC 5115. CMS proposed to continue this assignment for 2027.

Selected Comments/Responses: A commenter requested that CMS reassign these codes to APC 5116 (Level 6 Musculoskeletal Procedures) because hospital inpatient knee and hip revision procedures are more resource-intensive and are assigned to a higher MS-DRG payment than the primary procedure in the hospital inpatient setting. In response, CMS disagrees, citing geometric mean costs for the procedures and the fact that hip arthroplasty and other revision procedures are currently in this APC.

Final Action: CMS is finalizing its proposal without modification.

42. Limb Cryocompression Therapy, APCs 1069T and 1070T

CPT Codes 1069T (placeholder code X601T) and 1070T (placeholder code X602T) describe a supportive care service that combines cooling and intermittent pneumatic compression of the limbs during chemotherapy to reduce the incidence and severity of chemotherapy-induced peripheral neuropathy. Both codes will become effective January 1, 2027. For 2027, CMS proposed to assign CPT code 1069T to APC 5735 (Level 5 Minor Procedures), SI "S". CMS also proposed to assign CPT code 1070T to APC 5732 (Level 2 Minor Procedures), SI "S".

Selected Comments/Responses: The manufacturer of the device used to furnish the fitting and cooling service described by these codes requested alternative APC assignments that more closely align with the resources used to furnish the service. Specifically, the commenter requested assignment of: CPT code 1069T to New Technology APCs 1561 or 1562; CPT 1070T to APC 5734 (Level 4 Minor Procedures). Upon review, CMS does not believe that the device has FDA marketing authorization.

Final Action: CMS is not finalizing its proposal at this time. For 2027, CMS will assign SI "E1" to CPT codes 1069T and 1070T until such time that the agency is able to confirm that the device has FDA marketing authorization.

43. Revision of Total Knee Arthroplasty, with or without Allograft; 1 Component, CPT Code 27486 (APC 5115)

CPT code 27486 describes a revision, repair, or reconstruction of a total knee replacement involving one component (with or without an allograft). For 2027, CMS proposed to continue assigning CPT code 27486 to APC 5115 (Level 5 Musculoskeletal Procedures), SI "J1".

Selected Comments/Responses: A commenter urged CMS to reassign CPT code 27486 to APC 5116 (Level 6 Musculoskeletal Procedures), arguing its current assignment fails to account for the procedure's high resource demands and that its geometric mean cost aligns better with APC 5116. Based on the updated geometric mean cost in the final rule, CMS continues to believe that

CPT 27486 is more closely aligned with APC 5115 and that there are other clinically similar revision procedure codes assigned to APC 5115.

Final Action: CMS is finalizing its proposal without modification.

44. TOPS System, CPT Code 0202T (APC 5117)

For 2026, CMS removed CPT code 0202T from the IPO list. This procedure was assigned to APC 5115 (Level 5 Musculoskeletal Procedures) based on clinical and resource utilization. CMS proposed to maintain this assignment for 2027.

Selected Comments/Responses: One commenter requested that CMS reassign CPT code 0202T to APC 5117 (Level 7 Musculoskeletal Procedures) based on its claims data and clinical similarity to CPT codes 22630 and 22633. CMS agrees that CPT code 0202T does share clinical similarity to CPT codes 22630 and 22633, but based on analysis of a limited number of claims, CMS believes the costs may better align with the payment for APC 5117.

Final Action: Due to its clinical and resource similarity, CMS is revising its proposal. For 2027, CMS is reassigning CPT code 0202T from APC 5115 to APC 5117.

45. Insertion of Endobronchial Valves, CPT Code 31647 (APC 5155) 5117, J1

CPT code 31647 describes a procedure used for conditions such as severe emphysema or persistent bronchopleural air leaks, where a device is placed to control airflow into a portion of the lung. For 2027, CMS proposed to continue to assign the procedure to APC 5155 (Level 5 Airway Endoscopy) and status indicator J1. At the August 24, 2026 HOP Panel Meeting, a presentation was made requesting the reassignment of CPT code 31647 from APC 5155 to New Technology APC 1575 (New Technology - Level 38). As a result, the Panel recommended CMS create a new Level 6 Airway Endoscopy APC.

Selected Comments/Responses: Commenters urged CMS to reassign CPT code 31647 from APC 5155 to New Technology APC 1575 as an interim measure until a permanent clinical APC is established. Commenters noted that the procedure's geometric mean costs have consistently exceeded AP 5155's payment rate by roughly $3,000 and is more than double that of many significant procedures in the APC. Commenters warned that continued underpayment would limit beneficiary access and recommended CMS adopt assignment to a New Technology APC as an interim measure. In response, CMS reaffirms its belief that APC 5155 appears to be the best clinical fit for CPT code 31647 of any existing clinical APC. CMS declines to establish a Level 6 in this APC family and does not believe interim assignment to a new technology APC is an appropriate crosswalk because this is not a new technology.

Final Action: CMS is finalizing its proposal without modification.

46. RejuvenAir System, CPT Code 1040T

CPT code 1040T describes flexible bronchoscopy with bronchial cryotherapy of one lung, including the trachea, when performed. For 2027, CMS proposed to assign to SI "E1" (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) to CPT code 1040T.

Selected Comments/Responses: A commenter stated that the RejuvenAir system, which is used to furnish the service described by CPT code 1040T, has received FDA Breakthrough Device Designation and that a Premarket Approval application was submitted to FDA in January 2026, but the device has not yet received FDA approval, as a result, CMS will maintain the SI assignment of "E1" and looks forward to hearing from the manufacturer when FDA marketing authorization has been obtained.

Final Action: CMS is finalizing its proposal without modification.

47. Electromagnetic Therapy for Ulcers, HCPCS Code G0329

HCPCS code G0329 was assigned SI "A" in the 2005 OPPS final rule and has continued to be assigned that status indicator under the OPPS.

Selected Comments/Responses: A commenter requested that CMS make available data used to develop the geometric mean cost for G0329 and to evaluate whether criteria are met for the universal low volume APC policy. In response, CMS explains that under SI "A", there is no OPPS APC assignment, and therefore OPPS ratesetting for developing OPPS payment weights for that code and associated policies like the universal low volume policy would not be applicable.

Final Action: CMS is finalizing the assignment of SI "A" to HCPCS code G0329 for 2027.

48. UltraMIST System Wound Care Service, CPT Code 97610 (APC 5051)

CPT code 97610 describes a wound care service using ultrasound. For 2027, CMS proposed to assign CPT code 97610 to APC 5051 (Level 1 Skin Procedures), SI "Q1".

Selected Comments/Responses: Commenters requested CMS assign SI "T" or "S" and APC 5052 (Level 2 Skin Procedures) to the code to better align its resource use and costs with comparable wound treatments like CPT code 97608. The manufacturer requested SI "T" based on a crosswalk to its closest clinical sibling, CPT code 97597, while another commenter requested SI "S" to ensure accurate, service-specific claims collection. Commenters stated that the proposed SI "Q1" would exclude most of the code's claims for ratesetting. In response, CMS agrees with commenters that a crosswalk to the SI for a debridement service is appropriate in terms of clinical and resource similarity. However, CMS maintains that the APC assignment is appropriate based on an analysis of the geometric mean costs.

Final Action: CMS finalizes its proposals with modifications. Specifically, CMS is finalizing assignment of CPT code 97610 to APC 5051, SI "T".

49. Unattended Sleep Study, CPT Code 95846, (APC 5723) 5051, T

CPT code 95846 (placeholder code 95X20) describes a high-complexity unattended sleep study and is currently assigned to APC 5722 (Level 2 Diagnostic Tests and Related Services) with a proposed payment of around $247, and SI "S."

Selected Comments/Responses: Several commenters requested reassignment of the code to a higher-level APC arguing that that the greater number of channels and physiologic parameters associated with the high-complexity unattended sleep study described by CPT code 95486, as well as the additional equipment, supplies, and technical resources associated with furnishing the service, support assignment to APC 5723 (Level 3 Diagnostic Tests and Related Services). In response, CMS agrees that APC 5723 more appropriately reflects the clinical and resource characteristics of the service.

Final Action: CMS is finalizing with modification its proposal and assigning CPT code 95846 to APC 5723 (Level 3 Diagnostic Tests and Related Services) with status indicator "S" for 2027.

50. Central Nervous System and Spinal Services, CPT Codes 62230, 62350, 61720, 63741, and 63744 (APCs 5432 through 5433)

For 2027, CMS proposed to continue to assign CPT code 63744 to APC 5432 (Level 2 Nerve Procedures), SI "J1". CMS proposed to continue assigning the following CPT codes to APC 5433 (Level 3 Nerve Procedures), SI "J1": 61720, 62230, 62350, and 63741.

Selected Comments/Responses: Commenters urged CMS to reassign the five CPT codes into musculoskeletal and neurostimulator APCs to better align payment classifications with actual hospital resource costs and clinical workflows. One of the commenters submitted an analysis demonstrating alignment of the codes with APCs 5114, 5461, and 5462. In response, based on the agency's review of the claims data and recommendations from CMS' Medical Officers, CMS do not believe that these procedures should be reassigned to other clinical APC families or moved to other Nerve Procedure APC Levels. Details of CMS' analysis that led to this conclusion may be found in the preamble of the final rule.

Final Action: CMS is finalizing its proposal without modification.

51. Diaphragmatic Hernia Repair, CPT Code 39542 (APC 5342)

Effective January 1, 2027, the AMA CPT Editorial Panel created CPT code 39542 (previously described by placeholder code 39XX3). CPT code 39542 describes the procedure for nontraumatic diaphragmatic hernia repair via a laparotomy approach. For 2027, CMS proposed to assign CPT code 39542 to APC 5342 (Level 2 Abdominal/Peritoneal/Biliary and Related Procedures).

Selected Comments/Responses: One commenter requested reassignment of CPT code 39542 to APC 5362 (Level 1 Laparoscopy and Related Services) based on similar clinical and resource utilization as other diaphragmatic procedures assigned to APC 5362. In response, CMS confirmed its proposed placement because it closely resembles other laparotomy procedures in that group. Because it is a new code, CMS will monitor utilization and adjust rates once claims data become available for 2029 rulemaking.

Final Action: CMS is finalizing its proposal without modification.

52. Radiofrequency Ablation of Lumpectomy Cavity, CPT Code 1955T

Effective October 1, 2026, the AMA CPT Editorial Panel created CPT code 1055T. Based on the OPPS packaging policy, CMS assigned SI "N" (packaged) to CPT code 1055T in the October 2026 quarterly update.

Selected Comments/Responses: A commenter requested that CMS assign CPT code 1055T to APC 1575 (New Technology – Level 38), SI "S" to ensure beneficiary access to the procedure and allow CMS to obtain hospital claims data for the procedure. In response, CMS notes that CPT code 1055T is an add-on code. As such, as specified under regulation 42 CFR 419.2(b)(18), add-on codes are generally packaged under the OPPS, and payment for the codes are bundled with the primary codes. Consequently, CPT code 1055T is not paid separately under the OPPS and its payment is packaged into payment for the primary code.

Final Action: CMS is finalizing its proposal without modification.

53. Digital Mental Health Treatment (DMHT) Services, HCPCS Code G0552 (APC 5012)

HCPCS code G0552 describes the supply of a digital mental health treatment device and initial patient education and onboarding. It is currently assigned to APC 5012 (Clinic Visits and Related Services), with a status indicator of "V" (Clinic or Emergency Department Visit). For 2027, CMS proposed maintaining its assignment.

Selected Comments/Responses: Commenters argued that HCPCS code G0552 should be reassigned because the payment rate is far too low to cover the upfront cost of furnishing a DMHT device. Commenters offered several alternative assignments, including reassignment to APC 5735 (Level 5 Minor Procedures), APC 5723 (Level 3 Diagnostic Tests and Related Services), or creating a new Level 4 Health and Behavioral Services APC 5824. However, CMS declines to reassign the code because the cost data does not justify moving it to a higher-paying group or creating a new APC and CMS believes it is clinically similar to other DMHT services assigned to APC 5012.

Final Action: CMS is finalizing its proposal without modification.

54. Clearance of Renal Calculi by Ultrasonic Propulsion, CPT Code 1054T (APC 5373)

The CPT Editorial Panel created CPT code 1054T (placeholder code X559T) to describe a new procedure to clear residual fragments of kidney stones out of the kidney by delivering low amplitude, low frequency focused ultrasound that pushes and propels the fragments towards the uretero-pelvic junction post-lithotripsy. For 2027, CMS proposed to assign CPT code 1054T to APC 5373 (Level 3 Urology and Related Services). CMS notes that since the proposed rule was published, the AMA revised the effective date for this code to October 1, 2026.

Selected Comments/Responses: A commenter requested that CMS assign CPT code 1054T to APC 5374 (Level 4 Urology and Related Services) stating based on its total resource costs and the geometric mean cost for the APC 5374. In response, CMS declines the request while questioning the interoperative time assumption in the commenters' analysis, given that the procedure is performed after the lithotripsy has already been completed.

Final Action: CMS is finalizing its proposal without modification.

55. Cystourethroscopy with Lithotripsy and Vacuum Aspiration of Kidney, HCPCS Codes C9761 and C0814 (APCs 5375 and 5376)

HCPCS code C9761 became effective October 1, 2020 and describes a minimally invasive procedure used to break up and remove kidney stone fragments and dust by use of a continuous irrigation and vacuum system. HCPCS code C9761 is assigned to APC 5376 (Level 6 Urology and Related Procedures), SI "J1". The long descriptor has been revised several times, with the most recent revision becoming effective July 1, 2026, after meeting with the specialty society. Additionally, CMS also recently established HCPCS code C8014 effective July 1, 2026, to describe cystourethroscopy procedures where a suction-enabled ureteral access sheath is used to vacuum kidney stone fragments. HCPCS code C8014 is assigned to APC 5375 (Level 5 Urology and Related Procedures) with SI "J1" based on clinical and resource similarities to other procedures assigned to APC 5375. For 2027, CMS proposed to maintain the APC assignments for both codes. CMS notes that the agency does not currently have any claims data for ratesetting purposes for HCPCS code C8014 because it is a new code.

Selected Comments/Responses: Public comments reflected conflicting views on code structure and payment placement, with one commenter urging CMS to merge them into a single technology-neutral code, another requesting reassignment of C8014 to APC 5376 alongside C9761, and a third supporting keeping C8014 separate in APC 5375 to track distinct resource costs. Despite this, commenters broadly agreed that ambiguous code descriptors risk billing errors and misuse of higher-paying codes and requested that CMS issue clear coding instructions that distinguish between suction-enabled access sheaths (FANS), suction-integrated ureteroscopes (DISS), and steerable vacuum-aspiration catheters (CVAC). In response, CMS declines the requests for reassignment, maintaining that that separate codes and payment levels are necessary to reflect distinct device costs, in response to stakeholder input. Additionally, CMS believes the descriptor language is clear. CMS notes that the agency does not provide coding guidance and recommends that if hospitals have coding questions, they should consult their MAC.

Final Action: CMS is finalizing its proposal without modification.

56. Optilume BPH Catheter System, CPT Code 52443 (APC 5376)

Effective January 1, 2026, the AMA CPT Editorial Panel created CPT code 52443, For 2027, CMS proposed to continue to assign CPT code 52443 to APC 5376 (Level 6 Urology and Related Services).

Selected Comments/Responses: A commenter requested that CMS reassign CPT code 52443 to APC 5377 (Level 7 Urology and Related Services), stating that the procedure would better align with procedures assigned to APC 5377 both clinically and from a resource perspective. CMS notes that the code is new and as such, CMS has no 2025 claims data to evaluate the commenter's assertion. CMS therefore determines that CPT code 52443 is appropriately assigned to APC 5376.

Final Action: CMS is finalizing its proposal without modification.

57. Permanent Prostatic Urethral Stent, CPT Code 52282 (APC 5375)

For 2026, CMS assigned CPT code 52282 (describing insertion of a permanent prostatic urethral stent procedure) to APC 5374 (Level 4) based on its geometric mean cost. For reasons explained in the proposed rule, for 2027, CMS proposed to reassign CPT code 52282 to APC 5375 (Level 5).

Selected Comments/Responses: While two commenters supported CMS' proposal, ten commenters requested assigning CPT code 52282 to a higher-level payment group (APC 5376), arguing that it shares the same clinical indications, anatomic targets, surgical approach, facility footprint, and recovery patterns as comparable procedures already in APC 5376 (such as the iTIND stent, Zenflow Stent/Scaffold, and UroLift). In response, CMS reiterates the concerns it discussed in the proposed rule related to accuracy of claims and determines the agency should wait for additional, more representative data before adjusting the payment rate for CPT code 52282 beyond APC 5375.

Final Action: CMS is finalizing its proposal without modification.

58. Transperineal Laser Ablation of Prostate, CPT Codes 0714T and 0867T (APC 5375)

Both CPT codes 0714T and 0867T describe the destruction of benign prostate tissue using laser ablation. For 2027, CMS proposed to maintain the APC assignments for CPT codes 0714T and 0867T to APC 5375 (Level 5 Urology and Related Services).

Selected Comments/Responses: One commenter requested reassignment of the codes to APC 5376 (Level 6 Urology and Related Services) because these codes have clinical and resource homogeneity with CPT code 55873 (Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)) which is assigned to APC 5376. However, after evaluation of the

service, as well as input from CMS' medical advisors, CMS is not persuaded that CPT code 55873 is a more appropriate crosswalk code for CPT codes 0714T and 0867T.

Final Action: CMS is finalizing its proposal without modification.

59. APC Assignments for Devices Coming Off of Transitional Payment Pathways

For 2027, CMS proposed to continue its device pass-through and new technology APC policies unchanged from 2026. CMS notes that these policies are meant to serve as temporary, transitional payment pathways prior to permanent payment through assignments to clinical APCs.

Selected Comments/Responses: Commenters urged CMS to establish a transparent, structured transition pathway featuring clearer criteria, timelines, data requirements, and advance notice when moving services out of New Technology APCs or expiring pass-through status into permanent clinical APCs.

Final Action: CMS is finalizing as proposed but is "considering whether changes are necessary to ensure that [CMS'] payment methodologies appropriately account for services coming off of a transitional payment pathway, like new technology APCs and pass through."

60. Bone Mass Measurement: Biomechanical Computed Tomography (BCT) Analysis

There are five existing CPT codes (0554T, 0555T, 0556T, 0557T, and 0558T) that describe biomechanical computed tomography (BCT) analysis which were not covered by Medicare as a preventive service until recently. On May 26, 2026, CMS issued Transmittal 13752 announcing the BCT codes (when used for diagnostic purposes) are now covered by NCD 150.3 Bone (Mineral) Density Studies with a retroactive date of January 1, 2024. Beneficiary copays are waived with most preventive services. A commenter noted that the Transmittal indicated a waiver of patient copays for the BCT services, but the proposed 2027 Addendum B file did not indicate that the patient copays were waived. In response, CMS has corrected the error.

61. Nerve Repair Procedure (APC 5433)

For 2027, CMS proposed to maintain assignment for CPT code 64910. CMS received one comment requesting revision to the code's short descriptor to more accurately reflect the conduit-focused nature of the procedure, however, CMS notes that CPT code descriptors are owned and copyrighted by the AMA and therefore this comment is out of scope for OPPS.

62. Suggested Drug-Intensive Procedure Policy

CMS received two public comments requesting a "drug-intensive" ASC payment policy, modeled after the existing device-intensive policy, that would hold high-cost packaged drugs neutral in rate calculations to ensure fair reimbursement, preserve patient access, and prevent site-of-service shifts. CMS thanks the submitters for the suggestion.

63. APC Specific Comments That Support the Proposed APC Assignment

Each year, in accordance with section 1833(t)(9)(A) of the Act, CMS reviews and revises the services within each APC group and the APC assignments under the OPPS. As a result of its annual review of the services and the APC assignments, CMS may reassign some services to another APC or maintain the current APC assignment. In the proposed rule, CMS proposed several changes, based on its review, that are not directly addressed in the final rule, including:

- Establishing a three-level Breast/Lymphatic Surgery and Related Procedures APC series by consolidating the current Level 2 and 3 APCs into a single Level 2 APC, and remapping the current Level 4 APC as the Level 3 APC.
- Reassigning CPT code 0786T from APC 5463 (Level 3) to APC 5464 (Level 4) based on resource cost and clinical homogeneity with procedures in APC 5464.
- Reassigning CPT code 0930T from status indicator "J1" to "N".
- Reassigning CPT code 0505T from APC 5193 (Level 3 Endovascular Procedures) to APC 1580 (New Technology - Level 43).

Final Action: For 2027, CMS is finalizing without modification the APCs and status indicators for the HCPCS codes listed in Table 48 based on supportive comments received. The table includes CPT codes 0786T, 0930T, and 0505T that were specifically discussed in the proposed rule. Regarding establishing a three-level Breast/Lymphatic Surgery and Related Procedures APC series, it appears, based on Table 4 in the final rule, that CMS is finalizing this proposal without modification.

IV. Payment for Devices

A. Pass-Through Payment for Devices

1. Beginning Eligibility Date for Device Pass-Through Status and Quarterly Expiration of Device Pass-Through Payments

a. Background

As implemented at 42 CFR 419.66, transitional device pass-through payments are intended for beneficiaries to have access to new and innovative devices by providing for adequate payments for new devices while the necessary cost data is collected to incorporate the device costs into the procedure APC rate. In accordance with statute, a category of devices is eligible for transitional pass-through payments for at least two, but not more than three years.[6] Since 2017, the pass-through eligibility period for a device category begins on the first date on which pass-through payment is made under the OPPS and, to allow a pass-through payment period that is as close to a full three years as possible, this pass-through status expires quarterly. Once devices are no longer eligible for pass-through payments, CMS packages the costs of the devices into the procedures with which the devices are reported in the claims data.

6 Under section 1833(t)(6)(B)(iii) of the Act

b. Expiration of Transitional Pass-Through Payments for Certain Devices

Currently, 21 device categories are eligible for pass-through payment. These devices are listed in Table 49 (reproduced from the preamble below) which includes the expiration dates of pass-through payment status for each.

TABLE 46: Devices with Pass-Through Status and Expiration Dates

HCPCS Code	Long Descriptor	Effective Date	Pass-Through Expiration Date
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
C1735	Catheter(s), intravascular for renal denervation, radiofrequency, including all single use system components	01/01/2025	12/31/2027
C1736	Catheter(s), intravascular for renal denervation, ultrasound, including all single use system components	01/01/2025	12/31/2027
C1737	Joint fusion and fixation device(s), sacroiliac and pelvis, including all system components (implantable)	01/01/2025	12/31/2027
C1738	Powered, single-use (i.e., disposable) endoscopic ultrasound-guided biopsy device	01/01/2025	12/31/2027
C1739	Tissue marker, uniquely detectable and identifiable with probe/sensor, any method (implantable), with delivery system	01/01/2025	12/31/2027
C9610	Catheter, transluminal drug delivery with or without angioplasty, coronary, non-laser (insertable)	01/01/2025	12/31/2027
C1740	Leadless electrode, transmitter, battery (all implantable), for sequential left ventricular pacing	10/01/2025	09/30/2028
C1741	Anchor/screw for bone fixation, absorbable (implantable)	10/01/2025	09/30/2028
C1742	Pressure monitoring system, compartmental intramuscular (implantable), continuous, including all components (e.g., introducer, sensor), excludes mobile (wireless) software application	10/01/2025	09/30/2028
C1607	Neurostimulator, integrated (implantable), rechargeable with all implantable and external components including charging system	01/01/2026	12/31/2028
C1608	Prosthesis, total, dual mobility, first carpometacarpal joint (implantable)	01/01/2026	12/31/2028
C1743	Scaffold, endovascular non-coronary, resorbable drug eluting, with delivery system (implantable)	04/01/2026	03/31/2029
C1609	Vertebral device, motion-preserving, with screw fixation	07/01/2026	06/30/2029

2. New Device Pass-Through Applications for 2027

a. Background

Eligibility for pass-through payment: The statute provides for pass-through payments for devices and requires CMS to use categories in determining eligibility.[7] The specific requirements are established at 42 CFR 419.66. The agency believes that pass-through payments for devices that offer substantial clinical improvement are important for ensuring hospitals can provide Medicare beneficiaries with access to the advantages of the new technologies.

To be eligible for transitional pass-through payment under the OPPS, a device must meet the following general criteria at §419.66(b)(1)-(3):

- The device must have received FDA premarket approval or clearance and the pass-through application must be submitted within 3 years from the date of the initial FDA approval or clearance;
- The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury; and
- The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted or applied in or on a wound or other skin lesion.

As finalized in 2026 OPPS/ASC final rule, skin substitutes with an approved Biologics License Application (BLA) will be considered under transitional drug pass-through payment status, and skin substitutes with FDA Premarket approval (PMA) or FDA 510(k) clearance will continue to be evaluated under transitional device pass-through payment status (90 FR 53636).

Under §419.66(b)(4), a device is not eligible for device pass-through payment if it is (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets; or (2) a material or supply furnished incident to a service.

Under §419.66(c)(1) and (2), CMS also uses the following criteria to determine whether a new category of pass-through devices should be established:

- The device is not described by an existing category (at §419.66(c)(1)).
- The device demonstrates a substantial clinical improvement, or a device is part of the FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.

Under §419.66(d), the device must have an average cost that is not "insignificant" relative to the payment amount for the procedure or service with which the device is associated. A device demonstrates this when, for at least one APC: (1) the estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices, (2) the estimated average reasonable cost of the

7 Section 1833(t)(6) of the Social Security Act

devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, and (3) the difference between the estimated average reasonable cost of the devices 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.

Device pass-through applications are submitted through the quarterly subregulatory process to allow for timely pass-through status. The applications are subject to notice-and-comment rulemaking in the next applicable OPPS/ASC annual rulemaking cycle to allow for a transparent, public review. All applications that are preliminarily approved during the quarterly review are automatically included in the next rulemaking cycle and are 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. Applications are publicly posted on a CMS website.

Rescission of the alternative pathway: In the 2020 OPPS/ASC final rule, CMS established an alternative pathway for devices that received FDA marketing authorization and were granted a Breakthrough Device designation, which was subsequently rescinded in the FY 2027 IPPS final rule. Under the alternative pathway, devices granted an FDA Breakthrough Device designation were not evaluated in terms of the current substantial clinical improvement criterion (§419.66(c)(2)) but did need to meet the other requirements for pass-through payment status. CMS would annually make proposals regarding these devices and whether pass-through payment status should continue to apply in the next applicable OPPS rulemaking cycle.

In the FY 2027 IPPS/LTCH PPS final rule (91 FR 49767 through 49789; 91 FR 50346 through 50347), CMS finalized its policy, with modification, that, unless specifically exempted, all applications received for device pass-through payment status on or after October 1, 2026, including all applications received through the remainder of the 2028 application cycle ending on March 1, 2027, and applications received for subsequent calendar years will have to demonstrate that the technology met the requirements currently reflected at §419.66(c)(2)(i). Applications submitted to CMS as of September 30, 2026 for devices that are part of the FDA's Breakthrough Devices Program that received FDA marketing authorization for the indication covered by the Breakthrough Device designation will be evaluated and could be approved under the alternative pathway, provided that all other criteria have been met. CMS finalized a limited exception for new devices that received FDA Breakthrough Device designation as of September 30, 2026, and has received marketing authorization for the indication covered by the Breakthrough Device designation. Such devices will remain eligible to apply for device pass-through payment under the alternative pathway, which will continue to accept applications for 2028 and 2029. In order to be considered for the limited exception, CMS must receive a complete application no later than March 1, 2028.

Existing device category codes established based on the approval, either preliminary or via a final determination made in an OPPS/ASC final rule, including any device category codes established for approved alternative pathway applications received as of September 30, 2026, will continue to be eligible for device pass-through payment status and remain in effect for at

least 2 years, but no more than 3 years, consistent with §419.66(g). Previously existing device category codes that were no longer eligible for device pass-through payment status remain unchanged.

b. Applications Received for Device Pass-Through Status for 2027

CMS received 19 complete applications by March 2, 2026, which was the last quarterly deadline for applications to be received in time to be included in the 2027 proposed rule. Six applications subsequently withdrew. CMS discussed the remaining 13 applications (10 under the alternative pathway and 3 under the traditional pathway). In the proposed rule, CMS preliminarily approved seven of the 13 applications. In the final rule, CMS is finalizing approval of nine, all of which are under the alternative pathway.

Applications received for the later deadlines for the remaining 2026 quarters (the quarters beginning June 1, September 1, and December 1 of 2026), if any, will be discussed in the 2028 OPPS/ASC proposed rule.

(1) Alternative Pathway Device Pass-Through Applications

CMS received 10 eligible device pass-through applications under the alternative pathway by the March 2026 application deadline. CMS preliminarily approved seven (MY01 Continuous Compartmental Pressure Monitor, RemeOs™ Screw LAG Solid, WiSE® CRT System, SetPoint System, TOUCH®CMC 1 Prosthesis, Esprit™ BTK Everolimus Eluting Resorbable Scaffold System, and TOPS™ System) and invited public comment on the preliminary approvals. Several commenters expressed support for device pass-through approval for one or more of the seven. CMS is therefore finalizing pass-through payment status for these seven devices under the alternative pathway, as proposed. For the remaining three which CMS proposed to deny pass-through status, two (Altius® Direct Electrical Nerve Stimulation System and TIDAL™ Fusion Cage System (Ossera™ AFX)) submitted information that persuaded CMS to reverse its proposed denial and approve.

A summary table of these technologies and CMS' final determination is provided below. The three technologies that CMS initially proposed to deny are discussed in more detail below the table.

Preliminary and Final Status for Devices Evaluated under the Alternative Pathway for Device Pass-Through Payments

Technology	Proposed Status	Final Status	Pass-through Effective Date
Altius® Direct Electrical Nerve Stimulation System	Denied	Approved	01/01/2027
ProSense® Cryoablation System	Denied	Denied	N/A
TIDAL™ Fusion Cage System (Ossera™ AFX)	Denied	Approved	01/01/2027
Esprit™ BTK Everolimus Eluting Resorbable Scaffold System	Approve	Approved	04/01/2026
MY01 Continuous Compartmental Pressure Monitor	Approve	Approved	10/01/2025
RemeOs™ Screw LAG Solid	Approve	Approved	10/01/2025
SetPoint System	Approve	Approved	01/01/2026
TOPS™ System	Approve	Approved	07/01/2026
TOUCH® CMC 1 Prosthesis	Approve	Approved	01/01/2026
WiSE® CRT System	Approve	Approved	10/01/2025

(a) Altius® Direct Electrical Nerve Stimulation System

The Altius® System is an implantable neuromodulation system that provides continuous, high frequency, high amplitude nerve stimulation to either the sciatic nerve or both the tibial and common peroneal nerves by directly stimulating targeted nerves via implanted cuff electrode leads that are wrapped circumferentially around target nerves in the amputated leg. While the system is composed of several components, the applicant sought a new device category for transitional pass-through payment status for only the Altius® IPG and the Altius® Cuff Electrode Lead components of the Altius® System. Table 51 in the final rule preamble summarizes this product's application information and CMS' preliminary denial based on concerns related to device category eligibility.

In the proposed rule, CMS did not express concerns about whether the device meets the newness (at §419.66(b)(1)), eligibility criteria (at§419.66(b)(3) and (b)(4)), or the cost criterion (at §419.66(d)). CMS invited public comment on these issues.

Regarding the device category eligibility criterion at §419.66(c), CMS stated its belief that the Altius® IPG and the Altius® Cuff Electrode Lead components may already be appropriately described by existing HPCPCS device categories C1778 and C1822. CMS summarized the reasons provided by the applicant as to why they do not believe that C1778 and C1822 describe the nominated device components. CMS disagreed, stating that, based on the description the applicant provided, the Altius® IPG is a rechargeable neurotransmitter device that generates a continuous high frequency, high amplitude alternating electrical stimulus (5kHz and 10kHz) via the Altius® Cuff Electrode Leads, which are circumferentially wrapped, anchored, and implanted around the nerve(s), and therefore, CMS stated its belief these could be appropriately described by C1778 (Lead, neurostimulator (implantable) and C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), respectively. CMS argued that the pass-through payment category C1778 may appropriately describe the Altius® Cuff Electrode Lead component because the pass-through payment category describes any device that is an implantable neurostimulator lead. Additionally, CMS argued that the pass-through payment category C1822 may appropriately describe the Altius® IPG because the category includes implantable neurostimulator pulse generators that deliver high-frequency stimulation (including approximately 10 kHz) and are rechargeable using an external charging system. Further, C1822 does not describe the amplitude, pulse frequency, or waveform of the stimulation generated by the device. CMS invited public comment on whether the Altius® IPG and the Altius® Cuff Electrode Lead components meet the device category eligibility criterion at §419.66(c)(1).

In summary, because the agency was unable to determine that the Altius® System, inclusive of the Altius® IPG and the Altius® Cuff Electrode Lead components, meets the device category eligibility criteria, CMS proposed to deny transitional pass-through payment status for 2027.

Final Action: CMS is approving the Altius® System for device pass- through payment status effective January 1, 2027.

Selected Comments/Responses: A few commenters agreed with CMS' proposed denial while others, including the applicant, urged CMS to approve device pass-through payment for the Altius® System, arguing that denial would create financial barriers that restrict Medicare beneficiaries' access to a safe, proven, non-opioid therapy for severe post-amputation pain that aligns with public health priorities. Regarding the newness, eligibility, and cost criteria, no comments were received.

Commenters were divided over whether the Altius® System requires a new HCPCS device category for pass-through payment or is already adequately described by existing neurostimulator codes (C1778 and C1822). The applicants and other commenters argued that CMS misclassified the FDA Breakthrough-designated device under legacy spinal cord and peripheral nerve stimulation (SCS/PNS) codes, which rely on percutaneously placed needle leads and low-amplitude pulsed currents to mask pain with paresthesia. By contrast, the Altius® System requires an open surgical procedure under general anesthesia to wrap a 360° circumferential cuff around the sciatic nerve and delivers a high-frequency (5–10k Hz), high-amplitude alternating current to create a true electrical nerve conduction block. An opposing stakeholder contended that existing HCPCS codes C1778 and C1822 already cover the device because the codes define broad functional classes rather than proprietary designs, waveforms, or amplitudes. The commenter noted that nerve-wrapping leads are not novel citing as an example LivaNova's VNS Therapy™ helical lead, which utilizes leads that wrap around and anchor to a target the vagus nerve. In response, instead of addressing any of the arguments directly, CMS simply thanks the submitters and states the agency now agrees with the applicant's position that there is no existing device category previously in effect, that appropriately describes a neurostimulator system that uses high- frequency, alternating current.

(b) ProSense® Cryoablation System

The ProSense® Cryoablation System is designed to destroy tissue by the application of extreme cold temperatures utilizing liquid nitrogen for the treatment of breast cancer for patients with low-risk tumors. The applicant sought a new device category for transitional passthrough payment status for only the ProSense® Cryoprobe component of the ProSense® Cryoablation System. Per the applicant, the ProSense® Cryoprobe is a rigid probe with a tip that creates ice balls to destroy target tissue through cycles of freezing and thawing. Table 52 in the final rule preamble provides an overview of the application and CMS' preliminary assessment.

In the proposed rule, CMS did not express concerns about whether the device meets the eligibility criteria (at §419.66(b)(3) and (b)(4)), or the cost criterion (at §419.66(d)). CMS invited public comment on those issues. However, CMS expressed concerns related to the newness criterion (at §419.66(b)(1)) the device category eligibility criterion at §419.66(c) and proposed to deny pass-through payment status.

With respect to the newness criterion at §419.66(b)(1), CMS stated its belief that the initial FDA marketing authorization date for the ProSense® Cryoablation System, inclusive of the nominated ProSense® Cryoprobe component, may be December 20, 2019 or earlier. The applicant submitted the pass-through payment application on December 26, 2025, which is more than 3

years after December 20, 2019; therefore, CMS disagreed that the ProSense® Cryoablation System, inclusive of the nominated ProSense® Cryoprobe, meets the newness criterion.

With respect to the device category eligibility criterion at §419.66(c), CMS indicated that the ProSense® Cryoprobe may be appropriately described by C2618, based on the description the applicant provided. Specifically, CMS stated its belief that the pass-through payment category C2618 may appropriately describe the ProSense® Cryoprobe because C2618 describes any probe used for cryoablation and is not specific to an anatomical location. As a result, CMS was unable to determine that the ProSense® Cryoablation System, inclusive of the ProSense® Cryoprobe, meets the new device category eligibility criteria and therefore proposed to deny transitional pass-through payment status for 2027.

Final Action: CMS is not approving the ProSense® Cryoablation System for device pass-through payment status for 2027 because the technology does not meet the newness criterion at §419.66(b)(1).

Selected Comments/Responses: While a commenter expressed its support for the denial of device pass- through payment for this device, the applicant submitted a public comment in support, arguing that the device meets all statutory criteria and removes financial barriers for hospitals adopting the only FDA-authorized, non-surgical local treatment for Medicare patients with low-risk breast cancer. The applicant argued it is inappropriate for CMS to extrapolate to previous 510(k) devices when FDA has already determined that the device qualifies for De Novo classification. The applicant concludes that CMS should use October 3, 2025, as the initial date of FDA marketing authorization, and recognize that the ProSense® Cryoablation System meets the criteria for the transitional pass-through payment. In response, CMS explains that while the October 3, 2025 De Novo order created a new classification for a specific low-risk breast cancer indication, obtaining a new indication or FDA regulatory pathway does not reset the pass-through newness period without demonstrating that the physical device itself is sufficiently different from previously cleared versions. CMS notes that no new information was submitted demonstrating that the device itself is sufficiently different from the previously cleared ProSense® Cryoablation System such that October 3, 2025 should not be considered its initial FDA marketing authorization for purposes of §419.66(b)(1).

(c) TIDAL™ Fusion Cage System (Ossera™ AFX)

The TIDAL™ Fusion Cage is a single, continuous, porous piece of titanium alloy containing a circular window for an intramedullary nail used during salvage procedures to restore bone length due to bone void, absent bone or surgical resection. The TIDAL™ Fusion System is not for standalone use and is intended for use as an accessory to the DynaNail® TTC Fusion System and with an autograft and/or allogenic bone graft. Table 53 in the final rule preamble provides an overview of the application and CMS' preliminary assessment.

In the proposed rule, CMS did not express concerns about whether the device meets the newness (at §419.66(b)(1)), eligibility criteria (at§419.66(b)(3) and (b)(4)), or the cost criterion (at §419.66(d)). CMS invited public comment on these issues.

Regarding the device category eligibility criterion at §419.66(c), CMS stated its belief that the TIDAL™ Fusion Cage may be appropriately described by existing HCPCS device category C1713, based on the description provided by the applicant. Specifically, CMS argued that C1713 may appropriately describe the TIDAL™ Fusion Cage because C1713 is defined as implantable pins and/or screws inserted or drilled into bone, principally with the intent to facilitate stabilization or oppose bone-to-bone contact and may include orthopedic plates with accompanying washers or nuts as well as synthetic bone substitutes that may be used to fill bony voids or gaps. As a result, CMS was unable to determine that the TIDAL™ Fusion Cage meets the new device category eligibility criteria, and therefore proposed to deny transitional pass-through payment status for 2027.

Final Action: CMS is approving the TIDAL™ Fusion Cage for device pass- through payment status effective January 1, 2027.

Selected Comments/Responses: While one commenter expressed support for CMS' proposal to deny pass-through payment status for the device, the applicant and a few commenters submitted public comments urging approval, stating that the TIDAL™ Fusion Cage provides an alternative treatment to certain patients who are at risk of limb loss and without other good treatment options. With respect to whether the TIDAL™ Fusion Cage may be appropriately described by C1713, the supporting commenters argued that the TIDAL™ Fusion Cage requires a new HCPCS device category for transitional pass-through payment because CMS overly broadened existing code C1713 beyond its intended scope of fixation hardware and non-structural bone void fillers, inappropriately including a broad range of musculoskeletal reconstructive implants. Unlike C1713 describing fixation hardware (anchors, screws, pins, plates) that attach or oppose bone and certain synthetic bone substitutes, the TIDAL™ Fusion Cage is a permanent structure scaffold that replaces missing segmental bone to restore limb length and enable limb-salvage fusion. According to the applicant, the appropriate question is not whether C1713 can be stretched to cover a device that touches bone or participates in fusion, but rather, whether C1713 appropriately describes the TIDAL™ Fusion Cage. Additionally, the applicant urged CMS to respect the FDA's separate classification of the device as an "Ankle Fusion Cage" (product code SAI, under 21 CFR 888.3020) which is distinct from FDA's product classification for resorbable implants (MQV, under 21 CFR 888.3045) and establish a dedicated pass-through category (e.g., *joint fusion device, ankle, including all system components (implantable)*) rather than denying pass-through status under C1713. In response, CMS is persuaded that there is no existing category or category previously in effect that appropriately describes the TIDAL™ Fusion Cage because no pass-through category describes a device that is a structural component used to replace absent bone and restore limb length in an ankle fusion, and not an anchor, screw, pin, plate, washer, nut, or conventional synthetic bone substitute.

(2) Traditional Device Pass-Through Applications

CMS received three eligible device pass-through applications under the traditional pathway by the March 2026 application deadline. CMS proposed to deny all three for pass-through payment for 2027. Commenters were unable to persuade CMS to reverse any of the agency's proposals. A summary table of these technologies and CMS' preliminary and final assessment of each is provided. All three are discussed in more detail in the table below.

Preliminary and Final Status for Devices Evaluated under the Traditional Pathway for Device Pass-Through Payments

Technology	Proposed Status	Final Status	Pass-through Effective Date
EndoForce™ Connector for Endovascular Venous Anastomosis	Denied	Denied	N/A
LINK™ External Fixator	Denied	Denied	N/A
Santreva™-ATK Endovascular Revascularization Catheter	Denied	Denied	N/A

(a) EndoForce™ Connector for Endovascular Venous Anastomosis

The EndoForce™ System provides an endovascular method for attachment of a non-autogenous arteriovenous graft (AVG) to a vein in the upper arm in patients with end stage renal disease (ESRD) requiring hemodialysis. The System is provided as a sterile, single-use EndoForce™ Connector Delivery System with a pre-mounted EndoForce™ Connector that is attached endovascularly at the venous anastomosis, in conjunction with a standard 6mm expanded polytetrafluoroethylene (ePTFE) vascular access graft, to establish an end-to-end endovascular anastomotic conduit designed to help absorb the shear forces of blood flow at the AVG-vein junction and to provide a physical barrier to the ingress of neointimal hyperplasia. Table 54 in the final rule preamble provides an overview of the application and CMS' preliminary assessment.

In the proposed rule, CMS did not express concerns about whether the device meets the newness or eligibility criteria at §419.66(b) or the cost criterion at §419.66(d). CMS did not express concerns related to the device category eligibility criterion at §419.66(c)(1), however, CMS raised several concerns related to the substantial clinical improvement criterion at §419.66(c)(2), including the following:

- Concerns related to the single published study submitted (Burgess et al. (2024)),[8] specifically:
    - The study may limit generalizability of results to the Medicare population.
    - What extent any improvement in cumulative patency is due to use of the EndoForce Connector versus the less invasive endovascular procedure used for implantation.
    - Validity of comparisons between Burgess study patient population, vascular location, and outcomes to those in the submitted unpublished studies.
- Concerns related to the claim that the EndoForce System improves patency and reduces AVG abandonment.
- Concerns related to the claim that the EndoForce System sustains patency and requires fewer interventions to maintain patency.
- CMS questioned whether Kramer et al. (n.d.)[9] conclusively demonstrates that the EndoForce™ System provides a substantial clinical improvement compared to other available treatments. CMS questioned comparisons made between this study and other studies submitted.

8 Burgess JS, et al (2024).Prospective multicenter study of a novel endovascular venous anastomotic procedure and device for implantation of an arteriovenous graft for hemodialysis. J Vasc Access, 25(4), 1244–1251.
9 Kramer A, et al (Pre-publication). Extended Follow-Up of an Endovascular Venous Anastomotic Connector for Arteriovenous Graft Creation in Hemodialysis: A Multicenter Study.

- CMS questioned whether the EndoForce System improves cumulative (secondary) patency compared to mature AV fistulas (AVFs), and existing devices used for AVF creation, including WaveLinQ™, and Ellipsys™.

As a result, CMS was unable to determine that the EndoForce System meets the new device category eligibility criteria, and therefore proposed to deny transitional pass-through payment status for 2027.

Final Action: CMS has determined that the device meets the newness criterion at §419.66(b)(1), the eligibility criteria at §419.66(b)(3) and (4), and the device category eligibility criterion at §419.66(c)(1). However, CMS is not approving the EndoForce System for device pass-through payment status for 2027 because the technology does not meet the substantial clinical improvement criterion at §419.66(c)(2).

Selected Comments/Responses: A commenter expressed their support for the denial of device pass-through payment whereas the applicant and several commenters recommended that CMS approve it, citing concerns that non-approval would, for example, disincentivize physician use, limit patient access, and impede generation of clinical evidence for CMS to determine long-term value. A few commenters agreed with the concerns raised by CMS in the proposed rule related to, for example, absence of a concurrent control group and differences among comparator populations, however, these commenters argued that these concerns alone should not warrant a negative determination of substantial clinical improvement. Rather, commenters encouraged CMS to consider the totality of the circumstances when making its determination.

In defense of its clinical evidence, the applicant argued that because no concurrent controlled trial exists, its reliance on well-conducted meta-analyses and historical comparators (Halbert et al. and Astor et al.) provides a valid, top-tier methodological basis for demonstrating improved 6-month cumulative patency over conventional sutured arteriovenous grafts (AVGs). The applicant and another commenter provided detailed point-by-point responses, which can be reviewed in the final rule preamble, to the concerns raised by CMS in the proposed rule.

In response, CMS agrees with the applicant and commenters that the EndoForce System and the endovascular procedure should be assessed together for the purposes of evaluating substantial clinical improvement, however, the agency concludes that the submitted evidence remains too uncertain and confounded to prove substantial clinical improvement over existing technologies. In particular, CMS continues to have significant concerns regarding:

- The unmatched control group and confounders in the pivotal study (Burgess *et al,* 2024 and others). Based on this, CMS asserts there is insufficient data to rule out the possibility that factors other than EndoForce may also have impacted cumulative and primary unassisted patency.
- Extreme meta-analysis heterogeneity across comparator studies (Astor *et al*, 2026 and Halbert *et al*, 2020). Thus, CMS remains concerned that the existing treatments for the study endpoints may not be reliable indicators of EndoForce's substantive clinical improvements.

- Flawed performance goal (reported in Burgess, *et al*, 2024). As a result, CMS is unable to determine whether EndoForce performs better than existing technologies in maintaining patency
- Data digitization tool used by Astor *et al*. (2026) and Halbert *et al*. (2020) to abstract data. CMS raises questions about the quality of the images analyzed by the studies, noting that errors introduced during digitization can propagate and affect downstream analyses, such as treatment effect estimation and meta-analysis.

(b) LINK™ External Fixator

The LINK™ External Fixator is a dynamic percutaneous bone external fixator that provides continuous compression during the healing of bony fractures, fusions, and osteotomies. Table 55 in the final rule preamble provides an overview of the application and CMS' preliminary assessment.

CMS proposed to deny transitional pass-through payment status for the LINK External Fixator for 2027 due to multiple device eligibility, category, and clinical evidence concerns. CMS did not raise concerns related to newness or cost criteria. Specifically, CMS questioned whether the device's components are surgically implanted or integral to the service (§419.66(b)(3)), whether its bone pins are merely supplies furnished incident to a service (§419.66(b)(4)), and whether the device is already adequately described by existing HCPCS category C1713 (§419.66(c)(1)). Furthermore, CMS concluded that the applicant failed to demonstrate substantial clinical improvement (§419.66(c)(2)), noting a lack of evidence showing improved recovery times, pain, adverse events, or clinical outcomes for an unresponsive patient population compared to existing treatments.

Final Action: CMS is not approving the LINK External Fixator for device pass-through payment status for 2027 because the technology does not meet the device category eligibility criterion at §419.66(c)(1).

Selected Comments/Responses: While the applicant and commenters argued that the LINK External Fixator qualifies for pass-through payment as a unified, surgically inserted dynamic construct distinct from incidental supplies and static hardware, CMS maintained its concerns and concluded the device remains ineligible. Specifically, commenters argued that the LINK External Fixator meets 42 CFR §419.66(b)(3) because its specialized locking bone pins, spring-like bridge, and protective cover function as a unified, surgically inserted construct that directly contacts tissue, making them neither depreciable equipment nor incidental surgical supplies interchangeable with standard k-wires or Steinman pins. Additionally, the commenters argued that the LINK External Fixator is not adequately described by existing HCPCS category C1713 because it provides active, dynamic elastic compression rather than static mechanical fixation. In response, CMS remains concerned that the LINK Bone Pins may be considered a supply, in which case the LINK External Fixator, considered as a whole device, may be ineligible. Moreover, CMS continues to believe that C1713 appropriately describes the LINK External Fixator because the device category code does not differentiate between static external fixators and those that use elastic mechanical energy. Therefore, CMS determined that the LINK External Fixator 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. As a result of this determination, CMS did not address whether the technology meets the remaining criteria required for device pass-through payment.

(c) Santreva™-ATK Endovascular Revascularization Catheter

The Santreva-ATK Catheter is an energy and wire-free platform for simultaneous intraplaque crossing and revascularization of complex occlusive peripheral artery disease, intended for facilitating intraluminal placement of guidewires beyond stenotic lesions. Table 56 in the final rule preamble provides an overview of the application and CMS' preliminary assessment.

In the proposed rule, CMS did not express concerns about whether the device meets the newness or eligibility criteria at §419.66(b) or the cost criterion at §419.66(d)(3). Regarding the device category eligibility criterion at §419.66(c)(1), CMS noted that the Santreva-ATK Catheter may already be described by existing pass-through category C1887 (guiding catheters), as both share the primary function of crossing peripheral stenotic lesions to establish a revascularization pathway. Additionally, regarding the substantial clinical improvement criterion at §419.66(c)(2), after reviewing the information provided by the applicant, CMS raised several concerns regarding whether the Santreva-ATK Catheter meets the substantial clinical improvement criterion, including:

- Whether the single Banerjee et al. (2026) study[10] supports claims of improved mechanism compared to other existing devices or techniques that facilitate wire crossing and whether the results of the study are generalizable to the Medicare population.
- Whether the device demonstrates that it substantially improves the diagnosis or treatment of an illness when compared to other available treatments, given the availability of other currently available treatments, including the Crosser™ Catheter S6 and the Viance™ Crossing Catheter.
- Comparator tables submitted do not identify the specific studies or datasets from which the comparator values originated, which are necessary for CMS' evaluation.
- Lack of sufficient supporting evidence for the claim that the Santreva-ATK Catheter is a substantial clinical improvement over current crossing devices and algorithms.
- Lack of sufficient supporting evidence that the Santreva-ATK Catheter substantially improves the clinical condition and quality of life of patients.
- How a substantial improvement for physicians in day-to-day clinical practice relates to the applicant's claims of improved clinical outcomes.

In summary, CMS was unable to determine that the Santreva-ATK Catheter meets the new device category eligibility criteria, and therefore proposed to deny transitional pass-through payment status for 2027.

Final Action: CMS is not approving the Santreva-ATK Catheter for device pass-through payment status for 2027 because the technology does not meet the device category eligibility criterion at §419.66(c)(1).

10 Banerjee S, et al (2026) Safety and effectiveness of the Santreva-ATK endovascular revascularization catheter in the RESTOR-1 peripheral CTO crossing pivotal study. The American Journal of Cardiology. Advance online publication. https://doi.org/10.1016/j.amjcard.2026.01.007.

Selected Comments/Responses: A commenter expressed support for denying device pass-through payment for the Santreva-ATK Catheter because it does not meet the criteria for device pass-through payment. The applicants and several other commenters urged CMS to approve transitional pass-through payment for the Santrev-ATK Catheter to expand provider adoption and patient access to a safe, effective treatment option for complex peripheral arterial disease. Commenters argued C1887 does not describe the Santreva-ATK Catheter because the device actively and directly revascularizes complex occlusions while only serving as a secondary conduit afterward. Additionally, the device uses a novel atheroplasty mechanism that is wireless and energy-free, and is distinct from other existing plaque-modifying codes with guidance capabilities that CMS previously created. CMS rejected the applicant's arguments and concluded that the Santrev-ATK Catheter fails to meet the device category eligibility criterion at §419.66(c)(1) because its primary function, crossing peripheral lesions to establish a revascularization pathway before removal, is already appropriately described by existing guiding catheter category C1887. Furthermore, CMS emphasized that pass-through categories are designed to encompass broad classes of devices rather than proprietary features, noting that the device's additional plaque-disrupting capabilities do not establish a distinct therapeutic function independent of lesion crossing. Because CMS determined that the device fails to meet eligibility criterion at §419.66(c)(1), CMS does not address whether the technology meets the remaining criteria in the final rule.

3. Other Comments

In this subsection, CMS addresses several other general comments it received related to its pass-through payment policies and review process.

Selected Comments/Responses: Several commenters urged CMS to establish a more transparent transition pathway from pass-through status to permanent payment, complete with clear criteria, timelines, advance notice, and public comment opportunities. A commenter requested that CMS revise its device pass-through cost significance methodology so that a new device's cost is compared and offset only against the specific devices it actually replaces, rather than automatically subtracting the entire device-related portion (DRP) of the associated Ambulatory Payment Classification (APC). Multiple commenters expressed their support for, or concerns regarding, CMS’s repeal of the alternative pathway.

In response, CMS acknowledged stakeholders' concerns while maintaining that its existing statutory framework already provides advance notice, public comment opportunities, and ongoing data tracking. CMS expressed appreciation for suggestions for improving its process and methodologies but declines to make changes at this time. CMS reaffirmed its policy sunsetting the alternative pathway for FDA Breakthrough Devices and notes the limited transition exception it created that will allow devices that already held FDA Breakthrough Device designation by September 30, 2026 (and subsequently receive marketing authorization for that designated indication) to remain eligible for the alternative pathway through the 2028 and 2029 cycles, provided a complete application is submitted by March 1, 2028.

B. Device-Intensive Procedures

1. Background

Procedures that meet certain criteria are identified as device-intensive procedures and are subject to all the policies applicable to procedures assigned device-intensive status under the agency's established methodology, including CMS' policies on device edits and no cost/full credit and partial credit devices discussed in sections IV.B.3. and IV.B.4. below. CMS determines device-intensive status at the HCPCS code level, under which the procedures are assigned device-intensive status regardless of their APC assignment, rather than at the APC-level as it did prior to 2017.

2. Device-Intensive Procedure Policy

Currently, device-intensive procedures require implantation of a device and additionally are subject to the following criteria:

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

To align the device-intensive policy with the criteria used for device pass-through status, for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA IDE and has been classified as a Category B device by the FDA in accordance with 42 CFR 405.203 – 405.207 and 405.211 – 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not any of the following:
    - 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
    - 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).

Beginning in 2025, for new CPT/HCPCS codes that both describe a procedure that requires the surgical implantation or insertion of a single-use device that exceeds 30 percent of the procedure's cost and lack claims data (from either the new HCPCS code or any predecessor code or clinically-similar code that uses the same device), CMS applies 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 applies for both the OPPS and ASC Payment System and applies to new procedures assigned to clinical APCs, but not to new procedures assigned to New Technology APCs. Additionally, for procedures subject to CMS' device edits policy that cannot report modifier "CG" to bypass the claims processing edit, the device offset percentages calculated (for the CPT/HCPCS code or its predecessor code) are based on hospital claims that reported a device code. For purposes of determining device offset percentages, CMS will not use claims data from procedures that have a status indicator of "E1" during the calendar year CMS is using for ratesetting and determining device offset percentages. Lastly, CMS uses available claims data from predecessor codes annually until the agency has available claims data from the successor code.

CMS proposed to continue these policies for 2027. Specifically, CMS proposed to continue:

- Using HCPCS code-level device-intensive determination and three criteria to designate device- intensive procedures, in accordance with existing policies.
- The device-intensive procedure policy, including 1) using 2025 claims information for determining device offset percentages and assigning device-intensive status, and 2) the device offset policy for determining device offset percentages in the absence of claims data.

Final Action: CMS is finalizing continued use of its criteria and device-intensive procedures with a modification for device-intensive procedures with fewer than ten claims in the ratesetting year, for which the agency will apply the greater of: (1) the device offset percentage calculated from the available claims; or (2) the device offset percentage calculated under the agency's default methodology, which is the greater of 31 percent or the device offset percentage of the APC to which the procedure is assigned. The full listing of the 2027 device-intensive procedures can be found in Addendum P.

Additional code-specific final actions in response to comments include:

- Designating CPT code 52282 as device-intensive for 2027 due to the lack of representative 2025 claims data following a nine-year market absence of an FDA-approved permanent prostatic urethral stent.
- Maintaining device-intensive status for CPT code 55882 (TULSA procedure) across both the ASC and OPPS settings for 2027, due to incomplete 2025 claims reporting and an earlier administrative oversight.
- Designating device-intensive status for CPT code 0786T for 2027 and will disregard invalid 2025 claims for CPT code 0786T because the procedure held a non-payable "E1" status indicator throughout that year.
- Declining to designate CPT code 0730T as device-intensive because the agency does not consider the patient interface system associated with this code to be an insertable medical device for purposes of device-intensive status.
- Declining to expand the device-intensive policy to permit histotripsy CPT codes 0686T and 0888T to qualify based on the cost of a nonimplantable ''single patient use device'' applied to the patient's skin.
- Applying its newly finalized low volume methodology to CPT code 0885T which would be assigned a default device offset of 34.95 percent based on the APC-wide device offset of APC 5331 (Complex GI Procedures).

- Declining to assign device-intensive status under the OPPS to CPT codes 31296, 31297, and 31298 for 2027 since the device offset percentage for each procedure is below CMS' device-intensive threshold of 30 percent and there are 10 or greater singles for each procedure based on claims data available for the final rule.
- Assigning a device offset percentage to CPT code 52284 based on the 2025 claims data available for this final rule with comment period.
- Finalizing the proposal to assign CPT code 64728 to APC 5431 (Level 1 Nerve Procedures) for 2027. The device offset percentage for APC 5431 is 1.4 percent; therefore, CMS is not accepting the commenter's recommended offset of 61.69 and is assigning a default 31-percent device offset to CPT code 64728 for 2027 instead of the requested increase.
- Declining to grant device-intensive status to CPT codes 66174 and 52649 because the device offset percentage calculated from claims is below the 30-percent device-intensive threshold.
- Finalizing an APC-level device offset percentage of approximately 67 percent instead of the requested 79 percent for APC 5231 (Level 1 ICD and Similar Procedures) reflecting weighted-average device costs associated with all procedures assigned to the APC.

Selected Comments/Responses: Commenters submitted a variety of specific requests and recommendations to CMS related to this issue. Several commenters recommended that CMS establish a specific process for determining device- intensive status for procedures removed from the inpatient-only list. In response, CMS agrees to modify the device-intensive status of several codes, as described above. In most cases, CMS declines to use invoices to calculate the device offset percentage, preferring to use its default device offset methodology. Finally, CMS acknowledges under the OPPS, CMS has adopted alternative methodologies when the available claims volume is insufficient to support reliable ratesetting and agrees with the commenters that the limited outpatient claims generated for procedures while they remained on the inpatient-only list may not reliably reflect the device costs that hospitals will incur when furnishing those procedures in the outpatient setting. Therefore, in response to commenters who raised concerns with determining device intensive status for services with very few claims, CMS agrees it would be appropriate to apply a low volume methodology for device intensive status. Specifically, for 2027 and subsequent years, when fewer than 10 claims are available in the ratesetting year, CMS will use the greater of the device offset percentage calculated from the available claims or calculated under the default methodology. CMS is adopting this policy for the ASC payment system as well.

3. Device Edit Policy

In this section of the preamble, CMS summarizes the historical development of its device edit policy. Beginning in 2025, CMS applies its device edits policy permanently once a procedure is designated as a device-intensive procedure in a given year. CMS did not propose any changes to its device edit policy for 2027.

Final Action: CMS is finalizing its proposal, without modification.

Selected Comments/Responses: Several commenters recommended that CMS: reinstate device-to-procedure edits for certain device-intensive services; establish or assign appropriate C-codes for certain specific procedures or for device-intensive procedures that are removed from the inpatient-only list; or provide specific reporting instructions for C1776 on total joint arthroplasty claims. In response, CMS declines all commenter suggestions. CMS noted that hospitals are experienced in coding and reporting significant device costs correctly on hospital claims using the existing device category HCPCS C-codes as well as revenue codes and therefore the agency does not believe it is necessary to reinstate specific procedure-to-device edits for device-intensive procedures. Additionally, CMS does not believe it is appropriate or necessary to create additional device category C-codes outside of the transitional pass-through approval process.

4. Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

To ensure equitable OPPS payment when a hospital receives a device without cost or with full credit, CMS reduces the OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit by the lesser of the device offset amount for the APC or the amount of the credit. CMS did not propose any changes to its policies regarding payment for no cost/full credit and partial credit devices for 2027.

Final Action: CMS is finalizing its proposal, without modification.

Selected Comments/Responses: CMS did not receive any public comments on this proposal.

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, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure.
- Drugs and biologicals that function as supplies when used in a surgical procedure.

Other drugs are threshold packaged meaning that their per day costs must exceed a fixed threshold (proposed $140 for drugs and biologicals other than radiopharmaceuticals and $665 for diagnostic radiopharmaceuticals in 2027) 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 on transitional pass-through payments.

A. Transitional Pass-Through Payment for Drugs and Biologicals

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 payment was first made under the OPPS. Transitional pass-through drugs and biologicals for 2027 and their designated APCs are assigned status indicator "G" in Addenda A and B of the final rule. For 2027, 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 mean unit cost (MUC) or ASP+6 percent depending on the availability of ASP.

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 57 of the final rule lists 49 drugs and biologicals where CMS will be expiring transitional pass-through payment by the end of 2026. Each of the products will have received the full 3 years of transitional pass-through payments once the additional payments expire. Table 58 of the final rule lists 28 drugs where CMS will end transitional pass-through payment status in 2027. Table 59 of the final rule lists 60 drugs and biologicals—15 more than were in the proposed rule—where CMS will continue transitional pass-through payment for all of 2027.

When policy-packaged or threshold packaged 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 with costs above the packaging threshold 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 2027, CMS proposed to maintain 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 the packaging threshold of $630 and paying separately for diagnostic radiopharmaceuticals above the packaging threshold. For 2027, CMS proposed to establish a packaging threshold of $665 for diagnostic radiopharmaceuticals.

The packaging threshold was initially set at $50 in 2005 for drugs, biologicals and therapeutic radiopharmaceuticals. To calculate the 2027 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 2027. CMS rounds the resulting amount ($142.40 in the proposed rule) to the nearest $5 increment ($140.00). Using the same methodology to trend the $630 threshold for diagnostic radiopharmaceuticals from the 3rd quarter of 2025 to the 3rd quarter of 2027, CMS proposed a threshold of $667.44 rounded to the nearest $5 increment ($665.00). CMS updated these amounts for final rule and determined a drug packaging threshold of $135.43 rounded to $135.00 for drugs and biologicals and $634.80 rounded to $635.00 for diagnostic radiopharmaceuticals.

CMS is continuing to use the following process to determine the 2027 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 2025 claims data processed through June 30, 2026, 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 2025 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 2025 (data that is being used to pay for drugs and biologicals in physicians' offices effective October 1, 2026). 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 2025 hospital claims data.

For diagnostic and therapeutic radiopharmaceuticals that do not have pass-through status as of April 1, 2026, CMS is using mean unit cost derived from the 2025 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 uses quarterly ASP updates as follows:

- 4th quarter of 2025: Per-day cost, budget neutrality estimates, packaging determinations, impact analyses, and Addenda A and B for the 2027 OPPS proposed rule.
- 2nd quarter of 2026: Per-day cost, budget neutrality estimates, packaging determinations, impact analyses, and Addenda A and B for the 2027 OPPS final rule.
- 3rd quarter of 2026: Payment rates effective January 1, 2027, for separately payable drugs and non-implantable biologicals (these are the same ASP data used to calculate payment rates effective January 1, 2027, for drugs and biologicals furnished in the physician office setting).

ASP-based payment rates for both the OPPS and physician office settings are updated quarterly using reported ASP data with a two-quarter lag, and these updates are available on the CMS website. CMS is continuing 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 2027 final rule will be subject to quarterly updates.

As in past years, CMS applied the following policies to determine the 2027 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 2026 and were proposed for separate payment in 2027 are separately payable in 2027 even if the updated data used for the 2027 final rule indicates per-day costs equal to or less than the $135 threshold ($635 for diagnostic radiopharmaceuticals).
- HCPCS codes that are packaged in 2026, proposed for separate payment in 2027, and have per-day costs equal to or less than $135 ($635 for diagnostic radiopharmaceuticals) based on the updated data used for the 2027 final rule are packaged in 2027.
- HCPCS codes for which CMS proposed packaged payment in 2027 and have per-day costs greater than $135 ($635 for diagnostic radiopharmaceuticals) based on the updated data used for the 2027 final rule are separately payable in 2027.

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

For 2027, 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 60 of the final rule.

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

a. Payment for Separately Payable Drugs and Biologicals

As indicated above, CMS will pay for separately payable drugs and biologicals at ASP+6 percent in 2027. 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 cost data 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 beginning on January 1, 2027. Payment rates effective January 2027 will be released near the end of December 2026 and will be based on ASP data submitted by manufacturers for the third quarter of 2026 (July 1, 2026, through September 30, 2026), 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, 2027.

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 2025 (used for payment in physicians' offices for the 2nd quarter of 2026) are based on WAC, AWP or mean unit cost in the available 2025 claims data. If ASP information becomes available for the 3rd quarter of 2026 (used for payment in physicians' offices for the 1st quarter of 2027), CMS will pay for these drugs and biologicals based on the newly available ASP information. For diagnostic radiopharmaceuticals with a per-day cost over $635, the rates in Addenda A and B are based on mean unit cost in the 2025 data.

b. 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 1847A(b)(8)(B) of the Act provides for 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.

c. Invoice Drug Pricing for 2027

In the 2025 OPPS rule, CMS adopted a policy effective January 1, 2026 to allow payment based on invoice cost for drugs where ASP, WAC, AWP, and mean unit cost information is not available. The drug or biological invoice cost would be the acquisition cost net of any rebates, chargebacks, or post-sale concessions. The National Uniform Billing Committee created value code 92 that would allow for the reporting of invoice prices of drugs, biologicals, and radiopharmaceuticals specifically for the purpose of this policy.

Before calculating an invoice-based payment amount (a) CMS would determine that the drug is not policy-packaged and (b) the Medicare Administrative Contractor (MAC) would use the invoice to determine whether the per-day cost of the drug, biological, therapeutic radiopharmaceutical or diagnostic radiopharmaceutical is above the threshold packaging amount.

The drug or biological invoice cost would be the net acquisition cost minus any rebates, chargebacks, or post sale concessions. CMS acknowledges that any rebates, chargebacks, or post-sale concessions may not be immediately available after treatment but hospital providers have 12 months from date of service to submit claims for payment and allowing providers to adjust submitted claims when the price concession becomes available.

3. Payment Policy for Radiopharmaceuticals

a. Therapeutic Radiopharmaceuticals.

For 2027, CMS proposed to 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 2027 payment rates based on 2025 geometric mean unit cost. CMS does not use WAC or AWP to price therapeutic radiopharmaceuticals.

b. Diagnostic Radiopharmaceuticals.

For 2027, CMS will pay separately for diagnostic radiopharmaceuticals with a per-day cost above $635. 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.

4. Payment for Blood Clotting Factors

CMS will continue paying for blood clotting factors at ASP+6 percent and a $0.270 per unit furnishing fee that reflects an update to the rate from 2026 by the Consumer Price Index for medical care for 2027.

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

CMS will continue the same payment policy in 2027 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.

6. High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

IHS and tribal facilities are paid under an All-Inclusive Rate (AIR) rather than under the OPPS for outpatient hospital services.[11] For 2026, the AIR is $733 for the lower 48 states and $1,233 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.

In the 2025 OPPS/ASC final rule, CMS adopted a policy to separately pay IHS and tribal facilities for drugs furnished in hospital outpatient departments with per day costs that exceed twice the AIR in the lower 48 states. CMS follows its existing methodology to calculate per-day costs for OPPS drugs to determine whether a drug's cost is above the IHS/Tribal facility packaging threshold. Payment will be at ASP with no add-on (or WAC if ASP is unavailable and 95 percent of AWP if ASP or WAC is unavailable).

For 2027, CMS is updating the IHS/Tribal packaging threshold to be twice the 2026 AIR for the lower 48 ($733 x 2 = $1,466). Addendum Q of the 2027 OPPS final rule will list qualifying drugs paid separately above the IHS/Tribal packaging threshold. ASPs for qualifying drugs will be updated quarterly.

C. Payment for Skin Substitutes

In the 2026 OPPS rule, CMS finalized a policy to separately pay for sheet form skin substitute products as incident-to supplies in the physician office, hospital outpatient, and ambulatory

[11] 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.

surgical center settings effective January 1, 2026 (90 FR 53729 through 53748). CMS assigned sheet-form skin substitute products to one of three clinical APCs based on their FDA regulatory category: APC 6000 (PMA Skin Substitute Products), APC 6001 (510(k) Skin Substitute Products), and APC 6002 (361 HCT/P Skin Substitute Products).

CMS set an initial payment rate of $127.14/cm^2 for all three APCs and said it intended to update payment rates for each category based on the ASP or MUC if ASP is unavailable. However, as skin substitutes would no longer be paid as a drug biological, manufacturers of skin substitutes are no longer required to report ASP effective January 1, 2026.

The proposed rule indicated that CMS does not have sufficient data upon which to propose a revised payment rate for all three skin substitute product APCs. Further, CMS would like more utilization data to evaluate use patterns reflecting the 2026 policy changes before making additional pricing changes for skin substitutes. For this reason, CMS proposed to maintain a payment rate of $127.14/cm^2 for all three skin substitute APCs in 2027

CMS' policy has been to package non-sheet form skin substitutes. Effective April 1, 2026, CMS created four new G codes for the application of non-sheet form skin substitutes (G0681-G0684). CMS proposed to package these non-sheet form skin substitute application codes for 2027 and continue packaging their associated non-sheet form skin substitutes under the OPPS for 2027.

Comments/Responses

Program Integrity. Public commenters reiterated comments made on this policy in the 2026 OPPS rule that CMS should use targeted program integrity efforts to address concerns about improper billing patterns for skin substitutes rather than payment changes. Commenters requested alternatives to a payment rate of $127.14/cm^2 and different methodologies for determining the higher rate. CMS responded that these comments were the same as those received on the 2026 OPPS proposed rule and directed readers to that rule for its responses (90 FR 53728 through 53748).

Apply an Inflation Update. Several commenters requested that CMS update the payment rate for skin substitute products based on the Consumer Price Index for All Urban Consumers (CPI-U) or the Medicare Economic Index (MEI). CMS responded that updating skin substitute payment rates based on ASP rather than CPI-U or MEI will be more responsive to market conditions for these products.

Eliminate Categorization. There were comments continuing to oppose categorizing skin substitute products by FDA regulatory category. These commenters indicate that the policy will create arbitrary payment disparities among products that serve the same clinical purpose based solely on how each product entered the market. CMS responded that it continues to believe that categorizing skin substitute products by FDA regulatory pathway remains appropriate but notes that each category will continue to receive payment at the same rate for 2027.

Non-Sheet Form Skin Substitute Products. Commenters requested that CMS align payment for non-sheet form skin substitutes with payment for sheet-form skin substitute products by

separately paying for HCPCS codes G0681-G0684 and the skin substitute products themselves as incident to supplies. CMS agrees with paying separately for the non-sheet form skin substitute application codes and has assigned HCPCS codes G0681 to APC 5053 (Level 3 Skin Procedures) and G0683 to APC 5054 (Level 4 Skin Procedures). G0682 and G0684 are add-on codes and will continue to be packaged like other add-on codes.

Non-sheet products are not manufactured, applied, or measured in the same standardized manner as sheet form products, which are billed in per cm^2 units. Because of these differences, CMS believes it is more appropriate to continue packaging payment for non-sheet form products under the OPPS.

Billing Guidance. Several commenters requested CMS clarify that providers may bill for the total amount of skin substitute product clinically necessary to treat a wound, rather than the two-dimensional surface area of the wound bed. CMS responded that the application codes already specify defined wound surface area amounts for purposes of reporting the applicable code making additional guidance unnecessary.[12]

Final Decision. CMS will pay $\$127.14/cm^2$ for all sheet form skin substitute products as proposed and separately for the non-add on G codes for applications of non-sheet skin substitutes.[13] Non-sheet skin substitutes will continue to be packaged.

D. 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) to encourage the development of domestically produced non-HEU molybdenum-99 (Mo-99). While CMS expected to end this additional payment at the end of 2025, it decided to continue this payment in 2026 for domestically produced Mo-99 to recognize the higher cost of this product produced domestically compared to purchasing it on the international market.

CMS did not make any proposals regarding this policy but noted two comments that it received—one supporting continuation of the policy and one opposed. CMS is not making any changes to this policy for 2027 based on these comments and will continue to provide an additional payment of $10 for domestically product Mo-99.

VI. Estimate of Transitional Pass-Through Spending

CMS estimates 2027 rule transitional pass-through payments of approximately $260.4 million, or 0.23 percent of total OPPS spending, which is less than the applicable transitional pass-through payment percentage statutory limit of 2.0 percent.

[12] The CPT codes for skin substitutes are for application of the skin substitute not the skin substitute itself and are "up to" a specific wound size such as 25 square centimeters or 100 square centimeters and not specific to the amount of product used.

[13] CMS shows a payment rate of $\$127.14/cm^2$ in Addendum B of the final rule but does not state whether the amount will be wage index adjusted and paid differently based on the location of the country where it is provided.

A. Devices

CMS estimates transitional pass-through spending of $248.40 million in 2026 for devices—$180.3 million for those recently eligible for transitional pass-through payments that will continue for 2027 and $67.7 million for those CMS knows or projects could be approved for 2027.

B. Drugs and Biologicals

CMS estimates transitional pass-through spending of $12.4 million in 2027 for drugs and biologicals—$2.4 million for those recently eligible for transitional pass-through payments that will continue for 2027 and $10 million for those CMS knows or projects could be approved in 2027.

VII. 340B Acquired Drug Related Issues

A. 340B Acquired Drugs Recoupment Adjustment

1. Background and History

CMS provides the regulatory and litigation history regarding its policy to pay for drugs acquired under the 340B program at ASP-22.5 percent rather than ASP+6 percent, its otherwise applicable default methodology. In summary:

- Beginning in 2018, CMS adopted a policy to pay for drugs acquired under the 340B program at ASP-22.5 percent to approximate a minimum average discount for 340B drugs based on findings of the Government Accountability Office and the Medicare Payment Advisory Commission (MedPAC) that hospitals acquire drugs at a significant discount under the 340B program. CMS made the reduction in payment for drugs acquired under the 340B program budget neutral by increasing payments for non-drug OPPS services by 3.19 percent or approximately $1.6 billion. This adjustment remained on the rates paid for non-drug OPPS services through September 27, 2022 and was not updated for changes to utilization of 340B drugs.
- On December 27, 2018, the U.S. District Court for the District Court of Columbia concluded that the Secretary lacked authority to bring the default rate in line with average acquisition cost.[14] While the initial decision applied only to CMS' 2018 policy, the District Court later made the same finding for CMS' 2019 policy.[15] The policy continued while CMS pursued its appeal.
- On June 15, 2022, the Supreme Court held that the Secretary could not vary payment rates for drugs and biologicals among groups of hospitals in the absence of having conducted a survey of hospitals' acquisition costs.[16]

[14] American Hospital Association v. Azar, 348 F. Supp. 3d 62 (D.D.C. 2018)
[15] Am. Hosp. Ass'n v. Azar, 385 F. Supp. 3d 1 (D.D.C. 2019)
[16] 142 S. Ct. 1896 (2022)

- On September 28, 2022, the District Court vacated CMS' 340B payment rate for the remainder of 2022 without requiring any offset for budget neutrality.[17] In response to this order, CMS changed its payment systems to make payment at ASP+6 percent for claims received shortly after the District Court's order with a date of service after September 27, 2022. Some of CMS' contractors allowed for reprocessing of *all* 2022 claims at the revised ASP+6 percent rate.
- On January 10, 2023, the District Court issued a remand to CMS giving it the opportunity to determine the proper remedy for the reduced payment amounts to 340B hospitals under the payment rates in the final OPPS rules for 2018 through 2022.[18]

Effective January 1, 2023, CMS is making payments for all 340B acquired drugs at ASP+6 percent. CMS made this policy budget neutral by applying a -3.09 percent adjustment to all non-drug OPPS rates.[19]

From January 1, 2018 through September 27, 2022, hospitals received $10.6 billion less in payment for 340B acquired drugs paid at ASP-22.5 percent relative to payment based on ASP+6 percent. CMS increased payments from January 1, 2018 through December 31, 2022 for non-drug OPPS services by an aggregate $7.8 billion. While the increase in non-drug OPPS services was intended as a budget neutral offset to the reduction in payment for 340B acquired drugs, it was a lesser amount because CMS did not update the budget neutrality adjustment after 2018 for increases in the utilization of 340B acquired drugs, despite repeated public comments asking the agency to do so. The two periods of time do not precisely align because the District Court vacated CMS' reduction to payment for 340B acquired drugs on September 27, 2022, but CMS could not accomplish rulemaking to adjust rates downward by 3.09 percent for non-drug OPPS services until January 1, 2023.

On November 8, 2023, CMS published a final rule[20] announcing its plan for applying a remedy to address the policy the Supreme Court found to be out of compliance with applicable law. In summary, CMS adopted policies to:

- Repay 340B hospitals for money owed from January 1, 2018, through September 27, 2022, through a lump sum payment less amounts already paid through claims reprocessing that occurred for services furnished between January 1, 2022, through September 27, 2022. These one-time lump sum payments were issued in early 2024.

- Provide the repayment amount to hospitals inclusive of any additional beneficiary coinsurance and not allowing hospitals to collect additional coinsurance.

- Maintain budget neutrality for these additional payments to 340B hospitals through a -0.5 percentage point adjustment to the annual OPPS payment rate update that applies to non-drug

[17] See Am. Hosp. Ass'n v. Becerra, 18-cv-2084 (RC), 2022 WL 4534617
[18] Am. Hospital Ass'n v. Becerra, 18-cv-2084 (RC), 2023 WL 143337
[19] See 87 FR 71975. The original adjustment multiplied the OPPS conversion factor by 1.0319 (3.19 percent). Reversing the adjustment requires dividing the OPPS conversion factor by 1.0319 or 1/1.0319 or 0.9691 which equals a reduction of 3.09 percent.
[20] 88 FR 77150

OPPS services beginning January 1, 2026, until such time as the full amount of the additional payment is recouped (estimated at the time to be 16 years).

Hospitals that enrolled in Medicare after January 1, 2018 and did not fully receive the benefit of the increase in payments for non-drug OPPS services are exempted from the 0.5 percentage point reduction to the OPPS update that began in 2026.

For 2026, CMS proposed to revise the 340B recoupment adjustment from a 0.5 percentage points reduction to the otherwise applicable OPPS update to 2.0 percentage points. With a shorter recoupment period, CMS believed the relative hospital utilization of non-drug items and services would more closely correlate to service utilization from 2018 through 2022. The more a hospital's utilization of non-drug items and services diverge, the less the hospital would be restored to as close as possible to the approximate financial position as they would have been in had the 340B drug policy never been implemented according to CMS in the 2026 OPPS rule.

By beginning the decrease to non-drug item and service payments in 2026, CMS argued there would already be an 8-year delay between the first year of the OPPS 340B payment policy and the first year of the prospective offset. In addition, CMS argued that some hospitals that received the benefit of the +3.19 percent adjustment for non-drug OPPS services may leave the market increasing the repayment burden on other hospitals. Further, CMS noted that $7.8 billion being recouped includes neither an adjustment for inflation nor interest costs.

CMS did not finalize its proposal in response to concerns brought forth by some commenters although did not explain why those concerns convinced CMS not to finalize its policy. Despite its disagreement with the commenters, CMS decided to delay the recoupment adjustment for one year indicating that hospitals should anticipate CMS making a larger adjustment beginning in 2027.

2. 2027 Prospective Adjustment

In the 2027 proposed rule, CMS proposed to increase the annual reduction to the update of the OPPS conversion factor from 0.5 percentage points to 3 percentage points effective January 1, 2027 excluding new providers with a CMS certification number (CCN) effective date of January 2, 2018, or later. CMS estimated this proposal will recoup $7.769 billion by the end of 2029. The proposed rule cited the following reasons for its proposal:

- The timeframe for recouping the additional 340B payments will be more closely aligned to the period during which these payments were made.
- A 3 percentage point payment reduction is the most logical and appropriate percentage to apply as it closely approximates the 3.19 percent payment increase hospitals received for non-drug items and services from 2018 through 2022.
- Hospitals were on notice in the 2026 OPPS rule that CMS planned to increase the reduction to the update from 0.5 percentage points to a higher amount beginning in 2027.

CMS presents the effects of a 3 percentage points reduction to the update relative to an alternative 2 percentage points reduction in Table 62 of the final rule reproduced below. The

proposed 3 percentage points reduction would fulfill CMS' goal of recouping the additional $7.769 billion over three years rather than five years as would occur with a 2 percentage points reduction.

Table 62: Illustration of Alternative Recoupment Reductions

	2024	2025	2026	2027	2028	2029	2030	2031
Total Applicable OPPS Non-Drug Item and Service Spending (millions)	Remedy Payments Made in Q1 of 2024	No Remedy Offset Applied	67.5	77.0	83.6	90.6	97.7	105.1
			Alternative 2 Percentage Point Payment Reduction					
Amount (millions)			300	1,500	1,700	1,800	2,000	500*
Estimated Total Cumulative Offset (millions)			300	1,800	3,500	5,300	7,300	7,679
			Proposed 3 Percentage Point Payment Reduction					
Amount (millions)			300	2,300	2,500	2,700		
Estimated Total Cumulative Offset (millions)			300	2,600	5,100	7,769		

Comments/Responses

Legal Arguments. Many commenters opposed making any recoupment adjustment at all, reiterating legal arguments made in past year rules. CMS did not summarize these legal arguments again in the final rule but disagreed with the commenters that it is not authorized by statute to pursue budget neutrality through a prospective recoupment adjustment to OPPS rates for additional 340B payments made in 2024. The rule directs readers to the final Remedy Rule (88 FR 77150 through 77194) for a complete discussion of these arguments.

Inconsistency with the IPPS Update. Commenters indicated that section 1833(t)(3)(C)(iv) of the Act requires the OPPS and IPPS to have the same update. As the recoupment adjustment will make the IPPS and OPPS update different, the commenters argue that CMS will not be following this provision of statute.

CMS responded that the commenter is fails to distinguish between the update and budget neutrality adjustments applied for system specific issues. The updates between the IPPS and the OPPS are same—3.2 percent less 0.9 percentage points for productivity —while the many

budget neutrality adjustments applied to the basic rate are different between the two systems. The 340B adjustment is a budget neutrality adjustment, not a factor in the annual update.

Differential Timing of the Budget Neutrality Adjustment. Several commenters argued that the statute does not allow for a budget neutrality adjustment at a different point in time than additional payment it is offsetting (described in the comment as "calibrat[ing] budget neutrality offsets based on temporal symmetry or administrative convenience"). CMS disagreed saying current utilization is a reasonable proxy for OPPS utilization for a hospital the closer in time it is to applying the offset but it becomes a less accurate proxy over time—the very reason that CMS is proposing to increase the adjustment and shorten the recoupment window.

Reliance Interests. Many commenters reiterated that when CMS finalized the 0.5 percent reduction in the final Remedy Rule, hospitals subsequently relied on that amount in good faith for three years in financial planning and making long-term investment decisions. CMS disagreed noting several statements made in the 2026 final rule placing hospitals on notice that it would be increasing the recoupment adjustment beginning in 2027.

Further, CMS indicates that it has changed hospital payments by over 3 percent annually several times since 2018 as part of applying or undoing the 340B payment policy. An additional 2.5 percentage point is typical of an annual payment rate change a hospital can reasonably expect. While CMS believes it has provided hospitals with more than adequate notice of the proposed increase in the recoupment percentage, CMS is finalizing a 2 percentage point reduction to the update rather than the proposed 3 percent reduction in recognition of hospital concerns about the burden of a larger reduction.

Changing a Previously Held Position without Explanation. Several commenters stated that CMS changed the criterion under which it is evaluating its recoupment policy. In the final Remedy Rule, CMS balanced its requirement to comply with statutory budget neutrality requirements with burden hospitals of reducing their rates. Now, CMS explains the rationale for accelerating the recoupment adjustment as restoring hospitals to the financial position they would have been in had the 340B Payment Policy not been implemented in 2018. CMS changed its evaluation criterion without any explanation or change in the underlying facts.

CMS responded citing several judicial precedents that it is not required to explain why it may have changed the criterion under which it is adopting a policy if it has a reasoned explanation for the policy it is adopting. Nevertheless, CMS continues to believe it is balancing between hospital burden and meeting its budget neutrality requirements while giving more weight to the latter for reasons explained in the rule.

Financial Burden: Many commenters stated CMS' proposal fails to appreciate the combined financial impact on hospitals of the recoupment adjustment, the reduction in payment for 340B acquired drugs, expansion of its site neutral policies and other factors reducing payment to hospitals. CMS responded that it recognizes the cumulative economic effect of the policies it has proposed but believes these effects must be balanced against the windfalls hospitals received previously that CMS is statutorily obligated to recover. The increased payment amounts first occurred in 2018, whereas the last of the recoupment amounts may not be until after 2031—in

effect a more than 10-year loan without any attached interest. The policy to reduce the recoupment adjustment from 3 to 2 percentage points was adopted specifically in consideration of this comment.

Impact on Hospitals Serving Vulnerable Communities. Multiple commenters expressed concern that the recoupment would reduce resources available to provide services to low-income, rural, underserved and vulnerable populations. CMS responded that future decreases are, on aggregate, the mirror image of prior payment increases that would otherwise be a windfall to providers. The response notes that allowing those payments to continue would have costs to beneficiaries through higher coinsurance and taxpayers through higher Medicare spending.

Adjustment Offsets the Statutory Update. Comments indicated that the proposed 3.0 percentage point reduction more than offsets the statutory update to OPPS rates. Like its response to a prior comment, CMS reiterates the distinction between a statutory update to OPPS rates that increases total payments and a budget neutrality adjustment that redistributes payment among services—in this case to offset increases in payment for 340B acquired drugs made in 2024.

Provider an Alternative Adjustment. Many commenters recognized CMS' statutory budget neutrality obligations but requested that CMS continue the current 0.5 percentage point adjustment, or adopt a lower one than 3.0 percentage points. CMS responded that it adopted a lower offset percentage in the final rule—2.0 percentage points instead of 3.0 percentage points.

Apply the Recoupment Adjustment to Selected Provider. Several commenters suggested that the recoupment adjustment only be applied to selected hospitals such non-340B hospitals, physician-owned hospitals, *et cetera*. CMS responded that the statute requires that it apply the recoupment adjustment to hospitals that received the increased payments for non-drug OPPS services.

Medicare Advantage (MA). Several commenters indicated that CMS has already finalized MA rates for 2027 based on a reduction in the OPPS payment update of 0.5 percentage points while the actual reduction will be 2.0 percentage points. This discrepancy will have the effect of creating a windfall to MA plans whose rates are based on the OPPS as they will apply a larger reduction in payments to providers than included in their rates.

There were also comments indicating that MA plans did not make the analogous payment under their contracts to the additional 340B payments made under the OPPS. However, as their payments from MA plans are made based on the OPPS, they expect MA plans to reduce their payments without having made the additional payments owed for 340B acquired drugs in past years.

CMS responded that contracts between MA plans and hospitals are private and not under CMS' authority. Section 1854(a)(6)(B)(iii) of the Act prohibits CMS from requiring an MA organization to contract with a particular hospital, physician, or other entity to furnish items and services, including 340B-acquired drugs, or requiring a particular price structure for payment under such a contract. Providers and MA organizations may engage in dispute resolution under

existing contracts and any contract negotiations or re-negotiations independently of CMS to address concerns raised by the commenters.

Final Decision: CMS is increasing the 340B recoupment adjustment from 0.5 percentage points in 2026 to 2.0 percentage points in 2027—1.0 percentage point less than the adjustment it proposed. Table 63 of the final rule reproduced below shows an estimate of the impacts of the offset for 2027.

TABLE 63
Illustrative Impact of a 2.0 Percentage Point 340B Recoupment Adjustment

	2024	2025	2026	2027	2028	2029	2030	2031
Total Applicable OPPS Non-Drug Item and Service Spending (millions)	Remedy Payments Made in Q1 of 2024	No Remedy Offset Applied	67.5	79.0	85.4	92.6	99.8	107.4
			Alternative 2 Percentage Point Payment Reduction					
Amount (millions)			300	1,600	1,700	1,900	2,000	300*
Estimated Total Cumulative Offset (millions)			300	1,900	3,600	5,500	7,500	7,769

* Note, the final year's offset is estimated to be less than 2 percent to meet the total estimated offset of $7.769 billion. The amounts illustrated in Table 63 reflect the total amount of reduced spending, which includes both Medicare and beneficiary cost-sharing. Note, the figures in the table are rounded, which may create some display discrepancies, but all figures are calculated with the final recoupment amount being $7.769 billion.

B. Payment for 340B Purchased Drugs

1. Background and History

Under section 1833(t)(14)(A)(iii) of the Act, CMS may either set payment rates for Part B drugs furnished in the hospital outpatient department based on a survey of hospital acquisition costs, or, if hospital acquisition costs are not available, default to the amount otherwise paid under various provisions of statute (generally section 1847A of the Act at ASP+6 percent).

In the 2026 OPPS rule, CMS indicated its intent to conduct a survey of the acquisition costs for each separately payable drug acquired by all hospitals paid under the OPPS from January 1, 2026 through March 31, 2026. CMS further indicated its intent to propose Part B drug payment policies based on this survey for setting 2027 OPPS rates.

2. Drug Acquisition Cost Survey Design and Implementation

CMS identified approximately 4,500 entities for inclusion in the survey study population. The survey collected acquisition cost data for separately payable outpatient drugs for 1,843 National

Drug Code (NDCs), which correspond to 519 drug HCPCS codes. The survey captured acquisition data for drugs purchased between July 1, 2024 and June 30, 2025. The 6-month lag between June 30, 2025 and the beginning of the survey period on January 1, 2026 allowed adequate time for all rebates, discounts, and price concessions to be incorporated into the NDC acquisition cost submitted by hospitals. The survey period closed on April 7, 2026.

Hospitals reported total units purchased, not net acquisition costs separately for 340B and non-340B acquired drugs. The survey asked hospitals to incorporate all rebates and discounts, including those directly applied to each individual NDC, those discounts not linked to a single NDC, and rebates received from membership in a Group Purchasing Organization (GPO) or other buying group.

3. Data Analysis and Methodology

CMS compared hospitals' survey-reported acquisition costs for all survey-eligible drugs to the equivalent ASP-based Medicare payment amount for those drugs under the OPPS, less any drug specific payment rate add-ons. This comparison was constructed as a percent difference between these two values, termed the acquisition cost margin.

The acquisition cost per unit was compared to the ASP payment rate per unit weighted by units reported in the survey by the hospital. CMS determined acquisition cost margin calculation separately for non-340B and 340B drug purchases using both the mean and median across four quarters of the data collection period. Margins were calculated at the NDC level and HCPCS level and stratified by therapeutic class and hospital characteristics.

CMS evaluated two different approaches for eliminating potential outliers and proposed to use the geometric mean approach of trimming records with per-unit acquisition costs more than three standard deviations from either the 340B or non-340B geometric mean per-unit acquisition cost for that NDC. This approach is consistent with standard OPPS outlier trimming methodology. It also ensures that CMS retains the maximum number of responses with nonextreme values to estimate acquisition cost relationships from the survey data.

In addition to eliminating potential outliers, CMS eliminated data:

- Where non-340B hospitals reported data in the 340B fields of the survey.
- For drugs that did not have a 340B ceiling price.
- Surveys where a sub-unit of a hospital reported identical data to its parent.
- Reported prices for 340B acquired drugs above the 340B ceiling price.
- Responses that reported units in international units or milligrams rather than the NDC-based units.

These exclusions resulted in deletion of 14,313 out of 160,430 records, leaving 91.1 percent of records retained or 146,717.

4. Survey Results

Approximately 43.6 percent of the 4,494 entities eligible for OPPS payment responded to the survey and 29.8 reported they had acquisition costs during the survey period. Before refining the population, approximately 34.9 percent of non-340B hospitals and approximately 23.1 percent of 340B hospitals responded to the survey and reported that they had acquisition costs for survey-eligible drugs during the surveyed period. Table 64 of the final rule provides descriptive survey statistics of these respondents.

CMS applied population refinements to consolidate subunits with their parent units and to remove entities from the survey that neither reported acquisition costs nor had outpatient billing volume for HCPCS codes corresponding to NDCs included in the survey during the specified period. Approximately 53.3 percent of non-340B hospitals and 28.6 percent of 340B hospitals in the refined population responded to the survey and reported that they had acquisition costs during the surveyed study period (Table 65).

Compared to the overall survey-eligible population, hospitals that responded to the survey and reported acquisition cost data were slightly more likely to have lower claims billing volume, be smaller, in a rural area, and not major teaching hospitals. Table 66 provides a comparison between respondents and non-respondents in the refined population.

CMS found that 340B hospitals' reported acquisition costs were approximately 33.4 percent below both the mean and the median ASP. Other hospitals' reported acquisition costs were 2.7 percent above the mean ASP and 2.8 percent above the median ASP. CMS validated these results by comparing them to aggregate 340B ceiling prices from the Health Resources and Services Administration (HRSA), the HHS agency that administers the 340B program. Based on this analysis, during the survey study period 340B ceiling prices were, in aggregate, 28.0 percent below the mean ASP and 29.2 percent below the median ASP, respectively. CMS notes that these findings generally validate the survey results and further states that hospitals can negotiate additional discounts that explain the difference between the survey results and the data from HRSA.

The proposed rule analyzed the alternative of weighting using OPPS claims volumes rather than from the survey. This alternative produced a largely consistent result with acquisition costs between approximately 29.9 percent and 33.4 percent below the average ASP and between 29.8 percent and 33.4 percent below the median ASP.

Hospitals' survey-reported 340B acquisition costs were at least 28.9 percent below the mean ASP—and for most therapeutic classes lower than that—for drugs in all high-spending therapeutic classes (that is, those with more than $100 million in reported acquisition costs). The margins for non-340B drugs displayed greater variation relative to the 340B drugs, which is likely attributable to greater heterogeneity in drug mix, provider type, and purchasing arrangements present outside the 340B Program.

CMS undertook various statistical methodologies demonstrating the response rate was sufficient to be statistically valid and respondents' data yielded statistically representative estimates of

hospital outpatient drug acquisition costs. These methodologies are described in complete detail in the *2026 Outpatient Prospective Payment System Drug Acquisition Cost Survey Technical Report* to be posted on the CMS OPPS website: https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/outpatient-prospective-payment-system-opps-drug-acquisition-cost-survey.

Comments/Responses

Response Rates. Many commenters contended that the response rate, especially from 340B hospitals, does not meet section 1833(t)(14)(D)(iii) of the Act's statutory threshold of a "large sample of hospitals" and is therefore too low to justify the proposed policy change. These commenters asserted that the low response rate calls into question the representativeness and comparability of the 340B and non-340B respondent populations.

CMS responded that the statute does not define "large sample of hospitals" but indicated that it undertook statistical techniques ("confidence intervals" (CI) and "inverse probability weighting" IPW) to validate the representativeness of the respondents. The IPW adjustment and calculation of CIs indicated that the response rate yielded sufficiently precise estimates of hospitals' acquisition costs as the results changed little from making these adjustments that are intended to test for representativeness of the responds relative to the survey population.

Representativeness. Many commenters noted slight differences in the composition of the respondent population and overall population of survey-eligible hospitals, suggesting a lack of representativeness among major teaching hospitals, rural hospitals, and high-volume purchasers or requested more information about responsiveness among these or other groups.

CMS responded that it previously published results that evaluated data representativeness along many of the hospital characteristics mentioned by commenters. The final rule acknowledges slight differences among the characteristics of the respondent population and the overall survey-eligible population but applied the IPW too account for under- or overrepresentation of particular hospital characteristics among respondents. As noted above, this adjustment did not significantly change the survey results.

The response further indicates that for drugs acquired outside the 340B Program, hospitals' survey-reported acquisition costs were 2.7 percent above the mean ASP before IPW adjustment and 2.8 percent above the mean ASP after IPW adjustment. For drugs acquired through the 340B Program, hospitals' survey-reported acquisition costs were 33.4 percent below the mean ASP before IPW adjustment and 33.1 percent below the mean ASP after IPW adjustment. The consistency between unadjusted and IPW-adjusted results supports the robustness and representativeness of the acquisition cost margins derived from survey responses according to CMS. Table 67 of the final rule illustrates these findings.

Statistical Adjustments. Many commenters raised concerns that the IPW adjustment can address how the survey results are affected by observable factors but cannot account for how the likelihood of survey response and drug acquisition costs are influenced by unobservable factors. CMS responded that the consistency of proxy drug acquisition costs among respondents and nonrespondents supports the conclusion that respondents are representative of the eligible

hospital population in terms of acquisition cost. The response described other statistical techniques that CMS applied to validate this conclusion.

Survey Findings. Some commenters cited other factors that could explain the differences (such as large hospitals could access bulk purchasing discounts) between hospitals that explain the survey results showing lower costs for some hospitals than others. CMS responded that the results show little variation based on all measured hospital characteristics regardless of stratification. Hospital acquisition cost margins for 340B drugs range from 30.4 percent to 39.7 percent below the mean ASP and 30.3 percent to 39.6 percent below the median ASP. Table 70 shows these findings.

Applying a Variable Offset Rather than a Single Uniform One. Several commenters discussed concerns regarding variation in acquisition costs by individual drug and/or therapeutic class, pointing out that a single adjustment to ASP may lead to underpayment for certain drugs and overpayment for others. CMS responded that it would not be practical to calculate a drug-specific offset. Using an average is not unique to 340B-acquired drugs. The OPPS is a prospective payment system. Payment for an individual item or service may be more or less than a hospital's cost in any specific case.

Other comments suggested CMS does not have the statutory authority to provide add-on or offset to ASP when basing payment on a survey. CMS responded that while the statute indicates that data should be collected for specific drugs, it is not prescriptive regarding how that data should ultimately be used to set payment rates.[21]

Weighting Methodology. Some commenters requested that CMS weight the results by OPPS claims volume rather than the total number of NDC units reported by survey respondents. CMS responded that drug survey captures all outpatient drug purchases, making weighting by survey volume necessary for internal consistency. Volume-weighting by OPPS claims only reflects Medicare FFS drug utilization.

Outlier Trimming. Commenters requested more information on outlier trimming and questioned how the trimmed providers affected the results. CMS responded that its outlier methodology was consistent with how it identifies outliers in other circumstances, most of the observations removed were from non-340B hospitals. Removing outliers resulted in 340B hospital drug acquisition costs being higher, not lower.

Penny Pricing. Some commenters raised concerns that "penny pricing"—where the ceiling price is only $0.01—could skew the acquisition cost downward. CMS responded that there were very observations reporting penny pricing. These observations had minimal impact on the results.

Other Data Issues. Some commenters indicated that inconsistency in how price concessions are reported will complicate the comparison of results. CMS acknowledged this point but indicated that any approach to address this issue would have lowered the acquisition costs further. Others indicated that because CMS had to exclude data, it evidences that the data was of low quality.

[21] Section 1833(t)(14)(A)(iii)(I) states that payment shall be equal "to the *average* acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group…taking into account the hospital acquisition cost survey data…"

CMS responded that very few observations met all the criteria to be excluded from the results.

5. 2027 OPPS Payment Methodology for 340B Purchased Drugs Based on Survey Results

CMS found that the results definitively indicate that average acquisition costs for 340B acquired drugs are significantly below a payment rate of ASP+6 percent. For non-340B drugs, the discrepancy is not as clear and significant as with 340B drugs. Based on the results of the drug acquisition cost survey, in the OPPS/ASC proposed rule for 2027, CMS proposed to pay for 340B acquired drugs at ASP-33.4 percent and maintain the ASP+6 percent payment rate for all other drugs.

The proposed rule indicated a survey conducted under section 1833(t)(14)(D)(i) and (ii) of the Act must "have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug." CMS explained how the survey results meet this requirement. In addition, CMS cited its legal authority under section 1833(t)(14)(A)(iii)(I) of the Act to vary payments by hospital group considering a hospital cost acquisition survey.

For 340B acquired drugs that do not have an ASP, CMS proposed to establish a parallel policy as all other drugs that do not have an ASP pricing them using WAC minus 33.4 percent and 59.69[22] percent of AWP if WAC is unavailable. For 340B drugs paid based on mean unit cost (MUC), CMS proposed to continue payment based on 100 percent of MUC that will already reflect any 340B discounts.

CMS proposed not to apply the 340B payment policy to vaccines, drugs with transitional pass-through payment status, and non-opioid pain management drugs. CMS may continue to validate the results of this survey on a periodic basis; for example, perhaps as often as every four years.

Comments/Responses

General. Many commenters supported CMS' proposal that Medicare's payment for drugs should more closely approximate hospital acquisition costs. Other comments were critical of the 340B program. CMS appreciated the support for its proposals and indicated that comments related to the 340B program were outside the scope of the proposed rule.

Coordinated Survey Response. In the proposed rule, CMS indicated that there was a coordinated effort among 340B hospitals not to be responsive to the drug cost survey. Several commenters objected to this statement saying that CMS did not present evidence to support this statement.

CMS emphatically disagreed with the comment that there was no evidence of a coordinated effort to be unresponsive to the survey. The response indicates that CMS received hundreds of nearly identical letters in response to its 340B survey providing evidence of such a coordinated

[22] This percent was calculated by first reducing the original 95 percent of AWP price by 6 percent to generate a value that is analogous to WAC with no percentage markup. Then CMS applied the 33.4 percent reduction WAC analogous AWP value to obtain the 59.69 percent of AWP.

response. The final rule further documented excerpts of letters from law firms advising hospitals not to be responsive to the survey.

The final rule also reveals a strong disagreement between hospital associations and CMS on whether hospitals were required to respond to the survey. CMS indicates that it advised hospitals of their obligation to respond to the survey in several documents. However, hospital associations advised their members that CMS was incorrect in telling them that they were required to respond to the survey.[23] CMS' response expresses frustration with hospital associations' criticisms of the response rate to the survey when it was these organizations advising their members not respond.

Ability to Support Low-Income Populations. Many commenters stated that the payment reductions would threaten their ability to continue providing services to vulnerable patients. These commenters indicated that CMS' policy indirectly subsidizes for-profit hospitals inconsistent with the statutory intent of the 340B program to stretch scarce Federal resources to provide services to low-income and uninsured patients.

CMS disagreed with this comment and notes that its policy will more directly benefit Medicare beneficiaries by lowering their coinsurance obligation for 340B acquired drugs rather than through drug discounts provided to the hospital. Further, CMS is fulfilling its statutory obligation to periodically conduct a survey of hospital acquisition costs and use the resulting data to inform payment rates.

Transition. Comment: Many commenters urged CMS to delay or phase-in implementation of the proposal. CMS responded that the payment misalignment that its policy will address has been in effect for many years and it is important to implement this policy now that it has conducted the required survey and have data clearly demonstrating that the existing payment rate for 340B-acquired drugs is not a representative proxy for the cost of their acquisition.

Other Payers. Many commenters indicated that Medicaid, commercial payers and MA will adopt CMS' policies magnifying the reduction in payment for 340B acquired drugs. CMS responded that what other payers may or may not do in the future would not be a valid reason for CMS to refrain from better aligning OPPS payment for 340B-acquired drugs with their acquisition costs.

Lack of Authority to Vary Payment for 340B Status. Many commenters stated that CMS lacks the authority to vary payments to hospitals based on its qualifications to be in the 340B drug discount program. 340B Program participation determinations made by HRSA and not CMS and are irrelevant to Medicare program considerations.

CMS disagreed indicating that the statute authorizes the Secretary to establish OPPS payment rates for drugs based on

[23] HPA's review of the statute indicates that section 1833(t)(14)(D)(ii) explicitly authorizes the Secretary to undertake a survey of hospital acquisition costs for 340B drugs but does not address hospitals' obligation to respond to such a survey.

> average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics).

The statute gives the Secretary broad authority to determine how to vary payment by hospital group.

ASP-28 percent. Some commenters supported the alternative proposal to set OPPS payment for 340B-acquired drugs at ASP minus 28.0 percent based on 340B ceiling price data because an approach grounded in objective, regularly updated ceiling price data would be less disruptive than the survey-based methodology. CMS agreed and noted that hospitals' survey-reported 340B acquisition costs were at least 28.9 percent below the mean ASP for drugs in all therapeutic classes with more than $100 million in reported acquisition costs.

Several commenters opposed this alternative stating that ASP-28 percent would not be based on the results of the survey but a ceiling price established by another Federal agency, as well as not being consistent with the Supreme Court decision that forecloses CMS from setting payment rate for 340B acquired drugs based on "subjective measures." CMS disagreed, stating that the statute require it to "take into account" the hospital acquisition survey, not require CMS to set the rates based on that survey.

Add-On Payment. CMS did not propose an add-on payment analogous to the 6 percent add-on to ASP, and instead indicated that the ASP-33.4 percent represents the average acquisition costs for 340B acquired drugs. Many commenters requested that CMS provide an add-on analogous to the 6 percent add-on to ASP for a variety of different costs that hospitals have associated with providing pharmaceutical services.

CMS acknowledged the many costs that are associated with the delivery of a drug but believes many of the costs mentioned by commenters are hospitals' and health care facilities' standard operating costs, and are not necessarily related to the cost of the drug. Further, CMS' finalizing the alternative ASP minus 28 percent payment rate is a conservative average acquisition cost making it unnecessary to provide an add-on.

Applicability. Specified covered outpatient drugs (SCODs) are a more circumscribed set of Part B drugs and biologicals paid under the OPPS. CMS' longstanding drug and biological payment policies under section 1833(t)(14) of the Act have applied to SCODs and drugs and biologicals that are not SCODs. Several commenters indicated that CMS lacks the statutory authority to apply the 340B differential to drugs that do not meet the definition of SCODs. CMS disagreed stating that if it was determined that its statutory authority was determined not to apply to SCODS, it would continue to apply its 340B policy to non-SCODs and vice versa.[24]

[24] CMS' response here is stated almost verbatim from the final rule and suggests the agency would continue to apply its 340B policies to either SCOD or non-SCODs if the policy was struck down by a Court for one or the other. However, CMS longstanding drug payment policies have not differentiated between separately payable drugs that are SCODs and those that are not SCODs. The response does not appear to answer the specific issue raised by the commenter but prior litigation on CMS' 340B policy did not distinguish between SCODs and other separately payable drugs.

Pass-Through Drugs and Biologicals. A commenter expressed concern about exempting pass-through drugs and biologicals from the 340B payment policy arguing that the exemption provides a strong incentive to use drugs on pass-through rather than other drugs subject to the 340B payment policy. CMS responded that it will consider how to address this policy issue in the future. However, the response notes that dispensing or furnishing drugs solely to take advantage of differences in reimbursement structures, rather than based on the patient's medical needs, may raise concerns under applicable federal fraud and abuse laws.

Revalidating the Survey. All commenters said CMS should periodically repeat or otherwise validate the survey so that the adjustment reflects changes in purchasing patterns, discounts, and the composition of the 340B market rather than allowing a one-time estimate to become a permanent payment convention. CMS responded with concerns about the administrative burden of an annual survey on hospitals but believes that now that the survey infrastructure exists, the marginal burden of a repeat administration is materially lower than the burden of conducting the survey the first time.

6. Beneficiary Coinsurance

CMS describes the interaction between its proposal and a statutory policy that requires drug manufacturers to provide Medicare with a rebate if the price of its drug increases faster than inflation known as a "rebatable drug." Beneficiary coinsurance for a rebatable drug will be based on the inflation adjusted amount rather than the higher ASP price. In the case of drugs acquired under the 340B program, CMS proposed the coinsurance provisions for rebatable drugs will not apply as CMS expects that the applicable coinsurance under the 340B-acquired drugs proposal will be lower than 20 percent of such inflation-adjusted payment amount.

CMS anticipates that its proposed policy to pay for separately paid drugs acquired under the 340B Program at ASP minus 33.4 percent will collectively reduce beneficiary copayments by an estimated $1.15 billion for 2027 although this savings will be offset by a budget neutrality adjustment on all non-drug OPPS services.

Comments/Responses

Commenters disputed CMS' emphasis on the beneficiary savings associated with lower coinsurance for Part B drugs at 340B hospitals as those savings will be offset by higher coinsurance on non-drug OPPS services. The policy will be redistributive among beneficiaries, not a savings. Further, many beneficiaries have supplemental insurance to Medicare. The insurance plans that will realize savings from lower coinsurance on Part B drugs, not the beneficiary.

CMS responded that from an individual beneficiary experience, the reduced payment for 340B drugs will be substantial and noticeable. Further, there will be an overall net savings to beneficiaries as the 340B policy does not require budget neutrality in non-excepted, off-campus PBDs. To the extent Medicare is lowering coinsurance, beneficiaries would still benefit from lowering the cost of supplemental plan coverage. Further, millions of Medicare beneficiaries do

not have supplemental coverage at all or covers all a beneficiary's cost-sharing obligation. The proposed policy would directly lower out-of-pocket spending on 340B-acquired drugs for these beneficiaries.

CMS expects that its final rule policy of paying for 340B acquired drugs under the OPPS at ASP-28 percent will collectively reduce beneficiary copayments for drugs by an estimated $1.1 billion for 2027.

7. 340B Payment Policy Exemptions

CMS proposed to exempt children's hospitals and PPS-exempt cancer hospitals from the 340B acquired drugs policy. As these hospitals are held harmless under the OPPS to their "pre-BBA" payments and receive hold harmless payments known as "transitional outpatient payments" (TOPS), the reduction in payment for 340B acquired drugs would be replaced by TOPS. CMS also proposed to exempt rural SCHs from the policy to recognize unique needs and financial challenges these hospitals face (including SCHs that are geographically urban but treated as rural for purposes of the IPPS).

Comments/Responses

Public commenters universally supported the exemption for rural SCHs and children's hospitals. Nearly all commenters supported exempting PPS-exempt cancer centers.

The one commenter opposed to PPS-exempt cancer hospital exemption acknowledged CMS' point about TOPS but argued that the proposed exemption would allow qualifying cancer hospitals to continue receiving ASP+6 percent even when the hospital's acquisition cost is substantially below ASP. Such a distinction would undermine CMS's objectives of aligning payment with acquisition cost, reducing inappropriate payment differentials, and reducing beneficiary cost sharing. CMS disagreed with this comment indicating that because of TOPS, any reduction to drug payments made on a per claim basis would be returned to these hospitals at cost report settlement.[25]

Many commenters requested CMS to provide exemptions for additional hospital types and services such as rural safety-net providers, all SCHs (not just rural ones), all rural hospitals, Medicare Dependent Hospitals, Low Volume Hospitals, disproportionate share hospitals, hospitals in health professional shortage areas among others. CMS responded that the exemptions it proposed are justified by the very specific circumstances of the hospital types proposed to be exempted. No additional exemptions are being adopted for the final rule.

8. Non-Excepted Off-Campus Provider-Based Departments

Non-excepted off campus provider-based departments (PBDs) are those hospital outpatient

[25] CMS' response is true with respect to total payments by Medicare to the PPS-exempt cancer hospitals. However, as there is no coinsurance associated with TOPS, the beneficiary would realize coinsurance saving that would be transferred to Medicare as a program cost through TOPS if PPS-exempt cancer hospitals were subject to the 340B policy.

departments that are off the campus of the main hospital and have opened since November 2, 2015. These departments are not paid under the OPPS. They are paid at 40 percent of the OPPS and ASP+6 percent for drugs (or WAC+6 percent or 95 percent of where ASP is unavailable).

While the statutory authority for CMS' 340B policy applies to the OPPS, CMS indicates that it has broad authority for setting payment rates in non-excepted off-campus provider-based departments under section 1833(t)(21) of the Act. To avoid perverse incentives that would result from paying non-excepted off-campus PBDs more for 340B acquired drugs than other hospital outpatient services, CMS proposed to pay ASP-33.4 percent, or equivalent, for drugs, biologicals, biosimilars, and radiopharmaceuticals acquired under the 340B Program in these sites.

As non-excepted off campus PBDs are not paid under the OPPS, this proposal would not be subject to the OPPS budget neutrality requirements. CMS estimated that this aspect of its proposal would result in savings of approximately $735 million to Medicare and reduce beneficiary coinsurance by an estimated $185 million.

Comments/Responses

There were comments that support applying the 340B policy in non-excepted off-campus provider-based department on the same basis that CMS used to justify its proposal. Several comments reiterated prior comments on the same policy in the 2019 OPPS rule arguing that CMS lacks the authority under 1833(t)(21)(C) of the Act to adjust drug payments to nonexcepted off-campus PBDs or to do so in a non-budget neutral manner. CMS directed readers to its responses on these comments in the 2019 OPPS final rule at 83 FR 59020 through 59022.

A commenter indicated that CMS provided no empirical evidence for its conclusion that not applying the reduction to nonexcepted off-campus PBDs could result in patients being directed there to avoid a lower payment in an excepted off-campus PBD. CMS responded that it is reasonable to assume that if an entity can furnish a drug in one setting and receive significantly more (nearly 40 percent) payment for the drug then it would receive furnishing the same drug in a different setting, that there exists an incentive for the entity to provide the drug in the setting in which they would receive the higher payment.

CMS estimates that applying the 340B payment policy in non-excepted off-campus PBDs will result in savings of approximately $640 million to the Medicare Part B Trust Fund and would collectively reduce beneficiary copayments by an estimated $160 million in 2027.

9. Billing Modifiers

Consistent with its prior and current policy regarding billing for 340B acquired drugs, CMS proposed to require hospitals subject to the 340B payment policy to use the JG modifier to indicate the drug was acquired under the 340B program and is subject to a payment of ASP-33.4 percent. For providers and drugs exempted from the 340B payment policy but acquired under the 340B program, CMS proposed that hospitals continue to use the TB modifier. Beginning January 1, 2027, CMS proposed to require a new modifier to be specified (placeholder modifier "XX" -

Drug or biological not acquired under the 340B Drug Pricing Program) to be reported on a claim for all separately payable drugs that were purchased outside of the 340B Program.

CMS proposed that one of these three modifiers would be required by all providers paid under the OPPS as well non-excepted off-campus providers not paid under the OPPS. The TB modifier and "XX" modifier would not trigger a payment reduction under CMS' 340B payment policy.

The proposed rule noted that CMS excludes separately payable billing units in claim lines for institutional claims that are billed with the "TB" modifier for claims with dates of service on or after January 1, 2025 from Part B rebate calculations under the inflation rebate program described above. Effective January 1, 2027, CMS proposed a conforming change to the applicable regulations to reflect the change in its modifier policies.

Comments/Responses

Several commenters supported CMS' proposal. Other commenters suggested uses for the modifiers beyond those stated by CMS in the proposed rule such as to annually recalculate the OPPS budget-neutrality adjustment factor, require the modifiers on Part D and Medicare Advantage claims and all drugs, not just those that are separately payable. CMS will consider these comments in future rulemaking.

Many commenters opposed the proposal as being administratively burdensome because of the costs associated with adapting their electronic health record and billing systems and training staff. These commenters requested an effective date later than January 1, 2027 to allow for these activities to occur. There were comments indicating that modifier XX is unnecessary and duplicative as a drug without a modifier means it is not acquired under the 340B program.

CMS responded that its proposed policy does not require the provider to obtain any additional information that it does not already have. Further, hospitals have been on notice since July 7, 2026 (the date of proposed rule display) that CMS was considering establishing a new modifier for non-340B drugs and will have until January 1, 2027 for the policy to be effective and up to a year after the date of service to submit a claim.

10. <u>OPPS Drug Payment Methodology for Non-340B-Acquired Drugs</u>

CMS estimates that hospitals' acquisition costs for non-340B drugs were approximately 2.7 percent above ASP during the survey period. However, the survey may not fully reflect all manufacturer rebates, chargebacks, administrative fees, or other post purchase price concessions received by hospitals because of the large variety of ways price concessions could be reported. Therefore, ASP+ 2.7 percent may overstate hospitals' net acquisition costs.

In addition, the survey results for non-340B drugs exhibit greater variation than the survey results for 340B-acquired drugs. Consequently, CMS believes the survey data should be interpreted further before applying a payment rate change for non-340B drugs. For this reason, CMS proposed to continue paying separately payable non-340B drugs, biologicals, biosimilars, and radiopharmaceuticals at ASP+6 percent.

Comments/Responses

Some commenters asserted that CMS should apply the survey results for other hospital groups—not just 340B hospitals. CMS responded that the acquisition cost margin calculated for non-340B drugs of ASP plus 2.7 percent was only slightly below the existing ASP plus 6 percent payment rate. The data are not conclusive enough for CMS to take policy action at this time on non-340B-acquired drugs.

11. Budget Neutrality

CMS estimated that its proposal will reduce payment for 340B acquired drugs by approximately $4.85 billion in 2027. To maintain budget neutrality for this reduction in payments, CMS proposed an 8.44 percent increase to the OPPS conversion factor for 2027.

If CMS were to adopt an alternative methodology to pay 340B acquired drugs at ASP-28 percent based on average acquisition cost calculated from the 340B ceiling prices and volume weighted by OPPS utilization data, CMS estimated OPPS payment for 340B acquired drugs would be reduced by approximately $4.68 billion in 2027. In this circumstance, CMS estimates that a proposed increase to the conversion factor of 8.14 percent would be needed to maintain budget neutrality for 2027.

Comments/Responses

Many commenters supported CMS' budget neutrality adjustment but oppose increasing beneficiary copayments for non-drug items and services and increasing the difference in payment rates between hospital and office settings. There were comments to recalculate the budget-neutrality adjustment annually unlike what CMS did with its prior 340B policy between 2018 and 2022 when the budget neutrality adjustment did not reflect the reductions in drug payments based on claims. CMS will consider recalculating the budget-neutrality adjustment on an annual basis for future rulemaking.

Several commenters requested that CMS focus the increase in payments for non-drug OPPS services on selected hospital types or those that have missions consistent with 340B Program. Other commenters indicated that CMS should apply budget neutrality at the hospital level to ensure that the policy does not result in payment losses for an individual hospital. CMS responded that 340B drug payment policy is not designed to replace the 340B program. It acknowledges that some hospitals will potentially experience revenue losses under its policy but that is a consequence of better recognizing hospital costs associated with administering Part B drugs acquired under the 340B program.

Many commenters requested that CMS conduct additional analyses and provide information relating to budget neutrality. CMS responded that the payment impact files on the OPPS website include all information requested by the commenters.

CMS estimates that OPPS payment for 340B-acquired drugs will be reduced by approximately $4.65 billion in 2027 because of its policy. When factoring in the finalized policy for 340B drug

payment in non-excepted PBDs, the total estimated reduction in 340B drug spending is $5.45 billion for 2027, which includes both Medicare and beneficiary payments

12. Final Decision

CMS is finalizing the following policies effective January 1, 2027:

- Pay for 340B acquired drugs at ASP-28 percent rather than ASP-33.4 percent.
- Pay drugs acquired outside of the 340B program at ASP+6 percent.
- Exempt rural SCHs, PPS-exempt cancer hospitals and children's hospitals from the 340B payment policy.
- Hospitals paid under the OPPS, other than a type of hospital excluded from the OPPS (such as CAHs or REHs), are required to report modifier "JG" on the same claim line as the HCPCS code for a drug acquired under the 340B Program.
- Hospitals are required to report modifier "TB" for all pass-through drugs, non-opioid treatment for pain relief drugs exempt from the 340B payment policy but acquired under the 340B Program.
- Rural SCHs, children's hospitals and PPS-exempt cancer hospitals are required to report modifier "TB" for drug acquired under the 340B program.
- Hospitals are required to report modifier "XX" (finalized as "ND") for all drugs that are not acquired through the 340B Program.
- All the above policies apply to both excepted and non-excepted off-campus PBDs of a hospital.

VIII. Hospital Outpatient Visits and Critical Care Services

CMS is not proposing for 2027 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. The agency also is not proposing any changes to its policy for how it pays for clinic visits provided in off-campus provider-based departments. As discussed in section XI.A., CMS points to its authority to control unnecessary increases in the volume of covered OPD services under section 1833(t)(2)(F) of the Act to expand its site neutral payment policy to imaging services without contrast furnished in an off-campus provider-based department.

IX. Partial Hospitalization Program (PHP) Services

A. Background

1. Partial Hospitalization

A partial hospitalization program (PHP) is an intensive outpatient program of psychiatric services provided as an alternative to inpatient psychiatric care for individuals who have an acute mental illness, which includes conditions such as depression, schizophrenia, and substance use disorders (SUD). CMS describes the evolution of its payment policies for PHP services. In past rulemaking, 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 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. However, it noted 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.

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.

In the 2026 OPPS/ASC final rule with comment period (90 FR 53770 through 53780), CMS modified the payment rate methodology for calculation of CMHC costs for PHP. Specifically, it applied the 40 percent MPFS Relativity Adjuster to the hospital-based PHP costs to determine the CMHC costs for PHP.

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 disorder. However, an IOP is considered to be less intensive than a PHP.

In the 2024 OPPS/ASC final rule, 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.

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.

For IOPs provided by an OTP, CMS established a payment adjustment based on three times the payment rate for APC 5861 beginning in 2024. Payment amounts for OTP intensive outpatient services are geographically adjusted using the Geographic Adjustment Factor (GAF) and are updated annually using the Medicare Economic Index; however, payment rates for IOP provided in the OTP setting are updated as part of the OTP fee schedule and are not addressed in this rule.

In the 2026 OPPS/ASC final rule (90 FR 53770 through 53780), CMS applied the 40 percent MPFS Relativity Adjuster to the hospital-based IOP costs to determine the CMHC costs for IOP.

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 is the level of intensity. To differentiate between IOP and PHP for billing purposes, CMS requires hospitals and CMHCs to report condition code 92 on IOP claims; hospitals and CMHCs report condition code 41 on their PHP 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.

[26] The 2027 payment policies for IOP services furnished by FQHCs and RHCs are in the 2027 Physician Fee Schedule final rule.
[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-and-guidance/guidance/manuals/downloads/clm104c04.pdf.

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

C. **Payment Rates for PHP and IOP**

For 2027, CMS proposed maintaining the current payment rate methodology that is used for calculating PHP and IOP payment rates for hospital-based providers.

In the 2026 OPPS/ASC final rule (90 FR 53775 and 53776), CMS first established its policy of applying the 40 percent MPFS Relativity Adjuster to calculate PHP and IOP payment rates for CMHCs. It proposed to continue using this methodology for 2027. Thus, CMS would multiply the 2027 rates established for the hospital-based PHP and IOP APCs by 0.4 to calculate the payment rates for the CMHC PHP and IOP APCs.

Final Action. The proposals are finalized without modification.

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

In the 2024 and 2025 final rules, CMS stated that because IOPs are a new benefit category and they furnish the same types of services as PHP, albeit at a lower intensity, it was appropriate to use the same data and methodology for calculating payment rates for both PHP and IOP. Thus, CMS applied the same per diem rates for IOP and PHP services, and it continues that policy for 2027. However, it notes that if future data analysis supports calculating rates independently, it may do so.

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.

CMS calculated the 2026 geometric mean per diem cost for CMHC PHP and IOP providers for the 2026 OPPS/ASC proposed rule using its previous methodology, which resulted in an inversion. The agency believed the inversion was due to the small number of CMHCs that bill

Medicare for PHP and IOP services and to CMHCs with low costs that first began billing Medicare for services in 2024. As noted above, CMS changed its methodology for CMHCs to address the inversion and calculated the 2026 geometric mean per diem costs for those facilities based on 40 percent of the corresponding hospital-based PHP and IOP APCs. It believes that the use of the 40 percent MPFS Relativity Adjuster is generally appropriate for estimating CMHC costs and notes that using the adjuster aligns with the methodology applied to other nonexcepted OPPS services furnished by nonexcepted off-campus hospital outpatient departments.

2. 2027 Payment Rate Methodology for PHP and IOP

CMS uses 2025 claims data and the latest available cost information from cost reports beginning three fiscal years before the year that is the subject of the rulemaking to update the payment rates for the four PHP APCs and the four IOP APCs.

Hospital-based PHP payment rates for 3 services per day and 4 services per day are calculated based on the geometric mean costs 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 results in more precise calculations. It also sets 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 final 2027 geometric mean per diem costs and payment rates are as follows:

2027 APC	Group Title	PHP and IOP APC Geometric Mean Per Diem Costs*	Payment Rates**
5851	Intensive Outpatient (3 services per day) for CMHCs	$123.94	$131.81
5852	Intensive Outpatient (4 or more services per day) for CMHCs	$202.96	$215.86
5853	Partial Hospitalization (3 services per day) for CMHCs	$123.94	$131.81
5854	Partial Hospitalization (4 or more services per day) for CMHCs	$202.96	$215.86
5861	Intensive Outpatient (3 services per day) for hospital-based IOPs	$309.85	$329.53
5862	Intensive Outpatient (4 or more services per day) for hospital-based IOPs	$507.39	$539.62
5863	Partial Hospitalization (3 per day) for hospital-based PHPs	$309.85	$329.53
5864	Partial Hospitalization (4 or more services per day) for hospital-based PHPs	$507.39	$539.62

* Table 78 in the final rule shows the 2027 PHP and IOP APC geometric mean per diem costs.
** The 2027 payment rates are from Addendum A to the final rule.

Comments/Responses. Some commenters have repeatedly stated over the years that CMHC cost estimates do not reflect the actual costs of providing PHP and IOP in CMHCs and that the resources involved are comparable to those required for hospital-based programs. They also believe higher hospital payment rates create arbitrary incentives for PHP and IOP services to be provided in settings other than CMHCs. CMS responds that it has regularly observed significant cost differences between CMHCs and hospital-based programs and denies the payment differential creates any incentives for services to be furnished in other settings. The agency has also observed sustained increases in the number of Medicare PHP and IOP days billed by CMHCs. Some of these same commenters argued that the 40 percent methodology for determining CMHC rates is arbitrary and capricious under the Administrative Procedure Act because the data is inadequate to support the rate. CMS disagrees, noting that it tested the 40 percent adjuster against several years of CMHC and hospital cost data, effectively increasing the CMHC dataset by adding years of cost reports, examining the ratio of CMHC costs to hospital costs per year, and taking an average to smooth out anomalies. It concluded that the 40 percent MPFS Relativity Adjuster provides stability and accuracy for CMHC rates.

D. Outlier Policy for CMHCs

For 2027, 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. No changes were proposed to any of the methodologies used for purposes of the outlier policy for CMHCs for 2027.

The methodology for calculating the CMHC outlier percentage was first established in the 2018 OPPS/ASC final rule (82 FR 59267), and it will be applied to payments for IOP services as well as PHP services for 2027. CMS projects that CMHCs will receive 0.01 percent of total hospital outpatient payments in 2027 (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.

The cutoff point for outlier payments for CMHCs for 2027 is set at 3.4 times the highest CMHC PHP APC payment rate, and CMS will pay CMHCs 50 percent of CMHC geometric mean per diem costs over that 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 2027, CMS continues to use its established outlier reconciliation policy to address charging aberrations related to OPPS outlier payments described in the 2023 OPPS/APC final rule (83 FR 58874) and to extend it to intensive outpatient services. The policy requires outlier reconciliation for providers whose outlier payments meet a specified threshold ($500,000 for hospitals and any outlier payments for CMHCs) and whose overall ancillary CCRs change by ±10 percentage points or more, pending approval of the CMS Central Office and Regional Office.

In the 2017 OPPS/ASC final rule (81 FR 79692), 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 2027 and applies it to both PHP and IOP; this only impacts CMHCs.

CMS does not set a fixed-dollar threshold for CMHC outlier payments, which applies to other OPPS outlier payments; this is due to the relatively low cost of CMHC services. This policy is continued for 2027 and applies to both PHP and IOP APCs.

E. Regulatory Impact

CMS estimates that payments to 42 CMHCs for PHP services will increase by 28.3 percent. The estimate is derived by combining the OPD fee schedule increase factor, along with the final changes in APC policy for 2027, the final FY 2027 wage index updates, and the final 340B payment policy.

X. Inpatient Only (IPO) List

A. Background

The Inpatient Only (IPO) list was established in rulemaking as part of the initial implementation of the Outpatient Prospective Payment System (OPPS) in 2000, pursuant to the Secretary's authority under section 1833(t)(1)(B)(I) of the Act (65 FR 18455). Designation of a service as inpatient only does not preclude the service from being furnished in a hospital outpatient setting, but Medicare will not make payment for the service if it is furnished to a Medicare beneficiary in the hospital outpatient setting (65 FR 18443).

Services on the IPO list have historically been believed to require inpatient care because of the invasive nature of the procedure, the need for at least 24 hours of postoperative recovery time, or the underlying physical condition of the patient requiring surgery. CMS annually reviews the IPO list to identify any services that should be removed from or added to the list based on the most recent data and medical evidence available using criteria specified annually in the OPPS rule.

In previous years, CMS received comments from stakeholders who believe the IPO list should be eliminated and deference given to the clinical judgment of physicians for selecting where to perform a service. Stakeholders have also commented that exclusion of services from payment under the OPPS is unnecessary and could have an adverse effect on advances in surgical care. Some stakeholders have suggested that when a service is removed from the IPO list, it creates an expectation among hospitals that the service must be furnished in the outpatient setting, regardless of the clinical judgment of the physician or needs of the patient. Over time, some stakeholders stated that they believed that CMS was making decisions, such as the site of service for a particular medical procedure, that should be left to the discretion of surgeons and their patients. Stakeholders also suggested that Medicare regulations should not supersede the physician's level of knowledge and assessment of the patient's condition, and that the physician can appropriately determine whether a procedure can be performed in a hospital outpatient setting.

Other stakeholders have supported maintaining the IPO list and consider it an important tool to ensure that Medicare beneficiaries receive quality care. Stakeholders have also supported use of the IPO list because services included on the IPO list are an exception to the 2-midnight rule and are considered appropriate for inpatient hospital admission and payment under Medicare Part A regardless of the expected length of stay.

While CMS previously saw a need for the IPO list, the agency came to believe that physicians should use clinical judgment, together with consideration of the beneficiary's specific needs, to select an inpatient or outpatient setting for care. As medical practice continues to develop, CMS believes the difference between the need for inpatient care and the appropriateness of outpatient care has become less distinct for many services. CMS further believes that the evolving nature of the practice of medicine, state and local licensure requirements, accreditation requirements, hospital conditions of participation (CoPs), medical malpractice laws, and CMS quality and monitoring initiatives and programs will continue to ensure the safety of beneficiaries in both the inpatient and outpatient settings, even in the absence of the IPO list.

In the 2021 OPPS/ASC final rule with comment period, CMS finalized a policy revising 42 CFR 419.22(n) to eliminate the IPO list over the course of three years that began January 1, 2021 (85 FR 86083 through 86110). As part of the first phase of this elimination of the IPO list, CMS removed 298 codes, including 266 musculoskeletal-related services, from the list beginning in 2021.

CMS subsequently halted the phase-out of the IPO list in the November 16, 2021 2022 OPPS final rule with comment (CMS-1753-FC, 86 FR 63671 through 63736). This rule also restored most of the codes that had been removed from the IPO list for 2021, and codified CMS' long-standing criteria for evaluating future changes to the IPO list on a code-by-code basis. CMS subsequently maintained the IPO list on an ongoing basis through 2025.

In the 2026 rulemaking cycle, CMS reversed course again on the IPO list, and proposed and finalized a policy of eliminating the IPO list over three years, beginning with 285 mostly musculoskeletal procedures (90 FR 53780 through 53802). CMS codified its processes for removing procedures from the IPO list at §419.23 and §419.22(n) to state that the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition period that began January 1, 2026, with the list eliminated in its entirety by January 1, 2029 (90 FR 53788 to 53789 and 53086; 91 FR 8384).

B. Final 2027 Changes to IPO List

Currently, the IPO list includes 1,438 services. In the OPPS/ASC proposed rule for 2027, CMS proposed to eliminate roughly half of those services, proposing to remove 637 from the following clinical families: auditory, digestive, endocrine, female genital, hemic and lymphatic systems, integumentary, male genital, maternity care and delivery, mediastinum and diaphragm, respiratory, and urinary. CMS indicates that it selected these clinical families based on stakeholder input received during the 2026 rulemaking cycle. Interestingly, CMS notes that the services that remain on the IPO list after this rulemaking cycle are more complicated in nature

and would require a lengthier review process; nevertheless, the agency continues to signal that these services would be removed in 2028.

CMS did not discuss issues relating to assigning these services to APCs in the proposed rule's preamble, but makes some mention of this process in the final rule. CMS determined the APC assignment for services removed from the IPO list by evaluating the clinical similarity and resource costs of the service compared to other services paid under the OPPS and reviewing the Medicare Severity Diagnosis Related Groups (MS-DRG) rate for the service under the IPPS.

Selected Comments/Responses: Unsurprisingly, CMS received extensive comments on this proposal. CMS states that "several" commenters supported its proposal to continue the elimination of the IPO list, but that "many" opposed this proposal, largely on the basis of patient safety concerns. These commenters asked CMS to reverse its decision and reinstate the IPO list and the five prior criteria. Alternatively, some commenters asked CMS to proceed with the elimination of the IPO list in a more deliberative, service-by-service fashion. CMS declined in no uncertain terms to act on these suggestions.

Beyond comments simply opposing the elimination of the IPO list, many commenters expressed second-order concerns about the proposal. Some commenters suggested CMS slow down the IPO list elimination until the effects of the first stage of its removal (in 2026) could be assessed. Commenters urged CMS to issue guidance to the effect that a procedure's removal from the IPO list does not signal that an outpatient setting is the most appropriate site of care for that procedure. Commenters were concerned about beneficiary cost implications and implications for access to skilled nursing facility (SNF) care (a three-day inpatient hospital stay being a prerequisite for a Medicare-covered SNF stay). Commenters were concerned that Medicare Advantage (MA) plans would use the IPO list elimination as context to no longer cover former IPO list services on an inpatient basis and asked CMS to issue guidance to MA plans reminding them of their coverage obligations. CMS asserted that this request was outside the scope of the OPPS/ASC final rule. Commenters also expressed concerns about the implications of the elimination of the IPO list for the "2-midnight" rule. CMS responded that "procedures removed from the IPO list on or after January 1, 2021, are indefinitely exempted from site-of-service claim denials, initial medical review contractor referrals to RACs, and RAC reviews for ''patient status'' (that is, site-of-service) until the Secretary determines that the service or procedure is more commonly performed in the outpatient setting than the inpatient setting."

CMS indicated that "many" commenters provided recommendations on the methodology for assigning procedures coming off the IPO list to APCs. Some commenters recommended that CMS wait to assign the remaining IPO procedures to APCs until the final year of the phase-out period or to extend the phase-out period to ensure that CMS does not assign procedures to inappropriate APCs just to meet the timeline. CMS was unpersuaded by any public comments to modify its proposed second phase of the IPO list elimination.

Final Rule Action: CMS is finalizing its proposal to remove 637 services from the IPO list for 2027. These services and their final status indicators and APC assignments (if applicable) are listed in the public use file titled "Final Procedures Removed from the IPO List for 2027," which is available on the CMS website. The complete list of codes that describe services that are

finalized to be paid by Medicare in 2027 as inpatient-only services is included as Addendum E to the 2027 OPPS/ASC final rule with comment period, which is available on the CMS website.

XI. Nonrecurring Policy Changes

A. Payment Reduction for Imaging without Contrast Services

1. Background

In the 2019 OPPS rule, CMS adopted a policy to reduce payment for a clinic visit (HCPCS code G0463) when furnished in an off-campus provider-based department. The policy was adopted without applying budget neutrality. CMS cited its authority under section 1833(t)(2)(F) of the Act to "develop a method for controlling unnecessary increases in the volume of covered OPD [outpatient department] services" to adopt this policy. CMS exempted rural SCHs from application of this policy. This policy is often referred to as being "site neutral" as it intends to pay services furnished in an off-campus provider-based department a similar amount for the same service provided in a physician's office.

The American Hospital Association (AHA) challenged CMS' use of section 1833(t)(2)(F) to adopt the payment reduction for a clinic visit but CMS' policy was upheld by the U.S. Court of Appeals for the District of Columbia Circuit. The Court concluded "a service-specific, non-budget-neutral rate reduction falls comfortably within the plain text of subparagraph (2)(F)." (*AHA v. Azar)*[28]

In the 2026 OPPS rule, CMS expanded application of its site-neutral policy to drug administration APCs. CMS also exempted rural SCHs from the expansion of its site-neutral policy.

2. Expanding the "Method" to Other Services

CMS expresses concern about payment differentials between hospital and non-hospital sites and hospital acquisition of physician offices referred to by CMS as vertical integration. Even when there is little variation in the nature of the service provided across settings, Medicare will pay more when that service is performed in an outpatient department than when the same service is performed in a physician office.

That payment differential creates an incentive for providers to shift the care of beneficiaries to an outpatient department (OPD) rather than a physician office or ASC, even if the services can be safely performed in the physician office or an ASC according to CMS. CMS has found correlation among the increasing volume of OPD clinic visits, vertical integration, and the higher OPPS payment rates for clinic visits.[29, 30]

[28] 964 F.3d 1230, 1245 (D.C. Cir. 2020)
[29] https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0830
[30] https://onlinelibrary.wiley.com/doi/10.1111/1475-6773.13613

The impact of vertical integration and the increases in volume of outpatient services extends to multiple clinical families. Studies have shown that after vertical integration, the number of imaging tests performed in hospital sites of care increased while the number of procedures performed in nonhospital sites of care decreased.[31]

3. Utilization of Imaging without Contrast Services

Imaging without contrast services are often high-volume, low-intensity services that can be provided in OPDs or freestanding offices safely and effectively without compromising diagnostic quality or patient safety. In the 2026 OPPS rule, CMS expressed concern that these services have experienced unnecessary growth in the outpatient department setting (90 FR 33690).

CMS continued its analysis of these services in the 2027 OPPS proposed rule. The proposed rule focused on HCPCS code 77080 which is a bone density scan at the axial skeleton (hips, pelvis, spine). HCPCS code 77080 is the most frequently billed imaging without contrast code furnished in excepted PBDs. In 2025, this service had a physician office payment rate of approximately $30 and an OPPS payment rate of approximately $106, making the same scan more than three times as expensive in the OPD than in the physician office.

The analysis in the proposed rule indicates that the volume of this service has grown by over 55 percent in excepted PBDs between 2016 and 2025. Conversely, from 2016 through 2024, the volume of HCPCS code 77080 has only grown by 2 percent in the freestanding physician office setting despite being able to be safely performed in either setting. CMS attributes the growth in the facility setting to clear financial incentives to perform this service in an excepted PBD. CMS repeated this analysis with several other imaging without contrast HCPCS codes and found similar results.

CMS indicates that 70 HCPCS codes account for over 95 percent of the volume of imaging without contrast services provided in excepted PBDs. From 2016 to 2025, the provision of these services grew over 38 percent. From 2016 to 2025, these increases in volume have resulted in a 33 percent increase in spending, corresponding to approximately $126 million additional spending in 2025.

Between 2016 and 2025, for the top 70 most frequently billed imaging without contrast HCPCS codes provided in excepted PBDs, there has been an over 67 percent increase in utilization per beneficiary. This upward trend persists despite a declining Part B FFS population. During this same time, for example, FFS enrollment decreased by approximately 17 percent, indicating that imaging services are being performed more frequently on a per-beneficiary basis rather than growth being driven by enrollment.

As these are stable high-volume codes that have not experienced coding changes, updates to clinical practice guidelines or shifts in beneficiary case mix, CMS discounted the possibility that factors other than the pricing incentives resulted in the increased volume of these imaging services being performed in the outpatient department.

[31] https://pmc.ncbi.nlm.nih.gov/articles/PMC9924392/

CMS considers OPPS utilization potentially unnecessary if the beneficiary can safely receive the same services in a lower cost setting but instead receives care in the hospital outpatient setting because of site-of-service payment differentials. As section 1833(t)(2)(F) of the Act authorizes a method for controlling unnecessary increases in the volume of OPD services, CMS proposed to apply its volume control mechanism to imaging services without contrast.

4. Payment for Imaging without Contrast Services at PBDs

Under the Balanced Budget Act (BBA) of 2015, off-campus PBDs of hospitals that first began billing Medicare under the OPPS after November 2, 2015 are paid at a site-neutral rate equal to 40 percent of the OPPS rate, and bill Medicare with a "PN" modifier on the claim. Other off-campus PBDs bill Medicare with a "PO" on the claim.

For the imaging without contrast codes analyzed by CMS, the majority were billed with both "PO" and "PN" modifiers, indicating that these imaging without contrast services were safely being provided in both excepted and non-excepted PBDs. This finding indicates that the PFS-equivalent rate is sufficient to support the provision of these services in an off-campus PBD.

Section 5102 of the Deficit Reduction Act (DRA) of 2005 (Pub. L. 109-171) caps Medicare's PFS rate for imaging services at the rates paid under the OPPS. As the DRA functions as a ceiling on PFS payments, CMS does not believe it constrains its authority to apply its volume control mechanism to imaging without contract services paid under the OPPS.

5. Patient Severity and Cost of Care

Public comments on prior rules have indicated that the higher payments for services in hospital outpatient settings are justified by the level of care patients need, the higher costs of providing care in hospitals, and the costs of maintaining emergency care and standby capacity. CMS believes imaging without contrast services are generally low- to moderate-complexity diagnostic procedures, such as standard CT, MRI, ultrasound, radiography, and bone density testing, that do not require the administration of contrast agents or the associated monitoring and infrastructure. These services can be safely and effectively furnished in multiple settings, including physician offices, without compromising quality or patient safety.

A 2023 literature review found no peer-reviewed evidence that shows differences in the quality of services delivered across hospital OPDs and physicians' offices.[32] Further, MedPAC found that, on average, while OPD patients have higher risk scores, the difference in patient severity between settings is small and not statistically significant as the services, like imaging without contrast, are generally of low complexity.[33]

6. Impact of Unnecessary Increases in Volume on the OPPS

CMS' concern with unnecessary increases in the volume of imaging services without contrast is tied to the health and sustainability of the OPPS. The OPPS was originally designed to manage

[32] Search | Tobin Center for Economic Policy
[33] https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch8_MedPAC_Report_To_Congress_SEC.pdf

Medicare spending growth by replacing a cost-based system with a prospective payment system. Contrary to this purpose, OPPS has continued to be one of the fastest growing Medicare payment systems under Medicare Parts A and B.[34] CMS believes that paying for imaging services without contrast provided at excepted off-campus departments at a site-neutral rate would be an effective method to control the volume of unnecessary services in this setting because the payment differential that is driving the site-of-service decision will be removed.

7. Payment for Imaging without Contrast Services for 2027 and Subsequent Years

CMS proposed to apply the site-neutral payment rate to HCPCS codes assigned to:

- Imaging without contrast APCs 5521 through 5524; and
- APCs 8004 (Ultrasound Composite), 8005 (CT and CTA without Contrast Composite), and 8007 (MRI and MRA without Contrast Composite)

This policy would apply when these services are furnished at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill modifier "PO" on claim lines). Under section 1833(t)(2)(F) of the Act, CMS will pay for these services at the site-neutral payment rate—40 percent of the OPPS payment amount.

CMS' composite APC policy applies to multiple imaging services (composite APCs 8004 through 8008). Both the OPPS multiple imaging composite APC policy and the PFS MPPR policy recognize that furnishing multiple imaging services during the same encounter generally requires fewer resources than furnishing those services separately. CMS proposed to apply its volume control methodology to the imaging without contrast APCs single image only and composite APCs to avoid different payment treatment for the same underlying imaging procedures based solely on whether those procedures were paid separately or through a multiple imaging composite APC.

The proposed rule indicated that CMS would apply its policy in a non-budget neutral manner reiterating legal arguments made in past rulemaking that the adjustment under section 1833(t)(2)(F) is not subject to budget neutrality. While budget neutrality applies to the entirety of section 1833(t)(2), CMS argues it only applies to "adjustments" not the volume control method under section 1833(t)(2)(F) which is a "method" and not an "adjustment."[35]

For 2027, CMS estimated savings of $260 million attributable to this policy, with $190 million accruing to Medicare, and $70 million to Medicare beneficiaries. From 2027-2036, CMS estimated that this policy will lower net Part B spending by $7.2 billion. Medicare Advantage (MA) rates for 2027 have already been determined but CMS indicates that additional savings will be realized in 2028 and subsequent years from this policy when setting MA rates.

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[34] https://www.govinfo.gov/content/pkg/FR-2018-11-21/pdf/2018-24243.pdf

[35] To determine the OPPS payment under section 1833(t)(2)(F), CMS multiplies the full OPPS payment by the PFS relativity adjustor. Therefore, CMS is arguing that the result of applying an adjustor is not an "adjustment." Nevertheless, the budget neutrality issue was adjudicated *American Hospital Assoc. v. Azar* and CMS' policy was upheld by the courts irrespective of whether the reduction in payment is considered a "method" or an "adjustment."

Comments/Responses

General Comments from Supporters of the Policy. Commenters in support of the policy made many of the same points that CMS did in justifying its proposal (e.g., higher payments to OPDs for imaging services that can be safely furnished in lower-cost settings increase costs for Medicare beneficiaries and taxpayers and may encourage care to shift toward higher-paid OPDs). CMS appreciated the support from commenters noting it is not prudent for the Medicare program to pay more for these services in one setting than another solely because of the site in which the service is furnished.

Expanding the Policy to On-Campus Departments. The final rule noted MedPAC's support for CMS's proposed policy. However, MedPAC's June 2023 recommendation recommended applying the site neutral payment limit in both on-campus and off-campus PBDs as did many other comments. MedPAC also stated that applying a budget-neutral payment adjustment with a site-neutral policy would increase OPPS payment rates for other services, including emergency department visits, which would support hospitals' emergency care and standby capacity.

CMS acknowledges MedPAC's recommendation to align payment rates for selected services furnished in on campus as well as off campus OPDs that it will consider in future rulemaking. However, CMS does not believe the policy needs to be applied budget neutral to increase support of hospitals' emergency care and standby capacity. Implementing a volume control method in a budget neutral manner would not reduce the overall unnecessary volume of covered OPD services and instead would simply shift payments within the OPPS.

Expanding the Policy to Other Services. Many commenters supported expanding the policy to additional services. Other commenters recommended that CMS proceed cautiously with any future expansion and consider beneficiary access, patient complexity, quality and safety, geographic availability of alternative sites of care, hospital infrastructure and emergency capabilities, and provider readiness. CMS appreciates the analyses and recommendations commenters provided regarding factors to consider in evaluating expansion of this policy to other services that will be considered in future rulemaking.

Changed Legal Environment under Loper Bright. Commenters noted that CMS' use of section 1833(t)(2)(F) to reduce payment under the OPPS was upheld under previous legal precedent (*Chevron*) that required Federal Courts to defer to a reasonable agency interpretation of statute has been overturned by a subsequent case (*Loper Bright*). Further, commenters noted that *Bridgeport Hospital v. Becerra*, established that CMS may not rely on general statutory authority to depart from a more specific, Congressionally prescribed Medicare payment methodology (e.g., CMS is applying site neutral payment to exempted off-campus PBDs under section 1833(t)(21) of the Act).

CMS responded that *Loper Bright* "do[es] not call into question prior cases that relied on the Chevron framework…despite our change in interpretive methodology"[36] with the implication being that *AHA v. Azar* remains precedential. Moreover, section 1833(t)(2)(F) of the Act delegates significant discretionary authority to the Secretary consistent with *Loper Bright* that the

[36] *Loper Bright*, 603 U.S. at 412

"best reading of a statute [may be] that it delegates discretionary authority to an agency"). CMS further cites the D.C. Circuit in *AHA v. Azar* that CMS's policy "falls comfortably within the plain text of subparagraph (2)(F)" and other precedents supporting Congress delegating significant discretion to the agency.

The response further argues that *Bridgeport* focused on the specificity and length of section 1886(d) of the Act's wage-index provision concluding that it did not give the Secretary discretion to change the wage-index values produced within the statutory formula. In contrast, section 1833(t)(2) of the Act expressly gives the Secretary significant discretion by instructing that "the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services."

Circuit Court Did Not Consider BBA 2015. Under section 603 BBA of 2015, Congress established a site neutral policy that explicitly exempted existing off-campus PBDs from its provisions when it was enacted in 2015. Commenters indicated that this point was not sufficiently considered by the Circuit Court upholding CMS application of a site neutral policy in 2019. CMS responded that Congress addressed the specific circumstances that lead to the proliferation of new off-campus provider-based departments with BBA 2015 while CMS' site neutral policy addresses the overutilization of specific services. Further, CMS's response indicates the court fully considered any impact of section 603 of the BBA of 2015 on the agency's authority under the OPPS statute.

Adjustments v. Method. Commenters reiterate that "adjustments" made under section 1833(t)(2)—which incorporates section 1833(t)(2)(F)—to OPPS payments are subject to budget neutrality under section 1833(t)(9). Other comments focused on section 1833(t)(9)(C) that permit the Secretary to adjust the conversion factor if spending under section 1833(t)(2)(F) increases more than established under the method created by the Secretary. CMS is not adjusting the conversion factor and is instead just reducing payment for specific services.

CMS reiterates prior responses that its site neutral payment is a "method" not an "adjustment"[37] subject to budget neutrality unlike the statutory paragraphs that authorize the wage index, outliers, transitional pass-through and the equitable payments that are explicitly subject to budget neutrality, the volume control mechanism under section 1833(t)(2)(F) is not. CMS interprets the section 1833(t)(2)(9)(C) provision to mean that it can implement the volume control method under section 1833(t)(2)(F) in a non-budget neutral manner in the year in which the method is implemented. Further, it would be non-sensical to establish a method intended to address unnecessary services in a non-budget neutral manner.

Time Frame for Analysis. Commenters recommended that CMS test its findings using alternative baseline years, such as 2017 or 2018 placing greater weight on more recent utilization trends. More recent data show relatively stable utilization in excepted off campus PBDs. Several commenters indicated that 70 HCPCS codes used for analysis underwent changes in coding making comparisons potentially misleading. Accounting for predecessor and successor codes and including the full set of imaging without contrast services produced substantially less growth than CMS's analysis. CMS responded that changing the base year for its analysis did not change

[37] See footnote 8.

its findings. Further CMS' analysis of historical utilization for the full set of imaging without contrast HCPCS codes continues to demonstrate growth in utilization in excepted off-campus PBDs.

Code Level Analysis Does Not Justify Expansion to Other Codes. CMS analyzed 70 codes but is applying the reduction to 300 services—some of which had little or no utilization to justify the payment reduction. CMS responded that it is not necessary to do an individual code analysis before applying its policy. Further, its analysis was done at the APC level rather than at the individual service level justifying application of its site neutral policy even though there may be some codes within the APC that demonstrate low utilization overall or slower utilization growth.

Other Reasons than Payment May Explain Utilization Shifts. Commenters indicated CMS' analysis is undermined by other services having service utilization increases in the physician office despite higher payments under the OPPS. Other commenters stated that increases in excepted off-campus PBD utilization may reflect factors other than shifts from freestanding physician offices attributable to payment incentives. Such factors may include shifts from inpatient to outpatient care, changes in clinical practice and screening recommendations, advances in imaging technology, changes in disease prevalence and beneficiary demographics, physician referral patterns, hospital investments in imaging capacity, and closures or acquisitions of independent imaging facilities.

CMS responded that it does not believe that an increase in utilization in the physician office setting, including an increase that occurs at the same time as growth in excepted off-campus PBDs, demonstrates that there is no unnecessary utilization in the excepted PBD setting. As CMS explained in the 2026 OPPS final rule, the existence of other factors may contribute to increased utilization in the OPD setting but the utilization remains unnecessary if the beneficiary can safely receive the same service in a lower-cost setting.

Growth the Same in Non-Excepted as Excepted Off-Campus PBDs. Commenters noted that non-excepted off-campus PBDs already receive the PFS-equivalent payment rate yet utilization of imaging without contrast services has continued to increase. CMS responded that growth in aggregate utilization in non-excepted off campus PBDs reflects, at least in part, growth in the number of departments subject to the site neutral payment methodology. Further, CMS notes that if growth in utilization is occurring in non-excepted off-campus PBDs, it shows the services can continue to be provided at a site neutral rate.

No Baseline Established for Necessary Services. Several commenters indicated CMS cannot determine that there have been unnecessary increases in the volume of imaging without contrast services without first identifying a necessary level or rate of growth. Commenters also recommended that CMS consider other methods for addressing unnecessary or inappropriate imaging utilization, including medical-necessity requirements, claims review, prior authorization or other utilization management policies, clinical practice guidelines, or appropriate use criteria.

CMS responded that because site-of-service payment differentials affect utilization throughout the OPPS, it would be extremely difficult to determine at the HCPCS or APC level the precise amount of volume that would have occurred absent that influence. But the basic point remains

the same, OPPS utilization is unnecessary if the same service can just as easily be performed in a lower cost setting.

The response appreciates commenters' recommendations regarding other approaches to addressing unnecessary utilization that CMS will continue to consider but it continues to believe that applying the PFS-equivalent payment rate is an appropriate method to address the site-of-service payment differential that is a substantial cause of unnecessary increases in the volume of covered OPD services.

Sicker Patients are Treated in OPD. Commenters stated OPDs are more likely to serve Medicare patients who are sicker, more clinically complex, and more likely to be disabled or living in poorer, rural communities than patients treated in independent physician offices. Commenters assert that these sicker beneficiaries, who they note are more commonly treated in OPDs, require a greater level of care.

CMS responded that OPDs may serve unique patient populations and provide services to medically complex beneficiaries, however the data provided by the commenter does not demonstrate how these factors necessitate a higher payment for all imaging without contrast services provided in OPDs. While commenters indicate that these patients are more frequently treated in OPDs, they do not show how OPDs alone are clinically capable of treating complex patients or how physician offices would be unequipped to safely treat these same beneficiaries.

Physician's Role. Commenters stated that it is the physician, not the hospital, that orders imaging services. Hospitals, therefore, have limited ability to control the volume of imaging services furnished in their outpatient departments. Further, physicians may determine that an OPD is the appropriate site of service for particular beneficiaries based on clinical complexity, comorbidities, availability of specialized equipment or personnel, or the potential need for other hospital resources. CMS responded that the fact that a physician determines that an imaging service is medically necessary does not establish that the service must be furnished in an excepted off-campus PBD or that the higher OPPS payment rate is necessary for that service.

Physicians Leaving Independent Practice. Commenters indicated that broader consolidation trends cannot be attributed solely to Medicare site-of-service payment differences. Increasing practice expenses, regulatory and administrative burden, workforce shortages, physician burnout, payer mix, and declines in Medicare physician payment are factors contributing to physicians leaving independent practice. Further, commercial insurers and private equity firms have acquired physician practices.

CMS responded that the existence of other factors that may contribute to consolidation or changes in utilization does not mean that the substantial difference between OPPS and PFS payment rates does not also create an incentive to furnish services in the higher-paid setting. While physician practices may also be acquired by private equity firms, commercial insurers, or other entities, only acquisition by a hospital can result in services that were previously paid under the PFS being paid at the higher OPPS rate because of conversion to a provider-based department.

Different Cost Structures. Many commenters indicated that hospitals have higher costs than physician offices as they must invest significant resources to meet the stricter regulatory requirements and safety standards to which they are subject. Further, hospitals maintain imaging capacity and specialized staff that allow them to furnish services to higher acuity patients and respond to complications or other clinical needs that are not reflected in PFS payment rates.

CMS responded that to the extent that similar services can be safely provided in more than one setting, it does not believe Medicare should pay more for services in one setting than another. The response further notes that freestanding physician offices also incur costs to adhere to regulatory and safety standards and ensure that they are appropriately equipped to provide these services. While some hospital outpatient departments may have additional costs that freestanding physician offices do not, hospitals may also have efficiencies that freestanding physician offices do not, such as greater purchasing power, that may offset some of the additional costs identified by commenters.

Payment Below the PFS. Commenters indicated that for some imaging services, application of the 40-percent relativity adjuster would result in payment below the applicable PFS technical component amount, while for other services it would result in payment above the PFS technical component amount. Further, some imaging services are already subject to a cap under the PFS at the OPPS rate under DRA 2005.[38]

CMS responded that the PFS relativity adjuster itself was established through separate rulemaking and was not proposed for modification in this rulemaking. The 40-percent relativity adjuster was not intended to establish exact code-specific PFS payment amount but instead recognizes service-level variation above and below the precise level of the adjuster which, in part, accounts for methodological differences between the OPPS and PFS.

The response also considered commenters' concerns regarding the DRA imaging cap. CMS commenters have raised important considerations regarding the continued use and design of the PFS relativity adjuster, including the variation between relativity-adjusted payment amounts and applicable PFS payment amounts for individual services. CMS intends to continue evaluating whether refinements to the PFS relativity adjuster, or the development of alternative relativity adjusters, may be appropriate.

Preventive and Screening Services. Several commenters expressed concern about lower payment for a variety of preventive and screening services such as low-dose CT for lung cancer screening, CT colonography, abdominal aortic aneurysm screening, and DXA bone density testing. Commenters stated that reductions in payment for these services could create barriers to beneficiaries obtaining recommended screening and preventive services that are not subject to coinsurance precisely to remove barriers to their utilization.

CMS does not believe that preventive or screening services, by itself, warrants exclusion from the volume control method. When a clinically appropriate service can safely be furnished in a lower-cost setting, it is unnecessary to be performed in a higher cost setting like an OPD. This

[38] Not stated but the implication of this comment is that there is circularity. The PFS rate is capped at the OPPS rate but then reduced to 40 percent of the OPPS rate only when the service is performed in off-campus PBD.

logic applies to screening and preventive services as well as other services.

Access to Care. Commenters expressed concern about worsening a variety of metrics of access to care (longer wait times or travel distances, delayed diagnosis, greater fragmentation of care, and increased reliance on emergency departments or other higher-cost settings). CMS responded that it does not believe that applying the PFS equivalent payment rate to imaging without contrast services furnished in excepted off-campus PBDs will generally result in the loss of access to these services as payment for these services appears to be adequate in physicians' offices.

Phase In Payment Reduction. Several commenters requested CMS phase-in the payment reduction if it finalizes its policy. CMS responded that its experience with non-excepted off-campus PBDs supports implementation of the PFS-equivalent payment rate without a phase-in.

Reduction in Payment May Increase Unnecessary Volume. Commenters stated that reducing the payment amount provides an incentive for hospitals to increase utilization to offset the reduction in revenue. CMS responded that its volume control method is specifically designed to address unnecessary increases in OPD volume that result from site-of-service payment differentials. By applying a PFS-equivalent payment rate, the method removes the payment differential that creates an incentive to furnish a service in the higher-paid OPD setting when the same service can safely be furnished in a lower-cost setting.

Final Decision: CMS is finalizing its proposed policy without change to apply the PFS relativity adjuster to imaging without contrast services effective January 1, 2027 without applying budget neutrality. The PFS relative adjuster will be applied to imaging without contrast services assigned to APCs 5521 through 5524 and multiple imaging composite APCs (APCs 8004, 8005, and 8007), when furnished by an excepted off-campus PBD that bills using the "PO" modifier.

8. Exemptions for Rural Sole Community Hospitals

In the 2023 OPPS final rule (87 FR 72047 through 72051), CMS exempted rural SCHs from its site-neutral policy on the basis that rural SCHs have historically received special treatment to account for their higher costs and the disproportionately harmful impact that payment reductions could have on them. For rural SCHs, CMS indicates that many rural providers, and rural SCHs in particular, are often the only source of care in their communities,[39] which means beneficiaries and providers are not choosing between a higher paying off-campus PBD of a hospital and a lower paying physicians' office setting. For this reason, CMS proposed to exempt imaging services without contrast from site-neutral payment at rural SCHs.

Commenters generally opposed CMS' site neutral policy but supported the exemption for rural SCHs. There were also comments recommending that CMS extend the exemption to additional types of hospitals.

[39] https://www.shepscenter.unc.edu/wp-content/uploads/dlm_uploads/2017/11/SCHs_Differences_in_Community_Characteristics.pdf

CMS acknowledged the nuanced perspective that many commenters took in supporting the proposed exemption while disagreeing with the volume control methodology overall. With respect expanding the exemption to other hospital types, CMS responded that rural SCHs have historically received special treatment under the OPPS due to their higher costs. CMS does not believe that commenters provided sufficient reasoning or data to demonstrate that the other hospital types subject to this policy have the additional resource costs to justify being exempted from this OPPS payment policy.

Final Decision: CMS is finalizing its proposal to exempt rural SCHs from its site neutral policy as proposed.

B. Payment for Software as a Medical Service (SaMS)

1. Payment for Software as a Medical Service (SaMS)

CMS has used the terminology "Software as a Service" (SaaS) to refer to algorithm-driven software that performs data analysis of diagnostic images and complex algorithms or statistical predictive modeling to aid in the diagnosis or treatment planning of a patient's condition. CMS is concerned that it needs to distinguish SaaS which has a medical purpose from general cloud-based computing service models outside of a health care context. To address this concern, CMS proposes using the term "Software as a Medical Service (SaMS)" to refer to software-based technologies that support clinical decision making through algorithmic analysis, including those that provide clinical or diagnostic functionality.

CMS has had challenges with pricing SaMS services under Medicare Part B. Current Medicare Part B payment systems for SaMS, including in the OPPS, are primarily designed to pay for services that rely on material resources, rather than technologies whose value is driven by proprietary algorithms and scalable, non-material costs. To address this issue, CMS proposes to reassign 36 HCPCS codes designated as SaMS services that are currently separately paid to new technology APCs that closely align with their current 2026 payment rates.

Further, CMS proposes to create status indicator "O1" (Software as a Medical Service, Paid under OPPS; separate APC payment) and assign this payment indicator to all SaMS services. Functionally, the status indicator O1 will be the same as status indicator "S" that allows separate payment under the OPPS although CMS requests comment on whether status indicator O1 should be comparable to status indicator "T" that provides for multiple procedure discounting.

There are a small number of codes CMS considers to be SaMS that are currently paid under the OPPS and conditionally packaged (paid separately when they are the only service on the claim) that are assigned to clinical APCs. CMS proposes to maintain the clinical APC to which these SaMS services are assigned and their conditional packaging status. There are other SaMS codes that are not paid separately under the OPPS (either not covered, unconditionally packaged or not billable under the OPPS). CMS did not propose to make any changes to the status indicator for these codes.

Comments/Responses

Terminology Change. Public commenters supported the terminology change from "Software as a Service" (SaaS) to "Software as a Medical Service (SaMS)". CMS is finalizing this terminology change.

Process for Identifying SaMS. CMS received several comments requesting information on CMS's process for identifying the 36 proposed HCPCS codes to be designated as SaMS. To identify the 36 proposed SaMS CPT codes, CMS examined all CPT codes currently paid under the OPPS to determine which codes aligned with the SaMS terminology provided in the 2027 OPPS proposed rule, specifically "software-based technologies that support clinical decision making through algorithmic analysis, including those that provide clinical or diagnostic functionality" as a framework. CMS excluded remote therapeutic management, remote patient monitoring non-device clinical decisions support and services CMS did not believe would fall under a Medicare benefit category, including those that are administrative in function.

Other Services. CMS received requests to include additional services as SaMS, others to maintain their clinical APC assignments, and others to be assigned to different new technology APCs. The response to these requests is included in the final rule. Table 83 provides the proposed, requested, and final APC and status indicator assignments for those services for 2027.

Applying a Multiple Procedure Discount. Commenters opposed CMS providing a status indicator that would allow for a multiple procedure discount for SaMS. CMS agreed that unlike other non-software based services which share physical resources, and therefore, subsequent procedures are less expensive, SaMS do not rely on shared resources where a multiple procedure discount would be applicable.

Table 84 of the final rule shows the proposed and final APC and SI assignment for SaMS for 2027.

2. SaMS Analyses Performed on Laboratory Tests

CMS expresses concerns about Medicare payment under the Clinical Laboratory Fee Schedule (CLFS) for "stand-alone" algorithmic analyses that are separate from a Clinical Laboratory Improvement Act's (CLIA) certified laboratory's examination of human material. Such stand-alone algorithmic analyses can be performed by a CLIA certified laboratory but may be performed independently of one.

Section 1861(s) of the Act specifies items and services included as "medical and other health services" under Part B, including diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests as described in paragraph (3) of section 1861(s) of the Act. Section 1861(s)(17) of the Act states that no diagnostic tests performed in any laboratory shall be included within that paragraph (3) unless such laboratory meets CLIA certification requirements under section 353 of the Public Health Service Act, among other requirements. To be paid under the CLFS, a test must be a "diagnostic laboratory test" under section 1861(s)(3) of the Act.

CMS does not believe it is appropriate to consider these stand-alone secondary algorithmic analyses to be diagnostic laboratory tests, as they can be performed by any non-regulated entity with the computer software needed to perform the analyses. Such tests may be considered "other diagnostic tests" rather than "diagnostic laboratory tests" under section 1861(s)(3) of the Act.

The proposed rule indicated that an entity that performs only algorithmic analyses of previously sequenced data may not qualify as a CLFS laboratory under 42 CFR §493.2 or require CLIA certification and qualify to be paid under the CLFS. CMS is further concerned about lack of transparency (*e.g.*, lack of pricing information on proprietary tests), beneficiary cost-sharing or budget neutrality that provide little incentive to control utilization of these services.

CMS believes SaMS analyses performed on laboratory tests are substantively similar to other SaMS technologies that are currently paid under the OPPS like algorithmic analysis of an imaging test. For 2027, CMS proposes to assign 10 HCPCS codes describing various SaMS analysis performed on laboratory tests to new technology APCs under the OPPS. CMS will use the latest available CLFS data to crosswalk to new technology APCs with payment rates that closely approximate the current 2026 CLFS payment rates. These codes will be assigned to new technology APCs with the newly proposed status indicator "O1" (Software as a Medical Service, Paid under OPPS; separate APC payment) for 2027.

If there were no laboratory methods included in the code descriptor, and only an algorithmic analysis was described, CMS identified the code as a SaMS laboratory analysis. CMS also proposed to apply the policy to any new SaMS analyses performed on laboratory test codes. Based on public comment, CMS indicated that it may apply policy to additional codes in the final rule.

Comments/Responses

General Comments from Supporters. Supporters of CMS' proposal indicated that the policy recognizes algorithmic analysis of previously obtained data as a separately payable clinical service. These commenters expressed support for establishing a consistent, cross-setting payment framework for algorithmic analyses that considers evidence of clinical benefit. There were also comments that CMS establish a payment mechanism for these services when the patient is not seen in a hospital outpatient department. These commenters also supported assigning SaMS codes to new technology APCs intended to maintain their current payment.

CMS responded to these comments by welcoming manufacturers of SaMS tests to provide data and information that will help CMS develop pricing for these tests. With respect to pricing a test according to its clinical benefit, CMS responded that it is using the rulemaking process to establish the category of SaMS analyses performed on laboratory tests and the general payment mechanism for those services. Finalizing this policy would not eliminate Medicare payment for these services, or prohibit certain facilities from billing Medicare, but rather, it would define how these services would be paid under the OPPS.

General Comments from Opponents. Opponents of the proposal asked CMS to not finalize the policy. This included large laboratory associations concerned that the proposed policy could

inadvertently create duplicate or inconsistent payment pathways. Also, the policy would fragment integrated laboratory services by separating algorithmic analyses from the laboratory responsible for validation, quality, clinical interpretation, and reporting. The commenters indicated that process as a whole, not the physical location where the final computational step occurs, is what defines a clinical diagnostic laboratory test. There were also concerns about beneficiaries being subject to cost-sharing when they previously were not. These commenters supported CMS conditioning Medicare payment for designated SaMS laboratory services on performance by a CLIA-certified, appropriately accredited laboratory.

CMS responded that cost sharing encourages greater efficiency by providers and more economical delivery of medically necessary services. The response disagrees that the policy would fragment integrated laboratory service as it would apply to HCPCS codes that already recognize a distinct SaMS analysis component not those tests that have an integrated wet lab and algorithmic component. CMS states that while underlying specimen collection, sequencing, or other data-generating steps may require laboratory services, the algorithmic analysis is a separate step that is performed on data that has already been generated and may not necessarily require access to the specimen or laboratory equipment.

Difficulty Identifying SaMS from Code Descriptors Commenters stated that CPT code descriptors do not always indicate whether activities, such as slide preparation or immunostaining, are included in the reported service. Several of the examples CMS identified as SaMS appear to involve wet lab components. CMS responded that for the proposed policy, it identified services as SaMS that indicated algorithmic analysis in the CPT long descriptor and in the description of intraservice work provided by the AMA to value the code. Based on public comments, CMS provided an opportunity to exclude codes identified as SaMS or include additional ones from the list.

The final rule includes many comments either requesting additional services to be considered SaMS or remove services that CMS classified as SaMS in the OPPS proposed rule and CMS' response. Table 85 of the final rule provides the list of services CMS is finalizing as SaMS analyses performed on laboratory tests.

Coordinate Policy with Related Regulations. Several commenters noted that CMS requested information on the appropriate level of Clinical Laboratory Improvements Improvement Act (CLIA) oversight of "dry lab" facilities that perform computational analyses without a traditional wet-lab component. Commenters requested that CMS defer any changes to this OPPS payment policy pending the outcome of the CLIA RFI. CMS plans to coordinate and collaborate across the relevant agencies to ensure oversight and payment policies are consistent.

Laboratory Developed SaMS Tests (LDTs). Commenters raised concerns that LDTs are not billable under the PFS by clinical laboratories. If LDTs are SaMSs and not clinical diagnostic laboratory tests, there would be no billing mechanism for laboratories to be paid for these services under the PFS. CMS did not address this issue in the OPPS rule but indicated that finalizing this policy would not eliminate Medicare payment for these services, or prohibit certain facilities from billing Medicare, but rather, it would define how these services would be paid under the PFS.

Laboratory Date of Service. The date of service for a laboratory test is the date the specimen is obtained (with some exceptions) that determines whether the test is bundled into payment under the IPPS, packaged under the OPPS or must be billed by the hospital if the date of service is during a hospital inpatient stay or outpatient encounter. A commenter requested CMS confirm that the laboratory date of service rule does not apply to SaMS as it is an "other diagnostic test." CMS confirmed that the laboratory date of service will not apply to SaMS.

Status Indicator. Public commenters opposed CMS applying a multiple procedure reduction to SaMS services assigned an "O1" status indicator. CMS agreed.

Final Decision. CMS is finalizing its proposed policy with changes based on public comments to change the SaMS designations. Additionally, CMS will assign any new SaMS analyses performed on laboratory test codes to new technology APCs for payment under the OPPS.

C. Cost-of-Living Adjustment (COLA) in Alaska and Hawaii

Under the IPPS, section 1886(d)(5)(H) of the Act, CMS applies an adjustment factor to the non-labor-related portion of the standardized amount for hospitals in Alaska and Hawaii to recognize their higher costs relative to hospitals in the lower 48 States. CMS believes that non-labor costs in Hawaii and Alaska would be similarly higher in the outpatient department as for inpatient services.

For this reason, CMS proposed to use its section 1833(t)(2)(E) of the Act equitable adjustment authority to apply the IPPS COLA factors to the non-labor share of OPPS payment amounts for hospitals located in Alaska and Hawaii for 2027 and future years. Consistent with the IPPS proposal for FY 2027, CMS proposed to use the Overseas Cost of Living Allowance (OCOLA) data published by the Department of Defense for the OPPS COLA.

Use of CMS' section 1833(t)(2)(E) of the Act equitable adjustment authority requires budget neutrality. Consistent with this requirement, CMS proposed to apply a budget neutrality adjustment of -0.07 percent for this policy.

Public comments generally supported CMS' proposals but made a variety of technical comments that CMS responded to. There were comments asking CMS to expand the COLA adjustment to rural communities in other States to address a variety of costs many of which were labor costs. CMS responded that the OPPS addresses this comment through other mechanisms such as the hospital wage index, geographic reclassification, and the out-migration adjustment. The OPPS COLA policy serves a narrower purpose. It recognizes the unique non-labor costs experienced by hospitals in the two non-contiguous states, Alaska and Hawaii, and aligns the OPPS treatment of those costs with the longstanding IPPS policy.

D. Payment for Cardiac and Pulmonary Rehabilitation in a Patient's Home

Section 6211 of the Consolidated Appropriations Act, 2026 authorized Medicare payment under the OPPS for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation to hospital outpatients in their homes via audio and video real-time communications technology

(excluding audio-only) through December 31, 2027. The law allowed CMS to implement this provision via sub-regulatory guidance which can be found at: https://www.cms.gov/medicare/coverage/telehealth. CMS is using this OPPS rule to inform readers of this new policy. Public commenters supported CMS implementing this provision of statute through sub-regulatory guidance.

XII. OPPS Payment Status and Comment Indicators

A. 2027 OPPS Payment Status Indicator Definitions

Each status indicator will identify whether a given code is payable under the OPPS or another payment system, and the OPPS policies that apply to the code.

For 2027, CMS proposed two status indicator changes:

Proposed Status Indicator	Proposed Descriptor	Proposed OPPS Payment Status
O1	Software as a Medical Service, paid under OPPS; separate APC payment.	Paid under OPPS; separate APC payment.
E2	Items and Services: For which pricing information and claims data are not available.	Not paid by Medicare when submitted on outpatient claims (any outpatient bill type). Exception: claims under drug invoice pricing policy are contractor priced.

CMS proposed new status indicator O1 for software as a medical service that is paid separately under the OPPS. CMS proposed to revise the definition of status indicator "E2" to comply with the drug invoice policy explained in section V.B. No comments were received on these proposals and CMS is finalizing them without change. The complete list of 2027 payment status indicators and their definitions are in Addendum D1 of the final rule.

B. 2027 Comment Indicator Definitions

For 2027, CMS proposed to continue to use the following comment indicators that are unchanged from 2026:

1. 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.
2. 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.
3. NI - New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code [in the final rule].
4. 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 did not receive any comments on the changes to comment indicators and is finalizing its proposal without change.

XIII. Medicare Payment Advisory Commission (MedPAC) Recommendations

OPPS Payment Rates Update: In its March 2026 "Report to Congress: Medicare Payment Policy," MedPAC recommended that Congress update Medicare OPPS payment rates in 2027 by the amount specified in current law. CMS indicated that it appreciates MedPAC's recommendation and, as discussed further in section II.B., it will increase the OPPS payment rates by the amount specified in current law. Not stated, CMS further adopted a reduction to the OPPS update of 2.0 percentage points for the 340B recoupment adjustment.

Medicare Safety Net Index: In its March 2026 "Report to Congress: Medicare Payment Policy," MedPAC stated that its recommended update to IPPS and OPPS payment rates of current law 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 $1 billion to the MSNI pool of funds to help maintain the financial viability of Medicare safety-net hospitals and recommended Congress transitional approaches for an MSNI policy.

CMS indicates that the FY 2027 final rule provides additional information regarding statutory requirements for disproportionate share hospital and uncompensated care payments. The agency looks forward to working with Congress on these matters were it to adopt the MSNI proposal.

XIV. Ambulatory Surgical Center (ASC) Payment System

Summary of Selected Key Elements of ASC Payment Rates for 2027		
	ASCs reporting quality data	**ASCs not reporting quality data**
2026 ASC Conversion Factor	$56.322	
Wage index budget neutrality adjustment	1.0018	
2027 Update		
Hospital market basket update	3.2%	
Productivity adjustment	-0.9%	
Net MFP adjusted update	2.3%	
Penalty for not reporting quality data	0.0%	-2.0%
Net MFP and quality adjusted update	2.3%	0.3%
2027 ASC Conversion Factor	$57.721	$56.592

The ASC update is based on the finalized 2027 IPPS hospital market basket (3.2 percent), reduced by the multifactor productivity adjustment (-0.9 percentage points), and is estimated to

be 2.3 percent, with a reduction of 2.0 percentage points for ASCs that do not submit quality data.

A. Background

For a detailed discussion of the legislative history and statutory authority related to payments to ASCs under Medicare, CMS refers the reader to a list of *Federal Register* notices.

Covered surgical procedures in an ASC are those that would not be expected to pose a significant risk to the beneficiary or require an overnight stay or active medical monitoring and care at midnight following the procedure. Payment for ancillary items and services (with some exceptions) are packaged into the ASC payment. The OPPS relative payment weights and, in some cases, payment rates are used as the basis for the payment of many covered surgical procedures and covered ancillary services under the revised ASC payment system. 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 recognizes Category I and III CPT codes and Level II HCPCS codes for reporting procedures, services, items, and supplies under the ASC payment system. Similar to the OPPS, 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.

CMS also undertakes annually a review of excluded surgical procedures, new codes, and codes with revised descriptors, to identify any that the agency believes meet the criteria for designation as ASC covered surgical procedures or covered ancillary services.

B. ASC Treatment of New and Revised Codes

1. Background on Process for New and Revised HCPCS Codes

On a quarterly basis, Level II HCPCS codes are released and revised throughout the year and become effective. New and revised Category III CPT codes are recognized by CMS in the July and January CRs. New and revised Category I CPT codes, except vaccine codes, are released only once a year, and are implemented only through the January quarterly CR update. New and revised Category I CPT vaccine codes are released twice a year and are implemented through the January and July quarterly CR updates.

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

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

Table 91 in the final rule (reproduced 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 2026	HCPCS (CPT and Level II codes)	April 1, 2026	2027 OPPS/ASC proposed rule	2027 OPPS/ASC final rule with comment period
July 2026	HCPCS (CPT and Level II codes)	July 1, 2026		
October 2026	HCPCS (CPT and Level II codes)	October 1, 2026	2027 OPPS/ASC final rule with comment period	2028 OPPS/ASC final rule with comment period
January 2027	CPT Codes	January 1, 2027	2027 OPPS/ASC proposed rule	2027 OPPS/ASC final rule with comment period
	Level II HCPCS Codes		2027 OPPS/ASC final rule	2028 OPPS/ASC final rule with comment period

2. April 2026 HCPCS Codes Proposed Rule Comment Solicitation

For the April 2026 ASC quarterly update, there were several new Level II HCPCS codes added to the list of covered ancillary services (but no new CPT codes). Table 64 in the proposed rule displayed the new HCPCS codes and descriptors.

CMS notes that the proposed payment indicators, comment indicators, and payment rates, where applicable, can be found in various addenda on the CMS website. CMS proposed to finalize the payment indicators in the 2027 OPPS/ASC final rule with comment period and invited public comment.

In the final rule,[40] CMS indicates that it received some public comments on the proposed OPPS APC and status indicator (SI) assignments for the new Level II HCPCS codes that were effective on April 1, 2026. The comments and the agency's responses are addressed in the applicable sections of this final rule, which include, but are not limited to sections III.C (New Technology APCs), III.E (OPPS APC-Specific Policies), and IV. (OPPS Payment for Devices). For those April 2026 codes for which CMS received no comments, the agency is finalizing the proposed APC and status indicator assignments as proposed. The list of finalized HCPCS codes effective April 1, 2026, is found at Table 12 of the final rule.

3. July 2026 HCPCS Codes Proposed Rule Comment Solicitation

In the July 2026 ASC quarterly update (Transmittal R13836, Change Request 14522, June 24, 2026), CMS added several separately payable CPT and Level II HCPCS codes to the list of

[40] This final rule is a final rule with comment period (FC). This summary uses the shorthand "final rule" for succinctness.

covered surgical procedures and covered ancillary services. Table 65 of the 2027 OPPS/ASC proposed rule lists the new HCPCS codes that are effective July 1, 2026 (98 new codes in total).

As with the April 2026 codes, CMS notes that the proposed payment indicators, comment indicators, and payment rates, where applicable, could be found in various addenda on the CMS website. CMS proposed to finalize the payment indicators in the 2027 OPPS/ASC final rule.

As with the April 2026 codes, CMS indicates that the agency received some public comments on the proposed OPPS APC and SI assignments for the new Level II HCPCS codes implemented on July 1, 2026. The comments and agency's responses are addressed in pertinent sections of this final rule, which include sections III.C (New Technology APCs), III.E (OPPS APC-Specific Policies), and IV (OPPS Payment for Devices). The list of finalized HCPCS codes effective April 1, 2026, is found at Table 13 of the final rule.

4. October 2026 HCPCS Codes Final Rule Comment Solicitation

For 2027, consistent with CMS' established policy, CMS proposed that the Level II HCPCS codes that will be effective October 1, 2026, would be designated with "NI" in Addendum BB to the 2027 OPPS/ASC final rule to indicate that the codes have interim ASC payment status for 2026. **CMS solicits public comments in the 2027 OPPS/ASC final rule with comment period and will finalize the codes in the 2028 OPPS/ASC final rule with comment period**. The codes are listed in Table 14 of the 2027 final rule.

5. January 2027 HCPCS Codes

a. Level II HCPCS Codes Final Rule Comment Solicitation

CMS released Level II HCPCS codes in the 2027 OPPS/ASC final rule, and will also do so in the January 2027 ASC Update CR and the CMS HCPCS website. In the OPPS/ASC proposed rule for 2027, CMS proposed to continue to assign comment indicator "NI" in Addendums AA and BB to the 2027 OPPS/ASC final rule with comment period for those new and revised Level II HCPCS codes that are effective January 1, 2027. **CMS invites comments in the 2027 OPPS/ASC final rule on the interim payment indicator assignments, which would then be finalized in the 2028 OPPS/ASC final rule**.

b. CPT Codes Proposed Rule Comment Solicitation

CMS sought comment on proposed new and revised CPT codes effective January 1, 2027 that were received from the AMA in time to be included in the OPPS/ASC proposed rule for 2027. The new, revised, and deleted CPT codes can be found in ASC Addendum AA and Addendum BB of the proposed rule and on the CMS website. These CPT codes are assigned indicator "NP" to indicate that the code is new or substantially revised for the next calendar year. CMS states that the agency received comments on several of the new CPT codes that were assigned to comment indicator "NP" in Addendum B to the 2027 OPPS/ASC proposed rule. The agency responded to those public comments in sections III.C, III.E, and IV of the final rule. CMS

finalizes the payment indicators and includes the final CPT code numbers in the 2027 OPPS/ASC final rule.

6. Proposed ASC Payment and Comment Indicators

a. Background

For Addenda AA and BB, CMS has created payment and comment indicators as follows:

(1) Payment indicators (see Addendum DD1) to provide payment information regarding covered surgical procedures and covered ancillary services under the revised ASC payment system. These are intended to capture policy-relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC covered procedures list (CPL) prior to 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services, including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, NTIOLs, or qualifying non-opioid devices.

- The payment indicator "K5" (Items, Codes, and Services for which pricing information and claims data are not available. No payment made) indicates services and procedures that CMS anticipates will become payable when claims data or payment information becomes available.
- The payment indicators "D1" (Ancillary dental service/item; no separate payment made) and "D2" (Non office-based dental procedure added in 2024 or later) indicate potentially payable dental services and procedures in the ASC setting.
- The payment indicator "L6" (Special payment; New Technology Intraocular Lens (NTIOL) or qualifying non-opioid devices) accounts for non-opioid devices paid for under the ASC payment system pursuant to section 4135 of the CAA, 2023.

(2) Comment indicators (see Addendum DD2) which serve to identify, for the revised ASC payment system, the status of a specific HCPCS code and its payment indicator with respect to the timeframe when comments will be accepted.

- The comment indicator "NI" is used in the OPPS/ASC final rule to indicate new and substantially revised codes for the next calendar year for which the interim payment indicator assigned is subject to comment.
- The comment indicator "NP" is used in the OPPS/ASC proposed rule to indicate new and substantially revised codes for the next calendar year for which the proposed payment indicator assigned is subject to comment.
- The "CH" comment indicators that are published in the final rule are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment.

b. Final ASC Payment and Comment Indicators for 2027

As noted above, proposed codes were included in ASC Addenda AA and BB to the OPPS/ASC proposed rule for 2027, and labeled with comment indicator "NP."

Final Rule Action: CMS did not receive public comments on this provision and therefore is finalizing as proposed. CMS refers readers to Addenda DD1 and DD2 of the final rule d (which are available on the CMS website) for the complete list of ASC payment and comment indicators finalized for the 2027 update. Addenda DD1 and DD2 to the final rule (which are available via the internet on the CMS website) contain the complete list of ASC payment and comment indicators for 2027.

C. Payment Policies Under the ASC Payment System

1. Final ASC Payment for Covered Surgical Procedures

a. Background

Currently, for procedures with payment indicators "G2" and "A2"[41] CMS uses the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year to calculate the national unadjusted payment rates for the procedure.

Payment rates for office-based procedures (payment indicators "P2," "P3," and "R2") are the lower of the PFS non-facility PE RVU-based amount or the amount calculated using the ASC standard ratesetting methodology for the procedure. CMS updates the payment amounts for these office-based procedures using the most recent available PFS and OPPS data.

The rate calculation established for device-intensive procedures (payment indicator "J8") is structured so only the service (non-device) portion of the rate is subject to the ASC conversion factor. CMS updates the payment rates for device-intensive procedures to incorporate the most recent device offset percentages calculated under the ASC standard ratesetting methodology.

Beginning in 2014, CMS conditionally packages payment for device removal procedures under the OPPS. Under the OPPS, a conditionally packaged procedure (status indicators "Q1" and "Q2") describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a covered surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indicator "N1") under the ASC payment system. Under the OPPS, device removal procedures are conditionally packaged and, therefore, would be packaged under the ASC payment system. There is no Medicare payment made when a device removal procedure is performed in an ASC without another surgical procedure included on the claim; therefore, no Medicare payment would be made if a device was removed but not replaced. To ensure that the ASC payment system provides separate payment for surgical procedures that only involve device removal, CMS has

[41] Payment indicator "A2" was historically used to identify surgical procedures subject to transitional payment. Although it is no longer required, CMS has retained this payment indicator because it is used to identify procedures that are exempted from the application of the office-based designation.

continued to provide separate payment since 2014 and assign the current ASC payment indicators associated with these procedures.

b. Update to the ASC Covered Surgical Procedure Payment Rates for 2027

CMS proposed to update the ASC payment rates for 2027 using the established rate calculation methodologies and using the definition of device-intensive procedures. CMS proposed to generally use the geometric mean cost to determine proposed relative payment weights under the ASC standard methodology and to continue to use the amount calculated for procedures assigned to payment indicators "G2" and "A2."

CMS proposed to calculate payment rates for office-based procedures (payment indicators "P2," "P3," and "R2") and device-intensive procedures (payment indicator "J8") according to its established policies and to identify device-intensive procedures. CMS proposed to update the payment amount for the service portion (the non-device portion) of the device-intensive procedures using the standard ASC ratesetting methodology and the payment amount for the device portion based on the proposed 2027 device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. Finally, CMS proposed to continue its policy for device removal procedures, such that device removal procedures that are conditionally packaged in the OPPS (status indicators "Q1" and "Q2") would be assigned the current ASC payment indicators associated with those procedures and would be paid separately under the ASC payment system.

Final Rule Action: CMS indicates that it received no public comments in response to any of these proposals and is therefore finalizing all of them as proposed, without modification.

c. Final Payment for ASC Add-on Procedures Eligible for Complexity Adjustments under the OPPS

(1) OPPS C-APC Complexity Adjustment Policy

In this section, CMS provides an overview of its policies related to C-APC complexity adjustments. In general, complexity adjustments are used to provide increased payment for certain comprehensive services. CMS explains that certain combinations of primary service codes and add-on codes that meet specified frequency and cost threshold criteria may qualify for a complexity adjustment. CMS applies a complexity adjustment by promoting qualifying paired "J1" service code combinations from the originating Comprehensive APC (C-APC) to the next higher paying C-APC in the same clinical family.[42] CMS notes that the highest payment for any claim including a code combination for services assigned to a C-APC would be the highest paying C-APC in the clinical family, even if the calculated cost is higher than the highest cost C-APC in the family.

CMS packages payment for add-on codes into the C-APC payment rate. If any add-on code reported in conjunction with the "J1" primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the

[42] A "J1" status indicator refers to a hospital outpatient service paid through a C-APC.

primary service, and the primary service code reported with the add-on code is not reassigned to the next higher cost C-APC. CMS listed the proposed complexity adjustments for "J1" and add-on code combinations for 2027, along with all of the other proposed complexity adjustments, in Addendum J to the proposed rule.[43]

(2) 2027 ASC Special Payment Policy Proposal for OPPS Complexity Adjusted C-APCs

For 2027, CMS proposed to continue its current special payment policy and methodology for OPPS complexity-adjusted C-APCs. For those ASC complexity adjustment codes for which CMS has claims data, CMS proposed to use the claims data to calculate the code combination utilization and estimated payments for the ASC payment system budget neutrality calculations (discussed in section XIII.H of the proposed rule).[44]

Final Rule Action: CMS indicates that it did not receive public comments on this provision and therefore is finalizing the ASC special payment policy for OPPS complexity-adjusted C-APCs as proposed.

d. 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.

Based on its analysis of claims data, CMS proposed to designate APC 2645 (Brachytx, non-stranded, gold-198) as a Low-Volume APC under the ASC payment system. This APC met CMS' criteria of having fewer than 100 single claims in 2025. CMS also proposed to continue the low-volume APC designation for four brachytherapy and four clinical APCs that had met the low-volume in the 2026 rulemaking cycle.

Final Rule Action: CMS states that commenters supported the continued use of the Low-Volume APC policy. Therefore, CMS is finalizing its proposal to designate five brachytherapy APCs and four clinical APCs as Low-Volume APCs under the ASC payment system. APC 2645 (Brachytx, non-stranded, gold-198) also met the claims count criteria, and CMS is finalizing its proposal to designate APC 2645 as a Low-Volume APC.

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[43] https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1850-p

[44] The full list of the finalized ASC complexity adjustment codes for 2027 can be found in the 2027 ASC Addendum AA and the supplemental policy file, which also includes both the existing ASC complexity adjustment codes and additions and published with the final rule on the CMS website at https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and-notices/cms-1850-fc. Note that the link provided in the public inspection version of the final rule is incorrect.

2. Final Payment for Covered Ancillary Services

a. Background

In this section, CMS outlines its payment policies for covered ancillary services under the ASC payment system, which vary according to the particular type of service and its payment policy under the OPPS. CMS' overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators "N," "Q1," and "Q2") under the OPPS.

Under the OPPS, a conditionally packaged procedure (status indicators "Q1" and "Q2") describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are generally packaged (payment indicator "N1") under the ASC payment system (except for device removal procedures). Thus, CMS' policy generally aligns ASC payment bundles with those under the OPPS. In all cases, in order for ancillary items and services also to be paid, they must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

CMS provides separate payment for the following:

Drugs and biologicals. CMS policies generally provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates and package payment for drugs and biologicals for which payment is packaged under the OPPS. CMS notes that, beginning in 2022, CMS unpackages and separately pays for the cost of non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure.[45]

Radiology services. CMS generally pays separately for radiology services at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology. However, payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services (including radiology services that use contrast agents) that are paid separately when provided integral to a surgical procedure on the ASC list are set to "Z2" so that payment is made based on the ASC standard ratesetting methodology rather than the PFS nonfacility PE RVU amount ("Z3"), regardless of which is lower.

Brachytherapy sources. ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at contractor-priced rates.

[45] As determined by CMS under §416.174 (86 FR 63483).

Contractor-priced services and implantables with pass-through payment status. CMS' ASC policies also provide separate payment for: (1) certain items and services that CMS designates as contractor-priced, including the procurement of corneal tissue; and (2) certain implantable items that have pass-through payment status under the OPPS. These categories do not have prospectively established ASC payment rates according to ASC payment system policies.

Devices that are eligible for pass-through payment. Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and are contractor-priced. The payment for the surgical procedure associated with the pass-through device is made according to CMS' standard methodology for the ASC payment system, based on only the service (non-device) portion of the procedure's OPPS relative payment weight if the APC weight for the procedure includes other packaged device costs. CMS refers to this methodology as applying a "device offset" to the ASC payment for the associated surgical procedure.

Certain diagnostic tests. Beginning in 2015, certain diagnostic tests within the medicine range[46] of CPT codes for which separate payment is allowed under the OPPS are covered ancillary services when they are integral to an ASC covered surgical procedure. CMS pays for these tests at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology. The diagnostic tests for which the payment is based on the ASC standard ratesetting methodology are assigned to payment indicator "Z2" and those for which the payment is based on the PFS nonfacility PE RVU-based amount are assigned payment indicator "Z3."

b. Final payment for covered ancillary items and services

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 2027 ASC payment rates and subsequent year payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for 2027 and subsequent year payment rates. For those covered ancillary services where the payment rate is the lower of the rate under the ASC standard ratesetting 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, 2027.

Final Rule Action: CMS did not receive any public comments on these proposals and is therefore finalizing its proposal to update the ASC payment rates and to make changes to ASC payment indicators, as necessary, to maintain consistency between OPPS and ASC payment systems regarding the packaged or separately payable status of services and the final 2027 OPPS and ASC payment rates and subsequent years' payment rates. CMS also finalizes without modification its proposal to continue to set the 2027 ASC payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for 2027 and subsequent years.

[46] Diagnostic tests within the medicine range of CPT codes include: all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999; and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT.

3. Covered Surgical Procedures Designated as Office-Based Procedures

a. Background

Beginning in 2008, "office-based" procedures are those that CMS determines are furnished predominantly (more than 50 percent of the time) in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. Office-based procedures are identified in Addendum AA with payment indicator "P2," "P3," or "R2," depending on whether CMS estimated the procedure would be paid according to the ASC standard ratesetting methodology based on its OPPS relative payment weight or at the PFS nonfacility PE RVU-based amount. Note that CMS exempts all procedures on the 2007 ASC list from application of this office-based classification.

Each year, CMS identifies covered surgical procedures as either temporarily office-based (these are new procedure codes with little or no utilization data that CMS has determined are clinically similar to other procedures that are permanently office-based), permanently office-based, or nonoffice-based, after taking into account updated volume and utilization data.

b. 2027 Final Office-Based Procedures

For 2027, CMS proposed to continue its historical practice of reviewing the most recent claims and utilization data for determining office-based assignments under the ASC payment system.

Based on its review of the 2025 utilization of covered surgical procedures claims data, CMS identified two surgical procedures that it proposed to permanently designate as office-based for 2027, specifically, CPT code 0102T (Extracorporeal shock wave performed by a physician, requiring anesthesia other than local, and involving the lateral humeral epicondyle), and 60660 (Ablation of 1 or more thyroid nodule(s), one lobe or the isthmus, percutaneous, including imaging guidance, radiofrequency).

CMS also reviewed the utilization for four surgical procedures designated as temporarily office-based in the 2026 OPPS/ASC final rule. CMS proposed to remove one of the procedures, HCPCS codes 53866 (Catheterization with removal of temporary device for ischemic remodeling (*i.e,*, pressure necrosis) of bladder neck and prostate), because there were more than 50 claims for this service available for 2025 and the service was not predominantly performed in offices in that year.

For the remaining three procedures temporarily designated as office-based in 2026, there was an insufficient number of claims to determine if the office setting was the predominant setting of care for these procedures. Therefore, CMS proposed to continue to designate such procedures as temporarily office-based for 2027 and assign one of the office-based payment indicators. These codes are listed and described in Table 70 in the proposed rule.

CMS did not propose to designate any new 2027 CPT codes for ASC covered surgical procedures as temporarily office-based.

Final Rule Action: CMS did not receive any comments in response to its proposals regarding the designation of office-based procedures and is thus finalizing all of them as proposed.

4. Device-Intensive ASC Covered Surgical Procedures

a. Device-Intensive Procedures for 2027

In 2019, CMS adopted a policy to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. CMS also lowered the device offset percentage threshold from 40 percent to 30 percent. Device-intensive procedures are subject to the following criteria:

- All procedures must involve implantable or insertable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost. The default device offset for new codes that describe procedures that involve the implantation of medical devices is 31 percent and is applied in the same manner as the policy CMS adopted for device pass-through status.[47]

To further align the device-intensive policy with the criteria used for device pass-through status, for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by FDA in accordance with 42 CFR 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not any of the following:
    - Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets;[48] or
    - A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker).

In 2022, CMS adopted a policy of assigning device-intensive status to procedures that involve surgically inserted or implanted, high-cost, single-use devices if their device offset percentage exceeds 30 percent under the ASC standard ratesetting methodology, even if the procedure is not designated as device-intensive under the OPPS. Additionally, if a procedure is assigned device-intensive status under the OPPS, but has a device offset percentage below the device-intensive threshold under the standard ASC ratesetting methodology, the procedure will be assigned

[47] 83 FR 58944 through 58948.
[48] As defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1).

device-intensive status under the ASC payment system with a default device offset percentage of 31 percent. The policies were adopted to provide consistency between the OPPS and ASC payment system and provide a more appropriate payment rate for surgical procedures with significant device costs under the ASC payment system.

In 2023, CMS created certain C-codes, or ASC complexity adjustment codes, that describe certain combinations of a primary covered surgical procedure as well as a packaged (payment indicator "N1") procedure that are otherwise eligible for a complexity adjustment under the OPPS (as listed in Addendum J). Each ASC complexity adjustment code's APC assignment is based on its corresponding OPPS complexity adjustment code's APC assignment. Under CMS' current policy, the ASC complexity adjustment code retains the device portion of the primary procedure (also called the "device offset amount") and not the device offset percentage. Therefore, for device-intensive ASC complexity adjustment codes, CMS sets the device portion of the combined procedure equal to the device portion of the primary procedure and calculates the device offset percentage by dividing the device portion by the ASC complexity adjustment code's APC payment rate. Further, CMS multiplies the OPPS relative weight by the ASC budget neutrality adjustment and the ASC conversion factor and sums that amount with the device portion to calculate the ASC payment rate.

Beginning in 2025, CMS modified the default device offset percentages for new codes that meet CMS' criteria for device-intensive status. Under both the OPPS and ASC payment system, for new device-intensive procedures that lack claims data, CMS applies the greater of the APC-wide device offset percentage or 31 percent (the previous default device offset percentage). CMS believes that an APC-wide average device offset percentage is, in most cases, a better reflection of device costs when the typical device costs of procedures assigned to such APC are significantly greater than 31 percent. This policy does not apply to new device-intensive procedures assigned to New Technology APCs.

In the 2026 OPPS/ASC final rule, CMS discussed the implementation of the "Final Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022 rule" and expressed its belief that the remedy's proposed prospective offset to the OPPS conversion would have had a very limited impact on the ASC payment system. At the time, the agency believed that it would be inaccurate and inappropriate to use OPPS payment rates that have been reduced by the remedy's prospective offset since this could accumulate to have a potentially noticeable impact on ASC payment rates for certain device-intensive procedures over time. Thus, CMS finalized a policy that the OPPS payment rates used for ratesetting under the ASC payment system for 2026 and subsequent years would not incorporate the prospective offset to the OPPS conversion factor as a result of the 340B remedy offset that the agency proposed to implement in the 2026 OPPS/ASC proposed rule.

In the 2027 OPPS/ASC proposed rule, CMS did not propose any changes to its device-intensive procedure policies under the ASC payment system for 2027, but solicited comment on whether its device-intensive calculation methodology should continue to exclude device portions from the ASC weight scalar or whether device portions should represent scalable prospective expenditures.

Selected Comments/Responses: CMS received several comments in response to these proposals. Several commenters supported continuing to exclude the device portion of device-intensive procedures from the ASC weight scalar. Several commenters requested that CMS designate CPT code 52282 (Cystourethroscopy, with insertion of permanent urethral stent) as device-intensive and establish its 2027 device offset using manufacturer invoice data. Several commenters opposed removing device-intensive status for CPT code 55882 (Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation; with insertion of transurethral ultrasound transducer for delivery of thermal ultrasound, including suprapubic tube placement and placement of an endorectal cooling device, when performed) for 2027 under the ASC payment system. Other commenters made similar code-specific recommendations or comments regarding a wide number of ASC device-intensive procedures.

Final Rule Action: As discussed in further detail in section XIII.G, CMS is finalizing its proposal to continue excluding the device portion of device-intensive procedures from the ASC weight scalar. CMS is also revising its device-intensive procedures policy to include a low-volume device-intensive procedures policy for 2027. Regarding procedure-specific comments, CMS was uncharacteristically receptive to the arguments several comments raised in opposition to specific proposals and is not finalizing certain proposals in light of these comments. CMS refers readers to Addendum FF of the final rule for final 2027 device offset percentages based on the claims data for the final rule, 2025 claims processed through June 30, 3036 [*sic*].[49]

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

CMS' ASC payment policy for costly devices implanted or inserted in ASCs at no cost/full credit or partial credit is set forth in §416.179 of the regulations. Currently, 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. Specifically:

- When the device is furnished at no cost or with full credit from the manufacturer, the contractor reduces 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 must 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 reduces payments to the ASC by 50 percent of the device offset amount. In order to report a partial credit, the ASC has 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 then submits the claim with a "FC" modifier if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the replacement device. Beneficiary coinsurance is based on the reduced payment amount.

[49] Presumably CMS means June 30, 2026.

CMS did not propose any changes to its policies related to no cost/full credit or partial credit devices for 2027.

Final Rule Action: CMS did not receive any comments on its policies related to no cost/full credit or partial credit devices and is finalizing the continuation of its existing policies for 2027 without modification.

D. Additions to ASC Covered Surgical Procedures and Covered Ancillary Services Lists

1. Final Additions to the List of ASC Covered Surgical Procedures

The statute[50] requires CMS, in part, to specify, in consultation with appropriate medical organizations, surgical procedures that are appropriately performed on an inpatient basis in a hospital but that can also be safely performed in an ASC, a CAH, or an HOPD, and to review and update the list of ASC covered surgical procedures at least every two years. Currently, CMS evaluates the ASC covered procedures list (CPL) each year to determine whether procedures should be added to or removed from this list, and changes to the list are often made in response to specific concerns raised by interested parties.

Beginning in 2019,[51] CMS defined a surgical procedure under the ASC payment system as any procedure described within the range of surgical Category I CPT codes (CPT codes 10000 through 69999), as well as procedures that are described by Level II HCPCS codes or by Category I CPT codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that CMS determines met the general standards established in previous years for addition to the ASC CPL.

CMS substantially changed its regulations governing the list of ASC covered surgical procedures in the 2026 rulemaking cycle. Under the revised regulations at §§416.2 and 416.166, covered surgical procedures furnished on or after January 1, 2026, are surgical procedures that meet the criteria specified in §416.166(b)(2). In the 2026 OPPS/ASC final rule with comment period, the agency expanded the ASC CPL by revising the criteria for adding surgical procedures to the ASC CPL (90 FR 53855 through 53886). Under the revised criteria, procedures added to the ASC CPL must be separately paid under the OPPS and are not:

(1) Currently designated as requiring inpatient care under §419.22(n),
(2) Only able to be reported using a CPT unlisted surgical procedure code, or
(3) Otherwise excluded under §411.15.

Additionally, CMS moved certain general standards and exclusions used to evaluate services for addition to the ASC CPL prior to January 1, 2026, to a new section of the following *non-binding physician considerations*:

(1) Is not expected to pose a significant safety risk when performed in an ASC;
(2) Is one of which standard medical practice dictates the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure;

[50] Section 1833(i)(1) of the Act.
[51] See 2019 OPPS/ASC final rule (83 FR 59029 through 59030).

(3) Generally results in extensive blood loss;
(4) Requires major or prolonged invasion of body cavities;
(5) Directly involves major blood vessels;
(6) Is generally emergent or life-threatening in nature; and
(7) Commonly requires systemic thrombolytic therapy.

2. Changes to the List of ASC Covered Surgical Procedures for 2027

Historically, CMS has reviewed the clinical characteristics of procedures and consulted with appropriate medical organizations, other interested parties, and the agency's clinical advisors to determine if those procedures would meet the agency's existing regulatory criteria. As part of the agency's evaluation process to add procedures to the CPL, CMS assesses potential procedures against the revised ASC CPL criteria at §416.166(b)(2). For 2027, CMS reviewed interested parties' nominations received in the pre-proposed rule nominations process. Additionally, CMS reviewed procedures that are proposed to be removed from the IPO list for 2027, as part of the continuation of the elimination of the IPO list, as described in section IX of the proposed rule. Based upon this review, CMS proposed to update the ASC CPL by adding 618 procedures that were proposed to be removed from the IPO list for 2027. These procedures included four procedures that were recommended by interested parties for addition to the ASC CPL.[52]

These procedures were listed in the public use file titled "Proposed Additions to the List of ASC Covered Procedures for 2027," which is available on the CMS website.

Selected Comments/Responses: CMS indicates that the agency received comments both supporting and opposing the proposed expansion of the ASC CPL. Commenters opposing the proposed expansion were especially concerned that these procedures are on the IPO list and many are associated with risks that would have previously excluded them from the ASC CPL under CMS' previous exclusion criteria. CMS indicates that some commenters recommended that CMS reinstate the previous exclusion criteria, with some stating that the expansion of the ASC CPL removed important safety guardrails. Multiple commenters also requested that CMS review the codes individually to determine if they were appropriate to perform in the ASC setting. CMS disagreed with these comments, asserting that current guardrails are sufficient to ensure patient safety (90 FR 53857). A number of commenters raised procedure-specific concerns.

Final Rule Action: CMS is finalizing its proposal to update the ASC CPL by adding 618 procedures that the agency proposed to remove from the IPO list for 2027. Additionally, CMS is finalizing adding an additional code, CPT code 64629, recommended by commenters, to the ASC CPL for 2027.

[52] CPT code 49596, CPT code 49616, CPT code 40617, and CPT code 40618.

3. Covered Ancillary Services

Beginning in 2019, CMS updates the ASC list of covered ancillary services to reflect the payment status for the services under the OPPS and the reconciliation of packaged status. For example, if a covered ancillary service was separately paid under the ASC payment system in 2026 but will be packaged under the 2027 OPPS, CMS would also package the ancillary service under the ASC payment system for 2027 to maintain consistency with the OPPS. All ASC covered ancillary services and their proposed payment indicators for 2027 were included in Addendum BB to the proposed rule.

Selected Comments/Responses: A commenter requested that CMS ensure that its policy for adding procedures to the list of covered ancillary services does not lead to fragmented care because a needed ancillary service is not on the list. The commenter requested that CMS maintain a transparent process for aligning ancillary service assignments with additions to the ASC CPL. Multiple commenters recommended adding specific codes to the 2027 list of covered ancillary services; CMS generally accommodated these recommendations.
Final Rule Action: CMS is adding the following six procedures recommended by interested parties to the list of ASC-covered ancillary services for 2027, including five procedures that commenters recommended for addition to the ASC CPL: CPT codes 1086T, 93313, 93314, 93315, and 93317. New CPT and HCPCS codes for covered ancillary services for 2027 can be found in section XIII.B of the final rule.

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

1. Background

Section 4135(a) and (b) of the CAA, 2023 directs CMS to unpackage and provide separate payment for non-opioid treatments for pain relief furnished between January 1, 2025 and January 1, 2028. CMS describes the policies finalized in the 2025 OPPS ASC final rule,[53] which outline payment for non-opioid pain management drugs, biologicals, and medical devices under both the ASC payment system and OPPS. CMS previously finalized several qualifying products for separate payment beginning January 1, 2025,[54] and it notes the temporary separate payments are made in a budget neutral manner.

Definition. A non-opioid treatment for pain relief is defined as follows:

- In the case of a drug or biological, the product has a label indication approved by the Food and Drug Administration (FDA) to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body's opioid receptors; and
- In the case of a medical device, the device has demonstrated in a clinical trial or through data published in a peer-reviewed journal the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed.

Medical Device Evidence Requirement. With respect to medical devices, CMS reviews all data submitted during the public comment period, and it encourages interested parties to submit with

[53] See 42 CFR 416.174 and 42 CFR 419.43(k).
[54] See table 158 in the 2025 OPPS ASC final rule, beginning 89 FR 94358.

their public comments any relevant literature that demonstrates that the named medical device replaces, reduces, or avoids opioid use. If there is no data or literature submitted for a medical device, or if the materials submitted do not demonstrate any ability of the medical device to replace, reduce, or avoid opioids, the medical device will not meet the evidence criterion to qualify for separate payment.

Non-Opioid Product Indications. CMS only approves 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. In the case of a medical device, the device must be used to deliver a therapy to reduce postoperative pain or produce post-surgical or regional analgesia to qualify for separate payment. Additionally, the device must have an application approved under section 515 of the Federal Food, Drug, and Cosmetic Act (FDCA), which has been cleared for market under section 510(k) of the FDCA, or be exempt from the requirements of section 510(k) of the FDCA pursuant to section 510(l) or (m) or 520(g) of the FDCA.[55]

Amount of Payment. For a drug or biological that qualifies for separate payment, the statute sets payment with the methodology used under section 1847A (generally, ASP+6 percent) less the amount included in the OPPS or ASC payment for the product and capped at 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 and capped at 18 percent of the OPPS or ASC payment.

In implementing this provision, CMS noted the similarity between the statutory language to allow separate payment for non-opioid pain products and transitional pass-through payment. While CMS will apply an offset to the APC for pass-through products paid separately, CMS does not apply a payment offset for non-opioid products paid separately as some of these products are new and their costs may not be fully reflected in the data that CMS uses for rate-setting; CMS refers to this policy as a zero-dollar offset.

CMS applies 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 are more reflective of the cost of the drug in that encounter. CMS bases the 18 percent payment limitation on the volume weighted average of the payment rates of the top five primary procedures by volume into which a non-opioid treatment for pain relief would have its payment packaged, absent this policy.

For products with no claims data,[56] CMS uses the services with which a product would be expected to be furnished and would typically be packaged absent this policy in order to calculate the payment limitation based on expected clinical use patterns.

[55] 89 FR 94346 through 94347

[56] For example, newly FDA-approved and marketed products or products that did not previously have their own product-specific HCPCS code by which to track payment and utilization data.

2. Final 2026 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023

CMS finalized continuing to use the policies it finalized in the 2025 OPPS ASC final rule without modification. The agency believes the zero-dollar offset policy is appropriate for all qualifying products. Last year, CMS also finalized a list of qualifying drugs, biologicals, and devices that meet the statutory criteria for separate payment under section 4135. CMS also finalized a modification to allow for more timely consideration of qualifying products by establishing a process to evaluate and approve additional non-opioid treatments for pain relief on a quarterly basis, rather than limiting consideration to annual rulemaking.

3. 2027 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023

For 2027, CMS proposed to continue the policies finalized in the 2026 OPPS/ASC final rule (90 FR 53448) without modification, aside from a technical modification to the payment limitation calculations. CMS continues to believe a zero-dollar offset is appropriate for all qualifying products regulated under the non-opioid policy as some of these products are new products or newly separately paid in the OPPS setting and their costs may not be fully reflected in the cost of procedures in which they may be used. A continued zero-dollar offset aligns with comment support for a zero-dollar offset as discussed in the 2026 OPPS/ASC final rule with comment period (90 FR 53892).

Selected Comments/Responses: CMS states that several commenters supported the agency's proposal to continue the policies finalized in the 2026 OPPS/ASC final rule with comment period. Some commenters took issue with the statutory 18 percent payment limitation, noting that the cap often results in payment below a facility's documented device cost, leaving hospitals and ASCs to absorb the difference. (CMS pointed out that the 18 percent limitation is required by statute.) Some commenters requested that CMS reconsider its interpretations of the statutory criteria for qualifying products; CMS declined to act on these suggestions. Some commenters supported CMS' proposal to continue to provide for separate payment for certain specific qualifying products.

Final Rule Action: CMS is finalizing its proposal to continue the policies finalized in the 2025 OPPS/ASC final rule with the 2026 OPPS/ASC final rule, with a minor modification to permit more timely consideration of payment requests. In addition, CMS approved Stimuplex needles (under HCPCS code C9812) as a qualifying product under the agency's revised process to review non-opioid products for separate payment more frequently than annual rulemaking.

Table 96 (summarized below) lists for 2026 the non-opioid alternatives identified for separate payment as a non-opioid pain management drug or device under section 4135 criteria. CMS refers readers interested in submitting additional products for the agency's consideration to the guidance posted on the CMS website at https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/non-opioid-treatments-pain-relief.

TABLE 96: FINAL LIST OF QUALIFYING PRODUCTS FOR SEPARATE PAYMENT IN 2027 UNDER SECTION 4135 OF THE CAA, 2023

Brand Name	HCPCS Code	Long Descriptor
Exparel	J0666*	Injection, bupivacaine liposome, 1mg
Omidria	J1097	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml
Dextenza	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg
Zynrelef	J0668 (previously C9088**)	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg
Ketorolac tromethamine Injection	J1885	Injection, ketorolac tromethamine, per 15 mg
Journavx	C9818	Suzetrigine, oral, 1 mg
Caldolor	J1741	Injection, ibuprofen, 100 mg
ON-Q Pump	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)
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)
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, 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)
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)
IceMan	C9XX0	Water circulating motorized cold therapy device (*e.g.*, IceMan) including all system components (*e.g.*, pads, console, disposable parts), non-opioid medical device (must be a qualifying Medicare non-opioid medical device for postsurgical pain relief in accordance with section 4135 of the CAA, 2023)
Sapphire Infusion Pump	C9811	Electronic ambulatory infusion pump (*e.g.*, Sapphire pump), including all pump components, including disposable 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)
Ultrasound-visible nerve block needles (SonoPlex, SonoBlock, SonoTap, Stimuplex)	C9812	Echogenic nerve block needles (*e.g.*, SonoPlex, SonoBlock, SonoTap), 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)
Perforated continuous infusion	C9813	Perforated continuous infusion catheter set (*e.g.*, InfiltraLong), including all components, non-opioid medical device (must be a qualifying Medicare non-

Brand Name	HCPCS Code	Long Descriptor
catheter set (InfiltraLong)		opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
Continuous anesthesia conduction catheter sets (SonoLong, E-Cath)	C9814	Continuous anesthesia echogenic conduction catheter set (*e.g.*, SonoLong, E-Cath), 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)
CADD-Solis infusion pump	C9815	Linear peristaltic pain management infusion pump (*e.g.*, CADD-Solis ambulatory infusion pump), 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)
ambIT Electronic Infusion Pump (Reusable)	C9816	Rotary peristaltic infusion pump (*e.g.*, reusable ambIT Pump) including all disposable system components, reusable 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)
Game Ready System	C9817	Electronic cryo-pneumatic compression, pain management system (*e.g.*, Game Ready® GRPro 2.1 System), including control unit, anatomically correct wrap(s), and other system component(s), 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)

*Previously described by HCPCS code C9290.
**HCPCS Code C9088 was replaced by HCPCS code J0668 (Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg) effective October 1, 2025.

F. 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 2027 by March 1, 2026, the due date published in the 2026 OPPS/ASC final rule with comment period (90 FR 53910). CMS did not propose to revise the current payment adjustment ($50 per lens) for NTIOLs.

Selected Comments/Responses: CMS did not receive any requests for review to establish a new NTIOL class for 2027 by March 1, 2026, the due date published in the 2026 OPPS/ASC final rule with comment period (90 FR 53909). However, CMS did receive comments on its existing policies, specifically from commenters requesting that CMS increase the current $50 payment adjustment to $100 per lens in 2027. CMS declined to act on this suggestion.

G. ASC Payment Rates and ASC Conversion Factor

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. In the proposed rule, CMS scaled the relative weights as under prior policy. Holding ASC use, the ASC conversion factor, and mix of services constant from 2025,[57] CMS computes the ratio of:

[57] The supporting data file is posted on the CMS Web site at: http://www.cms.gov/Research-Statistics-Data-and-

- Estimated total payments using the 2026 relative payment rates, to
- Estimated total payments using the 2027 relative payment rates.

The 2027 total payments would also include spending and utilization related to ASC complexity adjustment codes or C-codes. CMS estimates that the change in ASC spending related to these codes for 2027 did not impact the ASC weight scalar. Regarding the application of the 18 percent payment limitation for separately payable non-opioid treatments for pain relief under section 4135, CMS estimates that the proposed 2027 payment limitations would not impact the ASC weight scalar.

The resulting ratio, 0.809,[58] was the proposed weight scalar for 2027. 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).

As the ASC payment system uses the OPPS conversion factor to determine payment for the device portions of device-intensive procedures, this alters the payment relativity between services under the OPPS because the entire portion of ASC payment rates for non-device-intensive procedures is based on the lower ASC conversion factor. Because of the proposed large increase in the device portions for device-intensive procedures in 2027 as a result of the proposed 340B drug payment policy discussed elsewhere in the final rule, CMS solicited comment on whether the device portions of device-intensive procedures calculated using the OPPS conversion factor should continue to be excluded from the ASC weight scalar, or alternatively, whether these device portions should be included in the expenditures subject to scaling through the ASC weight scalar.

Selected Comments/Responses: Commenters opposed the proposed 2027 ASC weight scalar of 0.809, stating that the secondary scaling adjustment unnecessarily reduces ASC payments, widens the disparity with HOPD payments, and discourages migration to lower-cost ASCs. Many commenters urged CMS to eliminate the ASC weight scalar because continued annual application is not statutorily required, or alternatively to establish a single budget-neutrality calculation using combined OPPS and ASC utilization and service mix. Some commenters supported CMS' alternative of including device portions of device-intensive procedures in scalable expenditures, which would increase the scalar to approximately 0.865 and mitigate reductions for non-device-intensive services, although some recommended phasing in or partially applying this approach. Other commenters opposed scaling device portions because device acquisition costs are fixed and warned that the resulting approximately 14 percent reduction could impair access to device-intensive procedures. CMS acknowledged these

Systems/Files-for-Order/LimitedDataSets/ASCPaymentSystem.html.

[58] CMS has historically displayed this figure rounded to the nearest ten thousandth; however, it now believes this level of specificity is unnecessarily burdensome for an ASC payment system that is less than one-tenth the size of the OPPS.

commenters' concerns, but is not changing its proposals in response. CMS indicates that the agency will continue to explore alternative
methodologies that maintain budget neutrality under the ASC payment system while advancing payment policies that expand access to site-neutral options for beneficiaries.

Commenters opposed proposed 2027 ASC payment reductions for ophthalmic, interventional pain, and dialysis vascular-access procedures. Commenters generally requested that CMS adopt payment methodologies that more accurately recognize ASC resource costs, stabilize or increase payment for these services, and preserve access to care in lower-cost non-hospital settings.[59]

Final Rule Action: CMS is finalizing its proposal to use scaled OPPS relative weights to establish ASC relative payment weights and to use the ratio of 2026 to 2027 total payments (the weight scalar) to ASC relative payment weights for 2027. CMS is also finalizing its proposal to continue using the OPPS conversion factor ($99.970 for 2027) to continue maintaining device portions between the OPPS and ASC payment systems for device-intensive surgical procedures. The final 2027 ASC weight scalar is 0.814.

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)[60] 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 2024 and using the 2026 national payment rates after application of the weight scalar, CMS computes the ratio of:

- ASC payments using the 2026 ASC wage indices, to
- ASC payments using the 2027 ASC wage indices.

The resulting ratio, 1.0016, was the proposed wage index budget neutrality adjustment to the conversion factor for 2027, as published in this year's OPPS/ASC proposed rule for 2027.

To update ASC rates, CMS proposed to use the hospital market basket update of 3.2 percent minus the productivity adjustment of 0.8 percent. This yielded an update of 2.4 percent for ASCs meeting quality reporting requirements. CMS would continue its policy of reducing the update by 2.0 percentage points for ASCs not meeting the quality reporting requirements, yielding an update of 0.4 percent for such ASCs. The resulting proposed 2027 ASC conversion factor was $56.206 for ASCs reporting quality data, and $55.109 for those that do not.

[59] Interestingly, CMS cited ASCs' lack of cost reports as limiting the agency's ability to independently assess whether its proposed rates adequately reflect the costs of the staff, supplies, devices, imaging, equipment, and other resources.

[60] Consistent with CMS' proposed changes to other FY and 2027 fee-for-service payment systems, CMS here 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.

Selected Comments/Responses: Most commenters supported CMS' proposal to extend use of the productivity-adjusted hospital market basket, rather than the CPI-U, as the ASC payment update factor through 2027. Other commenters, however, opposed the extension, stating that hospitals and ASCs have different cost structures and patient populations and that the hospital market basket does not accurately measure ASC input costs. These commenters recommended that CMS collect minimally burdensome ASC cost data and develop an ASC-specific market basket, while some supporters stated that any new index should apply consistently to both ASCs and HOPDs to preserve alignment between the payment systems.

Final Rule Action: For 2027, CMS finalized its proposal to utilize the final inpatient hospital market basket percentage increase of 3.2 percent reduced by the productivity adjustment of 0.9 percentage point, resulting in a final hospital market basket update of 2.3 percent for ASCs meeting the quality reporting requirements. Therefore, CMS is finalizing its proposal to apply a 2.3 percent hospital market basket update factor to the 2026 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the 2027 ASC payment amounts.

	ASCs reporting quality data	**ASCs not reporting quality data**
2026 ASC conversion factor	$56.322	
Wage adjustment for budget neutrality	x 1.0018	
Net MFP-adjusted update	x 1.023	x 1.003
2027 Final ASC conversion factor	$57.721	$56.592

H. Impact

CMS provides the estimated aggregate payment changes for the six specialty groups that account for the most ASC utilization and spending, assuming the same mix of services from the 2025 claims data. (Table 113 of the final rule shown below.) The finalized update to ASC payment rates for 2027 would result in a 1 percent decrease in aggregate payment amounts for eye and ocular adnexa procedures, but a 6 percent increase in aggregate payments for musculoskeletal system procedures and for nervous system procedures.

Table 113: Estimated Impact of the Final 2027 Update to the ASC Payment System on Aggregate 2026 Medicare Program Payments by Surgical Specialty or Ancillary Items and Services Group

Surgical Specialty Group	Estimated 2026 ASC Payments (in Millions)	Estimated 2027 Percent Change
Total	**$8,349**	**2%**
Eye	$2,120	-1%
Musculoskeletal	$2,019	6%
Nervous system	$1,580	6%
Gastrointestinal	$1,059	-1%
Cardiovascular	$635	5%
Genitourinary	$365	1%

CMS provides estimated increases for 30 selected procedures in Table 114 in the 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 2 percent decrease in payment. The second largest aggregate payment procedure, CPT code 27447 (total knee arthroplasty), is expected to see a 4 percent increase.

Excerpt from Table 114: Estimated Impact of the Final 2027 Update to the ASC Payment System on Aggregate Payments for the Top 10 Procedures			
CPT/ HCPS Code	Short Descriptor	Estimated 2026 ASC Payments (in Millions)	Estimated 2027 Percent Change
66984	Xcapsl ctrc rmvl w/o ecp	$1,383	-2
27447	Total knee arthroplasty	$529	4
63685	Ins/rplc spi npg/rcvr pocket	$421	13
27130	Total hip arthroplasty	$284	5
45385	Colonoscopy w/lesion removal	$273	-1
45380	Colonoscopy and biopsy	$253	-1
23472	Reconstruct shoulder joint	$215	7
43239	Egd biopsy single/multiple	$174	-1
63650	Implant neuroelectrodes	$161	5
64590	Ins/rpl prph sac/gstr npg/r	$131	8

Addenda tables available only on the website provide additional details, at https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and-notices/cms-1850-fc. They include:

- AA: ASC Covered Surgical Procedures for 2027 (Including surgical procedures for which payment is packaged)
- BB: ASC Covered Ancillary Services Integral to Covered Surgical Procedures for 2027 (Including Ancillary Services for Which Payment is Packaged)
- DD1: Proposed ASC Payment Indicators for 2027
- DD2: ASC Comment Indicators for 2027
- EE: Surgical Procedures to be Excluded from Payment in ASCs for 2027
- FF: ASC Device Offset Percentages for 2027
- O: Long Descriptors for New Category I CPT Codes, Category III CPT Codes, C-codes, and G-Codes Effective January 1, 2027.

XV. Measure Removal: Follow-Up for Normal Colonoscopy in Average Risk Patients

A. Background

Background on the Hospital Outpatient Quality Review Program (HOQRP) and ASC QRP is provided under sections XV and XVII, respectively.

B. Remove Measure: Follow-Up for Normal Colonoscopy in Average Risk Patients

The Colonoscopy Follow-Up Interval measure is included in both the HOQRP and ASC QRP. The measure assesses the percentage of patients aged 45 to 75 years who receive a screening colonoscopy without biopsy or polypectomy and had documented in their colonoscopy report a

recommended follow-up interval of at least 10 years for a repeat colonoscopy. The measure was intended to increase provider and patient awareness of appropriate screening intervals by assessing whether the recommended follow-up interval was documented; it does not assess whether the follow-up screening was performed according to the recommended interval.

Final Action. CMS is finalizing, without modification, its proposal to remove the measure from both the HOQRP and ASC QRP beginning with the 2027 reporting period/2029 payment determination. The removal is based on removal factor 6, which permits removal in the case of availability of a measure that is more strongly associated with a desired patient outcome for the particular topic.[61] The agency points to the Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure, which is already included in both reporting programs and assesses the incidence of hospital returns within seven days of a colonoscopy. CMS believes that the Facility 7-Day measure is a more patient-outcome focused measure of procedure-related adverse-events in comparison to the Colonoscopy Follow-Up Interval measure.

Comments/Responses. Many commenters supported removal of the measure for multiple reasons, including because the measure assesses whether a recommended follow-up interval was documented and does not assess whether appropriate clinical care occurred or patient outcomes, and the proposal would streamline quality reporting and reduce administrative burden. Some commenters expressed concern that the Facility 7-Day measure does not assess the same clinical areas as the Colonoscopy Follow-Up Interval measure that was proposed for removal. CMS states that the existing Facility 7-Day measure provides an outcome-focused assessment of procedure-related adverse events and the agency aims to focus on patient outcome measures.

XVI. Hospital Outpatient Quality Reporting Program (HOQRP)

A. Background

CMS provides references to the legislative and regulatory histories of the HOQRP.[62] Section 1833(t)(17)(A) of the Act provides a 2.0 percentage point reduction in the annual Hospital Outpatient Department (HOPD) fee schedule increase factor (Annual Payment Update, APU) for each subsection (d) hospital that does not submit data as required for the HOQRP's measures. For 2027, CMS finalizes its policy to continue to implement the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements by applying a reporting ratio of 0.9804 to the OPPS payments and copayments for all applicable services. The final reporting ratio, when multiplied by the final full conversion factor of $99.970, equals a final reduced conversion factor for hospitals that fail to meet the requirements of the HOQRP of $98.011, which will apply for the 2027 payment determination.[63]

[61] Measure removal factors are under 42 CFR 419.46(i)(3)(i) and 416.320(c)(2) for the HOQRP and ASC QRP, respectively.
[62] 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.
[63] Note that these conversion factors take into account the finalized 340B remedy adjustment.

In addition to the cross-program policy discussed in section XIV, CMS finalizes, with modifications, changes to the validation of HOQRP data and to the HOQRP validation reconsiderations and appeals procedures. CMS also summarizes feedback it received in response to its request for information on the potential inclusion in the HOQRP of the Advance Care Planning eCQM, described in greater detail below.

B. Program Measure Set

CMS did not propose any changes to the HOQRP measure set other than the cross-program proposal being finalized to remove the Colonoscopy Follow-Up Interval measure, which is discussed in section XIV.

The table below (based on the information provided in Table 97 in the rule) summarizes the previously finalized measure set for the 2028 to 2032 payment determinations and reflects the finalized removal of the Colonoscopy Follow-Up Interval measure.

HOQRP Measure Set for 2028 to 2032 Payment Determinations (PDs)

CBE	Measure	2028 PD	2029 PD	2030 PD	2031 PD	2032 PD
Chart-Abstracted Measures						
None	Median Time from ED Arrival to ED Departure for Discharged ED Patients	X	X	Removed	Removed	Removed
None	Left Without Being Seen	X	X	Removed	Removed	Removed
0661	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 ED Arrival	X	X	X	X	X
0658	Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients	X	Finalized for Removal	Finalized for Removal	Finalized for Removal	Finalized for Removal
Claims-Based Measures						
None	Abdomen CT – Use of Contrast Material	X	X	X	X	X
2539	Facility 7-Day Risk Standardized Hospital Visit Rate After Outpatient Colonoscopy	X	X	X	X	X
3490	Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	X	X	X	X	X
2687	Risk-Standardized Hospital Visits 7 Days After Hospital Outpatient Surgery	X	X	X	X	X
None	Breast Cancer Screening Recall Rates	X	X	X	X	X
Survey-Based Measures						
None	Outpatient and Ambulatory Surgery Consumer Assessment	X	X	X	X	X

CBE	Measure	2028 PD	2029 PD	2030 PD	2031 PD	2032 PD
	of Healthcare Providers and Systems (OAS-CAHPS)					
Electronic Clinical Quality Measures (eCQMs)						
None	ST-Segment Elevation Myocardial Infarction (STEMI)	X	X	X	X	X
3663e	Excessive Radiation	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary
4625e	Emergency Care Access & Timeliness (ECAT)		Voluntary	X	X	X
Patient-Reported Outcomes-Based Performance Measures (PRO-PMs)						
None	Risk-Standardized PRO-PM Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty in the HOPD Setting (THA/TKA PRO-PM)	Voluntary	Voluntary	Voluntary	X	X
4210	Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery PRO-PM (Information Transfer PRO-PM)	Voluntary	X	X	X	X
None	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary
X = Measure is mandatory for the specified payment determination year. Voluntary = Submission of the measure is optional; HOPDs that do not report the measure are not subject to a payment reduction.						

C. RFI: Advance Care Planning Electronic Clinical Quality Measure

Background and RFI. The agency discusses its policy finalized in the 2026 OPPS/ASC final rule to phase out the Inpatient-Only (IPO) list and the likely resulting shift of complex procedures to the HOPD setting. CMS believes this will provide opportunities for HOPD clinicians to build relationships with patients and that this in turn presents opportunities in which advance care planning could facilitate shared decision-making and ensure that care is aligned with patients' goals across settings.

In the 2027 OPPS/ASC PPS proposed rule, CMS provided an overview of the Advance Care Planning eCQM, which has since been finalized for a number of inpatient settings and sought feedback on the potential inclusion in the HOQRP of the Advance Care Planning eCQM and other quality measure concepts related to advance care planning. In the 2027 OPPS/ASC PPS final rule, CMS summarizes comments received in response to the RFI. The agency does not respond to comments, but states it will take them into account for future measure development.

Overview of Advance Care Planning eCQM. In the 2027 IPPS/LTCH PPS final rule, CMS finalized adoption of the Advance Care Planning eCQM in the Hospital Inpatient QRP, PPS-

Exempt Cancer Hospital QRP, and Medicare Promoting Interoperability Program.[64] CMS believes that adoption of the eCQM across quality reporting programs could promote standardized advance care planning documentation to facilitate communication of patients' stated preference across their care continuum.

The Advance Care Planning eCQM[65] calculates the proportion of adult patients with one or more inpatient hospitalizations during the measurement period who, by the time of hospital discharge for at least one encounter, have an advance care planning document or documentation of an advance care planning discussion resulting in a documented decision in the patient's electronic health record (EHR). The measure is calculated as a proportion by dividing the number of patients who meet the numerator criteria by the number of eligible patients who meet the denominator criteria.

- *Numerator*. All adult patients with one or more inpatient encounters during the measurement period who have an advance care planning document or documentation of an advance care planning discussion resulting in a documented decision in the patient's EHR by the time of hospital discharge during at least one of the inpatient encounters.
- *Denominator*. All patients aged 18 years and older at the start of the measurement period who are discharged from an inpatient hospitalization during the measurement period.[66]

Comments. Many commenters supported the measure concept of advance care planning as an important component of patient care, some of whom supported adopting the Advance Care Planning eCQM in the HOQRP. Many commenters opposed adopting the Advance Care Planning eCQM in the HOQRP because they believed it was not appropriate across hospital outpatient encounters and may create various burdens. Many commenters recommended a more limited measure, including by limiting the measure to only patients, procedures, departments, or encounters for which advance care planning is clinically relevant and there is opportunity for meaningful discussion.

D. Updates to the Validation of HOQRP Data

1. eCQM Data Validation

CMS finalizes its proposal that, for purposes of incorporating eCQMs into the HOQRP validation process, validation begins for an eCQM after mandatory reporting of a full year of data is in effect for that eCQM. There are three eCQMs that have been previously finalized for inclusion in the measure set (excessive radiation, STEMI, and ECAT). The excessive radiation eCQM is voluntary so is not eligible for validation under this policy. Hospitals are required to submit all four quarters of data for the STEMI eCQM beginning with data from the 2027 reporting period; therefore, validation for the STEMI eCQM will begin with data from the 2027 reporting period. Validation for the ECAT eCQM will begin with data from the 2028 reporting period, since that is the first year for which four quarters of data for the measure is mandatory.

[64] 91 FR 49932 through 49942.
[65] Details on the eCQM can be found at https://www.p4qm.org/prmr-measures/muc2025-020.
[66] The measurement period is a 12-month period that would run from January 1 through December 31 of each applicable CY.

2. Changes to Selection Process for HOQRP Validation

a. Validation Selection Pool

Currently, a random sample of 450 hospitals is selected for validation and an additional 50 hospitals are selected based on specific targeting criteria. CMS has found that randomly selected hospitals generally have high accuracy rates for chart-abstracted measures. The agency believes the number of randomly selected hospitals could be reduced without affecting its ability to assess accuracy of the data and that the number of hospitals selected based on targeting criteria should be increased.

CMS finalizes its proposal, beginning with hospital selections for validation affecting the 2030 payment determination, that up to 200 hospitals be randomly selected and up to 200 hospitals be selected using targeting criteria. Any hospital selected for validation will be required to submit for validation both chart-abstracted measure data and eCQM data (that is, for eCQMs eligible for validation under the finalized policy discussed above). The existing validation policy will apply to hospital selections for validation affecting the 2029 payment determination, and hospitals so selected for that validation will submit only chart-abstracted data for validation since no eCQMs would yet be eligible for validation for that payment determination year.

b. Targeting Criteria

CMS also finalizes its proposal to apply the existing targeting criteria at §419.46(f)(3)(i) through (v) that currently applies to chart-abstracted measures to all measures eligible for validation in the HOQRP (i.e., also eCQMs).

3. Case Selection for Validation

Under current policy, CMS validates up to 48 randomly selected patient cases (12 cases per quarter) from the total number of cases that a hospital (selected for validation) successfully submitted to the CMS Clinical Data Warehouse via the HQR system.

Final Action. CMS finalizes its proposal to reduce the case number validation requirements, but with modification to reduce the number even further than it had proposed. CMS finalizes a policy to validate up to 28 (instead of the proposed 32) randomly selected patient cases for each measure, starting with validation of 2027 data affecting the 2030 payment determination.[67] For each chart-abstracted clinical process of care measure, cases will be submitted quarterly (with up to 7 (instead of the proposed 8) cases validated per quarter) and for each eCQM up to 28 (instead of the proposed 32) cases will be submitted annually, allowing validation of up to 7 (instead of the proposed 8) cases from each quarter.

Comments/Responses. A commenter raised concern about the cumulative burden associated with validating an increasing number of measures over time. CMS conducted an analysis to assess

[67] See section XV.D.5 for a discussion of the finalized policy to shift the payment impact of validation from 2 years after the reporting period to 3 years.

whether the proposed sample size (32 cases annually/ 8 cases per quarter) could be further reduced without compromising validation accuracy. The analysis showed that a sample size of 28 cases annually continued to provide a reliable and statistically sound basis for validation. Therefore, CMS is finalizing its proposal with modification to apply a sample size of 28 cases annually/ 7 cases per quarter.

4. Timing and Electronic File Submission for Medical Records Requests

CMS finalizes, without modification, its proposal to apply the same electronic file submissions policy to eCQM medical records requests as currently applies to the chart-abstracted measures.[68] A hospital, upon written request by CMS, will be required to submit, within 30 days of the written request, PDF copies of medical records using direct electronic file submission via a CMS-approved secure filing transmission process. CMS will continue to reimburse hospitals at $3.00 per chart.

5. Submission Quarters

Currently, hospitals selected for validation are required to submit data from 2 years prior to the applicable payment determination year, consisting of 4 calendar quarters of chart-abstracted data. However, eCQMs are reported annually (not quarterly) so CMS believes a 3-year cycle is necessary to allow sufficient time to complete steps needed in the validation process.

CMS is finalizing its proposal that hospitals selected for eCQM validation for a payment determination year be required to submit data from the year that is 3 years prior to the applicable payment determination. Since CMS is finalizing a combined validation process (for both chart-abstracted measures and eCQMs), the agency finalizes its proposal to also shift to the 3-year cycle for chart-abstracted measures—meaning that the payment impact of validation will affect the payment determination occurring 3 years (rather than 2 years) after the reporting period.

To transition to this policy, the validation results for 2027 chart-abstracted data will affect both 2029 and 2030 payment determination. This means there will be no change from the current policy for the 2029 payment determination, but for the 2030 payment determination, 2027 chart-abstracted data will again be used, plus the 2027 eCQM data will also be used for validation. CMS emphasizes that hospitals selected for validation based on 2027 data affecting the 2029 payment determination will not be selected again (randomly or through targeted selection) for validation of the same data affecting the 2030 payment determination.

Beginning with 2028 chart-abstracted and eCQM data, validation results will impact the payment determination 3 years after the reporting period.

6. Scoring Method

CMS finalizes its proposal, with modification (described further below), to determine the eCQM validation scores by using the same methodology the agency currently uses to score chart-

[68] Section 419.46(f)(1) includes policies on the use of electronic file submissions for chart-abstracted measure medical requests and the period for data validation.

abstracted measure validation. Validation scoring will be based on the extent to which data abstracted for validation matches the data submitted to CMS, a minimum score of 75 percent accuracy will be required, and an upper bound of a 90 percent two-sided confidence interval will be used.[69] The same eCQM scoring method has been adopted for the Hospital Inpatient QRP.[70]

Consistent with its existing policy for chart-abstracted data, any missing medical records will be treated as mismatches. Mismatches count against the agreement rate.

Beginning with the validation of 2027 data for the 2030 payment determination, hospitals will receive two validation scores: one for chart-abstracted measure data and one for eCQM data. If a hospital does not meet either validation requirement (e.g., does not attain at least a 75 percent validation score for each of chart-abstracted measure validation and eCQM data validation), the hospital will not receive the full OPPS annual payment update (APU) – with the modification discussed below that for the first year of eCQM validation (2027 data), even though selected hospitals will need to undergo validation and submit the requested records, the eCQM validation scores will not be applied to the hospital's payment determination (only chart-abstracted validations scores will affect payment for that validation cycle).

As proposed, the policy would apply beginning with validation of the 2027 eCQM data affecting the 2030 payment determination. However, CMS is finalizing the validation policy with a modification to delay the payment penalties associated with eCQM validation score until the second full year an eCQM has been mandatory in the program. During the first full year of mandatory reporting, validation scores will be used only to provide selected hospitals with an opportunity for educational review. The validation scores will not result in a payment penalty for the first full year of mandatory reporting, but even for that first unscored year if a hospital does not submit at least 75 percent of the requested records for the eCQM under validation the hospital will fail validation and will then be subject to payment penalty.

Comments/Responses. In response to a commenter, CMS clarifies that data validation scoring is at the measure level and not the individual data element level. The agency explains that while individual data elements are assessed during the validation process, the validation score for the measure reflects whether the CMS validation obtained the same measure outcome as the hospital's submission.

Many commenters supported validation, but suggested modifications to the process, including providing a phased implementation through an initial reporting-only year before being subject to formal audits and financial penalties. Many commenters were concerned about beginning validation with the 2027 reporting period data for the STEMI eCQM because of issues with accurately identifying patients in the numerator and denominator. CMS agrees that payment penalties associated with validation scores should be delayed for the STEMI eCQM because the measure specifications were recently revised. Therefore, CMS is finalizing the data validation policy with a modification to delay payment penalties associated with validation scores until an eCQM has been mandatory in the program for one year of reporting. During the first year of mandatory reporting, validation scores will be provided *only for educational review*. Of note,

[69] The current data validation scoring threshold for chart-abstracted measures is under §419.46(f)(2).
[70] 89 FR 69574-69577.

even during the unscored initial mandatory reporting year (e.g., for the STEMI eCQM, the first mandatory reporting period is the 2027 reporting period impacting the 2030 payment determination), payment penalties will still be assessed if the hospital fails to submit at least *75 percent of the requested records* for the applicable eCQM under validation. Then with the second mandatory reporting period (e.g., for the STEMI eCQM, the 2028 reporting period impacting the 2031 payment determination), payment penalties will be based on attaining at least a *75 percent validation score* for eCQM data validation.

7. Educational Review Process

Under existing policy for chart-abstracted measures, if a hospital requests an educational review for any of the first three quarters of validation and the review yields incorrect CMS validation results, the corrected quarterly score is used to compute the final confidence interval.[71] Educational reviews for the final quarter of data are not completed soon enough to affect validation results and hospitals must use the reconsideration process. However, the finalized proposal to extend the validation timeline from a 2-year cycle to a 3-year cycle will provide sufficient time to complete educational reviews for all four quarters.

CMS finalizes its proposal to allow, beginning with the 2030 payment determination, the results of educational reviews for all four quarters of chart-abstracted measure validation to be reflected in the final validation score before the calculation of the confidence interval.

CMS also finalizes its proposal to extend the educational review process to eCQM validation beginning with validation affecting the 2030 payment determination. Hospitals have 30 calendar days from receipt of validation results to contact CMS' Validation Support Contractor requesting a written explanation of its performance. Hospitals may request an educational review once annually for eCQM data since eCQM validation results will be received on an annual basis.

Table 100 in the rule shows the finalized validation process policies for the 2029 to 2032 payment determinations.

E. Validation Reconsiderations and Appeals Procedures

Under existing requirements at §419.46(g)(2)(vii), hospitals that submit reconsideration requests must submit a copy of all materials that the hospital submitted to comply with the requirements of the affected payment determination year. Beginning with validation affecting the 2024 payment determination, hospitals must submit only electronic files of medical records for HOQRP data validation. Given that electronic file-only requirement, CMS believes that the current reconsideration request requirement to resubmit medical documentation creates duplicative files and burden. A similar requirement to resubmit medical records as part of a request for reconsideration of a validation determination was removed from the Hospital Inpatient QRP beginning with 2023 discharges affecting FY 2026 payment determination.

[71] Policies regarding the educational review process are under §419.46(f)(4).

CMS finalizes, without modification, its proposal to remove, beginning with data from the 2026 reporting period affecting the 2028 payment determination, the requirement for hospitals to resubmit medical documentation as part of their request for reconsideration of validation.

F. Payment Reduction for Failing HOQRP Requirements

CMS finalizes its proposal to continue its existing policies with respect to computing and applying the payment reduction for hospitals that fail to meet the HOQRP requirements for the 2027 update factor. The resulting final reduction ratio for hospitals that fail to meet HOQRP requirements, called the "reporting ratio," for the 2027 payment determination will be 0.9804. CMS will continue calculating the reporting ratio to four decimals. The final reporting ratio is calculated by dividing the final reduced conversion factor of $98.011 (i.e., the final conversion factor for hospitals that fail to meet the requirements of the HOQRP) by the final full conversion factor of $99.970. 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 HOQRP's reporting requirements. All other applicable standard adjustments to the OPPS national unadjusted payment rates will continue to apply, and OPPS outlier eligibility and outlier payments will also be based on the reduced payment rates.

XVII. Rural Emergency Hospital Quality Reporting Program (REH QRP)

Section 1861(kkk) of the Act establishes rural emergency hospitals (REHs) as a Medicare provider type that furnishes emergency department services and observation care. The REH must have a staffed emergency department 24 hours a day, 7 days a week and may elect to furnish other medical and health services on an outpatient basis. Payments specific to REHs began on January 1, 2023.

Section 1861(kkk)(7) of the Act establishes the REH QRP by requiring the Secretary to establish quality reporting requirements for REHs, require data submission at least quarterly, and publicly post performance data. There is no statutory incentive for submitting this data, nor statutory penalty for failing to submit the data. Program requirements are codified at 42 CFR 419.95.

CMS did not propose any changes to the REH QRP. Below is a table showing the REH QRP measure set for 2026 through 2031 payment determinations (PDs), as previously finalized.

Previously Finalized REH QRP Measure Set by Data Collection Method and PD

CBE #	Measure Name	2026 PD	2027 PD	2028 PD	2029 PD	2030 PD	2031 PD
Chart-Abstracted Measures							
None	Median Time from ED Arrival to ED Departure	X	X	X	Optional	Optional	Optional

CBE #	Measure Name	2026 PD	2027 PD	2028 PD	2029 PD	2030 PD	2031 PD
Chart-Abstracted Measures							
	for Discharged ED Patients*						
Claims-Based Measures							
None	Abdomen Computed Tomography (CT) – Use of Contrast Material	X	X	X	X	X	X
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy	X	X	X	X	X	X
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery	X	X	X	X	X	X
Structural Measures							
None	HCHE		Removed	Removed	Removed	Removed	Removed
Process Measures							
None	Screening for SDOH		Removed	Removed	Removed	Removed	Removed
None	Screen Positive Rate for SDOH		Removed	Removed	Removed	Removed	Removed
eCQMs							
4625e	Emergency Care Access & Timeliness eCQM*				Optional	Optional	Optional
X Measure is mandatory for the program determination year * REHs will have the option to report either the Median Time from ED Arrival to ED Departure for Discharged ED Patients measure OR the Emergency Care Access & Timeliness eCQM beginning with the 2027 reporting period/2029 PD.							

CMS estimates that for the 2027 reporting period there will be 48 REHs (an increase of 10 REHs from its estimate provided in the 2026 OPPS/ASC final rule) required to report under the REH QRP based on hospital conversions as of April 6, 2026.

XVIII. Ambulatory Surgery Center Quality Reporting Program (ASC QRP)

A. Background

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 before the payment determination year (e.g., 2027 reporting is linked to 2029 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).[72] Many of the statutory provisions applied to the HOQRP are applied by statute to the ASC QRP. CMS provides references to the legislative and regulatory histories of the program.[73]

[72] See §416.305(c). Also, under §416.305(b), ASCs may elect to withdraw from ASCQR program participation for a year but will be subject to the 2.0 percent payment reduction for that year.

[73] 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.

CMS states that of 6,930 ASCs billing Medicare, 4,399 were required to participate in the ASC QRP for 2026 payment determinations. Of those not required, 650 ASCs chose to participate and met full requirements. Based on the 2026 payment determination data, CMS estimates that 5,149 ASCs will submit data for the program for the 2027 reporting period/2029 payment determination.[74]

B. Program Measure Set

CMS did not propose any changes to the ASC QRP measure set other than the newly finalized cross-program proposal discussed in section XIV to remove the Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients measure beginning with the 2027 reporting period/2029 payment determination.

The table below (based on Table 101 in the rule) lists the previously finalized and newly finalized measure set for the 2028 to 2032 payment determinations (PDs), including the newly finalized measure removal.

Previously and Newly Finalized ASC QRP Measure Set by Data Collection Method and PD

Measure Name	2028 PD	2029 PD	2030 PD	2031 PD	2032 PD
Chart-Abstracted Measures					
Patient Burn	X	X	X	X	X
Patient Fall	X	X	X	X	X
Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant	X	X	X	X	X
All-Cause Hospital Transfer/Admission	X	X	X	X	X
Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (CBE #0658)	X	Finalized for Removal	Finalized for Removal	Finalized for Removal	Finalized for Removal
Normothermia Outcome	X	X	X	X	X
Unplanned Anterior Vitrectomy	X	X	X	X	X
Claims-Based Reporting					
Facility 7-Day Risk Standardized Hospital Visit Rate after Outpatient Colonoscopy (CBE #2539)	X	X	X	X	X
Hospital Visits After Orthopedic ASC Procedure (CBE #3470)	X	X	X	X	X
Hospitals Visits After Urology ASC Procedure CBE #3366)	X	X	X	X	X
Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at an ASC (CBE #3357)	X	X	X	X	X
Patient-Reported Outcomes-Based Performance Measures					
Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PROPM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee	Voluntary	Voluntary	Voluntary	X	X

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

Measure Name	2028 PD	2029 PD	2030 PD	2031 PD	2032 PD
Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO–PM)					
Cataracts Visual	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary
Survey-Based Measures					
Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS-CAHPS) - 5 measures***	X	X	X	X	X
X= Measure is mandatory for the payment determination year. Voluntary= Submission of the measure is optional; ASCs that do not report on the measure are not subject to a payment reduction. *** 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.					

C. RFI on Stratification of the All-Cause Transfer/Admission Measure

The All-Cause Transfer/Admission measure is an outcome measure included in the ASC QRP that assesses the rate of ASC patients who require transfer to a hospital or admission to a hospital upon discharge from the ASC. The measure does not distinguish the phase of care (e.g., pre, during, or post procedure) in which the transfer occurs.

CMS is considering whether adding a phase of care stratification could improve the usefulness of the measure, provide insight into care processes between facilities, and support patient safety monitoring. In the 2027 OPPS ASC PPS proposed rule, the agency sought comment on clinically meaningful and feasible approaches for incorporating such a stratification for the measure, including on appropriate time anchors, their operational definitions, and corresponding timeframes that could be used to define each stratification category. In the final rule, CMS summarizes comments it received in response to the RFI. The agency did not respond to the feedback but indicates it will take it into consideration for future efforts.

Many commenters supported a phase-of-care stratification because they believed it could improve the measure's usefulness and provide more meaningful information about patient safety and circumstances around transfers. Many commenters suggested distinguishing transfers into phases, according to those occurring pre-procedure, intra-procedure, and post-procedure. Some commenters recommended accounting for patient complexity, case mix, procedural risk, clinical context, and differences among patients, facilities, and procedures. Several commenters expressed concerns about how phase-specific results would be reported and used. Other commenters did not support phase-of-care stratification and questioned if it could provide actionable data.

D. Form, Manner and Timing of Data Submission

CMS had not proposed any changes to its data submission and reporting requirement policies.[75]

[75] Data submission and reporting requirements are at §416.310.

E. Payment Reduction for ASCs Failing ASC QRP

CMS finalizes its proposal to continue applying 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, D2, 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, biologicals, and radiopharmaceuticals; pass-through devices that are contractor-priced; brachytherapy sources that are paid based on OPPS payment rates; skin substitute supplies; software-as-a service codes; and others. All other applicable adjustments to the ASC national unadjusted payment rates apply (e.g., wage index adjustment, multiple procedure adjustment, interrupted procedure adjustment, and the adjustment for devices furnished with full or partial credit or without cost). When the update reduction is applied to a facility, beneficiary copayments are based on the reduced payment rate.

XVIX. Accrediting Organizations and Emergency Medical Treatment and Labor Act

A. Background

The Emergency Medical Treatment and Labor Act (EMTALA) applies to hospitals that participate in Medicare and operate emergency departments, including critical access hospitals (CAHs) and rural emergency hospitals (REHs). EMTALA requires that:

- When an individual comes to a hospital's emergency department and requests examination or treatment, the hospital must provide an appropriate medical screening examination to determine whether an emergency medical condition exists.
- If the hospital determines that the individual has an emergency medical condition, the hospital must provide either necessary stabilizing treatment within its capability or arrange for an appropriate transfer to another medical facility.
- Hospitals with specialized capabilities or facilities shall not refuse to accept appropriate transfers of individuals requiring such capabilities or facilities if the receiving hospital has the capacity to treat the individual.

The statute also authorizes the Office of Inspector General (OIG) to impose civil monetary penalties or exclude physicians from participation in Federal health care programs for EMTALA violations and permits CMS to terminate a hospital's Medicare provider agreement for non-compliance.

42 CFR §489.24 includes detailed provisions governing the provision of medical screening examinations, stabilizing treatment, appropriate transfers, and receiving hospital responsibilities, referred to below as the "core EMTALA requirements." 42 CFR §489.20(l), (m), (q) and (r) set forth requirements to post EMTALA signage, maintain a central log of individuals who present to the emergency department, retain transfer records for five years, and maintain an on-call physician list, referred to below as the "EMTALA administrative requirements."

Enforcement of EMTALA has historically occurred through complaint investigations conducted by State Survey Agencies (SAs) under CMS direction, not Accrediting Organizations (AOs). AOs that meet or exceed applicable Medicare requirements are approved by CMS to accredit hospitals. CMS' proposals will authorize AOs to take on some EMTALA responsibilities.

B. Proposals

CMS made two proposals:

- An AO with CMS-approved accrediting programs for hospitals may assess compliance with the EMTALA administrative requirements as part of their initial accreditation and reaccreditation surveys.
- If an AO identifies EMTALA deficiencies at 42 CFR §489.24 during an accreditation or reaccreditation survey, the matter would be referred to CMS for further review and possible SA investigation.

If an AO identifies deficiencies with EMTALA administrative requirements, the AO will require the hospital or CAH to submit an acceptable Plan of Correction (PoC). If the PoC is accepted and the hospital has returned to compliance, then no further enforcement action would be taken. If the PoC is rejected, the AO would be required to contact CMS for further review.

The incorporation of EMTALA administrative requirements into the accreditation and reaccreditation survey process means that AOs will assess whether hospitals are maintaining the documentation, recordkeeping, and operational safeguards that support transparency and accountability in emergency care. Because these obligations are record-based and procedural, CMS proposed to review AO survey processes as part its hospital accreditation program approval.

CMS would retain ultimate oversight responsibility and could take additional action as appropriate under its survey and enforcement authorities. This policy would not authorize AOs to assess or enforce compliance with the core EMTALA requirements. CMS and OIG would retain enforcement authority over those provisions.

Under section 1865(b) of the Act, the Secretary is prohibited from disclosing any accreditation survey conducted by a CMS-approved AO, unless it relates to an enforcement action or to a home health agency or hospice program survey. However, the statute does not prohibit the AO or a client hospital from disclosing its own survey findings.

Comments/Responses

Commenters generally supported CMS's proposal to have AOs review administrative EMTALA requirements (signage, logs, transfer records, and on-call lists) during accreditation surveys. In response to specific comments, CMS indicates that it intends to issue standardized interpretive guidance and survey protocols specific to the administrative EMTALA elements, which all approved AO accreditation programs should include in their own standards. This guidance will

clearly delineate the respective roles of AOs, SAs, and hospitals and is distinct from, and does not establish compliance with, Federal civil rights conscience (protections) laws; it will also affirm that individuals retain the right to file a complaint with the HHS Office for Civil Rights. OCR staff are available to review the civil rights content of that material at CMS's request.

AO activities under this rule are limited to the administrative requirements and do not extend to clinical screening, stabilization, or transfer decision review requirements at §489.24, which remain within CMS and SA exclusive investigation authority.

Final Decision. CMS is finalizing its two proposals without modification while indicating that it plans to provide interpretive guidance that fully explains AO responsibilities related to these policies.

XX. Prior Authorization Botulinum Toxin Injection Codes

A. Background

In the 2020 OPPS final rule with comment period, CMS established a prior authorization process for certain hospital OPD services (84 FR 61142, 61446 through 61456) using its authority under section 1833(t)(2)(F) of the Act, which requires the Secretary to develop "a method for controlling unnecessary increases in the volume of covered OPD services. CMS added additional services to the prior authorization process in 2021 and 2023 (see 42 CFR §§419.80 through 419.89; the specific service categories are listed in 42 CFR §419.83).

B. Controlling Unnecessary Increases in the Volume of Covered OPD Services

1. Expansion of Service Category

In accordance with 42 CFR §419.83(b), CMS proposed to expand prior authorization requirements to include eight additional botulinum toxin injection services. The eight additional botulinum toxin injection codes would require prior authorization on or after July 1, 2027.

2. Basis for Expanding Service Category

CMS reviewed over 100 million OPD claims from 2017 through 2024. On average, the number of OPD claims submitted to Medicare decreased yearly by 1.1 percent. In contrast, over this same period, the volume of claims for the eight botulinum toxin injection services increased by 42.8 percent. The codes CMS proposed to add to the current prior authorization process represent approximately $102 million in annual Medicare payments and constitute a subset of overall botulinum toxin utilization selected based on observed utilization volume, growth trends, and program integrity considerations.

The agency believes prior authorization for these additional codes will be an effective method for controlling unnecessary increases in the volume of these services and expects that it will reduce the instances in which Medicare pays for services that are determined not to be

medically necessary. CMS requested comments on the addition of these new services, specifically on the potential for unintended clinical consequences that may result from their addition to the list of services subject to prior authorization.

Comments/Responses

Administrative Issues. Several commenters raised administrative issues such as how providers and consumers will be aware that additional services are being made subject to prior review and whether CMS will issue guidance in advance of the effective date of the policy. CMS replied that MAC websites generally provide tools or searchable resources that allow providers to determine whether a particular service or procedure is subject to prior authorization requirements. Further, CMS intends to provide education and implementation guidance well in advance of the July 1, 2027 effective date to support provider preparation and facilitate implementation of the expanded prior authorization requirements.

Clinical Concerns. Several commenters indicated that botulinum toxin injections are recurring, individualized treatments. Requiring prior authorization for each treatment cycle could disrupt established treatment plans. A beneficiary's clinical condition and treatment needs may change between authorization and the date of service requiring practitioners to modify how the patient will be treated.

CMS responded that prior authorization requests are generally reviewed within 7 calendar days for standard requests, though the average review time over the past year was 3.6 days, and expedited review within 2 business days is available when a delay could seriously jeopardize the beneficiary's life, health, or ability to regain maximum function. Current rules allow CMS to exempt a provider that submits at least 10 prior authorization requests and receives provisional affirmations for at least 90 percent of its initial requests.

Provider Burden. Several commenters expressed concern about provider burden and whether CMS's burden estimates fully account for the clinical and administrative staff time associated with these activities. CMS responds that prior authorization does not establish new Medicare coverage or documentation requirements; rather, it requires documentation supporting applicable Medicare coverage, coding, and payment requirements to be submitted before the service is furnished. CMS continues to believe that the average time for office clerical activities associated with preparing and submitting a prior authorization request is 30 minutes, which is equivalent to the time estimated for prepayment or post-payment medical review.

Botulinum Injections Utilization is Not Unnecessary. Several commenters stated that utilization growth may reflect expanded indications, evolving clinical practice, improved access, changes in the Medicare population, or shifts in site of service. CMS acknowledged that expanded FDA-approved indications may have contributed to utilization growth. However, the magnitude of the utilization increase supports additional oversight to ensure that applicable Medicare coverage, coding, and payment requirements are met.

Final Decision. CMS is finalizing its proposal to add eight botulinum toxin injection codes to the hospital OPD prior authorization process effective July 1, 2027. Table 102 of the final rule lists

the codes that will newly be subject to prior authorization. Table 103 lists the codes and the effective dates for all codes already subject to prior authorization under the OPPS.

3. Information Collection Requirements

The burden associated with the prior authorization process for the additional Botulinum Toxin Injection codes will be the same as for codes already subject to prior authorization—the time and effort necessary to provide the relevant supporting documentation to CMS or the MAC. CMS estimates the total annual number of submissions would be 78,358 (54,851 submissions via fax or electronic means and 23,507 mailed submissions). Using a rate of $44.28 for the clerical staff expected to undertake these activities, the annual burden hours for the new services, allotted across all providers, would be 41,555 hours (0.5 hours x 78,358 submissions plus 3 hours x 792 providers for staff education on the new requirements). The annual burden cost would be $1,957,592 (41,555 hours x $44.2 plus $117,537 for mailing costs). The ICR approved under OMB control number 0938-1368 will be revised and submitted to OMB for approval.

XXI. Provider-Based Requirements

A. Background

The provider-based rules (42 CFR §413.65) establish criteria that an entity must meet to be considered "provider-based" or a part of a provider. Among other requirements, off-campus provider-based facilities must be no more than 35 miles from the main provider or they must demonstrate that they serve the same patient population as the main provider. Outpatient provider-based departments are paid under either the OPPS or the "applicable system" under section 1833(t)(21) of the Act. The "applicable system" applies to off-campus provider-based departments that first began providing outpatient services after November 2, 2015. Payment under the "applicable system"—which by statute is not the OPPS—is 40 percent of the OPPS amount.

B. Section 6225 of the Consolidated Appropriations Act (CAA), 2026

Section 6225 of the CAA, 2026 prohibits Medicare payments under either the OPPS or the applicable system beginning January 1, 2028, unless an off-campus outpatient department of a provider bills using a separate National Provider Identifier (NPI) and the main provider has submitted an attestation that the department meets the provisions of 42 CFR §413.65. An initial attestation is required during the 2-year period ending on the date such items and services are furnished. A subsequent attestation is required within a timeframe specified by the Secretary. The initial attestation can be submitted under the current 42 CFR §413.65 requirements until the Secretary establishes the new attestation process.

C. Modifications to Implement the Provisions of Section 6225 of the CAA, 2026

1. Defining an "Off-Campus of a Provider"

Under current regulations, an "off-campus department of a provider" is not defined. CMS proposed to add a definition to 42 CFR §413.65(a)(2) describing an off-campus outpatient

department of a provider as one that is not located on the campus of the main provider or within 250 yards of a remote location of a hospital. An outpatient department that is not on the campus of the main provider or within 250 yards of a remote location of a hospital is required to meet the NPI and attestation requirements of section 6225 of CAA 2026.

Comments and Responses

CMS received comments asking whether the relevant remote location encompasses the broader area surrounding the inpatient facility or is limited to the specific building or buildings providing inpatient services. The response indicated that any outpatient department within 250 yards of a remote location facility would not be an "off-campus outpatient department of a provider" (e.g., any building providing inpatient or outpatient services within 250 yards of the remote location's main building providing inpatient services would be on the campus of a provider).

Other comments asked how CMS will measure 250 yards. CMS responded that the 250-yard measurement could begin at any point of the remote location facility that provides patient care using publicly available satellite mapping software and straight-line measurements from the main building to the nearest point of the potential provider-based department. In some cases, applicants may supply additional survey material to assist in this measurement process. Certain features, like awnings or walkway overhangs, would not be an appropriate measuring point as patient services are not provided.

Final Decision. CMS is finalizing the addition of the definition of an "off-campus department of a provider" to the regulations.

2. Initial and Subsequent Attestations

Before a hospital can submit an attestation, it must obtain an NPI. CMS proposed to require initial attestations between January 1, 2026 and December 31, 2027 for services furnished before January 1, 2028 and within two years of the date of service for services furnished on or after January 1, 2028. Subsequent attestation(s) would be submitted at an interval to be specified by CMS and not to exceed five years thereafter.

For a provider that has not received a provider-based determination, the submission of the initial attestation will fulfill the CAA, 2026 attestation requirement to be paid under the OPPS or the applicable system. For a provider that has received a provider-based determination, CMS is considering having an authorized official attest using a letter with evidence of the prior provider-based determination and affirming continued compliance with the provider-based rules without having to separately attest to meeting all the requirements of the provider-based rules.

Comments and Responses

Numerous commenters strongly opposed the mandatory NPI and attestation requirements. They requested CMS consider a longer implementation timeline and exercise enforcement discretion due to downstream operational impacts on hospital billing, NPI assignments, and system testing and updates.

CMS responded that the statute establishes January 1, 2028, as the date on which Medicare must stop making payments for items and services furnished at an off-campus outpatient department of a provider unless the NPI and attestation requirements are met. Nevertheless, CMS understands the commenters' concerns about the administrative burden and will seek to minimize it through the development of billing, enrollment, and other sub-regulatory guidance.

Other commenters asked whether an off-campus location providing multiple hospital services (such as providing both laboratory and radiology services) would need separate NPIs for each service line. CMS responded that a "department of a provider" is identified by the hospital's submission of its physical facility location in the enrollment system— its street address, including suite or floor number, where applicable. A single off-campus location operating at one address is one "department of a provider" and therefore needs only one NPI even if multiple types of services are being provided there.

Some commenters raised concerns about conflict with requirements of the Health Insurance Portability and Accountability Act (HIPAA) standard claim format that only permits only one billing NPI on a claim and the requirement to consolidate all services provided by a single hospital on one claim. CMS responded that it is taking measures to allow the entry of multiple NPIs on a claim—the claim level NPI of the hospital plus the service line NPIs for the various services provided during a given day.

Commenters generally supported timing of the initial attestation although some commenters requested that CMS allow attestation approvals granted prior to January 1, 2026 to meet the initial attestation requirement or only require new departments to meet the requirement. One commenter requested CMS link the initial attestation to the department's enrollment date as the department does not yet legally exist within the Medicare system until it is enrolled. CMS cannot adopt the suggestions by the commenters because they are not consistent with the statute. However, CMS clarified that a provider could satisfy the initial attestation requirement even if CMS has not decided provider-based status before the first day on which the outpatient department renders services.

Several commenters requested different time periods for the subsequent attestation than 5 years or only require one attestation unless there is a material change to the office-campus PBD. One commenter also requested CMS clarify when the proposed 5-year "countdown" for the subsequent attestation begins. CMS responded that the 5-year period for the subsequent attestation would begin on the date the attestation is submitted. Currently, CMS continues to believe that a maximum 5-year subsequent attestation period is an appropriate timeframe to balance provider burden while ensuring continued provider-based compliance.

Final Decision. CMS is finalizing the separate NPI and attestation requirements for payment under the OPPS for items and services furnished on or after January 1, 2028, with the modification to address situations where CMS has not issued a provider-based status determination before the first date services are furnished.

3. NPI and Attestation Rule for Providers that Don't Bill OPPS

The final rule also indicates that the NPI and attestation requirements do not apply to facilities not paid under the OPPS and not subject to the provider-based rules such as Indian Health Service and Tribal facilities, Federally Qualified Health Centers (FQHCs and FQHC look-alikes), CAHs, Rural Health Clinics (RHCs), and hospitals in Maryland participating in the Achieving Healthcare Efficiency through Accountable Design (AHEAD) payment model.

4. Attestation Template

CMS proposed to replace the current MAC-specific attestation templates with a standardized attestation form. Until the standardized form and centralized electronic system are finalized, providers may continue to submit attestations using the current process. Providers must have an NPI for an off-campus provider-based department before submitting an attestation.

Under the current attestation process, providers submit their attestations and supporting documentation to their MAC, which performs a preliminary review and forwards its recommendation to CMS for the initial determination. CMS proposed to modify this process so that the MACs conduct standardized review and validation activities in support of initial determination rather than requiring separate CMS review of each attestation recommendation. The MAC will provide written acknowledgment of receipt, review the attestation for completeness and consistency, and determine whether the facility or organization is provider-based.

For providers that submit attestations for more than one off-campus outpatient department, CMS is considering streamlined supporting documentation requirements. In the proposed rule, CMS sought comment on how best to minimize burden while ensuring robust oversight. Further, CMS anticipates leveraging system capabilities to reduce duplicative documentation submissions by allowing supporting documentation applicable to multiple locations to be submitted a single time, where appropriate.

Comments and Responses

Providers generally supported CMS's proposals related to developing a standardized attestation form and revised processes for submitting the form. There were comments on the form itself that CMS will consider when finalizing it. The final rule also clarifies that providers will not be required to submit supporting documentation with the initial attestation. Supporting documentation will be provided by the hospital on request from CMS.

When CMS requests supporting documentation, it intends to use the centralized electronic system to minimize duplicative submissions, including by allowing providers to submit documentation once when the same information applies to multiple off-campus departments or demonstrates compliance with multiple provider-based requirements.

CMS will provide written notification of the outcome of an attestation review, including a determination as to whether the department satisfies the applicable provider-based requirements. If CMS determines that a department does not satisfy the requirements, the notification will

identify the basis for the adverse determination and provide information with applicable appeal rights. As appropriate, providers that CMS determines would otherwise satisfy the provider-based requirements but have minor attestation-based deficiencies may also be afforded an informal opportunity to correct those deficiencies before CMS issues a determination.

Final Decision. CMS will continue to develop an attestation template and provide further guidance on its use.

D. Documentation Requirements for Provider-Based Attestations

CMS proposed the following documentation requirements:

- Attestation Form: Providers must submit a completed attestation using the CMS standardized attestation form, signed and dated by an authorized official of the main provider as identified in the Provider Enrollment, Chain, and Ownership System (PECOS). The attestation would be required to identify both the main provider and each off-campus outpatient department of the provider for which provider-based status is sought, including the applicable NPIs, provider numbers, addresses, and the date on which provider-based conditions were met or the date the department was acquired.
- Location: CMS anticipates the attestation system would have the ability to measure the distance requirement but also be supported with documentation from the provider.
- Licensure: Providers must be prepared to demonstrate that the off-campus outpatient department is operated under the same licensure as the main provider or document that the State does not require a separate license for the department.
- Clinical Services Integration: Providers must be prepared to demonstrate that the off-campus outpatient department professional staff hold privileges at the main provider; that appropriate monitoring and oversight of the department by the main provider is in place; that inpatient and outpatient services of the department and the main provider are integrated; and that patients treated at the department who require further care have full access to all services of the main provider.
- Financial Integration: Providers must be prepared to demonstrate that the revenues and expenses of the off-campus outpatient department are integrated with those of the main provider and that it does not maintain a separate general ledger or trial balance independent of the main provider.
- Public Awareness: Providers must be prepared to demonstrate that the off-campus outpatient department is clearly identified to the public as part of the main provider and that patients are aware they are receiving services from the main provider.
- Obligations Specific to Off-Campus Outpatient Departments: Off-campus provider-based departments must be prepared to demonstrate compliance with EMTALA, site-of-service billing requirements, and the requirement to provide written notice to Medicare beneficiaries of their potential financial liability prior to the delivery of services (likely a reference to the Medicare Outpatient Observation Notice or MOON).[76]

[76] The MOON is formal notification hospitals are required to give beneficiaries that they are receiving observation services as outpatients rather than being admitted as inpatients within 36 hours of the observation services being initiated.

- Ownership, Control, Administration, and Supervision: Providers must be prepared to demonstrate that the department operates under the ownership and control of the main provider, including final approval over administrative decisions, personnel policies, and medical staff appointments, and that administrative functions of the department are integrated with those of the main provider.

Commenters requested greater clarity and consistency regarding the documentation CMS may require demonstrating compliance with the provider-based requirements. CMS responded that it plans to provide specific guidance on the required documentation for each provider-based requirement in future rulemaking or sub-regulatory guidance.

Final Decision: CMS will further address specific documentation requirements in sub-regulatory guidance.

E. CMS Verification and Oversight Activities

Section 6225 of the CAA, 2026 directs the Secretary to establish a process for determining compliance with its requirements and the provider-based rules. CMS proposed the following process:

- Initial Review: CMS and the MACs will conduct automated validation and screening of attestations to verify completeness, consistency with PECOS enrollment records, and the presence of required attestation elements. Attestations that pass automated validation would be processed for initial determination.
- Targeted Review: Additional documentation would be required for attestations that present indicators of incompleteness, inconsistency, or elevated compliance risk.
- Extended Review: CMS and its contractors, including program integrity contractors, would employ risk-based methodologies to select a subset of attestations for remote audits of provider records and documentation and site visits conducted by CMS or its contractors.

The criteria and methodologies CMS would use to select attestations for extended review would be established through operational guidance and would be designed to focus oversight resources on providers and departments that present the highest risk of non-compliance with the provider-based requirements. Failure to submit requested documentation within the timeframe specified by CMS may result in a determination of non-compliance and recovery of overpayments.

Commenters generally supported CMS's use of risk-based verification and oversight but requested greater clarity regarding the criteria and procedures for targeted reviews, documentation requests, remote audits, and site visits. CMS responded that it anticipates prioritizing resources to perform extended reviews for hospitals with only a single off-campus outpatient department and targeted extended reviews for hospitals with multiple off-campus departments by selecting a random sample of submissions. The response states that CMS will continue to develop policies and procedures, such as remote audits, data analysis, alternative data sourcing approaches and site visits, as it gains experience with the oversight of these off-campus provider-based requirements.

Final Decision: CMS will provide further guidance as it undertakes enforcement of its review of provider-based attestations.

F. Information Collection Requirements

CMS believes its policy to establish a standardized attestation form for provider-based determinations submitted through a centralized electronic system will reduce the time required to submit each attestation by 25 to 75 percent. As a result of the new mandatory attestation requirement, CMS expects there to be an increase in both the number of main providers submitting attestations and the number of attestations submitted by each main provider.

For the proposed rule, CMS estimated 1,832 main providers would take 5 hours per attestation, and, on average, each main provider would submit 9 attestations for provider-based departments. Therefore, CMS calculated the burden as 16,488 responses times 5 hours per response = 82,440 burden hours.

CMS indicated the attestation will come from an executive officer of the hospital. Using the most recent Bureau of Labor and Statistics Occupational and Employment Data (May 2024) for the position of Top Executives ($67.24 doubled to $134.48 per hour for fringe benefits), CMS estimated total costs of $11,086,531 (82,440 hours x $134.48 per hour). This estimated increase is relative to $327,150 from the current requirements.

Based on public comments, CMS revised these estimates from 5 hours to 8 hours (representing a 25 percent reduction of the currently approved estimate of 10 hours to account for the streamlined process). Under this revised estimate, CMS calculated the burden as follows: 16,488 responses times 8 hours per response = 131,904 burden hours.

Rather than estimating that the 8 hours will be done solely by a chief executive, CMS estimates the following staffing mix for each attestation: Compliance Officers account for 3.5 hours, Lawyers for 1 hour, Medical and Health Service Managers for 2 hours, Secretaries and Administrative Assistants for 1 hour, and Top Executives for 0.5 hours.

CMS' revised cost estimate burden is $14,292,952.56, an increase from $11,068,531 in the proposed rule relative to the current requirements of $327,150.

XXII. Notice of Closure of Teaching Hospital

Section 5506 of the Affordable Care Act authorizes the Secretary to redistribute residency slots of a hospital that trained residents in an approved medical residency program after its closure. CMS is notifying the public of the closure of St. Luke's Des Peres Hospital Located in Des Peres, MO and Franciscan Health Hammond Located in Hammond, IN:

Available Resident Cap FTEs

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME Resident Cap	DGME Resident Cap
260176	St. Luke's Des Peres Hospital	Des Peres, MO	41880	July 31, 2025	25.16	26.02
150004	Franciscan Health	Hammond, IN	29414	December 31, 2022	4.39	4.36

Application Process for Available Resident Slots

The application period for hospitals to apply for slots under section 5506 is 90 days following notification to the public of a hospital closure. Therefore, hospitals must apply to the CMS Central Office to be eligible to receive slots from this closed hospital by February 2, 2027.

CMS will only accept applications submitted via MEARIS™ (MEARIS™ (cms.gov)). Applications submitted through any other method will not be considered. CMS has not established a deadline for when CMS will issue the final determinations to hospitals that receive slots under section 5506. However, CMS says it reviews all applications received by the deadline and will notify applicants of its determinations as soon as possible.

XXIII. Separate IPPS Payment: Personal Protective Equipment and Essential Medicines

In the 2026 "Ensuring Safety Through Domestic Security With Made in America Personal Protective Equipment (PPE) and Essential Medicine Procurement by Medicare Participating Hospitals" advance notice of proposed rulemaking (ANPRM) (91 FR 3851), CMS sought public comment on potential options that the agency could consider for Medicare participating hospitals to help foster a more resilient supply chain for American-made PPE and essential medicines to secure our nation's health and safety, and to reflect the additional resource costs incurred when procuring these domestically manufactured items.

In the OPPS/ASC proposed rule for 2027, CMS sought further public input on this issue after reviewing the comments on the ANPRM. Specifically, the agency sought public comment on potentially eligible PPE and essential medicines, the applicable definitions of "domestic" for PPE and essential medicines, respectively, the use of standardized cost differentials for eligible domestic PPE and essential medicines, a potential manufacturer attestation of domestic origin, potential approaches under the IPPS to separately pay for the additional resource costs that hospitals face when purchasing eligible domestic PPE and essential medicines, and an appropriate maximum annual amount of aggregate separate payment under this potential policy.

In the final rule, CMS takes no action in response to comments received via the proposed rule solicitation. The agency thanks commenters for the many thoughtful comments it received on this topic and indicates it will consider them for future rulemaking as appropriate.

XXIV. RFI: Standardization and Comparability of Hospital Price Transparency Data

Since January 1, 2021, CMS has required each hospital operating in the United States to provide clear, accessible pricing information online about the items and services they offer in two ways: (1) as a comprehensive machine-readable file and (2) via a consumer-friendly display. CMS

describes the regulatory actions it has recently undertaken in response to Executive Order (E.O.) 14221, “Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information” (90 FR 11005) and reaffirms its commitment to “continue to promote universal access to clear and accurate healthcare prices” and “identify opportunities to further empower patients with meaningful price information” as directed by that E.O.

In the proposed rule CMS included a request for public comment on strengthening the standardization and comparability of the hospital price transparency data. Specifically, CMS asked questions on how to strengthen the transparency and utility of the machine-readable files and on how to enhance the comparability of the consumer-friendly display. CMS states that the agency received 185 timely pieces of correspondence that were submitted in response. CMS appreciates this input and will take it into consideration for future rulemaking.

TABLE 112: 2027 Impact Table

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**340B Adjustment**	**All Budget Neutral Changes (combined cols 2-4) with Market Basket Update**	**Payment Adjustment for Imaging w/o Contrast at Off Campus Providers**	**All 2027 Changes**	*Impact of Adjustment only for Providers Subject to 340B Remedy Offset*
ALL PROVIDERS*	3,620	0.0	0.1	0.0	2.4	-0.4	**1.7**	-2.0
ALL HOSPITALS (excludes hospitals held harmless and CMHCs)	3,502	0.1	0.1	-0.1	2.3	-0.4	**1.7**	-2.0
URBAN HOSPITALS	2,837	0.1	0.0	-0.5	2.0	-0.4	**1.3**	-2.0
LARGE URBAN (>1 M)	1,342	0.2	-0.2	-0.8	1.4	-0.4	**0.8**	-2.0
OTHER URBAN (<=1 M)	1,495	0.1	0.3	-0.2	2.4	-0.4	**1.7**	-2.0
RURAL HOSPITALS	665	-0.3	0.3	3.3	5.6	-0.1	**5.3**	-2.0
SOLE COMMUNITY	324	-0.3	0.6	5.3	7.9	0.0	**7.7**	-2.0
OTHER RURAL	341	-0.3	-0.1	0.0	1.9	-0.3	**1.4**	-2.0
BEDS (URBAN)								
0 - 99 BEDS	1004	0.7	-0.1	4.5	7.6	-0.2	**7.1**	-1.8
100-199 BEDS	787	0.3	0.4	2.7	5.8	-0.3	**5.2**	-2.0
200-299 BEDS	425	0.4	0.0	1.8	4.5	-0.5	**3.9**	-2.0
300-499 BEDS	387	0.3	-0.1	0.5	3.0	-0.4	**2.3**	-2.0
500 + BEDS	234	-0.3	0.0	-4.8	-2.9	-0.5	**-3.7**	-2.0
BEDS (RURAL)								
0 - 49 BEDS	309	-0.1	0.7	4.3	7.3	0.0	**6.9**	-2.0
50- 100 BEDS	203	-0.2	0.3	3.8	6.3	0.0	**6.0**	-2.0
101- 149 BEDS	87	-0.4	-0.3	1.6	3.2	-0.2	**3.0**	-2.0
150- 199 BEDS	36	-0.4	0.6	3.5	6.2	-0.2	**5.3**	-2.0
200 + BEDS	30	-0.5	0.1	2.6	4.6	-0.2	**4.4**	-2.0
REGION (URBAN)								
NEW ENGLAND	122	-0.1	0.1	-0.8	1.5	-0.6	**0.7**	-2.0
MIDDLE ATLANTIC	300	0.0	0.4	-1.1	1.6	-0.8	**0.7**	-2.0
SOUTH ATLANTIC	474	0.2	0.4	-0.1	2.8	-0.4	**2.3**	-1.9
EAST NORTH CENTRAL	426	0.0	0.3	-0.7	1.9	-0.6	**1.2**	-2.0

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**340B Adjustment**	**All Budget Neutral Changes (combined cols 2-4) with Market Basket Update**	**Payment Adjustment for Imaging w/o Contrast at Off Campus Providers**	**All 2027 Changes**	*Impact of Adjustment only for Providers Subject to 340B Remedy Offset*
EAST SOUTH CENTRAL	177	0.0	-1.0	-2.6	-1.4	-0.4	**-1.8**	-2.0
WEST NORTH CENTRAL	182	0.0	0.0	-1.6	0.7	-0.2	**-0.6**	-2.0
WEST SOUTH CENTRAL	478	0.7	-0.5	1.4	4.0	-0.4	**3.6**	-2.0
MOUNTAIN	239	0.3	-0.1	1.0	3.5	-0.2	**2.6**	-1.9
PACIFIC	387	0.2	-0.3	-0.6	1.6	-0.3	**1.1**	-2.0
PUERTO RICO	52	0.9	-2.3	4.5	5.4	0.0	**5.4**	0.0
REGION (RURAL)								
NEW ENGLAND	20	-0.6	0.8	3.8	6.3	0.0	**6.2**	-2.0
MIDDLE ATLANTIC	45	-0.4	0.0	1.4	3.3	-0.2	**3.2**	-2.0
SOUTH ATLANTIC	109	-0.3	0.8	2.8	5.6	-0.4	**5.3**	-2.0
EAST NORTH CENTRAL	110	-0.2	0.3	3.1	5.6	-0.2	**5.4**	-2.0
EAST SOUTH CENTRAL	124	-0.2	-1.1	1.0	1.9	-0.1	**2.0**	-2.0
WEST NORTH CENTRAL	72	-0.4	-0.2	5.1	6.9	0.0	**6.1**	-2.0
WEST SOUTH CENTRAL	121	0.3	-0.5	4.7	6.9	-0.2	**6.9**	-2.0
MOUNTAIN	39	-0.4	1.3	5.2	8.5	0.0	**6.7**	-1.9
PACIFIC	24	-0.6	2.8	2.9	7.6	0.0	**7.6**	-2.0
PUERTO RICO	1	0.8	3.6	9.3	16.9	0.0	**9.8**	0.0
TEACHING STATUS								
NON-TEACHING	2,081	0.4	0.2	3.5	6.5	-0.3	**6.0**	-1.9
MINOR	955	0.3	0.1	0.8	3.5	-0.4	**2.8**	-2.0
MAJOR	466	-0.3	0.0	-3.9	-2.0	-0.5	**-2.7**	-2.0
DSH PATIENT PERCENT								
0	11	1.4	-0.8	7.4	10.5	0.0	**10.5**	-0.7
> 0 - 0.10	254	0.8	0.2	6.5	10.1	-0.4	**9.5**	-1.9
>= 0.10 - 0.16	263	0.6	0.5	6.3	9.9	-0.5	**9.2**	-1.9
>= 0.16 - 0.23	546	0.6	0.2	5.6	8.9	-0.5	**8.3**	-2.0
>= 0.23 - 0.35	1,135	-0.1	0.2	-0.8	1.6	-0.4	**0.9**	-2.0
>= 0.35	743	-0.3	-0.3	-5.2	-3.6	-0.3	**-4.2**	-2.0
DSH NOT AVAILABLE **	550	4.5	-0.8	6.4	12.9	-0.3	**12.7**	-1.9

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**340B Adjustment**	**All Budget Neutral Changes (combined cols 2-4) with Market Basket Update**	**Payment Adjustment for Imaging w/o Contrast at Off Campus Providers**	**All 2027 Changes**	*Impact of Adjustment only for Providers Subject to 340B Remedy Offset*
URBAN TEACHING/DSH								
TEACHING & DSH	1,234	0.0	0.0	-1.8	0.5	-0.5	**-0.2**	-2.0
NO TEACHING/DSH	1,067	0.5	0.1	3.4	6.4	-0.4	**5.8**	-1.9
NO TEACHING/NO DSH	9	1.6	-0.2	7.3	11.3	0.0	**11.4**	-1.0
DSH NOT AVAILABLE**	526	4.5	-0.7	6.4	13.0	-0.4	**12.7**	-1.9
TYPE OF OWNERSHIP								
VOLUNTARY	1,989	0.0	0.1	-0.4	2.1	-0.4	**1.4**	-2.0
PROPRIETARY	1,106	1.3	-0.2	6.8	10.5	-0.2	**10.1**	-1.9
GOVERNMENT	407	-0.3	-0.2	-2.9	-1.1	-0.3	**-1.7**	-2.0
CMHCs	42	17.2	-0.4	7.4	28.3	0.0	**29.0**	-0.1

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

Column (2) includes all 2027 OPPS policies and compares those to the 2026 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the FY 2027 hospital inpatient wage index. The rural SCH adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the cancer hospital adjustment is 0.9996 because the 2027 target payment-to-cost ratio is higher than the 2026 PCR target.

Column (4) shows the impact of the final 340B drug payment adjustment and the corresponding increase in non-drug payment.

Column (5) shows the impact of all budget neutrality adjustments and the addition of the 2.3 percent OPD rate update factor (3.2 percent reduced by 0.9 percentage points for the productivity adjustment).

Column (6) shows the separate impact of the payment adjustment for imaging without contrast APC services furnished at excepted off campus providers.

Column (7) shows the combined impact of columns 5 and 6, plus 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.

The column for providers subject to the 340B Remedy Offset shows the separate impact of applying the final 2.0 percentage point reduction to the OPPS conversion factor update as part of the 340B Remedy Offset.

We estimate that 3,322 providers would be subject to the reduction to payments that result from the 340B remedy offset.

** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.