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Medicare Program: 2026 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 2026[1] final rule for Medicare's hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system (CMS-1834-FC) on November 21, 2025. Policies in the final rule will generally go into effect on January 1, 2026, unless otherwise specified. The final rule was published on November 25, 2025 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 end on January 20, 2026. CMS is also accepting applications for available graduate medical education residency positions until February 19, 2026 as explained in section XXII.**

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

Among other provisions, CMS adopted policies to:

- Reduce the otherwise applicable update for non-drug OPPS services by 0.5 percent as part of recouping additional spending resulting from adverse litigation against the Secretary for 340B acquired drugs.
- Reduce payments for drug administration services furnished in off-campus provider-based departments.
- Eliminate the inpatient only (IPO) list.
- Make health and safety requirements to perform surgical procedures in an ASC non-binding while expanding the list of procedures Medicare will pay for in an ASC.
- Conduct a survey of hospital acquisition costs for Medicare Part B drugs in early 2026.
- Revise Medicare payments for skin substitutes in hospital outpatient departments.
- Modify hospital price transparency reporting requirements.

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

- Base the relative weights under the inpatient prospective payment system (IPPS) using hospital reported data on negotiated charges with Medicare Advantage Organizations (MAO).

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-1834-fc.

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I. Overview

A. Estimated Impact on Hospitals

The increase in OPPS spending due only to changes in the 2026 OPPS final rule is estimated to be approximately $1.77 billion. Considering estimated changes in enrollment, utilization and case-mix for 2026, CMS estimates that OPPS expenditures, including beneficiary cost-sharing, will be approximately $101.0 billion, which is approximately $8.0 billion higher than estimated expenditures in 2025. These figures do not account for the reduction to the OPPS payment update for recoupment of additional spending for 340B acquired drugs resulting from adverse litigation against CMS. CMS estimates a 0.5 percentage point reduction to the update for non-drug OPPS services for most hospitals will reduce OPPS payment by $275 million relative to the reduction not being applied.

CMS estimates that the update to the conversion factor net of productivity will increase payments 2.6 percent in 2026 (market basket of 3.3 percent less 0.7 percentage points for productivity). However, this increase is before application of a 0.5 percentage point reduction in the payment update for non-drug OPPS services for recoupment of past additional spending for 340B acquired drugs. Accounting for this adjustment will make the update for non-drug OPPS services 2.1 percent.

Hospitals that satisfactorily report quality data will qualify for the full update of 2.1 percent (inclusive of the 340B recoupment adjustment) while hospitals that do not will be subject to a 2.0 percentage point reduction in the applicable update or 0.1 percent. All other adjustments are the same for the two sets of hospitals. Of the 3,014 hospitals that meet eligibility requirements to report quality data, CMS determined that 96 hospitals will not receive the full OPPS increase factor (42 hospitals that did not meet the reporting requirements and 54 hospitals that chose not to participate).

CMS' impact table indicates that Medicare makes payments under the OPPS to approximately 3,543 facilities (3,439 hospitals excluding CMHCs, cancer and children's hospitals held harmless to their pre-OPPS payment to cost ratios). Table 167 of the final rule (reproduced in the Appendix to this summary) includes the estimated impact of the final rule by provider type. It shows an estimated increase of 2.4 percent (less an additional 0.5 percentage point adjustment to the update for the 340 remedy offset) in Medicare spending for all facilities and a 2.5 percent increase for all hospitals (less an additional 0.5 percentage point to the update for the 340B remedy offset) after accounting for all factors:

Factor	% Change All Facilities
Fee schedule increase factor, Wage and Provider Adjustments	2.70
Drug Administration Reduction	-0.30
Difference from 2025 outlier payments (0.95% vs. 1.0%)	0.05
Difference in Pass-Through Payments	0.07
Subtotal	2.52
340B Acquired Drugs Recoupment Adjustment	-0.50
All changes	2.02

For 2025, CMS estimated that transitional pass-through payments for drugs, biologicals and devices will be 0.37 percent of OPPS spending. For 2026, CMS estimates that transitional pass-through spending will be $307 million, or 0.30 percent of OPPS spending. The difference between these figures (0.37 – 0.30 = 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 2025 will represent 0.95 percent of total OPPS payments compared to the 1.0 percent set aside for 2025, a 0.05 percentage point change in 2026 payments. Taken together, these factors produce a total increase in 2026 OPPS payments of approximately 2.0 percent.

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

Although CMS projects an estimated increase of approximately 2.4 percent for all facilities (prior to the 0.5 percent reduction to the update for the 340B recoupment), 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	2026 Impact
All Hospitals	2.5
All Facilities (including CMHCs and cancer and children's hospitals)	2.4
Urban	2.6
Large Urban	2.5
Other Urban	2.6
Rural	2.3
Beds	
0-99 (Urban)	2.6
0-49 (Rural)	2.3
500+ (Urban)	2.3
200+ (Rural)	2.4
Major Teaching	2.4
Type of ownership	
Voluntary	2.5
Proprietary	3.3
Government	2.1

Generally, an increase or decrease larger than the average will be accounted for by recalibration of APC weights or changes to the wage index. The higher increase for proprietary hospitals appears to be accounted for by APC recalibration according to table 167.

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 2026. 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), 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 2026, CMS is using 2024 hospital final action claims for services furnished from January 1, 2024, through December 31, 2024, processed through the Common Working File as of June 30, 2025 (approximately 81 million claims). CMS is using Medicare cost reports beginning in 2023 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/2026-nfrm-opps-claims-accounting.pdf.

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

For the 2026 final rule, CMS is bypassing the 175 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 2024 but were deleted for 2025.

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 2026, 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: https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1834-fc.

CCRs are calculated for the standard and nonstandard cost centers accepted by the electronic cost report 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 is continuing to follow this basic process for 2026. CMS eliminates 2024 claims from off-campus provider-based departments paid at a physician fee schedule (PFS) comparable amount under section 603 of the Bipartisan Budget Act (BBA) of 2015 as these claims are not paid under the OPPS.

a. Calculation of single procedure APC criteria-based costs

The calculation of geometric mean costs for some APCs follows various special rules, as described below.

(i) Blood and blood products

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

(ii) Brachytherapy sources

The statute requires the Secretary to create APCs for brachytherapy consisting of a seed or seeds (or radioactive source)—i.e., "brachytherapy sources"—separately from other services or groups of services, to reflect the number, isotope, and radioactive intensity of the brachytherapy sources furnished. Since 2010, CMS has used the standard OPPS payment methodology for brachytherapy sources, with payment rates based on source-specific costs as required by statute. CMS did not propose any changes to its brachytherapy policy for 2026.

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 2025, 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 2024 utilization data. For this reason, CMS proposed to use its equitable adjustment authority under section 1833(t)(2)(E) of the Social Security Act (henceforth, "the Act") to continue the rate of $4.69 per mm^2 for 2026 for HCPCS code C2645. CMS did not receive any public comments on this proposal that it is finalizing without change.

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 2026, CMS proposed to price six low volume brachytherapy APCs under this policy (excluding those that are priced using external data). CMS did not receive any public comments on this proposal that it is finalizing without change.

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 2026

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.

In the past, CMS has received a variety of requests for changes to its complexity adjustment criteria such as:

1. Modify eligibility criteria of 25 or more claims and the requirement there be a 2 times violation to reassign a code combination to a higher weighted APC. As an alternative criterion, one suggestion was to reassign a code combination to a higher level APC if its geometric mean cost is a 2 times violation OR exceeds the geometric mean cost of the next higher weighted APC.
2. Allow complexity adjustments for clusters of procedures including a J1 code pair and multiple add-on codes rather than just a J1 code with a single add-on code.

Multiple commenters requested that CMS apply a complexity adjustment to additional code combinations than were proposed. Of these, CMS indicated that 9 code combinations met the criteria for a complexity adjustment that are included in Addendum J to the final rule.

CMS did not propose any changes to its criteria for making a complexity adjustment but requested public comment on these and other issues. In response to this comment solicitation, commenters provided the same comments that they have brought to CMS' attention in the past that are provided above as well as suggestions to:

- Create a new higher weighted APC if a code combination is already assigned to the highest level APC within a clinical family.
- Maintain a complexity adjustment for at least three years or permanently if the code combination qualifies for a complexity adjustment for three consecutive years.

- Allow complexity adjustments for procedures newly removed from the inpatient only list.
- Evaluate non-J1 procedure code combinations for complexity adjustments.
- Review bilateral procedures with high-cost implantable supplies for a complexity adjustment.

Other commenters raised concerns that CMS' packaging policy discourages coding of packaged costs. CMS thanked commenters for their suggestions that it will evaluate for future rulemaking.

(i) Procedures Assigned to New Technology APCs

Beginning in 2019, CMS excluded procedures assigned to new technology APCs from packaging into C-APCs because of a concern that packaging payment reduces the number of claims for the new technology that are available for APC pricing. This policy includes new technology services that are assigned to the "Comprehensive Observation Services" C-APC.

Beginning in 2023, CMS adopted a new policy to exclude HCPCS Code C9399 (Unclassified drugs or biologicals) from being packaged into a C-APC. Section 1833(t)(15) of the Act requires drugs billed under an unclassified code to be paid based on 95 percent of average wholesale price (AWP). Excluding HCPCS code C9399 from the C-APC policy will ensure that drugs that do not yet have a specific HCPCS code will be priced at 95 percent of AWP. CMS added a new definition to status indicator "A" to include unclassified drugs and biologicals that are reportable with HCPCS code C9399.

(ii) Gene Therapies

Beginning with 2025, CMS excluded specific gene therapies listed in Table 3 of the final rule from the C-APC policy. If HCPCS codes for these cell and gene therapies appear on the same claim as a HCPCS code that is subject to the C-APC policy, CMS' 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 2026.

Based on public comments, CMS added HCPCS code Q2056 to Table 3. HCPCS code Q2056 is a gene therapy that received pass-through payment through June 30, 2025. Once pass-through payment, CMS has been paying separately for this code when it is furnished in conjunction with a code subject to the C-APC policy.

(iii) 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 C-APCs. This policy is discussed in more detail in section XIII. E. of this summary. CMS did not propose any other changes to its overall packaging policy.

(iv) C-APCs for 2026

As a result of its annual review of the services and APC assignments under the OPPS, CMS did not propose to convert any existing APCs to C-APCs. The full list of C-APCs, the data CMS used to evaluate creating a C-APC, and C-APC complexity adjustments are found in 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 only for mental health services and multiple imaging services. CMS did not propose any changes to its composite APC policies for 2026.

For the mental health composite APC 8010, CMS policy has been to cap the payment to be no more than APC 5864 for partial hospitalization (4 services furnished in a day). Partial hospitalization is the most intensive of the outpatient mental health services. CMS does not believe the mental health composite APC payment should be higher than the highest partial hospitalization payment. For 2026, CMS proposed to continue this policy. CMS did not receive any comments on this policy that it is finalizing without change.

3. Packaging Policy

CMS' packaging policies support its strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. There were no proposals to change CMS' packaging policies but commenters suggested that CMS discontinue its packaging policies or no longer package clinical diagnostic laboratory services. CMS is not adopting any changes to its packaging policies for 2026.

4. Separate OPPS Payment for Diagnostic Radiopharmaceuticals

Beginning with 2025, CMS adopted a policy to pay separately for diagnostic radiopharmaceuticals with per day 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 2026 and rounds the

resulting dollar amount to the nearest $5 increment. Based on this methodology, CMS determined an updated threshold of $654.23 rounded to the nearest $5 increment or a threshold of $655 per day for 2026.

Some public commenters supported increasing the threshold of $630 as CMS proposed while others opposed increasing the threshold suggesting it should remain at $630 until the policy to pay separately for diagnostic radiopharmaceuticals above $630 can be evaluated. Others objected to CMS' methodology for updating the packaging threshold suggesting CMS use radiopharmaceutical-specific cost data to update the threshold. CMS continues to believe it is appropriate to subject the diagnostic radiopharmaceutical packaging threshold to the same update factor that is used for the OPPS drug packaging threshold as supported by the majority of commenters.

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 being received 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 requested comment on this guidance: *Submission of OPPS ASP Data for Nonpass-Through Separately Payable Therapeutic Radiopharmaceuticals and Radiopharmaceuticals with Pass-Through Status* (https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/opps_asp_radiopharm_guidance10302009.pdf).

Public commenters indicated that hospitals inconsistently report diagnostic radiopharmaceutical costs and units making MUC inaccurate. For this reason, commenters suggested CMS transition to ASP-based payment that will be more reflective of the true cost of diagnostic radiopharmaceuticals. CMS agrees with using ASP to price diagnostic radiopharmaceuticals but inaccurate reporting makes it unusable. For instance, the ASP for one product would result in billions of dollars in spending making this product the among the 10 highest paid HCPCS codes under the OPPS. CMS will continue to work with industry to improve ASP reporting to make it usable in pricing separately paid diagnostic radiopharmaceuticals.

CMS proposed to base the initial payment for new diagnostic radiopharmaceuticals with HCPCS codes, but which do not have pass-through status and are without claims data, on ASP or 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. There were no public comments on these policies that CMS is finalizing without change.

The HCPCS codes for diagnostic radiopharmaceuticals that will be paid separately appear in Addendum B with status indicator "K." Those remaining packaged are assigned status indicator

"N." The list of diagnostic radiopharmaceuticals that CMS will pay for separately 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 provider-based department at a PFS equivalent rate under a site neutral policy, CMS will continue to use visits in these settings to determine the relative weight scaler because the PFS adjuster is applied to the payment, not the relative weight. CMS' site neutral policy is not budget neutral while changes to the weights are budget neutral.

CMS is following its past practice of using utilization from the preceding year (2024) to determine budget neutrality for changes in the OPPS relative weights for the payment rule year (2026). Holding all other variables constant, CMS multiplies the 2025 final relative weights and the 2026 final relative weights respectively for each APC by its associated volume from 2024. It sums the 2025 final relative weights and the 2026 final relative weights respectively and divides the 2025 aggregate relative weights by the 2026 final aggregate unscaled relative weights to determine the weight scaler. Using this process, CMS determined a weight scaler of 1.4879. The unscaled 2026 relative payments are multiplied by 1.4879 to determine the 2026 scaled relative weights that are shown in Addenda A and B of the final rule.

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 2025 and 2026 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 2026 conversion factor will be $90.970 for most hospitals—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 $91.415. The components of the update are shown below:

	Full Update	
2025 Conversion Factor	**$89.169**	**Resulting CF**
Remove pass-through & outliers from prior year CF	1.0139	$90.408
Wage Index Budget Neutrality	0.9990	$90.317
Cap on Wage Index Reductions	0.9995	$90.272
Cancer Hospital Adjustment	1.0000	$90.272

	Full Update	
2025 Conversion Factor	**$89.169**	**Resulting CF**
Rural Hospital Adjustment	1.0000	$90.272
Update	1.026	$92.619
Pass-Through/Outlier	0.9870	$91.415
2026 Conversion Factor		**$91.415**

CMS removes the prior year's pass-through (0.0037) and outlier adjustment (0.0100) from the 2025 conversion factor, which equals 1.0139 (1.39 percent).[2] Wage index budget neutrality is 0.9990 (-0.10 percent) for 2026. The cap on reductions to the wage index requires a budget neutrality adjustment of 0.9995 (-0.05 percent) for 2026. The cancer hospital and rural sole community hospital adjustments are 1.0000 (0.0 percent) for 2026.

The update of 1.026 (2.6 percent) equals the market basket of 3.3 percent less 0.7 percentage points for productivity for 2026. This update is the same as was included in the FY 2026 IPPS final rule and is based on the IGI 2nd quarter 2025 forecast of the FY 2026 hospital market basket with historical data through the 1st quarter of 2025. The productivity estimates are from the same period.

CMS estimates that pass-through spending for drugs, biologicals and devices for 2026 will be $307 million, or 0.30 percent of OPPS spending. The outlier adjustment is 0.99 (-1.0 percent). The combined adjustment for pass-through and outliers is 0.9870 (-1.3 percent).

The 2026 conversion factor for hospitals that submit quality data before application of the 340B recoupment adjustment will be $91.415. Application of the 340B recoupment adjustment is the equivalent of a 2.1 percent update rather than a 2.6 percent update and reduces the conversion factor for hospitals subject to the recoupment to $90.970.

The conversion factor for hospitals that do not submit quality data is subject to all the same adjustments except the update is 1.006 (0.6 percent) instead of 1.026 (2.6 percent). If these hospitals are also subject to the 340B recoupment adjustment, the effective update would be 0.1 percent, and the conversion factor would be $89.188 although CMS does not provide this figure in the final rule or the claims accounting.

Several commenters expressed concern about the proposed market basket update net of productivity after accounting for the proposed 340B recoupment adjustment. These commenters:

- Requested that CMS use more accurate and timely data to better reflect labor costs in the market basket.
- Requested that CMS make a one-time forecast error adjustment to account for past understatements of the market basket.

[2] Removing the budget neutrality adjustment from the prior year requires division so the factor equals 1.0/(1-0.01-0.0037) or 1.0139.

- Stated that the increase will be insufficient considering CMS' proposals to accelerate the 340B recoupment and reduce payment for drug administration services.
- Indicated that the update is insufficient and unsustainable for rural hospitals given that 196 hospitals have closed or ceased to provide inpatient services since 2010, and there are 432 rural hospitals vulnerable to closure.
- Noted the update was insufficient relative to inflation when compared to the consumer price index.

CMS responded that under section 1833(t)(3)(C)(iv) of the Act, the OPD fee schedule increase factor for a year must be equal to the IPPS market basket percentage increase.

Commenters also requested that CMS eliminate or waive the productivity adjustment for 2026 and forward using CMS' special exceptions and adjustments authority because the adjustment is based on general economy wide productivity that cannot be achieved by the hospital sector. CMS replied that section 1833(t)(3)(F)(i) of the Act requires that CMS apply the productivity adjustment to the OPPS market basket update.

C. Wage Index Changes

CMS proposed to continue using a labor share of 60 percent, the fiscal year IPPS post-reclassified wage index and all the other adjustments that apply to IPPS hospitals for hospital paid under the OPPS in 2026. 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.

In 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 have also applied under the OPPS since 2020. CMS discontinued the low wage index policy under the IPPS for FY 2025 in response to adverse litigation against the Secretary. However, CMS continued the low-wage index policy under the OPPS in 2025 for reasons explained in the 2025 OPPS final rule (89 FR 93975).

CMS' decision to continue the low-wage index hospital policy under the OPPS for CY 2025 (and thus to diverge from the IPPS wage index for FY 2025) was due principally to the unique circumstances presented by the timing of the court's decision after the OPPS proposed rule had been published. Also, the statutory authority that CMS relied upon to implement the low-wage index hospital policy under the OPPS was different than the statutory authority that CMS relied upon for the policy under the IPPS. CMS concluded that it could legally retain the low-wage index

policy for the OPPS in 2025 while it could not for the IPPS in FY 2025 because of the court's decision.

Consistent with the FY 2026 IPPS proposed rule (90 FR 18233), CMS proposed to discontinue the low-wage index hospital policy under the OPPS for 2026 and subsequent years and return to aligning the IPPS and OPPS wage index. To effectuate full realignment of the IPPS and OPPS wage index values in 2026, CMS proposed that the 5 percent cap on reductions to the wage index will be relative to the FY 2025 IPPS wage index—not the 2025 OPPS wage index. Because the 2025 OPPS wage index for a low wage index hospital was higher than its FY 2025 IPPS wage index, this policy may result in more than a 5 percent decrease in the hospital's OPPS wage index in 2026.

One commenter recommended that CMS transition a hospital's wage index from the one it received in 2025 under the OPPS rather than the one it received under the FY 2025 IPPS to avoid a reduction of more than 5 percent until such time as the wage indexes under the two systems are fully aligned. CMS responded that its goal is to fully align the wage index across both systems in 2026 rather than having discrepancies and inconsistencies continue into future years based on ongoing transition policies.

For the FY 2026 IPPS, CMS is allowing hospitals with a wage index that was increased by the low-wage index policy to benefit from a transition policy that will mitigate the reduction to their wage indexes. Under the transition policy, CMS will compare the hospital's wage index for FY 2026 to its wage index under the low-wage index policy in FY 2024. If the hospital's wage index decreases by more than 5 percent annually (or 9.75 percent over two years)[3], the hospital would be eligible for the transitional policy. The limit on the reduction in the wage index would be 5 percent from the otherwise applicable policy that would apply in FY 2026 if the low-wage index policy had continued. As CMS proposed to align the 2026 OPPS wage index with the FY 2026 IPPS wage index, it proposed to apply this same transition policy to the 2026 OPPS wage indexes. CMS is finalizing these proposals.

For non-IPPS hospitals paid under the OPPS for 2026, CMS proposed to continue its past policies of assigning the wage index that would be applicable if the hospital were paid under the IPPS and allowing the hospital to qualify for the out-migration adjustment—an adjustment that a hospital may qualify for if a high proportion of its workers commute to adjacent higher wage areas. For CMHCs, CMS proposed to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. CMS notes that, consistent with its current policy, the wage index that applies to CMHCs includes the rural floor adjustment but not the out-migration adjustment, which only applies to hospitals. These proposals are being finalized without change.

[3] Over a 2-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 its wage index from two years earlier or 0.9025 which would be a reduction of 9.75 percent.

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

In cases where there is no data to calculate a hospital's CCR, CMS is continuing to use the statewide average CCR to determine outlier payments, payments for pass-through devices, and other purposes. The statewide average is used for hospitals that are new, hospitals that have not accepted assignment of an existing hospital's provider agreement, and hospitals that have not yet submitted a cost report. CMS also uses the statewide average default CCRs to determine payments for hospitals that appear to have a CCR falling outside the predetermined ceiling threshold for a valid CCR or for hospitals in which the most recent cost report reflects an all-inclusive rate status. 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/2026-1

E. Sole Community Hospital (SCH) Adjustment

For 2026, 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 under the pass-through payment policy, and items paid at charges reduced to costs. The adjustment is budget neutral and is applied before calculating outliers and copayments.

Several commenters requested that CMS extend the adjustment to urban SCHs and Medicare Dependent Hospitals (MDHs). One commenter stated that CMS should publish data on whether the rural SCH adjustment is improving access to outpatient services. CMS responded that its authority to provide the SCH adjustment only applies to rural hospitals. It will consider the other comment in future rulemaking.

F. Cancer Hospital Adjustment

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

To calculate the 2026 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 2026 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 2023 and 2024. CMS estimated a

PCR of 0.88 (or 88 percent) for non-cancer hospitals. After reducing this PCR by 1.0 percentage point, the target PCR is 0.87 (or 87 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 2026 ranging from 11.9 percent to 49.4 percent. While the cancer hospital adjustment is budget neutral, CMS indicates that the budget neutrality adjustment is 0.0 percent (1.0) for 2026.

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 2026, 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 2025 and previous years. For 2026, CMS proposed to continue setting the outlier payment equal to 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount when both the 1.75 multiple payment threshold and the fixed-dollar threshold are met.

CMS proposed to set aside a portion of the 1.0 percent outlier pool—specifically, an amount equal to less than 0.01 percent of outlier payments—for CMHCs' partial hospitalization program outlier payments. If a CMHC's cost for partial hospitalization services paid using APC 5853 (Partial Hospitalization for CMHCs) exceeds 3.40 times the payment rate for APC 5853, the outlier payment will be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 5853 payment rate.

Hospitals that fail to 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 is using 2024 Medicare claims data to set the 2026 outlier threshold. To model hospital outlier payments and set the outlier threshold, CMS applied a charge inflation factor of 1.11313 to approximate 2026 charges from 2024 claims.

The final rule indicates that CMS is using hospital-specific overall ancillary CCRs from the July 2025 update to the Outpatient Provider-Specific File to determine the 2026 final rule outlier threshold. CMS adjusted the July 2025 CCRs by 0.956081 to approximate the 2026 CCRs.

For 2026, CMS is adopting a fixed dollar threshold of $6,225 (compared to $7,175 in 2025). 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.

Using 2024 Medicare utilization, CMS estimates that it will pay 0.95 percent of total OPPS payments as outliers in 2025, or 0.05 percentage points less 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.[4] 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)[5] and APCs and annually finalizes these interim assignments in the OPPS/ASC final rule. CMS notes that it is the APC assignment that determines the payment rate for an item, procedure, or service.

The proposed and final status indicators, APC assignments, and payment rates for each HCPCS code can be found in Addendum B to the final rule. The complete list of status indicators and definitions used under the OPPS can be found in Addendum D1 to the final rule, while the complete list of final comment indicators and definitions can be found in Addendum D2.

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

Table 15: Comment and Finalization Timeframes for New or Revised OPPS-Related HCPCS codes

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2025	HCPCS (CPT and Level II Codes)	April 1, 2025	2026 OPPS/ASC proposed rule	2026 OPPS/ASC final rule
July 2025	HCPCS (CPT and Level II Codes)	July 1, 2025	2026 OPPS/ASC proposed rule	2026 OPPS/ASC final rule
October 2025	HCPCS (CPT and Level II Codes	October 1, 2025	2026 OPPS/ASC final rule	2027 OPPS/ASC final rule

[4] CMS recognizes the following codes on OPPS claims: Category I CPT codes (surgical procedures, diagnostic and therapeutic services, and vaccine codes; Category III CPT codes (new and emerging technologies, services, and procedures: multianalyte assays with algorithmic analyses (MAAA) CPT codes; proprietary laboratory analyses (PLA) services CPT codes; and Level II HCPCS codes (codes that primarily identify drugs, devices, supplies, temporary procedures and services not described by CPT codes).
[5] Status indicators are discussed in section XI of the final rule.

Table 15: Comment and Finalization Timeframes for New or Revised OPPS-Related HCPCS codes				
OPPS Quarterly Update CR	**Type of Code**	**Effective Date**	**Comments Sought**	**When Finalized**
January 2026	CPT Codes	January 1, 2026	2026 OPPS/ASC proposed rule	2026 OPPS/ASC final rule
	Level II HCPCS Codes	January 1, 2026	2026 OPPS/ASC final rule	2027 OPPS/ASC final rule

1. April 2025 HCPCS Codes Proposed Rule Comment Solicitation

In the April 2025 update, CMS established 104 new HCPCS codes that became effective on April 1, 2025. In the proposed rule, CMS sought and received comment on some of the proposed APC and status indicator assignments for these codes. CMS has chosen to respond to the comments in conjunction with other sections of the final rule, rather than duplicate them here. For codes that received no comments, CMS is finalizing the APC and status indicator assignment as proposed. Table 12 in the final rule lists the new HCPCS codes effective April 1, 2025.

2. July 2025 HCPCS Codes Proposed Rule Comment Solicitation

For the July 2025 update, CMS established 110 new HCPCS codes that became effective July 1, 2025. In the proposed rule, CMS sought and received comment on some of the proposed APC and status indicator assignments for these codes. CMS has chosen to respond to the comments in conjunction with other sections of the final rule, rather than duplicate them here. For codes that received no comments, CMS is finalizing the APC and status indicator assignment as proposed. Table 13 in the final rule lists the new HCPCS codes effective July 1, 2025.

3. October 2025 HCPCS Codes Final Rule Comment Solicitation

In the proposed rule, CMS solicited comments on the new CPT and Level II HCPCS codes that would be effective October 1, 2025, which allows the agency to finalize the status indicators and APC assignments for the codes in the 2026 OPPS final rule. The new codes were released through the October 2025 OPPS Update Change Request[6] and are listed in Table 14 of the final rule. CMS proposed to assign indicator "N1" to these new codes to indicate that CMS is assigning them an interim status indicator, which is subject to public comment. CMS notes that several of the temporary C-codes have been replaced with permanent J-codes effective January 1, 2026. **CMS invites public comments** in the final rule on the interim payment indicators, which will be finalized in the 2027 OPPS/ASC final rule. CMS further notes that the proposed APC assignments and status indicators for these same codes will be subject to comment in the 2027 OPPS/ASC proposed rule and will be finalized in the 2027 OPPS/ASC final rule.

[6] See: Transmittal 13425, Change Request 14223, dated September 22, 2025

4. January 2026 HCPCS Codes

a. New Level II HCPCS Codes Final Rule Comment Solicitation

In the final rule, **CMS is soliciting comments** on the new Level II HCPCS codes that will be effective January 1, 2026. Because most Level II HCPCS codes are not available until November, CMS is unable to include them in the OPPS/ASC proposed rules. Consequently, for 2026, CMS proposed to include the new Level II HCPCS codes that will be effective January 1, 2026 (that would be incorporated in the January 2026 OPPS quarterly update CR), in Addendum B to the CY 2026 OPPS/ASC final rule. Specifically, for CY 2026, CMS proposed to continue the agency's established policy of assigning comment indicator "N1" in Addendum B to the final rule to the new HCPCS codes that will be effective January 1, 2026, to indicate that CMS is assigning them an interim status indicator, which is subject to public comment.

CMS is inviting public comments in the final rule on the status indicators and APC assignments, which would then be finalized in the 2027 OPPS/ASC final rule. Similar to the codes effective October 1, 2025, the proposed APC assignments and status indicators for these new Level II HCPCS codes that will be effective January 1, 2026, will also be subject to comment in the 2027 OPPS/ASC proposed rule, and will be finalized in the 2027 OPPS/ASC 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 comments on the proposed 2026 status indicators and APC assignments for the new and revised CPT codes that would be effective January 1, 2026. CMS proposed to finalize the status indicator and APC assignments for these codes in the final rule. The codes were listed in proposed rule Addenda B, along with their proposed status indicator and APC assignments. CMS received comments on several of the new CPT codes that were assigned to comment indicator "NP" in Addendum B. CMS has chosen to respond to these comments in other related sections of the final rule, rather than replicate them here.

B. Variations Within APCs

1. Background

In accordance with statute,[7] CMS developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs). 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. Into the payment

[7] Section 1833(t)(2)(A) of the Act

for each procedure or service within an APC group, CMS packages the 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 2026, 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.

2. Application of the 2 Times Rule

In accordance with statute,[8] 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.

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 2026 OPPS and CMS' responses are discussed in relevant sections throughout the final rule.

For 2026, CMS identified APCs with violations of the 2 times rule and proposed changes to the procedure codes assigned to these APCs in proposed rule Addendum B (identified with comment indicator "CH") other than those for which CMS proposed an exception to the 2 times rule. CMS proposed to reassign these procedure codes to new APCs that contain services that are similar with regard to both their clinical and resource characteristics. CMS noted that in many cases, the proposed procedure code reassignments and associated APC configurations for 2026 are related to changes in costs of services that were observed in the 2024 claims data.

[8] Section 1833(t)(2) of the Social Security Act

3. Proposed APC Exceptions to the 2 Times Rule

CMS may make exceptions to the 2 times limit on the variation of costs within each APC group in unusual cases, such as low-volume items and services. CMS uses the following criteria[9] to decide whether to propose exceptions: resource homogeneity; clinical homogeneity; hospital outpatient setting utilization; frequency of service (volume); and opportunity for upcoding and code fragments.

Table 12 in the proposed rule listed the 26 APCs for which CMS proposed to make an exception under the 2 times rule for 2026 based on the criteria cited above and claims data submitted between January 1, 2024, and December 31, 2024, and processed on or before December 31, 2024, and CCRs, if available.

Based on the updated final rule 2024 claims data used for the final rule, CMS found a total of 27 APCs with violations of the 2 times rule. Of these 27 total APCs, 24 were identified in the proposed rule and three are newly identified in the final rule (APCs 5024, 5052, and 5722). CMS notes that two APCs (APCs 5613 and 5811) appeared in the proposed rule as violating the 2 times rule, however, after further analysis, CMS finds they no longer violate the 2 times rule.

CMS received comments on the APCs located in Table 12 of the proposed rule (90 FR 33537), along with comments on APC assignments for specific HCPCS codes which are addressed in section III.E. of the final rule. Based on its analysis of the 2024 costs from hospital claims and cost report data available for the final rule, **CMS is finalizing its proposals with some modifications**. Specifically, CMS is finalizing its proposal to except the 24 proposed APCs that continue to have 2 times violations from the 2 times rule. CMS will also except three additional APCs that did not violate the 2 times rule in the proposed rule data, but now violate the 2 times rule based on the updated data. In total, 27 APCs qualify for exceptions in 2026 (listed in Table 16, reproduced from the final rule below).

Table 16: Final 2026 APC Exceptions to the 2 Times Rule

APC	APC Group Title
5012	Clinic Visits and Related Services
5024	Level 4 Type A ED Visits
5052	Level 2 Skin Procedures
5054	Level 4 Skin Procedures
5071	Level 1 Excision/Biopsy/Incision and Drainage
5301	Level 1 Upper GI Procedures
5502	Level 2 Extraocular, Repair, and Plastic Eye Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5572	Level 2 Imaging with Contrast
5611	Level 1 Therapeutic Radiation Treatment Preparation
5612	Level 2 Therapeutic Radiation Treatment Preparation

[9] For a detailed discussion of these criteria, readers are referred to 65 FR 18457 through 18458.

Table 16: Final 2026 APC Exceptions to the 2 Times Rule	
APC	**APC Group Title**
5627	Level 7 Radiation Therapy
5671	Level 1 Pathology
5674	Level 4 Pathology
5691	Level 1 Drug Administration
5692	Level 2 Drug Administration
5722	Level 2 Diagnostic Tests and Related Services
5724	Level 4 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5734	Level 4 Minor Procedures
5791	Pulmonary Treatment
5821	Level 1 Health and Behavior Services
5822	Level 2 Health and Behavior Services
5823	Level 3 Health and Behavior Services

C. New Technology APCs

1. 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[10] and is reasonable and necessary.[11]

For 2025, 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)).

In this section of the preamble, 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

[10] Under section 1832(a) of the Act.
[11] In accordance with section 1862(a)(1)(A) of the Act (66 FR 59898 through 59903).

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.[12]

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. Where utilization of services assigned to a New Technology APC is low, it can lead to wide variations in payment rates from year to year, resulting in even lower utilization and potential barriers to access of new technologies. To mitigate these issues, in 2019, CMS established a policy to use its "equitable adjustment authority" under section 1833(t)(2)(E) of the Act. When CMS uses this authority, it will also calculate and present the results of each statistical methodology (arithmetic mean, geometric mean, and median) based on up to 4 years of claims data and solicit public comment on which methodology should be used to establish the payment rate for the low-volume new technology service. Since 2022, CMS uses its universal low volume APC policy for clinical APCs, brachytherapy APCs, and procedures assigned to New Technology APCs. Under this policy, CMS 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.[13]

Additionally, in 2025, CMS established a new 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. Therefore, in 2025, 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 (CY 2024).[14]

2. Policy to Continue to Exempt Services with Under 10 Claims in the 4-year Lookback Period from APC Reassignment Based on the Universal Low Volume Policy

CMS continues to be concerned about payment stability for services assigned to New Technology APCs, specifically services with fewer than 10 claims in the 4-year lookback period used under the universal low volume APC policy. As discussed above, for 2025, CMS established and applied a method for addressing this issue which CMS proposed to continue for 2026. Instead of assigning these services to a different clinical or New Technology APC based on the very few claims available, CMS proposed to continue to maintain the New Technology APC assignment for each service from the prior year. Consistent with the agency's overall policy regarding use of updated claims data in the final rule, CMS proposed to repeat its analysis and update the APC placement as needed in the final rule. CMS proposed to continue this policy in future years, until (or unless) an alternative policy is finalized.

Comment/Response: Commenters generally supported CMS' proposal. As a result, **CMS is finalizing its proposal** to continue 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.

[12] See 77 FR 68314 for more discussion on this issue.
[13] See 2022 OPPS/ASC final rule (86 FR 63529) for further discussion regarding this policy.
[14] See the 2025 OPPS/ASC final rule (89 FR 94016 through 94018) for a discussion on the policy.

3. Procedures Assigned to New Technology APC Groups for 2026

CMS generally retains a procedure in the New Technology APC to which it is initially assigned until the agency has obtained sufficient claims data to justify reassignment of the procedure to a clinically appropriate APC. In cases in which (i) CMS finds that its initial New Technology APC assignment was based on inaccurate or inadequate information (although it was the best information available at the time), (ii) CMS obtains new information that was not available at the time of its initial New Technology APC assignment, or (iii) the New Technology APCs are restructured, CMS may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a different New Technology APC that more appropriately reflects its cost.

For CY 2026, CMS proposed to retain services within New Technology APC groups until the agency has obtained sufficient claims data to justify reassignment of the service to an appropriate clinical APC.

Comment/response: A commenter stated that the New Technology APC pathway is vital for bringing innovative services to patients before sufficient claims data exist for permanent APC assignment and suggested that CMS incorporate the perspectives of patients and caregivers into its review to ensure payment decisions reflect unmet needs and treatment burdens. In response, CMS expresses appreciation for the comment and notes that the agency accepts a variety of information as part of the New Technology APC application process. **CMS is finalizing its proposal** to retain services within New Technology APC groups until the agency has obtained sufficient claims data to justify reassignment of the service to an appropriate clinical APC.

Based on the policies described above, the table below (developed by HPA) reflects CMS' proposed and final New Technology APC assignments for 2026.[15] A brief summary of updates and response to comment for each of these codes can be found below the table. CMS refers readers to Addendum B for final 2026 payment rates and Addendum D1 for the status indicator meanings for all codes reported under the OPPS. These Addenda are found on the CMS website: CMS-1834-FC | CMS

HCPCS/CPT code	Long Descriptor	Proposed 2026 SI	Proposed 2026 APC	Final 2026 SI	Final 2026 APC
0810T	Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies	T	1563	T	1563
G0562	Therapeutic radiology simulation-aided field setting; complex, including acquisition of PET and CT imaging data required for radiopharmaceutical-directed radiation therapy treatment planning (i.e., modeling)	S	1514	S	1521
G0563	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image	S	1525	S	1524

[15] Note that in the proposed rule, scalp cooling placeholder CPT codes 9XX01, 9XX02, and 9XX03 were initially discussed by CMS in this section. In the final rule, CMS discusses the scalp cooling replacement CPT codes (97007, 97008, and 97009, respectively) in section III.3. We have therefore removed the codes from this table.

HCPCS/CPT code	Long Descriptor	Proposed 2026 SI	Proposed 2026 APC	Final 2026 SI	Final 2026 APC
	guidance and real-time positron emissions-based delivery adjustments to 1 or more lesions, entire course not to exceed 5 fractions				
C9758	Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study	D	N/A	T	1590
C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g., aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s).	D	N/A	D	N/A
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	S	1522	S	1522
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability);	S	1519	S	1517
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability); with concurrently acquired computed tomography transmission scan	S	1522	S	1522
C9782	Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study	T	1590	T	1590

HCPCS/CPT code	Long Descriptor	Proposed 2026 SI	Proposed 2026 APC	Final 2026 SI	Final 2026 APC
0625T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography	D	N/A	D	N/A
75577 (75XX6)	Quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, derived from augmentative software analysis of the data set from a coronary computed tomographic angiography, with interpretation and report by a physician or other qualified healthcare professional	S	1511	S	1511
C9760	(Non-randomized, non-blinded procedure for NYHA class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (for example, ultrasound, fluoroscopy)	T	1592	T	1592
0693T	Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report	S	1505	S	1550
C9789	Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed	T	1553	T	1551
0620T	Endovascular venous arterialization, tibial or peroneal vein, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed	S	1579	S	1580
0686T	Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance	S	1579	S	1576
0648T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session; single organ	S	1511	S	1511
0649T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	S	1511	S	1511

HCPCS/CPT code	Long Descriptor	Proposed 2026 SI	Proposed 2026 APC	Final 2026 SI	Final 2026 APC
0721T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging	S	1508	S	1508
0722T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset (list separately in addition to code for primary procedure)	S	1508	S	1508
0697T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session; multiple organs	S	1511	S	1511
0698T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure); multiple organs (list separately in addition to code for primary procedure)	S	1511	S	1511
0723T	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session	S	1511	S	1511
0724T	Quantitative magnetic resonance cholangiopancreatography (QMRCP), including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) (list separately in addition to code for primary procedure)	S	1511	S	1511
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 professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation	S	1512	S	1512
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	S	1517	S	1518

HCPCS/CPT code	Long Descriptor	Proposed 2026 SI	Proposed 2026 APC	Final 2026 SI	Final 2026 APC
	esketamine nasal self-administration, includes 2 hours post-administration observation				
C9780	Insertion of central venous catheter through central venous occlusion via inferior and superior approaches (e.g., inside-out technique), including imaging guidance	S	1534	S	1534
C9792	Blinded or nonblinded procedure for symptomatic New York Heart Association (NYHA) Class II, III, IVa heart failure; transcatheter implantation of left atrial to coronary sinus shunt using jugular vein access, including all imaging necessary to intra procedurally map the coronary sinus for optimal shunt placement (e.g., TEE or ICE ultrasound, fluoroscopy), performed under general anesthesia in an approved investigational device exemption (IDE) study	S	1537	S	1537
C9791	Magnetic resonance imaging with inhaled hyperpolarized xenon-129 contrast agent, chest, including preparation and administration of agent	T	1551	T	1551
0889T	Personalized target development for accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation derived from a structural and resting-state functional MRI, including data preparation and transmission, generation of the target, motor threshold-starting location, neuronavigation files and target report, review and interpretation	S	1511	S	1511
0890T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including target assessment, initial motor threshold determination, neuronavigation, delivery and management, initial treatment day	S	1521	S	1525
0891T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent treatment day	S	1522	S	1525
0892T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent motor threshold redetermination with delivery and management, per treatment day	S	1525	S	1525
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training	T	1561	T	1563
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation	T	1561	T	1563
15013	Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin	S	1532	S	1532

HCPCS/CPT code	Long Descriptor	Proposed 2026 SI	Proposed 2026 APC	Final 2026 SI	Final 2026 APC
C8002	Preparation of skin cell suspension autograft, automated, including all enzymatic processing and device components (do not report with manual suspension preparation)	S	1532	S	1532
0888T	Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including image guidance	S	1576	S	1576

a. Administration of Subretinal Therapies Requiring Vitrectomy (APC 1563). CMS did not receive any comments. One additional claim has been processed since the proposed rule which did not significantly alter CMS' analysis. Therefore, CMS is finalizing as proposed.

b. BgRT (APC 1521 and 1525). Commenters supported CMS' proposal to assign HCPCS code G0563 to APC 1525 with a payment rate of $3750.50 for 2026. Several commenters did not support the proposal to assign HCPCS code G0562 to APC 1514 with a payment rate of $1,250.50 for CY 2026 because they do not believe the resulting decrease in payment would cover the costs to provide the service. In response, CMS agreed with the commenters' concerns. CMS notes that there was one additional claim that was processed since the proposed rule. After consideration of comments and the revised statistical methodologies, CMS is not finalizing its proposals. Instead, for CY 2026, CMS is finalizing the assignment of HCPCS code G0562 to APC 1521 and status indicator "S" and HCPCS code G0563 to APC 1524 and status indicator "S".

c. Blinded procedure for NYHA class III/IV heart failure (APC 1590). A commenter requested that CMS not delete HCPCS code C9758, as Corvia Medical is conducting an ongoing clinical study that utilizes this code. In response, CMS is not finalizing its proposal to delete the code for CY 2026. CMS notes that its updated claims data shows only 8 claims for HCPCS code C9758. In accordance with policies finalized above for New Technology APC services with fewer than 10 claims in the 4-year lookback period, CMS will continue to assign HCPCS code C9758 to APC 1590 for CY 2026.

d. Bronchoscopy with Transbronchial Ablation of Lesion(s) by Microwave Energy (APC 1562). CMS did not receive public comments on its proposal to delete HCPCS code C9751 for CY 2026. Additionally, CMS' updated claims data remains unchanged. Therefore, CMS is finalizing as proposed.

e. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies (APCs 1519 and 1522). Commenters supported the proposed APC assignments for CPT codes 78431 and 78433 for CY 2026. Some commenters did not support the proposed APC assignment for CPT code 78432 to APC 1519 with a payment rate of $1,750.50 and explained that this code consumes more resources than CPT code 78431. In response, CMS reminds readers that the agency adjusts New Technology APC assignments based on the claims data available rather than clinical characteristics of a service. Finally, CMS notes that additional claims for CPT codes 78431 through 78433 have been processed since the proposed rule. Based on updated claims data, the

APC assignment for CPT codes 78431 and 78433 are unchanged, and CMS is therefore finalizing their assignments without modification. Based on the updated claims data for CPT code 78432, the arithmetic mean cost is outside of the cost band for the proposed assignment to APC 1519, therefore, CMS is assigning this code to ACP 1517 instead.

f. CardiAMP (APC 1590). CMS did not receive public comments on this provision, and the updated claims data did not show any additional claims for HCPCS Code C9782. Therefore, CMS is finalizing as proposed.

g. Atherosclerosis Imaging-Quantitative Computer Tomography (AI-QCT) (APC 1511). Several commenters supported CMS' assignment of new CPT code 75577 to APC 1511. CMS notes that nine additional claims for the legacy CPT code 0625T have been processed, however, CMS states it is not certain that it has enough claims data to be confident in the calculated geometric mean cost for this code. Therefore, CMS is finalizing its proposal, without modification.

Multiple commenters requested that CMS proactively ensure that Medicare Administrative Contractors (MACs) do not issue an edit that restricts certain revenue codes for CPT code 75577 (placeholder code 75XX6), as had previously been issued for CPT code 75580. In response, CMS states it is unable to confirm that there are no MAC edits in place for CPT code 75577. Facilities may bill CPT 75577 with any appropriate revenue code in accordance with CMS' longstanding policies.

h. Corvia Medical Interatrial Shunt Procedure (APC 1592). A commenter supported CMS' proposal. CMS notes that there were no additional claims for HCPCS code C9760 in the updated claims data. Therefore, CMS is finalizing its proposal without modification.

i. DARI Motion Procedure (APC 1505). CMS did not receive any comments on its proposal, and there continue to be no claims for this service. CMS is therefore finalizing as proposed, without modification.

j. Instillation of Anti-Neoplastic Pharmacologic/Biologic Agent into Renal Pelvis (APC 1551). A commenter supported HCPCS code C7989 remaining in a New Technology APC but requested that HCPCS C7989 remain assigned to New Technology APC 1559, citing concerns for beneficiary access and their belief that providers are using alternative codes when reporting the procedure. In response, CMS states that providing coding guidance is out of scope for the OPPS/ASC final rule. CMS states that if hospitals have questions about appropriate coding, the hospital should consult the HCPCS code descriptors or consult the appropriate Medicare Administrative Contractor (MAC) for their jurisdiction. CMS additionally notes that providers may receive separate payment for both the drug and installation procedure when providing this service.

CMS notes that the geometric mean cost and claims data for HCPCS code C9789 has changed since CMS' analysis in the proposed rule. Based on the updated claims data for the final rule with comment period, CMS believes that the observed number of single frequency claims is adequate

for ratesetting for this service and is finalizing, with modification, a New Technology APC assignment for HCPCS code C9789 to APC 1551.

k. LimFlow TADV procedure CPT Code 0620T (APC 1580). A commenter supported the proposal to assign CPT code 0620T to APC 1579 based on the application of the universal low volume APC policy. CMS notes that three additional claims for have been processed since the proposed rule. Based on its updated analysis, CMS is assigning CPT code 0620T to APC 1580 based on the application of the universal low volume APC policy.

l. Liver Histotripsy Service (APC 1579). A commenter supported the proposal to reassign CPT code 0686T to APC 1579 based on the 94 claims data available at the time of the proposed rule. CMS notes that six additional claims have been processed, bringing the total number of claims to 100. Since claims for this procedure now exceed the 99-claim threshold for the universal low volume APC policy, CMS would use the geometric mean cost to set the payment rate for 2026 under its standard ratesetting methodology, rather than the highest of the three statistical methodologies over a 4-year lookback period. Therefore, based on its analysis of the updated claims and the resulting geometric mean cost, CMS is finalizing a New Technology APC assignment for HCPCS code 0686T to APC 1576.

m. LiverMultiScan Service (APC 1511). CMS received a number of comments in support of maintaining the APC assignments to New Technology APC 1511. In response, CMS expresses its hope that by having additional information from the Software as a Service (SaaS) comment solicitation, CMS will be able to put forth a policy in future rulemaking that provides a more stable payment method for SaaS technologies. CMS is finalizing its proposal without modification to use its equitable adjustment authority to continue to assign CPT codes 0648T and 0649T to New Technology APC 1511.

n. Optellum Lung Cancer Prediction (LCP) (APC 1508). Commenters were supportive of CMS' proposal to use its equitable adjustment authority to continue to assign CPT codes 0721T and 0722T to APC 1508. However, commenters expressed concern that the claims data do not accurately reflect the true cost of delivering the service, and a commenter stated that they believe the inaccurate claims data was the result of hospitals reporting inappropriate revenue codes for the service. In response, CMS encouraged manufacturers and distributors to provide outreach to hospitals regarding billing practices that are most appropriate for their individual technologies. CMS notes it will explore how to appropriately pay for software as a service in future rulemaking. After consideration of the public comments, CMS is finalizing its proposal, without modification.

o. Quantitative Magnetic Resonance (QMR) for Analysis of Tissue Composition (APC 1511). A commenter supported the proposed APC assignment to APC 1511 and also provided possible explanations for the payment variability noted by CMS. CMS hopes the information gathered in the SaaS comment solicitation will enable the agency to put forth a policy in future rulemaking that provides a more stable payment method for SaaS technologies. CMS is finalizing its proposal without modification.

p. Quantitative Magnetic Resonance Cholangiopancreatography (QMRCP) (APC 1511). A commenter supported CMS' proposals to continue to assign 0723T and 0724T to APC 1511. CMS notes that no new claims were identified since its analysis in the proposed rule. Therefore, CMS is finalizing its proposal without modification.

q. Supervised Visits for Esketamine Self-Administration (APCs 1512 and 1518). Commenters supported the proposed APC assignment but others requested that CMS maintain the APC assignment for HCPCS code G2082 in APC 1513. A commenter suggested that CMS create a new APC for this service. In response, CMS expresses its appreciation for the suggestion to create a new APC for this service, noting that the agency has not yet been able to determine what clinical APC would be appropriate in terms of clinical and resource homogeneity. CMS states it will continue to consider potential clinical APC placements for HCPCS codes G2082 and G2083 through future rulemaking. Further, CMS notes that the geometric mean costs for both HCPCS codes G2082 and G2083 have changed since the proposed rule. Based on updated claims data available for the final rule, CMS is finalizing a New Technology APC assignment for HCPCS code G2083 to APC 1518.

r. Surfacer® Inside-Out® Access Catheter System (APC 1534). CMS did not receive any public comments on its proposal to continue to assign CPT code C9870 to APC 1534. There were no additional claims in the updated data. Therefore, CMS is finalizing its proposal without modification.

s. Transcatheter Atrial Shunt System (TASS) (APC 1537). CMS did not receive public comments on this provision, and therefore, CMS is finalizing as proposed. HCPCS Code C9792 will remain assigned to APC 1537.

t. Magnetic Resonance Imaging with Inhaled Hyperpolarized Xenon-129 Contrast Agent (APC 1551). CMS did not receive public comments on its proposal to continue to assign HCPCS code C9791 to APC 1551. The updated claims data showed only five claims which continues to be fewer than 10 claims in the 4-year lookback period. Therefore, CMS is finalizing its proposal without modification.

u. SAINT Neuromodulation System (APCs 1511 and 1525). Many commenters requested that CMS maintain the current New Technology APC assignments because the current assignments more appropriately reflect the resources required to provide this highly resource intensive therapy. Commenters stated that the limited claims data does not accurately reflect the costs of providing SAINT and that one of the early providers of SAINT confirmed with them that their reported costs were made in error and were highly inaccurate. CMS notes that, based on its analysis of updated claims information: CPT code 0889T now has 11 single frequency claims; CPT code 0890T has an updated geometric mean cost; CPT code 0891T now has 41 single frequency claims and an updated geometric mean cost; and there were no changes to CPT code 0892T. After consideration of the updated analysis and consideration of comments, CMS is not finalizing its proposal for CY 2026. Instead, CMS is using its equitable adjustment authority to maintain the current APC assignments for CPT codes 0889T, 0890T, 0891T, and 0892T.

v. Implantable Glucose Monitoring System (APC 1563). A commenter requested that CMS reassign CPT codes 0446T and 0448T to APC 1530 citing the increased cost of the implanted 365-day glucose sensor and the value of the longer sensor duration. The commenter also requested that CMS align OPPS payment with the PFS payment to provide consistent payment regardless of setting. In response, CMS agrees with the commenter about increased costs, but does not agree that costs have increased to the extent suggested by the commenter. After consideration of the comments, CMS is finalizing its proposal with modification. Using its equitable adjustment authority, CMS will assign CPT code 0446T and 0448T to APC 1563.

w. Skin Cell Suspension Autograft (SCSA) Procedures (CPT Code 15013 and HCPCS code C8002) (APC 1567). CMS did not receive public comments on this provision, and therefore, CMS is finalizing as proposed.

x. Renal Histotripsy Service (APC 1576). A commenter supported the proposed New Technology APC assignment. CMS notes that based on updated claims data, there are eight single frequency claims for CPT code 0888T. CMS is therefore finalizing its proposal without modification to assign CPT code 0888T to APC 1576 with a status indicator of "S" for 2026.

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

Beginning in 2022, CMS adopted a policy to designate clinical and brachytherapy APCs as low volume APCs if they have fewer than 100 single claims that can be used for ratesetting purposes in the claims year used for ratesetting for the prospective year.[16] This policy was adopted in order to reduce the volatility in the payment rate for APCs with fewer than 100 single claims. Under its low volume APC payment adjustment policy, CMS determines the APC cost as the greatest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data. CMS excludes APC 5853 (Partial Hospitalization for CMHCs) and APC 5863 (Partial Hospitalization for Hospital-based PHPs) from the universal low volume APC policy given the different nature of policies that affect the partial hospitalization program. CMS also excludes APC 2698 (Brachytx, stranded, nos) and APC 2699 (Brachytx, non-stranded, nos) because its current methodology for determining payment rates for non-specified brachytherapy sources is appropriate.

Based on claims data available for the proposed rule, CMS proposed to designate six brachytherapy APCs and five clinical APCs as low volume APCs under the OPPS because they had fewer than 100 single claims. Based on data for the proposed rule, APC 2645 (Brachytx, non-stranded, gold-198) had 103 single claims and no longer met criteria to be designated as a low volume APC; however, APC 2643 (Brachytx, non-stranded, c-131) had only 88 single claims and met criteria to be designated as a low volume APC.

Comment/response: Commenters supported CMS' proposal to continue its low volume APC policy. After consideration of public comments, and based on updated claims data available for the final rule, **CMS is finalizing its proposal** to designate six brachytherapy APCs and five clinical

[16] For the 2026 OPPS proposed and final rules, CY 2024 claims are generally the claims used for ratesetting.

APCs as low volume APCs under the OPPS. Table 42, reproduced below from the final rule, includes each of the APCs CMS is designating as low volume APCs for 2026. The final cost statistics for the 2026 low volume APCs, such as the median, arithmetic mean, and geometric mean cost are available for download on the CMS website.

Table 42: Final Low Volume APCs Using the Comprehensive (OPPS) Ratesetting Methodology for 2026		
APC	**APC Description**	**CY 2024 Claims Available for Ratesetting**
2632	Iodine I-125 sodium iodide	1
2635	Brachytx, non-str, HA, p-103	9
2636	Brachy linear, non-str, p-103	0
2642	Brachytx, stranded, c-131	49
2643	Brachytx, non-stranded, c-131	88
2647	Brachytx, NS, Non-HDRIr-192	3
5244	Level 4 Blood Product Exchanges and Related Services	46
5494	Level 4 Intraocular Procedures	72
5495	Level 5 Intraocular Procedures	41
5496	Level 6 Intraocular Procedures	15
5881	Ancillary Outpatient Services When Patient Dies	57

E. APC-Specific Policies

This section discusses comments and CMS responses for APC policies and APC-specific assignments that are addressed in the 2026 final rule (as listed in the table below). The numbering in the table is consistent with the preamble format. Highlights of some of these assignments are summarized below the table. The reader is referred to the final rule for specific details. The final 2026 payment rates for these codes can be found in Addendum B on the CMS website.

Proposed and Final OPPS APC and SI Assignments for 2026						
	Service or Issue	**Code(s)**	**Proposed SI**	**Proposed APC**	**Final SI**	**Final APC**
1*	APC Structure for: a. Diagnostic Tests and Related Services (APCs 5721 through 5724) b. Nerve Procedures (APCs 5431 through 5432) c. Endovascular Procedures (APCs 5191 through 5194) d. Laparoscopy and Related Services (APCs 5361 through 5362) e. Musculoskeletal Procedures (APCs 5111 through 5117)	*	*	*	*	*
2	ActiGraft System	G0465	T	5054	T	5054
3	Audiology-Related Services	92540 92579 92588	**	5722	S	5722

4*	Fully Implanted Active Middle Ear Implant (FI – AMEI)	0951T through 0955T	E1	N/A	E1	N/A
5	Ablation of Breast Tumor Procedures	0970T 0971T	J1	5091	J1	5091
6*	Lymphovenous Bypass	1019T	J1	5091	J1	5092
7*	Cardiac CT Services	75572 75573 75574	S	5572	S	5572
8	Cardiac Magnetic Resonance (CMR) Imaging	75557	Q3	5523	Q3	5523
		75559	Q3	5524	Q3	5524
		75561	Q3	5572	Q3	5572
		75563	Q3	5573	Q3	5573
9*	Computational Electrocardiogram (ECG) Analysis System (vMap)	0897T	S	5724	S	5724
10*	Fractional Flow Reserve Derived From Computed Tomography (FFRct)	75580	S	5724	S	5724
11*	Chimeric Antigen Receptor (CAR–T) Administration	38228	S	5694	S	5694
12*	CVi® Contrast Delivery System	N/A	N/A	N/A	N/A	N/A
13	Malignant Tumor/Lesion Removal Dental Procedures	D7440-D7441	J1	5164	J1	5164
14*	Biliary Endoscopy Procedure	47555	J1	5341	J1	5342
15	Endoscopic Procedure - Upper GI Tract, CPT Code	43252	J1	5302	J1	5302
16	Endoscopic Retrograde Cholangiopancreatography (ERCP) with Stone Destruction Procedure	43265	J1	5331	J1	5331
17*	Endoscopic Submucosal Dissection (ESD) Procedure	C9779	J1	5303	J1	5303
18*	Esophageal Balloon Distention Study	91040	J1	5723	J1	5723
19	Transnasal EGD	0652T 0653T	J1	5302	J1	5302
		0654T	J1	5303	J1	5303
20	Gastric Electrophysiology Mapping With Simultaneously Validated Patient System Profiling (GEMS) Service	0868T	**	5723	S	5723
21*	IB – Stim	64567	S	5724	T	5301
22	Computed Tomographic Colonography	74263	S	5523	S	5523
23	Computed Tomographic Services (Head, Neck, and Cerebral Perfusion)	70471	S	5572	S	5572
		70472	N	N/A	N	N/A
		70473	S	5571	S	5571
24	Duplex Scan of Extracranial Arteries	93880	S	5523	S	5523
25	Duplex Scan of Hemodialysis Fistula	0876T	E1	N/A	E1	N/A
26*	Non-Cardiac Contrast Enhanced Ultrasound (CEUS)	76978	S	5571	S	5572
		76979	N	N/A	N	N/A
27	Irreversible Electroporation Ablation of Tumors (NanoKnife® System)	0600T 47384 55877	J1	5362	J1	5362
28*	Diagnostic Biomarker Tests for Alzheimer's Disease	0551U	Q4	N/A	N/A	N/A
		0568U	Q4	N/A	Q4	N/A
29	PreciseBreast Test	0220U	Q4	N/A	Q4	N/A

30	Screening DNA / RNA Test for Hepatitis C Virus	G0567	A	N/A	A	N/A
31	Laparoscopic Hernia Repair and Appendectomy, Procedures	49650 49651 44970	J1	5361	J1	5361
32*	Medical 3D Printing	0559T 0561T	Q1	5733	Q1	5734
33*	Continuous EEG Monitoring	0956T 0960T	S	1577	J1	5117
34	Transcutaneous Magnetic Peripheral Nerve Stimulation	0766T 0767T	S	5722	S	5722
		0767T	N	N/A	N	N/A
35	Ultrasound Guided Carpal Tunnel Release Procedure	64728	J1	5431	J1	5431
36* and 37*	Neurostimulator and Related Procedures (APCs 5461 Through 5465) and Creation of a Level 6 Neurostimulator APC	61885	J1	5465	J1	5465
		61891	J1	5464	J1	5465
		64568	J1	5465	S	1580
		0786T	E1	N/A	J1	5463
		0817T	J1	5464	J1	5464
		0988T	J1	5464	E1	N/A
38a-c*	Digital Mental Health Treatment (DMHT)	G0522	V	5012	**	**
	Leadless Pacemaker (WiSE CRT System)	0515T	J1	5231	J1	5231
	Paired Vagal Nerve Stimulation (Vivistim® System)	64568	J1	5465	S	1580
39	Noncontact Near-Infrared (NIR) Spectroscopy	0640T	S	5732	S	5732
40	Nuclear Medicine Services: Single-Photon Emission Computed Tomography (SPECT) Studies	78803	S	5592	S	5592
41	Nuclear Medicine Study (1 area)	78800	S	5591	S	5591
42*	Administration of Lacrimal Ophthalmic Insert Into Lacrimal Canaliculus,	68841	Q1	5503	Q1	5503
43*	Comprehensive Aqueous Outflow Procedure	N/A	N/A	N/A	N/A	N/A
44*	First Carpometacarpal Total Joint Arthroplasty	1003T	J1	5114	J1	5115
45	Fusion of Foot Bones	28740	J1	5114	J1	5114
46*	Radiation Oncology Treatment Delivery	77402	S	5621	S	5621
		77407	S	5622	S	5622
		77412	S	5622	S	5623
47*	Radiofrequency Ablation of Bone Tumors	20982	J1	5115	J1	5116
48	Scalp Cooling	97007	S	1517	S	1516
		97008 97009	N	N/A	N	N/A
49	Group Respiratory Therapy	G0239	S	5732	S	5732
50	Insertion of Endobronchial Valves	31647	S	5155	S	5155
51*	Non-Invasive Gas Exchange and Cardiorespiratory Status (AGM 100)	0893T	Q1	5733	S	5734
52*	3D Anatomical Segmentation Imaging Software Service	C8001	S	5721	S	5721
53	3D Image Generation Used in Surgical Planning and Navigation for Placement of Implants and Devices (BoneMRI)	G0566	S	5721	S	5721
54	Augmentative Analysis of CT Imaging Data for Interstitial Lung Disease	0877T	S	1508	S	1508
55*	Noninvasive Arterial Plaque Analyses	0712T	S	5521	S	5722

56	Aquabeam Waterjet Ablation Procedure	52597	J1	5376	J1	5376
57*	Enhanced Lithotripsy System	0991T	E1	N/A	J1	5376
58	Insertion of Permanent Urethral Stent	52282	J1	5374	J1	5374
59	Penile Prosthesis	54417	J1	5377	J1	5378
60	Prostate Biopsy Codes	55712	J1	5374	J1	5374
		55713 55714	J1	5375	J1	5375
		55715	N	N/A	N	N/A
61	Ureteroscopy	C9761	**	5376	J1	5376
62	Water Vapor Thermotherapy	0582T	E1	5377	J1	5377
63	Arteriovenous Fistula (AVF) Creation Procedures	36836 36837	J1	5194	J1	5194
64*	Atherectomy with Angioplasty	92924	J1	5193	J1	5193
65*	Coronary Therapeutic Services and Procedures	92930	J1	5193	J1	5194
		92945	J1	5193	J1	5193
66*	Lower Extremity Revascularization	37254 to 37299	46 new codes assigned to APCs 5192, 5193, 5194		Finalized without modification (see Table 94 in the final rule)	
67*	Percutaneous Transcatheter Therapeutic Drug Delivery	0913T	J1	5192	J1	5193
68	APC Specific Comments that Support the Proposed APC Assignment	Various	Finalized without modification (see Table 96 in the final rule)			
69a-d*	Dialysis-Related Amyloidosis (DRA) Treatment with Lixelle® Apheresis Columns	N/A	N/A	N/A	N/A	N/A
	Dialysis Technologies	N/A	N/A	N/A	N/A	N/A
	Open Surgical Fistula Creation	36821	J1	5183	J1	5183
	Peritoneal Dialysis (PD) Catheter Placement	49324	J1	5361	J1	5361
		49418 49421	J1	5341	J1	5341
70*	Mobile Stroke Units	N/A	N/A	N/A	N/A	N/A

* See HPA summary below
** CMS did not discuss in the final rule preamble. More information can be found in Addendum B on the CMS website online.

The numbered headers that follow in this section correspond to the numbers in the table above, for those OPPS APC and SI assignments selected for summary below. They are also noted with an asterisk in the table above.

1. APC Structure

a. Diagnostic Tests and Related Services (APCs 5721 through 5724)

CMS created this series as part of the agency's APC restructuring in 2016. In the 2026 proposed rule, CMS proposed to make changes to this APC series and included those changes in the associated cost statistics files and addenda made available with each proposed and final rule via the internet on the CMS website.

Comment/response: Several commenters requested that CMS refrain from shifting services in the APC family until there was sufficient opportunity for meaningful public comment on such changes. Others noted the impact on geometric mean costs for each of the APCs. Commenters also noted individual impacts on codes related to the proposed changes, for example, CPT codes 95924 and 93017. In response, CMS notes that, as part of its required annual review and update process, CMS made changes to the APC assignments within the APC series such that the cost and clinical APC groupings would be more reflective of the codes assigned to them, and that the changes in geometric mean costs for these ACPs are associated with CMS' APC recalibrations. Changes for CPT codes 95924 and 93017 were both proposed to be placed in APC 5722 (Level 2 Diagnostic Tests and Related Services). CMS recognizes that APC geometric mean costs can fluctuate based on a variety of factors, however, the geometric mean costs of both codes suggests that they are appropriately placed in the Level 2 APC based on their estimated resource costs.

A few commenters recommended that CPT code 90870 be maintained in its current assignment or moved to a clinically coherent APC since the code represents a therapeutic procedure and not a diagnostic test. In response, CMS states that, based on the claims available for OPPS ratesetting for this final rule, the proposed placement of CPT code 90870 in APC 5724 remains appropriate.

Final action: After consideration of the public comments, CMS is finalizing the proposed APC recalibration changes for the Diagnostics Tests and Related Procedures APC series. In addition, CMS is finalizing the assignments of CPT codes 95924 and 93017 to APC 5722, and CPT code 90870 to APC 5724.

b. Nerve Procedures (APCs 5431 through 5432)

The current APC structure of the Nerve Procedures series was developed during the broader 2016 OPPS reorganization and consolidation of APCs. Since that time, CMS has maintained that same two-level APC structure.

Comment: A few commenters noted that there was a significant decrease in the estimated geometric mean cost of the Level 2 Nerve Procedures APC due to the impact of a new eligible complexity adjustment code combination. They requested that CMS either map the complexity adjustment 6471R back into the Level 1 Nerve Procedures APC (APC 5431) or alternatively develop a Level 3 APC that could accommodate some of the higher cost procedures in the current Level 2, such that there was less of an impact on some portion of the procedures. Commenters requested a number of specific codes be included in a new Level 3 Nerve Procedures APC. A commenter also requested special consideration for CPT code 64912, and that the CPT code also be included in a new Level 3 Nerve Procedures APC.

Final Action: CMS agrees that a Level 3 Nerve Procedures APC is appropriate, in particular to resolve what would otherwise be a significant "two times rule" violation in the Level 2 APC. CMS is therefore including the codes requested by commenters in the new Level 3 Nerve Procedures APC. CMS identified several additional codes which the agency believes would appropriate (from

a clinical and resource cost similarity perspective) to include in the new Level 3 APC. These are: 61720, 62230, 62350, 64840, 64856, 64905, 64910, 64911, and 0442T.

c. Endovascular Procedures (APCs 5191 through 5194)

Since the 2017 OPPS, the Endovascular Procedures APC series has been maintained as a 4-level APC series.

Comment: A commenter requested that APC 5200 (Implantation Wireless PA Pressure Monitor) be converted into a new Level 5 Endovascular Procedures APC, and recommended several specific codes that the commenter believes should be included. The commenter believes that doing so would be appropriate based on the similarity of the codes' geometric mean costs, and in light of CMS' proposal to eliminate the inpatient only list over three years beginning in 2026.

Final action: In response, for reasons explained in the preamble of the final rule, CMS is finalizing the 4-level APC structure of the Endovascular Procedures APC series as proposed. CMS notes that it will continue to monitor the available claims and cost data for the APC series and in the context of codes being removed for the IPO list.

d. Laparoscopy and Related Services (APCs 5361 through 5362)

As part of the CY 2016 OPPS APC restructuring process, the four-level APC series for Laparoscopy and Related Services was consolidated into a 2-level APC series which CMS has maintained based on the clinical and resource homogeneity of the services assigned to those APCs.

Comment/response: A commenter requested that CMS create a Level 3 Laparoscopy and Related Services APC that would include the highest cost and complexity services in the current Level 2 APC. The commenter believes that it would be appropriate to place services with geometric mean costs of $12,000 or more into the new Level 3 APC. In response, CMS notes that while some of the services in the cost range indicated by the commenter have significant claims volume, CMS does not believe that there is a current need for an additional APC level given that the estimated geometric mean cost of the requested Level 3 APC would be significantly distinct from a cost perspective. Additionally, CMS notes that the agency is not removing any services from the IPO list in 2026 that would require assignments to the Laparoscopic and Related Services APC series. However, CMS states it will continue to monitor the claims data as they become available and the need for additional APC levels in the future.

Final action: CMS is finalizing the 2-level APC structure for the Laparoscopy and Related Services APC series as proposed.

e. Musculoskeletal Procedures (APCs 5111 through 5117)

For 2026, based on CMS' evaluation of the claims data and proposed removal of musculoskeletal codes from the IPO list, CMS proposed to establish a 7 level Musculoskeletal Procedures APC

series. Table 42 of the proposed rule displayed the proposed 2026 Musculoskeletal Procedures APC series' structure and APC geometric mean costs.

In this section of the final rule, CMS does not revisit its proposal. It appears, however, that CMS has summarized the comments received in section IX.C.5 of the final rule preamble. In that section, CMS states it is finalizing its proposal to create a Level 7 Musculoskeletal APC. CMS notes that the agency will continue to monitor the APC series as updated claims data continues to be available. The complete list of codes assigned to APC 5117 (Level 7 Musculoskeletal Procedures) can be found in Addendum B, which is available on the CMS website.

4. Audiology-Related Services: Fully Implanted Active Middle Ear Implant (FI – AMEI), CPT codes 0951T – 0955T

For 2026, CMS proposed to assign CPT codes 0951T-0955T to status indicator "E1" to indicate that these codes are not paid by Medicare when submitted on outpatient claims (any outpatient bill type) because CMS stated its belief that these codes meet the definition of a hearing aid and therefore are not covered by Medicare. A commenter stated that FI-AMEI is not a hearing aid but instead is a prosthetic device that meets the definition of an osseointegrated implant and therefore should be covered by Medicare. As a result, the commenter requested that CMS change the proposed OPPS status indicator assignment for CPT codes 0951T-0955T from status indicator "E1" to status indicator "S". Additionally, the commenter requested CMS assign codes 0951T – 0953T to New Technology APC 1577, code 0954T to New Technology APC 1575, and code 0955T to New Technology APC 1534. In response, CMS notes that middle ear implants, including fully implanted active middle ear hearing devices, do not function like osseointegrated implants and are not excepted. Therefore, CMS is finalizing the assignment of status indicator "E1" for CPT codes 0951T-0955T without modification to indicate that these codes are not paid by Medicare when submitted on outpatient claims (any outpatient bill type).

6. Breast and Lymph Procedures: Lymphovenous Bypass, CPT Code 1019T (APC 5092)

The CPT Editorial Panel created Category III CPT code 1019T (placeholder code X476T) effective January 1, 2026. For 2026, CMS proposed to assign CPT code 1019T to APC 5091 and a status indicator of "J1." Several commenters requested higher payment for this procedure while others suggested alternative crosswalk codes to determine APC placement such as CPT code 19357 and CPT code 35883. In response, CMS agrees that CPT code 1019T should be reassigned to APC 5092, noting that there are currently other lymph procedures assigned to APC 5092. After consideration of the public comments, CMS is finalizing its proposal with modification, to assign CPT code 1019T to APC 5092 with a status indicator of "J1".

7. Cardiac Related Procedures and Services: Cardiac CT Services, CPT Codes 75572, 75573, and 75574 (APC 5572)

In the final rule preamble, CMS summarizes the history of these CPT codes, including changes in revenue code edits and procedural hurdles encountered by providers who bill them, and how CMS

addressed these issues. For 2026, CMS proposed to continue assignment of CPT codes 75572, 75573, and 75574 to APC 5572, noting that the agency anticipates it may take 3 to 4 years to see an impact from changes in billing practices.

Comment/response: Several commenters supported the APC assignment of CPT codes 75572, 75573, and 75574 to APC 5572. Many commenters believe that these services are underutilized, in part due to historical underpayment and billing restrictions that they encountered in the past and expressed concern about the continued challenges with making changes to billing patterns. Many commenters requested educational materials and guidance that specifically indicate that it is appropriate to bill the cardiology revenue codes with cardiac CT services. In response, CMS states that the agency continues to monitor the claims data for these services and reiterates the expectation that it may take several years before seeing changes. CMS states that if the agency does not see a significant change in the geometric mean costs after several years, CMS would revert payment for these services to the standard OPPS payment methodology and assign the cardiac CT codes to the appropriate APCs based on their geometric mean costs.

Many commenters requested guidance from CMS (Medicare Learning Network or "MLN") that explicitly states that it is appropriate to use the cardiology revenue codes when billing for cardiac CT services. In response, CMS acknowledges that it had stated in last year's final rule that it would provide public education and instruction through MLN and continues to anticipate that it will do so, however, CMS reminds readers that the agency does not provide specific coding guidance.

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).

9. Cardiac Related Procedures and Services: Computational Electrocardiogram (ECG) Analysis System (vMap), CPT Code 0897T (APC 5724)

For 2026, CMS proposed maintaining CPT code 0897T assignment to APC 5724, noting that there were no single frequency claims for ratesetting under OPPS and 34 multiple frequency claims, meaning the procedure was completed with other primary services.

Comment/response: The manufacturer requested that CMS reassign CPT code 0897T to a New Technology APC when the procedure is performed on the day of, but separate from, the ablation procedure itself until there are sufficient claims data available to support an appropriate clinical APC assignment. In addition, the commenter urged that CMS pay for all SaaS technologies separately from any underlying procedures and assign these services to New Technology APCs until there are sufficient claims data to support an appropriate clinical APC assignment. In response, CMS reviews its criteria for being assigned to a New Technology APC and disagrees that the vMap procedure would meet them.

Final action: After consideration of the public comment, CMS is finalizing its proposal without modification to assign CPT code 0897T to APC 5724.

10. Cardiac Related Procedures and Services: Fractional Flow Reserve Derived From Computed Tomography (FFRct) CPT Code 75580 (APC 5724)

In the proposed and final rule preamble, CMS summarizes the coding and assignment history of Fractional Flow Reserve Derived from Computed Tomography (FFRCT), also known by the trade name HeartFlow®. CMS discussed its belief that the calculation of geometric mean cost may have been impacted by an outdated automated return-to-provider (RTP) HCPCS-to-revenue code edit that occurred when the Category I CPT code became effective, an issue that was identified by a commenter in the 2025 OPPS/ASC final rule.[17] Although the edit was removed, and providers were notified to resubmit any incorrectly returned claims, CMS indicated its belief that the outdated edit may have impacted the geometric mean for CPT code 75580. Therefore, under its authority under section 1833(t)(2)(E), CMS proposed to continue to assign CPT code 75580 to APC 5724 which CMS believes best reflects the cost of the service at this time.

Comment/response: Commenters were supportive of the continued APC assignment to APC 5724; however, the commenters universally requested that CMS exclude the "flawed" or "erroneous" data due to the claims edit that was in place that prohibited them for choosing a revenue center that they deemed most appropriate for the service provided. In response, CMS states that the agency generally does not exclude available claims data, based on its assumption that what is being billed to Medicare is in compliance with coding and billing guidance. CMS acknowledges that there are a number of procedural and logistical hurdles associated with changing billing practices and will continue to monitor the claims data.

Final action: After consideration of the public comments, CMS is finalizing its proposal without modification to continue to assign CPT 75580 to APC 5724.

11. Chimeric Antigen Receptor (CAR–T) Administration, CPT Codes 38228 (APC 5694)

In the final rule, CMS summarizes the history of CAR-T coding and APC assignment. As listed in Addendum B to the proposed rule, CMS proposed to continue to assign CPT code 38228 to status indicator "S" and APC 5694.

Comment/response: Several commenters recommended the reassignment of CPT code 38228 to APC 5242 stating that APC 5242 more accurately reflects the higher facility costs associated with the significant nurse monitoring for the outpatient administration of CAR T-cell therapy. Others noted that CMS initially assigned CAR-T related codes to autologous stem cell transplant MS-DRGs 016 and 017, which they believe is the appropriate crosswalk for OPPS. Another commenter disagreed with the current APC 5694 assignment and stated that CPT code 38338 (and CPT codes 67028 and 67516) do not have the facility NA indicator in the Medicare Physician Fee Schedule and the RUC assigned both facility and non-facility RVUs. In response, CMS believes CPT code 38228 is appropriately assigned to APC 5694, which shares similar clinical and resource use as other complex cancer drug administrations. CMS notes that CAR-T therapies are no longer assigned to MS-DRGs 016 and 017. CMS believes it is inappropriate to use the IPPS MS-DRGs as

[17] 89 FR 94094

an analog to the APC assignments in the OPPS because there are significant differences in resource consumption between the HOPD and inpatient setting. Additionally, CMS responds that the RUC assignment of both facility and non-facility RVUs do not support the reassignment of CPT codes 38338, 67028 and 67516 to APC 5242 as the agency relies on input from a variety of sources for our APC assignments.

Final action: After consideration of the public comments, CMS is finalizing its proposed APC assignment and status indicator for CPT code 38228 to APC 5694 without modification.

12. CVi® Contrast Delivery System

Comment/response: A commenter requested that CMS establish a G-code to provide additional payment to recognize the cost of automated contrast management systems with angiography procedures. In response, CMS has determined that this equipment is only used in conjunction with another procedure and would be packaged for payment consistent with the agency's policy of packaging items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service.

Final action: CMS declines to create a G-code to describe the use of an automated variable rate contrast injector with multiuse syringe for the administration of iodinated contrast media for CY 2026.

14. Endoscopy Procedures: Biliary Endoscopy Procedure, CPT code 47555 (APC 5341)

For 2026, CMS proposed to continue assigning CPT code 47555 to APC 5341. A commenter requested that CMS reassign CPT code 47555 to APC 5342 stating that the cost of this procedure exceeded the payment rate for APC 5341. In response, CMS notes that CPT code 47555 has an updated geometric mean cost that would be more appropriately reflected by APC 5342.

Final action: CMS is finalizing its proposal with modification to assign CPT code 47555 to APC 5342 (instead of APC 5341) for 2026.

17. Endoscopy Procedures: Endoscopic Submucosal Dissection (ESD) Procedure, HCPCS Code C9779 (APC 5303)

In the final rule preamble, CMS summarizes this code's history and previous APC assignment to APC 5303. For 2026, CMS proposed to maintain HCPCS code C9779. Commenters requested that CMS reassign HCPCS code C9779 to APC 5331 stating that HCPCS code C9779 would be more appropriately placed in APC 5331 due to its similarity to CPT code 43479. Additionally, the commenters stated that as HCPCS code C9779 includes both combined upper and lower GI ESD procedures, there is great variability in the costs reported by hospitals which could affect the accuracy of the geometric mean cost. In response, CMS notes that while the geometric mean cost for HCPCS code C9779 is slightly closer to the payment rate for APC 5331, the agency continues

to believe that HCPCS code C9779 is appropriately assigned, based on both clinical and resource similarity, to APC 5303.

Final action: CMS is finalizing its proposal, without modification, to continue to assign CPT code C9779 to APC 5303.

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

For 2026, CMS proposed to continue to assign CPT code 91040 to APC 5723. Commenters requested that CMS reassign CPT code 91040 to APC 5724 because CPT code 91040 has the highest geometric mean cost of all codes assigned to APC 5723 and had a higher device offset percentage than other procedures in the same APC. In response, CMS believes that based on the updated geometric mean cost for CPT code 91040, in addition to the higher costs of the packaged items, the costs from the other procedures that are performed with CPT code 91040 have driven up the geometric mean cost of CPT code 91040. Based on review of this procedure, other procedures in the same APC family, and the claims data, CMS believes that the clinical and resource characteristics of CPT code 91040 are sufficiently like other procedures assigned to APC 5723.

Final action: As a result, CMS is finalizing its proposal, without modification, to continue to assign CPT code 91040 to APC 5723.

21. IB – Stim, CPT 64567 (APC 5301)

CPT code 64567 replaces placeholder code 64X11 and is effective January 1, 2026. For 2026, CMS proposed to assign CPT code 64567 to APC 5724 and delete predecessor CPT code 0720T.

Comment/response: A commenter requested that CMS reassign CPT code 64567 to APC 1515 with a higher payment rate. The commenter believes the procedure requires more resources than other services currently assigned to APC 5724, and that it is not clinically similar to those other procedures since it represents a therapeutic intervention rather than a diagnostic service. In response, after careful review of the service, CMS agrees with the commenter that continued assignment of CPT code 64567 to APC 5724 would not be appropriate because CPT code 64567 represents a therapeutic service rather than a diagnostic procedure, based on the information available. CMS notes that there were no claims for the service in 2024 to consider in its analysis.

Final action: For 2026, CMS is finalizing its proposal with modification. Specifically, CMS is finalizing its proposal to delete CPT code 0720T because CPT code 64567 is replacing the predecessor code. Additionally, CMS is assigning CPT code 64567 to APC 5301 with a payment rate of $926.63. CMS notes that the agency will continue to monitor the claims data and update the payment rate in future rulemaking based on the available claims.

26. Imaging Services: Non-Cardiac Contrast Enhanced Ultrasound (CEUS), CPT Codes 76978 and 76979 (APC 5572)

For 2026, CMS proposed to assign CPT codes 76978 and 76979 to APC 5571. CPT code 76978 had a geometric mean cost of around $287 based on 710 single frequency claims and CPT code 76979 was packaged with a primary procedure. Several commenters requested reassignment of CPT codes 76978 and 76969 to APC 5572. The commenters stated that the current APC assignment does not adequately reflect the resource costs associated with these specialized contrast-enhanced ultrasound procedures. In response, after revising the clinical characteristics and resource costs associated with CPT 76978, CMS agrees with the commenter. CMS believes the change recognizes the specialized nature of contrast-enhanced ultrasound technology and ensures appropriate payment for these services.

Final action: CMS finalizing its proposal with modification. CMS will reassign CPT code 76978 from APC 5571 to APC 5572. CPT code 76978 will be assigned status indicator "S" (separately payable) under APC 5572, while CPT code 76979 will maintain status indicator "N" (packaged) and will continue to be packaged with the primary procedure code 76978 under the new APC assignment.

28. Laboratory related services:[18] Diagnostic Biomarker Tests for Alzheimer's Disease, CPT Codes 0551U and 0568U

CPT code 0551U became effective April 1, 2025, and CPT code 0568U became effective October 1, 2025. For 2026, CMS proposed to assign CPT codes 0551U and 0568U status indicator "Q4." A commenter expressed support for CMS' proposal. In response, CMS expresses appreciation for the supporting comment, however, CMS notes that on October 1, 2025, the AMA CPT Editorial Panel deleted CPT code 0551U effective January 1, 2026. Therefore, for 2026, CMS will delete this code from this final rule and the January 2026 Update. CMS is, however, finalizing its proposal to assign status indicator "Q4" to CPT code 0568U for CY 2026.

32. Medical 3D Printing, CPT codes 0559T, 0561T (5734)

For 2026, CMS proposed to continue to assign CPT codes 0559T and 0561T to APC 5733 (Level 3 Minor Procedures) and status indicator "Q1." A commenter requested that CMS assign CPT codes 0559T and 0561T to APC 5735 (Level 5 Minor Procedures) because the resources and supplies needed to provide these services are greater than the proposed payment rates. In response, based on the geometric mean cost of both codes, CMS agrees with the commenter that the proposed payment rate is not appropriate for CPT codes 0559T and 0561T, as the payment rate is significantly lower than the geometric mean cost of the codes.

[18] CMS conditionally packages laboratory tests and only pays separately for such tests if the test satisfies certain conditions. When laboratory tests are not packaged under the OPPS and listed on the clinical laboratory fee schedule (CLFS), they are paid at the CLFS payment rates, outside the OPPS, under Medicare Part B.

Final action: CMS is finalizing its proposal with modification to assign CPT codes 0559T and 0561T to APC 5734 and status indicator "Q1."

33. Neuro and Nerve Related Procedures: Continuous EEG Monitoring, CPT codes 0956T, 0960T (APC 5117)

The AMA CPT Editorial Board created five new Category III CPT codes to describe various procedures associated with a sub-scalp bilateral continuous EEG monitoring system to assist in identifying seizure activity for patients with drug resistant epilepsy (DRE), effective July 1, 2025. The new CPT codes are 0956T, 0957T, 0958T, 0959T, and 0960T. For 2026, CMS proposed to assign CPT codes 0956T and 0960T to status indicator "S" and APC 1577 (New Technology - Level 40 ($20,001-$25,000)) with a proposed payment rate of $22,500.50.

Comment/Response: Several commenters requested that CMS reexamine and revise the reimbursement rates for CPT codes 0956T and 0960T because, according to the commenters, outpatient reimbursement for services associated with sub-scalp EEG monitoring is substantially below the actual resources required to deliver them. A few commenters urged CMS to move CPT codes 0956T and 0960T to a higher-paying New Technology APC. In response, based on clinical similarity and resource homogeneity of the procedures described by CPT codes 0956T and 0960T to existing procedures assigned to the Level 7 Musculoskeletal Procedures APC, and based on input from CMS' medical advisors, CMS is revising its proposal.

Final action: CMS is assigning CPT codes 0956T and 0960 to status indicator "J1" and APC 5117 (Level 7 Musculoskeletal Procedures) for 2026.

36. Neurostimulators: Creation of a Level 6 Neurostimulator APC

Some interested parties requested that CMS create a "Level 6 Neurostimulator and Related Procedures" APC, due to their concerns around clinical and resource cost similarity in the Level 5 Neurostimulator and Related Procedures APC.[19] CMS proposed to maintain the current 5 level structure for the Neurostimulator and Related Procedure series because the agency believes the current structure provides for an appropriate distribution of clinical and cost similarity at the different APC levels under the OPPS which is a prospective payment system. CMS explained that in the OPPS, any individual procedure may potentially be overpaid or underpaid because the payment rate is based on the geometric mean of the entire group of services in the APC. However, the impact of these payment differences should be mitigated when distributed across a large number of APCs (85 FR 85968).

While CMS continued to believe that a five-level structure for the Neurostimulator and Related Procedures APC series remained appropriate, CMS solicited comments from interested parties on the need for a Level 6 APC. CMS notes that CPT code 64568 is currently assigned to APC 5465, status indicator of "J1."

[19] For additional discussion, CMS most recently responded to this request in the 2025 OPPS/ASC final rule (89 FR 94064).

Comment/response: Many commenters requested the creation of a Level 6 Neurostimulator and Related Procedures APC, with some requesting that specific codes or codes with similar costs be included in that Level 6 APC, stating that this would provide a longer-term solution for higher cost procedures. However, a few commenters supported maintaining the current 5 level structure. Commenters provided recommendations for specific codes that are described in the preamble of the final rule. The August 2025 HOP panel made a recommendation to consider assignment of CPT code 64568 to New Technology APC 1580 and that CMS establish a Level 6 Neurostimulator and Related Procedures APC.

In response, CMS expresses appreciation for the thoughtful responses commenters provided. CMS agrees that placing CPT code 64568 in APC 1580 would be appropriate, based on the code's geometric mean cost. Because of this placement, CMS does not believe that the creation of a C-code pairing CPT code 64568 and device code C1827 is necessary or appropriate. At this time, CMS believes that the 5-level APC structure for the APC series remains appropriate.

Final action: CMS is assigning CPT code 64568 to New Technology APC 1580 and maintaining the 5-level APC structure for the Neurostimulator and Related Procedures APC series for 2026. CMS states it will continue to monitor the claims data for these procedures as more information around their volume and estimated costs become available.

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

CPT code 61885: In the proposed rule, based on the estimated resource costs and clinical similarity of HCPCS code 61885 to other procedures assigned to APC 5465, CMS proposed to reassign HCPCS 61885 to APC 5465. Some commenters supported these proposals and other commenters were concerned that the payment rate for CPT code 61885 will decline significantly, limiting beneficiary access. Other commenters requested that CMS utilize the adjustment authority at section 1833(t)(2)(E) of the Act to ensure equitable payments under the OPPS. In response, CMS notes that based on its evaluation of updated claims data, the geometric mean cost for CPT code 61885 is much more consistent with the geometric mean cost for APC 5465. CMS is therefore finalizing without modification its proposal to assign CPT code 61885 to APC 5465 for 2026.

CPT codes 61891: In the proposed rule, CMS proposed to continue assigning CPT code 61889 to status indicator "C" since this procedure is only performed in the inpatient setting. CMS proposed to continue assigning CPT code 61891 to status "J1", APC 5464. CMS notes that at the August 25, 2025 meeting, the HOP Panel recommended that CMS reassign CPT code 61891 to APC 5465 for 2026. Commenters requested that CMS reassign CPT code 61891 to APC 5465, citing the inadequacy of APC 5464 from a cost and payment perspective, the fact that the predecessor CPT code 61886 was assigned to APC 5465, and that revision procedures are extremely rare. In response, CMS agrees with commenters and the HOP Panel that CPT code 61891 should be reassigned to APC 5465 and is therefore modifying its proposal.

CPT code 0786T: In the proposed rule, CMS proposed to continue assigning CPT code 0786T to status indicator "E1" to indicate that it is still pending the FDA approval. However, this service received FDA approval on June 17, 2025. At the August 25, 2025, the HOP Panel recommended that CMS assign CPT code 0786T to APC 5464. A few commenters recommended assignment of CPT code 0786T to either APC 5462 or APC 5463, stating that these APCs would be more accurate, given the cost and resources required to perform the procedure with an integrated device. In response, CMS agrees that APC 5463 is the most appropriate assignment based on the cost and resources required to perform the procedure with an integrated device and is therefore reassigning CPT code 0786T from status indicator "E1" to status indicator "J1", APC 5463 for 2026.

CPT codes 0817T and 0988T: For 2026, CMS proposed to continue assigning CPT code 0817T to APC 5464 with status indicator "J1." CMS also proposed to assign new CPT code 0988T (placeholder code X400T) to APC 5464 with status indicator "J1." A commenter recommended assigning CPT codes 0988T and 0817T to either APC 5462 or APC 5463 because the commenter believes that either APC is a more accurate assignment given the cost and resources required to perform the procedure with an integrated device. In response, CMS notes that the agency inadvertently listed CPT code 0988T (aka X400T) as receiving FDA-approval when it has not. As a result, CMS is changing the status indicator for CPT code 0988T to status indicator "E1" (Not covered by any Medicare outpatient benefit category; Statutorily excluded by Medicare; Not reasonable and necessary; Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)). CMS agrees that CPT code 0817T is appropriately placed in APC 5464 based on resource cost and clinical homogeneity to other similar codes in that APC. As a result, CMS continues to believe that assignment to APC 5464 for CPT code 0817T is appropriate.

38. New Technology Applications

a. Digital Mental Health Treatment (DMHT), HCPCS code G0552 (APC 5012)

CMS proposed to assign HCPCS code G0552 to APC 5012 and status indicator "V" for 2026. Commenters recommended that CMS not finalize the proposal to continue to assign HCPCS code G0552 to APC 5012 for 2026, stating that the proposed payment rate of approximately $134 would not cover the costs associated with furnishing the service. In response, CMS will continue to consider the assignment of G0552 and render a decision through the subregulatory process through which the New Technology APC placement was initially requested.

b. Leadless Pacemaker (WiSE CRT System), CPT Code 0515T (APC 5231)

For 2026, CMS proposed to continue assignment of CPT code 0515T to APC 5231. A commenter requested that CMS reassign CPT code 0515T to New Technology APC 1576 to ensure that there is adequate payment for the non-device costs as this code is tentatively approved for pass-through payment (device costs). In response, CMS notes that the New Technology APC application is currently under consideration and that CMS will render a decision through the sub-regulatory process through which the New Technology APC placement was initially requested.

c. Paired Vagal Nerve Stimulation (Vivistim® System), CPT Code 64568 (APC 5465)

Currently, CPT code 64568 is assigned to APC 5465, status indicator of "J1." Many of the commenters expressed concern about the lack of reimbursement once the transitional pass-through payments expire and encouraged CMS to create a Level 6 Neurostimulator and Related Procedures APC to ensure that there is adequate and sustainable reimbursement for this advanced therapy. A commenter provided options to CMS that are summarized in the final rule preamble. In response, CMS points to the prior discussion under III.E.36 (Creation of a Level 6 Neurostimulator APC) and its decision to assign the primary procedure code to New Technology APC 1580.

42. Ophthalmology Related Services: Administration of Lacrimal Ophthalmic Insert Into Lacrimal Canaliculus, CPT Code 68841 (APC 5503)

In the preamble of the final rule, CMS summarizes the assignment history of this code. For 2026, CMS proposed to continue to assign CPT code 68841 to APC 5530, status indicator "Q1" and an ASC payment indicator of "N1". Commenters requested that CMS revise the status indicator to "J1" to allow for separate ASC payment, stating that the lack of payment disproportionately and negatively affects the ASC setting where this procedure is done 80 percent of the time. The commenter did not agree with CMS that the fact that CPT code 68841 was performed as a standalone procedure a small percentage of the time was adequate justification for assigning a "Q1" status indicator. In response, CMS states that that the agency has long maintained that Dextenza is a drug that functions as a surgical supply and should be packaged under its packaging policy at §419.2(b). For reasons discussed more fully in the preamble of the final rule, CMS states that CPT code 68841 should be packaged as an intraoperative service under §419.2(b)(14). CMS does not agree that the HCPCS codes referenced by the commenter are analogous to CPT code 68841. CMS also does not agree that the current status indicator disincentivizes its use, as demonstrated by the increasing number of claims for this procedure, and that Dextenza is a qualifying product for separate payment in both the OPPS and ASC under CMS' policy to implement section 4135 of the CAA, 2023.

Final action: After consideration of the public comment, CMS is finalizing its proposal, without modification, to assign CPT code 68841 to APC 5503 with OPPS status indicator "Q1" (STV Packaged Codes) for 2026.

43. Comprehensive Aqueous Outflow Procedure

A commenter stated that current coding structure does not adequately reflect the differences between the comprehensive aqueous outflow procedures and the other in procedures currently reported with CPT code 66174 and the comprehensive aqueous outflow procedure. Commenters requested that CMS create a C code and finalize a New Technology APC assignment that appropriately recognizes this unique procedure. In response, CMS declines, stating that it does not believe that the commenter has provided sufficient explanation to justify the creation of a new C-code at this time.

44. First Carpometacarpal Total Joint Arthroplasty, CPT Code 1003T (APC 5115)

The CPT Editorial Panel established CPT code 1003T to describe a total joint arthroplasty procedure involving the thumb effective January 1, 2026. For 2026, CMS proposed to assign CPT code 1003T to APC 5114, status indicator "J1," based on clinical similarity to CPT code 26531. The August 25, 2025 HOP panel recommended that CMS reassign CPT code 1003T to APC 5116. Commenters believe that CPT 1003T is more similar to other arthroplasty procedures in APC 5116 and suggested CPT code 25446 (which describes a total wrist arthroplasty) and CPT code 25442 (which describes a distal ulna arthroplasty) as appropriate crosswalks. In response, CMS agrees with the commenters that CPT code 1003T should not be assigned to APC 5114; however, CMS disagreed that CPT code 1003T should be reassigned to APC 5116. After reviewing the comments and taking into consideration the HOP Panel recommendation, CMS believes that CPT code 1003T should be reassigned to APC 5115 crosswalking to CPT code 25441.

Final action: CMS is finalizing the APC and status indicator assignment for CPT code 1003T with modification. Specifically, for 2026, CMS is assigning CPT code 1003T to APC 5115 with a status indicator of "J1".

46. Oncology Related Services: Radiation Oncology Treatment Delivery, CPT codes 77402, 77407, 77412 (APCs 5621, 5622, 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. In the proposed rule, CMS proposed to continue to assign CPT code 77402 to APC 5621, status indicator "S". CMS also proposed to continue to assign CPT codes 77407 and 77412 to APC 5622, status indicator "S".

Comment/response: CMS notes that a comment letter was submitted to the HOP Panel in advance of the August 25, 2025 HOP Panel Meeting that provided information about CPT codes 77407 and 77412 and advised the Panel to request that CMS reassign CPT code 77407 to APC 5623 and CPT code 77412 to APC 5624 for CY 2026. The HOP Panel, however, had no recommendations. Commenters expressed concern that CMS' proposed APC assignments for CPT codes 77407 and 77412 did not adequately reflect the procedures described by the revised codes and would not provide sufficient payment. Some commenters suggested that for the purposes of rate setting, CMS should treat the three revised CPT codes as new codes. Several commenters suggested alternative APC assignments. Finally, a few commenters suggested that CPT code 47702 be reassigned from APC 5621 to APC 5622.

CMS agreed that the proposed APC assignments and the resulting payment rates for CPT codes 77407 and 77412 could more properly account for the revisions made to those codes and that the geometric mean costs of CPT codes 77385 ($568) and 77386 ($634) should be considered when

assigning the appropriate APC for these codes. Accordingly, CMS crosswalked the claims in the manner summarized in the final rule preamble.

Final action: After consideration of the public comments, CMS is (1) finalizing as proposed to continue to assign CPT code 77402 to APC 5621 and CPT code 77407 to APC 5622, while noting that the payment rate for APC 5622 is much greater than in the 2026 OPPS/ASC proposed rule as a result of the code crosswalk; and (2) reassigning CPT code 77412 to APC 5623.

47. Radiofrequency Ablation of Bone Tumors, CPT 20982 (APC 5116)

For the proposed rule, CPT code 20982 had a geometric mean cost of around $18,375 and CMS proposed to continue to assign the procedure to APC 5115. A commenter requested that CMS reassign CPT code 20982 from APC 5115 to APC 5116 on the basis of the resource costs related to CPT code 20982. In response, and after additional evaluation, CMS agrees with the commenter that it is appropriate to reassign CPT code 20982 from APC 5115 to 5116 based on the resource costs related to CPT code 20982.

51. Non-Invasive Gas Exchange and Cardiorespiratory Status (AGM 100), CPT code 0893T (APC 5734)

For 2026, CMS did not have any claims for rate setting, so the agency proposed to continue to assign the procedure to APC 5733, status indicator "Q1". CMS notes that at the August 25, 2025, HOP Panel Meeting, a presentation was made requesting the reassignment to APC 5723, however the Panel made no recommendation. Commenters on the proposed rule requested that CPT code 0893T be reassigned from APC 5733 to APC 5723, stating that the proposed payment rate falls far short of adequate reimbursement and threatens patient access to the procedure. Some commenters additionally stated that the current APC assignment is inappropriate because there are no clinically similar procedures in that classification. In response, and in the absence of claims and based upon the input provided by commenters, CMS agrees that CPT code 0893T should be reassigned to an APC that better reflects the costs of the procedure. However, CMS does not agree that the appropriate APC is 5723, and CMS is not persuaded that the device is diagnostic in nature because the device itself is not diagnosing a specific condition.

Final action: After consideration of the public comments, CMS has decided to reassign 0893T to APC 5734.

52. 3D Anatomical Segmentation Imaging Software Service, HCPCS Code C8001 (APC 5721)

For 2026, CMS proposed to continue to assign HCPCS code C8001 to APC 5721 which has a proposed rate of around $132. CMS notes that because this is a new service, CMS does not have any claims data. Commenters requested for HCPCS code C8001 to be reassigned from APC 5721 to APC 5723. The commenter cited the technical expertise required by the technologist and the additional hardware and software costs as justification for the higher-level APC assignment. In response, after careful review of the request, CMS does not believe it would be appropriate to

reassign the APC for C8001 until the agency has claims data for this service. CMS will continue to monitor claims and utilization patterns for C8001 and may reconsider the APC assignment in future rulemaking.

Final action: After consideration of the public comment received, CMS is finalizing the APC assignment for HCPCS code C8001 without modification.

55. Noninvasive Arterial Plaque Analyses, CPT code 0712T (5722)

For 2026, CMS proposed to assign CPT code 0712T to APC 5521. At the 2025 HOP Panel Meeting, several presenters advised the Panel to request that CMS reassign 0712T to New Technology APC 1511 with a payment rate of $950.50. However, the HOP Panel did not make a recommendation to CMS. In the final rule, several commenters requested that CMS reassign CPT code 0712T to a New Technology APC 1511. Several commenters recommended using CPT code 0625T as a crosswalk code for CPT code 0712T, as they believe that CPT code 0625T and CPT code 0712T resemble each other in methodology, clinical purpose, and resource demands. In response, CMS does not agree with the recommended crosswalk code of CPT code 0625T; CMS believes that CPT code 0712T is more similar clinically and in terms of resource requirements and procedure costs to the procedures assigned to APC 5722.

Final action: After consideration of the public comments received, CMS is finalizing its proposal with modification and reassigning CPT code 0712T to APC 5722.

57. Enhanced Lithotripsy System, CPT Code 0991T (APC 5376)

The AMA CPT Editorial Panel established CPT code 0991T effective January 1, 2026. As this is a new code in 2026, CMS has no claims data for the code. For 2026, CMS proposed to assign CPT Code 0991T with the status indicator "E1."

Comment/response: A few commenters stated that CPT code X432T has transitioned to CPT code 0991T, effective July 1, 2025 and that CMS incorrectly assigned status indicator "E1" to CPT code X432T in the proposed rule. Additionally, the commenters requested the assignment of CPT code 0991T to APC 5376 based on the commenter's resource cost of $10,131, and be designated as device intensive with a device offset of 44 percent. In response, CMS notes that while CPT code 0991T was released on the AMA website on July 1, 2025, the code is not effective until January 1, 2026. CMS notes that the proposed status indicator of "E1" for CPT code 0991T (X432T) was appropriate in the proposed rule because the agency determined that, at the time of the proposals, the enhanced lithotripsy service involved a non-FDA approved device not excepted by any IDE status. CMS states that, as a result of further review, CMS agrees with the commenter's request to assign CPT code 0991T (X432T) to APC 5376, based on a crosswalk to HCPCS code C9761.

Final action: After consideration of the public comments, CMS is finalizing its proposal with modification to assign CPT code 0991T (X432T) to APCs 5376 with a status indicator of "J1".

64. Atherectomy with Angioplasty, CPT code 92924 (APC 5193)

For 2026, CMS proposed to maintain the APC assignment to APC 5193 based on the geometric mean costs associated with several hundred claims, with a proposed payment of around $11,873.

Comment/response: Commenters requested that CMS reassign CPT code 92924 to APC 5194 because the code is a technically demanding complex procedure and is more clinically similar to other procedures assigned to APC 5194. Additionally, the commenters believe that the assignment to APC 5194 is appropriate based on the geometric mean cost of CPT code 92924. In response, CMS notes that the agency determines APC assignments based on both resource and clinical homogeneity. CMS continues to believe that CPT code 92924 is more clinically similar to the procedures assigned to APC 5193, and concludes the proposed assignment is appropriate. CMS notes that, as with many APC families, there may be services and procedures that have higher geometric mean costs than other procedures in the next level.

Final action: After consideration of the public comments, CMS is finalizing its proposal without modification, to assign CPT code 92924 to APC 5193 (Level 3 Endovascular Procedures).

65. Coronary Therapeutic Services and Procedures CPT Codes 92930, 92945 (APCs 5194, 5193)

The CPT Editorial Panel created 2 new Category I codes 92930 and 92945, effective January 1, 2026. The new final CPT codes (along with their placeholder codes) are 92930 (92X01) and 92945 (92X02). For 2026, CMS proposed to assign both of these procedures to APC 5193 (Level 3 Endovascular Procedures) and a status indicator (SI) of "J1" with a proposed payment of $11,873.70. CMS notes that, based on a presentation at the August 25, 2025, HOP Panel Meeting, the HOP Panel recommended that CMS reassign both CPT codes 92930 and 92945 from APC 5193 (Level 3 Endovascular Procedures) to APC 5194 (Level 4 Endovascular Procedures).

Comment/response: Commenters requested that CMS reassign CPT codes 92930 and 92945 to APC 5194 to better reflect the increased complexity of these procedures and resource utilization. Commenters noted that while CMS crosswalked these codes to the straightforward versions of these procedures, the new codes include additional procedural work and resources that warrant a higher APC assignment. Commenters suggested using C9607 as a crosswalk code for CPT code 92945. In response, CMS agrees with commenters that CPT code 92930 is more complex and utilizes more resources (in particular, additional stents) than its crosswalk code. However, CMS disagrees that more resources are used with CPT 92945.

Final action: After consideration of the public comments, further review, and the HOP Panel recommendations, CMS is finalizing the APC and status indicators for CPT codes 92930 and 92945 with modification. Specifically, CMS is assigning CPT 92930 to APC 5194 and continuing to assign CPT 92945 to APC 5193.

66. Lower Extremity Revascularization, CPT Codes 37254 through 37299 (APCs 5192, 5193, and 5194)

For 2026, the CPT Editorial Panel deleted 16 CPT codes that described lower extremity revascularization and replaced them with 46 new codes. The new codes establish an additional peripheral vessel territory as well as additional granularity in describing the procedures. The 16 revascularization codes will be deleted December 31, 2025, and replaced with the new CPT codes effective January 1, 2026. In the final rule preamble, CMS lists the deleted codes in Table 93. Table 94 lists the new revascularization CPT code, the long descriptor, status indicator, APC assignment, and the crosswalk code that was used to determine the proposed APC assignment.

Comment/response: Commenters were supportive that CMS used the corresponding codes that are being deleted as crosswalks for the new codes, noting that the agency has extensive claims history for the codes that are being deleted, and this approach provides payment stability. Several made comments related to complexity adjustments and device offset percentages involving these new codes. In response, CMS believes that the agency assigned codes to appropriate APCs utilizing the predecessor codes as crosswalks.

Final action: After consideration of the public comments, CMS is finalizing its proposals without modification, to assign CPT codes 37254 through 37299 to the APCs and status indicators noted in Table 94 in the final rule preamble.

67. Percutaneous Transcatheter Therapeutic Drug Delivery (CPT code 0913T)

For 2026, CMS proposed to assign CPT code 0913T to APC 5192 based on the crosswalk code CPT 92920 which is assigned to APC 5192, status indicator of "J1." Because CPT code 0913T became effective January 1, 2025, CMS has no claims for ratesetting. CMS notes that the device associated with this procedure (AGENT™ Paclitaxel-Coated Balloon Catheter) received device pass-through status effective January 1, 2025. In the final rule, commenters requested that CMS reassign CPT code 0913T to APC 5193, stating that 0913T is more clinically coherent with procedures assigned to APC 5193. Commenters suggested that CMS consider crosswalking CPT code 0913T to HCPCS C9600, which commenters believe is more clinically similar. Commenters also provided an analysis that indicated that the geometric mean cost is $11,000. Finally, commenters argued that assignment of CPT code 0913T to APC 5192 would pose a two-times rule violation. In response, CMS states that APC 5192 does not have a two-times rule violation, based on the final rule data. However, after consideration of the public comments and additional review, CMS believes that the resource costs of CPT code 0913T is more aligned with the procedures in APC 5193, which includes HCPCS code C9600.

Final action: After consideration of the public comments, CMS is finalizing its proposal with modification and reassigning CPT code 0913T to APC Level 5193.

69. Dialysis Related Services and Technologies

a. Dialysis-Related Amyloidosis (DRA) Treatment with Lixelle® Apheresis Columns

In the final rule, several interested parties commented requesting coverage for Lixelle® apheresis columns for treating dialysis-related amyloidosis (DRA). Commenters noted that Lixelle® has FDA Humanitarian Use Device approval and has been successfully utilized in Japan. In response, CMS recognizes the clinical need for effective treatments for dialysis-related amyloidosis and appreciates the information provided by commenters. The agency is actively reviewing coverage pathways for innovative treatments that address unmet medical needs in the ESRD population.

b. Dialysis Technologies

A commenter supported the payment of dialysis technologies not included in the ESRD bundle through the OPPS. The commenter noted that CMS continues to evaluate potential avenues of payment for treatments using medical devices administered during dialysis procedures that are not considered "renal dialysis services" under the Medicare statute and requested that CMS provides payment for such services through the OPPS. In response, CMS states that it recognizes the importance of ensuring appropriate payment pathways for innovative treatments that may be administered during dialysis but fall outside the definition of a renal dialysis service and thus are not paid for under the ESRD PPS. The agency will continue to evaluate the appropriate payment mechanisms for such technologies for future rulemaking.

c. Open Surgical Fistula Creation

CPT code 36821 describes an open surgical fistula creation for hemodialysis procedures and is currently assigned to APC 5183, status indicator of "J1." In the final rule, a commenter expressed concern about payment disparities between traditional surgical arteriovenous fistula (AVF) creation and endovascular procedures. The commenter expressed concern that low payment may cause skilled surgeons to preferentially choose better-paying procedures and potentially diminish the availability of AVF creation. In response, CMS acknowledges the concerns and indicates that both approaches serve important clinical roles in vascular access for dialysis patients. CMS states that it will continue to evaluate payment rates for these procedures to ensure appropriate payment that reflects the clinical value and resource costs associated with each approach.

d. Peritoneal Dialysis (PD) Catheter Placement

There are a number of CPT codes that describe placing a catheter for peritoneal dialysis, including 49324 (assigned to APC 5361, status indicator "J1"), 49418 (assigned to APC 5341, status indicator "J1"), and 49421 (assigned to APC 5341, status indicator "J1"). For 2026, CMS proposed to continue the current assignments. In the final rule, a commenter expressed concern that current CMS payment for peritoneal dialysis (PD) catheter placement may have created a disincentive for performing the procedure. The commenter specifically noted that low payment for PD catheter placement relative to vascular access procedures may create barriers to patients

receiving more convenient home-based treatment. The commenter requested that CMS equalize payment between PD catheter procedures and vascular access procedures to avoid possible disincentives to home treatment and provide patients with additional quality care options. In response, CMS states that the agency supports policies that facilitate appropriate home-based dialysis care when clinically appropriate, and its desire to ensure its payment policies do not inadvertently create barriers to home dialysis modalities, including peritoneal dialysis. CMS will review current payment rates for PD catheter placement procedures and consider any adjustments for future rulemaking.

70. Mobile Stroke Units

Mobile stroke units (MSU) are specialized ambulances equipped with various skilled healthcare personnel, specialized equipment, including imaging capability to diagnose and treat acute stroke in the prehospital setting. In the final rule, a commenter requested that MSU services be reimbursed as hospital outpatient services rather than ambulance transport services. The commenter noted that the current Ambulance Fee Schedule (AFS) payment does not cover the cost of CT scans and other essential components of an MSU, leading to financial challenges for MSU operators. The commenter cited clinical evidence pointing to improved outcomes associated with the use of MSUs. In response, CMS expresses appreciation for the details shared regarding MSU payment challenges and will consider them in future rulemaking. CMS further notes that MSUs are paid under the Ambulance Fee Schedule.

F. Comment Solicitation on Payment Policy for Software as a Service (SaaS)

In recent years, there have been rapid developments in the use of software-based technologies with new functionalities, including artificial intelligence, to support clinical decision-making in the outpatient and physician office settings. Prior to 2018, SaaS procedures were considered supportive or ancillary services and therefore payment for SaaS was packaged into the payment for the underlying clinical service. In recent years, CMS has paid separately for SaaS procedures under the OPPS through New Technology APCs. Interested parties have requested that CMS consider development of a payment policy for these services that is stable and consistent across settings of care, payment systems, and types of SaaS.

In the proposed rule, CMS outlined some of the ambiguities associated with pricing such technologies including: wide variations in the purported costs of clinically similar SaaS technologies; lack of publicly verifiable data; questions related to what extent Medicare should pay for the research and development costs of SaaS that could be frequently used by non-Medicare beneficiaries in hospital outpatient departments and ambulatory surgical center settings; lack of comparison technologies that could be used to determine clinical and resource similarity; and limited amount of Medicare claims data for these services. CMS expressed its interest in developing payment policies that reflect the underlying value of a service or technology to the practice of medicine. As a result, CMS requested public comment on future SaaS payment ideas and posed a number of questions that are reproduced in the final rule preamble. Additionally, CMS welcomed input on any additional suggestions that would enhance the agency's ability to provide

accurate and consistent payment for SaaS procedures.[20] CMS summarizes the comments it received in response to its solicitation. While a high-level summary is provided here, the comments can be viewed in more detail in the final rule preamble.

Comment/response: Commenters requested that CMS address the definition of technologies that would be considered SaaS, with some suggesting that CMS align with the FDA's definition of Software as a Medical Device (SaMD). Others provided suggestions on categories of SaaS for purposes of payment. Commenters generally supported a dedicated payment policy and framework that balances innovation, patient access, and value to the Medicare program, however, some commenters expressed concerns about the potential for costs to increase if CMS were to establish a new payment policy specific to SaaS. Some commenters suggested that the framework CMS has established for New Technology APCs could be adapted to address payment for SaaS while others endorsed the payment pathway that is outlined in The Health Tech Investment Act (S. 1399). Commenters made suggestions to enable CMS to improve collection of cost data and to establish appropriate valuation for SaaS, for example, by creating new revenue codes or cost centers to facilitate more accurate hospital cost reporting or working with Congress to establish authority to incentivize standardized vendor disclosures, stratified by practice or facility size, setting, and geography. Some commenters encouraged CMS to develop (or to work with the AMA to develop) SaaS-specific codes. Finally, many commenters recommended that CMS adopt a site-neutral payment policy for SaaS across the facility and non-facility settings.

CMS notes that the comments illustrate the complexities intrinsic to paying for SaaS and that the agency will proceed with awareness of the challenges. CMS states it will continue to recognize the need for a payment policy that accounts for the unique and heterogenous characteristics of SaaS; ensure that any such payment policy reflects the value provided to Medicare providers and beneficiaries; and take the comments submitted into consideration for future rulemaking.

G. Radiation Therapy Services: Non-Excepted Off-Campus Provider Based Departments

1. Background on Section 603 of the Bipartisan Budget Act of 2015 and the PFS Relativity Adjuster

Section 603 of the Bipartisan Budget Act of 2015 amended the Social Security Act[21] such that, as a general matter, applicable items and services furnished by certain off-campus outpatient departments (OPDs) of a provider on or after January 1, 2017, are not considered covered OPD services for purposes of payment under the OPPS. Instead, such items are paid "under the applicable payment system" under Medicare Part B if the requirements for such payment are otherwise met. As a result, CMS finalized policies that define whether certain items and services furnished by a given off-campus PBD may be considered excepted and, thus, continue to be paid under the OPPS; established the requirements for the off-campus PBDs to maintain excepted status

[20] Note: there was a similar comment solicitation on a payment policy for SaaS in the 2026 Physician Fee Schedule proposed rule.
[21] Section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114-74) (BBA, 2015) (referred to as "section 603") amended section 1833(t) of the Act by adding a new clause (v) to paragraph (1)(B) and adding a new paragraph (21).

(both for the excepted off-campus PBDs and for the items and services furnished by such excepted off-campus PBDs); and described the applicable payment system (generally, the PFS) for nonexcepted items and services.

To implement payment for nonexcepted items and services, CMS established a PFS Relativity Adjuster that is applied to the OPPS rate for the billed nonexcepted items and services furnished in a nonexcepted off-campus PBD. Nonexcepted items and services furnished by nonexcepted off-campus PBDs are generally paid under the PFS at the applicable OPPS payment rate adjusted by the PFS Relativity Adjuster of 40 percent (that is, 60 percent less than the OPPS rate).[22] CMS also created modifier "PN" to collect data for purposes of implementing section 603 but also to trigger payment under the adopted PFS-equivalent rates for nonexcepted items and services. Nonexcepted off-campus PBDs bill for nonexcepted items and services on the institutional claim using modifier "PN" to indicate that an item or service is a nonexcepted item or service.

2. Payment for Radiation Therapy Services furnished at Nonexcepted Off-Campus PBDs

The PFS Relativity Adjuster is not applied to radiation therapy services furnished by nonexcepted off-campus PBDs. Instead, when CMS implemented the section 603 requirements, nonexcepted off-campus PBDs were instructed to bill the PFS G-codes for these services. As discussed in the 2026 Physician Fee Schedule (PFS) final rule, CMS is finalizing its proposal to delete radiation therapy G-codes (G6001, through G6017) that describe imaging guidance for radiation treatment and radiation treatment delivery because CPT codes 77402, 77407, and 77412 have been revised and may be used to report these services instead. Tables 97 and 98 in the final rule preamble list the deleted and replacement codes, respectively.

In order to preserve the existing policy of paying nonexcepted off-campus PBDs a specific radiation treatment rate (which is the technical component for the code under the Medicare PFS), CMS proposed that, effective January 1, 2026, nonexcepted off-campus PBDs would use revised CPT codes 77402, 77407, and 77412. Additionally, CMS proposed that nonexcepted off-campus PBDs would continue to append the "PN" modifier to each applicable claim line for these services.

Comment/response: A commenter supported the deletion of the G codes and the use of the revised CPT codes by all radiation treatment providers. However, the commenter requested that CMS not apply the PFS Relativity Adjustor to the revised codes when billed by nonexcepted off-campus provider-based departments because in doing so, the reimbursement for IMRT would fall well below cost. In response, CMS notes that the payment amount for services when billed with modifier "PN" will be set to reflect the technical component rate for the code under the Medicare PFS. CMS states that the agency does not intend for radiation therapy services furnished by nonexcepted off-campus PBDs to be paid any differently than they were paid previously when billed as G codes. Additionally, CMS believes that the concerns for adequate payment for codes involving IMRT are further addressed by CMS' final APC assignments for CPT codes 77407 and 77412 discussed in section III.E. of the final rule.

[22] For a detailed discussion of the current PFS Relativity Adjuster related to payments under section 603, see the 2018 OPPS/ASC final rule (82 FR 52356 through 52637) and the 2019 PFS final rule (82 FR 59505 through 59513).

Final action: CMS is finalizing, without modification, its proposal that, effective January 1, 2026, nonexcepted off-campus PBDs use the revised radiation treatment CPT codes (CPT codes 77402, 77407, and 77412) and append modifier "PN" to each applicable claim line for nonexcepted items and services. The payment amount for these services when billed with the "PN" modifier will be set to reflect the technical component rate for the code under the Medicare PFS.

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

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.[23] Under statute, a device category is eligible for transitional pass-through payments for at least 2, but not more than 3 years.[24] To allow a pass-through payment period that is as close to a full 3 years as possible, CMS established quarterly expiration of pass-through payments status for devices.[25] For devices that are no longer eligible for pass-through payments, CMS packages the costs of the devices into the procedures with which the devices are reported in the claims data.

CMS makes OPPS device pass-through applications publicly available online. This policy applies to applications CMS received on or after March 1, 2023, beginning with the issuance of the 2025 proposed rule.[26]

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

Currently, there are 20 device categories eligible for pass-through payment. Of these devices, 17 were listed in Table 46 in the proposed rule. In addition, HPA notes that HCPCS codes C1740, C1741 and C1742 were preliminarily approved as part of the device pass-through quarterly review process with an effective date of October 1, 2025.[27] Under CMS' quarterly review process, applications received after the March 3, 2025, deadline for the remaining 2025 quarters (the quarters beginning June 1, September 1, and December 1 of 2025) will be discussed in the 2027 OPPS/ASC proposed rule. As such, CMS expects to include and discuss the device applications

[23] 87 FR 72032-72033
[24] Section 1833(t)(6)(B)(iii) of the Social Security Act
[25] 81 FR 79648 through 79661, in accordance with section 1833(t)(6)(B)(iii)(II) of the Social Security Act
[26] 87 FR 71934 through 71938
[27] Centers for Medicare & Medicaid Services (2025). Pub 100-04 Medicare Claims Processing, Transmittal 13425, Change Request 14223, dated September 22, 2025. Accessed at https://www.cms.gov/files/document/r13425cp.pdf.

associated with HCPCS codes C1740, C1741 and C1742 in the 2027 OPPS/ASC proposed and final rules with comment period.

Table 99 (reproduced from the final rule below) lists all 20 devices and the expiration dates of pass-through payment status.

TABLE 99: Devices with Pass-Through Status and Expiration Dates

HCPCS Code	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1826	Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system	01/1/2023	12/31/2025
C1827	Generator, neurostimulator (implantable), non- rechargeable, with implantable stimulation lead and external paired stimulation controller	01/01/2023	12/31/2025
C1747	Endoscope, single-use (*i.e.* disposable), urinary tract, imaging/illumination device (insertable)	01/01/2023	12/31/2025
C1600	Catheter, transluminal intravascular lesion preparation device, bladed, sheathed (insertable)	01/01/2024	12/31/2026
C1601	Endoscope, single-use (*i.e.* disposable), pulmonary, imaging/illumination device (insertable)	01/01/2024	12/31/2026
C1602	Orthopedic/device/drug matrix/absorbable bone void filler, antimicrobial-eluting (implantable)	01/01/2024	12/31/2026
C1603	Retrieval device, insertable, laser (used to retrieve intravascular inferior vena cava filter)	01/01/2024	12/31/2026
C1604	Graft, transmural transvenous arterial bypass (implantable), with all delivery system components	01/01/2024	12/31/2026
C1605	Pacemaker, leadless, dual chamber (right atrial and right ventricular implantable components), rate-responsive, including all necessary components for implantation	07/01/2024	06/30/2027
C1606	Adapter, single-use (*i.e.* disposable), for attaching ultrasound system to upper gastrointestinal endoscope	07/01/2024	06/30/2027
C8000	Support device, extravascular, for arteriovenous fistula (implantable)	10/01/2024	9/30/2027
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, probe detectable 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

HCPCS Code	Long Descriptor	Effective Date	Pass-Through Expiration Date
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

2. New Device Pass-Through Applications for 2026

a. Background

The statute provides for pass-through payments for devices and requires CMS to use categories in determining the eligibility of devices for pass-through payments.[28] The specific requirements are established at 42 CFR 419.66. To be eligible for transitional pass-through payment under the OPPS, a device must meet the following general criteria:

- The device must have received FDA premarket approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA), and the pass-through application must be submitted within 3 years from the date of the initial FDA approval or clearance, unless there is a documented, verifiable delay in the U.S. market availability, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability;
- 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 (either permanently or temporarily), or applied in or on a wound or other skin lesion.

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.

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. The device has 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: (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 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

[28] Section 1833(t)(6) of the Social Security Act

the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service, and

- 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.

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.

CMS has established an alternative pathway for devices that receive FDA marketing authorization and are granted a Breakthrough Device designation. Under this alternative pathway, devices granted an FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion but do need to meet the other requirements for pass-through payment status. Such devices can be approved through the quarterly process and announced through that process. Proposals regarding these devices and whether pass-through payment status should continue to apply are included in the next applicable OPPS rulemaking cycle. This process promotes timely pass-through payment status for innovative devices, while also recognizing that such devices may not have a sufficient evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization. In addition, CMS is amenable to meeting with applicants or potential applicants to facilitate information sharing to support the evaluation of an OPPS device pass-through payment application or discuss general application criteria, including the substantial clinical improvement criterion.[29]

CMS notes that 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.

b. Applications Received for Device Pass-Through Status for 2026

CMS received eight complete applications by March 3, 2025, which was the last quarterly deadline for applications to be received in time to be included in the proposed rule. One application was withdrawn prior to the proposed rule publication. Two of the applications (VasQ and SCOUT MD™ Surgical Guidance System) were preliminarily approved for device pass-through payment

[29] More details on the requirements for device pass-through payment applications are included on the CMS website in the application form itself at: Pass-Through Payment Status and New Technology Ambulatory Payment Classification (APC) | CMS, in the "Downloads" section.

during the quarterly review process under the alternative pathway and included for discussion in the proposed rule. Applications received for the later deadlines for the remaining 2025 quarters (the quarters beginning June 1, September 1, and December 1 of 2025), if any, will be discussed in the 2027 OPPS/ASC proposed rule.

If an application was discussed in the proposed rule and subsequently withdrawn, CMS does not include it in this final rule. The summaries below provide a high-level review of the comments and responses for each application as well as CMS' final determination; readers are advised to reference the proposed rule preamble for greater detail, as well as the online application.

(1) Alternative Pathway Device Pass-Through Applications.

CMS received four device pass-through applications by the March 2025 quarterly application deadline for devices that received Breakthrough Device designation from FDA and therefore were eligible to apply under the alternative pathway. HPA has developed a summary table of CMS final determinations for three[30] of the applications that are addressed by CMS in this final rule:

Alternative Pathway Device Pass-Through Applications	
Device	**CMS Determination**
aprevo® Cervical ACDF System	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.
SCOUT MD™ Surgical Guidance System	CMS is finalizing approval for device pass-through payment status under the alternative pathway for devices that have an FDA Breakthrough Device designation.
VasQ™	CMS is finalizing approval for device pass-through payment status under the alternative pathway for devices that have an FDA Breakthrough Device designation.

(a) aprevo® Cervical ACDF system, aprevo® Cervical ACDF-X system, aprevo® Cervical ACDF-X NO CAM system.[31] Applicant: Carlsmed, Inc.

The aprevo® Cervical ACDF System is designed to stabilize the cervical spinal column and facilitate fusion. The personalized aprevo® Cervical ACDF System devices incorporate patient-specific features to allow the clinician to tailor the deformity correction to the individual needs of the patient and include an aperture for the packing of bone graft.

[30] Per CMS policy, applications discussed in the proposed rule that are subsequently withdrawn are not addressed by CMS in the final rule. HPA cannot definitively ascertain the adjudication of the fourth new technology application, the FARAPULSE™ PFA System, which was discussed by CMS in the proposed rule. We therefore assume the applicant withdrew from consideration and that it was not inadvertently omitted by CMS.

[31] Please refer to the online application for the aprevo® Cervical ACDF System, available at: https://mearis.cms.gov/public/publications/device-ptp/DEP250303GJ8LW.

In the proposed rule, CMS raised a number of concerns related to the ability of this device to meet pass-through eligibility criteria. Additionally, with regards to establishing a new device category, CMS stated its belief that the aprevo® Cervical ACDF System may be similar to devices described by C1831 and may therefore not be eligible for pass-through payment in the OPPS.

Comment/Response: The applicant and a commenter expressed support for pass-through status. With regards to eligibility and exclusion criteria, the applicant submitted clarifications to many CMS questions, including clarifications regarding the device's name change, device configurations and components, and other issues. As a result of these clarifications, CMS has determined that the aprevo® Cervical ACDF System meets eligibility criteria (§419.66(b)(1)-(3)) and is not excluded (§419.66(b)(4)).

Regarding establishing a new device category, the applicant and a commenter assert that the aprevo® Cervical ACDF System is substantively distinct and significantly different from the expired device category C1831 because there is no overlap in FDA anatomical indications for use or patient population. The commenter pointed to examples of instances where CMS has made such distinctions for other pass-through devices and raised arguments related to differences in coding determinations. However, CMS was not swayed and explains that the agency compares the nominated device to the device category descriptor. In this case, per the applicant, the aprevo® Cervical ACDF System is a personalized interbody cage that is implanted using an anterior surgical approach, which matches the descriptor for C1831 (interbody cage, anterior, lateral or posterior, personalized (implantable)). CMS further explains that the examples shared by the commenter were intentionally defined with anatomically specific descriptors from their inception, which was not the case for C1831. Moreover, the list of procedure codes do not define the device category code and are not unalterable. CMS also notes that the aprevo® (IFD) (which uses the device category code descriptor C1831) has some overlap in anatomical approach with the aprevo® Cervical ACDF System. Finally, the applicant requested that CMS reinstate C1831 to ensure a full 3 years of device pass-through payment status to capture the necessary data costs. CMS notes that the agency cannot reinstate the pass-through payment status of C1831 because reinstatement would make the pass-through payment status effective longer than the maximum 3-year period permitted under section 1833(t)(6)(B)(iii) of the Act and §419.66(g).

Final determination: After consideration of the public comment, CMS has determined that the aprevo® Cervical ACDF System 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. Therefore, is not approving the aprevo® Cervical ACDF System for transitional pass-through payment status for 2026 because the technology does not meet the device category eligibility criterion at §419.66(c)(1).

(b) SCOUT MD™ Surgical Guidance System.[32] Applicant: Merit Medical Systems

The SCOUT MD™ Surgical Guidance System communicates the location of tumor tissue during a tumor excision procedure and consists of the SCOUT MD™ Delivery System, SCOUT MD™

[32] Please refer to the online application posting for the SCOUT MD™ Surgical Guidance System, available at

Guide, SCOUT MD™ Handpiece, and SCOUT MD™ Console. The applicant is only seeking a new device category for transitional pass-through payment status for the SCOUT MD™ Delivery System component. Each SCOUT MD™ Delivery System is used to implant one SCOUT MD™ Reflector, which is used to identify the location of the tumor tissue to be excised and/or the boundaries of the region of tissue to be excised during a separately scheduled procedure.

CMS preliminarily approved the SCOUT MD™ Delivery System application for transitional pass-through payment under the alternative pathway effective January 1, 2025. In the proposed rule, CMS did not note any strong concerns related to eligibility criteria. Upon review, CMS did not identify an existing pass-through payment category that would describe the SCOUT MD™ Delivery System. CMS noted its belief that the SCOUT MD™ Delivery System met all three cost significance requirements.

Comment/Response: The applicant submitted comments reiterating its application information and confirming CMS' proposed rule cost analysis. The applicant cited concerns that the code descriptor for C1739, the device category established upon the preliminary approval, is overly broad and believes the change is necessary so that only those devices truly eligible for device pass-through status can use the HCPCS code and so that the claims data appropriately reflects accurate billing. The applicant notes that CMS has been paying for devices submitted using C1739 that should not be included for pass-through status, raising concerns related to fraud, waste, and abuse. Additionally, the applicant notes the implications for establishing the pass-through period since the pass-through period begins on the first date on which pass-through payment is made. The applicant therefore requested that CMS withdraw C1739 and issue a new HCPCS code with descriptor language including, "radar detectable implantable reflectors", effective January 1, 2026, to ensure that the SCOUT MD™ Delivery System receives the full 3 years of pass-through status.

In response, CMS acknowledges the commenter's concerns but disagrees that the C1739 should be withdrawn and replaced with a new code effective January 1, 2026. CMS provides several reasons for its disagreement including the fact that CMS revised the descriptor of C1739, per the commenter's request, and issued the revision on October 1, 2025, which CMS believes will address the commenter's concerns. CMS reiterates that the device category codes are not device specific. Rather, CMS establishes device categories that are intended to encompass all devices that can be appropriately described by the category, and therefore any device described by the descriptor associated with a currently payable device pass-through category code qualifies for pass-through payment. Therefore, for the purposes of C1739, CMS considers the start of the device pass-through payment status eligibility period to be January 1, 2025. CMS states that the agency will continue to monitor utilization and payment trends for C1739 to ensure accurate and appropriate payment.

Final determination: After consideration of the public comment and its review of the application, CMS is finalizing approval for device pass-through payment status for the SCOUT MD™ Delivery System under the alternative pathway for devices that have an FDA Breakthrough Device designation.

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https://mearis.cms.gov/public/publications/device-ptp/DEP240830W9M8U

(c) VasQ™.[33] Applicant: Laminate Medical

VasQ™ is a nitinol implant which is surgically placed outside and/or around an artery and/or vein to provide external support to arteriovenous fistulas created for vascular access by means of vascular surgery.

CMS preliminarily approved the VasQ™ application for transitional pass-through payment under the alternative pathway effective October 1, 2024. In the proposed rule, CMS did not note any strong concerns related to eligibility criteria. Upon review, CMS did not identify an existing pass-through payment category that would describe VasQ™. CMS noted its belief that the VasQ™ met all three cost significance requirements.

Comment/response: CMS did not receive any comments on this application.

Final determination: CMS is finalizing approval for device pass-through payment status for VasQ™ under the alternative pathway for devices that have an FDA Breakthrough Device designation.

(2) Traditional Device Pass-Through Applications

Alternative Pathway Device Pass-Through Applications	
Device	**CMS Determination**
Axoguard HA+ Nerve Protector™	Not approved because the technology does not meet the substantial clinical improvement criterion at §419.66(c)(2).
LithoVue™ Elite System	Not approved because the technology does not meet the device category eligibility criterion at §419.66(c)(1).
VersaVue™ Single-Use Flexible Cystoscope	Not approved because the technology does not meet the substantial clinical improvement criterion at §419.66(c)(2).

(a) Axoguard HA+ Nerve Protector™.[34] Applicant: Axogen Corporation

Per the applicant, the Axoguard HA+ Nerve Protector™ is a porcine small intestinal submucosa (SIS) decellularized extracellular matrix (ECM), with a dry coating of sodium hyaluronate and sodium alginate applied to both sides of the device that forms a thin layer of lubricous hydrogel when hydrated. It is designed to be a protective interface between the nerve and the surrounding tissue to minimize the potential for soft tissue attachments and tethering that restricts the nerve's ability to glide and move through the tissue structures during anatomic movement.

[33] Please refer to the online application posting for VasQ™, available at https://mearis.cms.gov/public/publications/device-ptp/DEP2405312T1JR

[34] Please refer to the online application posting for the Axoguard HA+ Nerve Protector™, available at https://mearis.cms.gov/public/publications/device-ptp/DEP240830YUKGT

In the proposed rule, CMS did not express strong concerns related to the eligibility criteria. CMS expressed its belief, however, that the Axoguard HA+ Nerve Protector™ may be appropriately described by C1763 and C1765. Additionally, CMS expressed several concerns related to whether the nominated device represents a substantial clinical improvement and indicated that additional supporting evidence would help the agency make a determination. Finally, CMS indicated its belief that the Axoguard HA+ Nerve Protector™ met all three cost significance requirements.

Comment/Response: CMS did not receive any comments related to eligibility, however, based on its review of the application, CMS has determined that the Axoguard HA+ Nerve Protector™ meets the eligibility criteria at §419.66(b)(1)-(4). The applicant submitted comments in response to CMS' concern that the Axoguard HA+ Nerve Protector™ may be appropriately described by C1763 and C1765, explaining the differences between the nominated device and devices described by the codes. In response, CMS continues to believe that C1763 and C1765 may describe Axoguard HA+ Nerve Protector™. With regards to demonstrating substantial clinical improvement, the applicant expressed an understanding of the importance of this criterion and its commitment to providing substantiating data. The applicant states that it is currently conducting an ongoing trial, and that although the study is not complete, the preliminary data demonstrate positive outcomes for patients. The applicant stated that it believes that the nominated device meets the substantial clinical improvement threshold, given its novel mechanism addressing unmet need for recurrent nerve compression injuries. In response, CMS expresses appreciation for the additional information, however, the agency continues to maintain some of its concerns, including lack of comparative data. For the reasons discussed in more detail in the proposed and final rules, CMS does not believe that the Axoguard HA+ Nerve Protector™ represents a substantial clinical improvement relative to existing therapies currently available.

Final determination: After consideration of the public comment and its review of the device pass-through application, CMS is not approving the Axoguard HA+ Nerve Protector™ for transitional pass-through payment status for 2026 because the technology does not meet the substantial clinical improvement criterion at §419.66(c)(2).

(b) LithoVue™ Elite Digital Flexible Ureteroscope System with Pressure Monitoring (the LithoVue™ Elite System).[35] Applicant: Boston Scientific Corporation

Per the applicant, the LithoVue™ Elite System consists of a single-use, disposable flexible ureteroscope (the LithoVue™ Elite Ureteroscope) and a workstation (the StoneSmart Connect Console), that provide real-time intraluminal pressure monitoring in the kidney and ureter during ureteroscopy and can be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract. The applicant stated that the distal tip of the LithoVue™ Elite Ureteroscope's shaft includes the working channel, the illumination optics, the digital imaging sensor, and a Micro-Electro-Mechanical Systems (MEMS) pressure sensor for monitoring the real-time intraluminal pressure during ureteroscopy. The applicant is only seeking

[35] Please refer to the online application posting for the LithoVue™ Elite Digital Flexible Ureteroscope System with Pressure Monitoring, available at https://mearis.cms.gov/public/publications/device-ptp/DEP2503038TF22

a new device category for transitional pass-through payment status for the LithoVue™ Elite Ureteroscope, a component of the LithoVue™ Elite System.

In the proposed rule, CMS questioned whether the LithoVue™ Elite System met eligibility criteria—in particular, whether the MEMS pressure sensor is integral to the service and whether there is sufficient evidence to support the assertion that continuous pressure monitoring is necessary and/or required to furnish or deliver the primary procedure (ureteroscopy) with which it is used. With regards to establishing a new device category, CMS indicated its belief that the LithoVue™ Elite could be appropriately described by C1747. Further, CMS expressed concerns related to substantial clinical improvement. Finally, CMS noted its belief that the LithoVue™ Elite Ureteroscope met all three cost significance requirements.

Comment/Response: A few commenters expressed support for approval of a pass-through payment for the nominated device while a few others indicated they did not believe that the applicant provided sufficiently robust, peer-reviewed evidence to demonstrate a clear benefit to patient outcomes over existing ureteroscopes. The applicant asserted that the MEMS pressure sensor is an intrinsic part of the LithoVue™ Elite Ureteroscope because it is not detachable, and this feature allows for fewer complications associated with high (and unchecked) intrarenal pressure (IRP) during ureteroscopy. By contrast, a few commenters agreed with CMS and stated they did not believe that the MEMS pressure sensor is integral to the procedures listed in the application, and that the utility of the sensor remains theoretical. In response, CMS notes that while the agency maintains its concern regarding the overall utility of the MEMS pressure sensor, CMS does agree with the applicant that the LithoVue™ Elite Ureteroscope, inclusive of the MEMS pressure sensor, meets the eligibility criterion because the MEMS pressure sensor is not a detachable or an adjunctive component to the ureteroscope itself.

With regards to CMS' concern that the LithoVue™ Elite Ureteroscope may be appropriately described by C1747, the applicant stated that the C1747 descriptor is over-broad and does not include the nominated device's key pressure-sensing feature. By contrast, a few commenters agreed with CMS' assessment, stating the device is already being used under C1747 and thus the nominated device has already benefited from transitional pass-through status for single-use ureteroscopes. In response, CMS disagrees with the applicant that the IRP monitoring capabilities merit a new pass-through device category. CMS continues to believe that C1747 appropriately describes the LithoVue™ Elite Ureteroscope, and agrees that the nominated device has already benefited from transitional pass-through status as a result.

Final Determination: After consideration of the public comments and its review of the application, CMS has determined that the LithoVue™ Elite Ureteroscope meets the eligibility criterion at §419.66(b)(1)-(4). However, CMS concludes that the LithoVue™ Elite Ureteroscope does not meet the device category eligibility criterion to be considered as a device for transitional pass-through payment. Therefore, CMS is not approving the LithoVue™ Elite Ureteroscope for transitional pass-through payment status for 2026 because the technology does not meet the device category eligibility criterion at §419.66(c)(1).

(c) VersaVue™ Single-Use Flexible Cystoscope.[36] Applicant: Boston Scientific Corporation.

Per the applicant, the VersaVue™ Single-Use Flexible Cystoscope is used in cystoscopy procedures to diagnose or treat diseases of the lower urinary tract. According to the applicant, this device is a single-use, disposable flexible cystoscope intended to be operated with the VersaVue™ Tablet or the VersaVue™ Video Box that provides live imaging of the lower urinary tract.

In the proposed rule, CMS expressed several concerns regarding whether the VersaVue™ Single-Use Flexible Cystoscope met the substantial clinical improvement criterion—in particular, that the evidence submitted did not demonstrate improvement over other single-use, disposable, or reusable cystoscopes. CMS did not express concerns related to the eligibility criteria at §419.66(b)(1) to (4). CMS did not identify an existing pass-through payment category that describes the VersaVue™ Single-Use Flexible Cystoscope. CMS stated its belief that the VersaVue™ Single-Use Flexible Cystoscope met all three cost significance requirements.

Comment/Response: The applicant provided responses to concerns raised by CMS regarding whether the VersaVue™ Single-Use Flexible Cystoscope represents a substantial clinical improvement. Among other things, the applicant stated its belief that a comparison between the VersaVue™ Single-Use Flexible Cystoscope and other types of cystoscopes would not be relevant to the application, and that the evidence provided was intended to demonstrate substantial clinical improvement in support of the category of single-use cystoscopes compared to reusable cystoscopes. The commenter points to other decisions and discussions by CMS in the past (in particular, for Uretero1™ (87 FR 71932)) that the applicant believes supports its position. The commenter provided additional responses to other concerns raised by CMS (such as critiques and concerns related to specific studies submitted as evidence, and other matters) which can be viewed in more detail in the preamble of the final rule.

In response, CMS maintains its concerns. CMS notes, in accordance with the regulatory provision, that the agency's expectation is that the specific device demonstrate a substantial clinical improvement. CMS notes that in the case of Uretero1™, CMS explained its evaluation of the evidence submitted which led to its conclusion that the device met criteria, and that the evaluation cannot be compared because CMS evaluates the evidence submitted for each device pass-through application as it applies to each nominated device. CMS reiterates its concerns related to the evidence submitted and specific aspects of certain studies. Further, CMS does not believe it is sufficient to simply argue that the elimination of risk must result in a substantial clinical improvement, especially if the risk itself is small. Moreover, CMS states that inferences derived from submitted evidence in this case does not establish substantial clinical improvement. Finally, CMS disagrees with the assertion that the agency's acceptance or approval of previous applications controls the outcome of its evaluation of evidence for this one, due to inherent differences in the devices themselves and the evidence submitted.

[36] Please refer to the online application posting for the VersaVue™ Single-Use Flexible Cystoscope, available at https://mearis.cms.gov/public/publications/device-ptp/DEP250211C4HRV

Final determination: After consideration of the public comment and its review of the application, CMS continues to believe that VersaVue™ Single-Use Flexible Cystoscope meets the eligibility criteria §419.66(b)(1) to (4) and that there is no category that appropriately describes the nominated device (§419.66(c)(1)). CMS continues to believe that the evidence submitted for the VersaVue™ Single-Use Flexible Cystoscope application fails to demonstrate a substantial clinical improvement as required. Therefore, CMS is not approving the VersaVue™ Single-Use Flexible Cystoscope for transitional pass-through payment status for 2026 because the technology does not meet the substantial clinical improvement criterion at §419.66(c)(2).

(d) Other comments

In this section of the final rule, CMS summarizes additional comments it received related to the agency's device pass-through payment policies. Multiple commenters expressed support for the OPPS transitional device pass-through payment pathway and highlighted the important role the program plays in the treatment of Medicare beneficiaries. Some commenters recommended CMS make changes to the method it uses to calculate the device-related portion of APCs for purposes of determining transitional pass-through payment status eligibility and the device offset. Commenters asserted that the refinement of the device offset calculation would ensure a more accurate and fair evaluation of device costs and reduce unnecessary barriers for a procedure to perform safely and successfully. Others recommended changes to the regulatory language, for example, removing the requirement that a device be "surgically inserted or implanted." Multiple commenters requested updates to the device offset amounts for existing device category codes and provided comments on devices that were not under consideration for device pass-through payment status for 2026.

In response, CMS expresses its appreciation for these comments and the ongoing support of the device pass-through payment program. CMS notes that while many of the comments were out of scope, the agency will continue to consider these recommendations, including issues related to the methodology for calculating the device-related portion of APCs for the purpose of determining the transitional pass-through payment status eligibility and the device offset of a nominated device.

B. Device-Intensive Procedures

1. Background

Prior to 2017, under the device-intensive methodology, CMS assigned device-intensive status to all procedures requiring the implantation of a device that were assigned to an APC with a device offset greater than 40 percent and, beginning in 2015, that met certain criteria. Historically, the device-intensive designation was at the APC level and applied to the applicable procedures within that APC. For reasons discussed in more detail in the preamble, in 2017, CMS changed its methodology to assign device-intensive status at the individual HCPCS code level rather than at the APC level. Under this policy, a procedure could be assigned device-intensive status regardless of its APC assignment, and device-intensive APC designations were no longer applied under the OPPS or the ASC payment system.

Under CMS' existing policy, procedures that meet the criteria listed below are identified as device-intensive procedures and are subject to all the policies applicable to procedures assigned device-intensive status under CMS' 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 in the proposed rule).

2. Proposed Device-Intensive Procedure Policy

In the 2019 OPPS/ASC final rule,[37] CMS finalized that device-intensive procedures would be subject to the following criteria:

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

Beginning in 2019, 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 to 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 (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets;[38] or (2) a material or supply furnished incident to a service.

CMS also finalized lowering the default device offset from 41 to 31 percent until claims data are available to establish the HCPCS code-level device offset. The device offset is used when CMS offsets the cost of the device from its payment such as when the hospital receives a device at no cost because the new device replaces a recalled device. CMS will continue temporarily assigning a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer, although CMS indicates this would happen very rarely.[39] Once claims data are

[37] 83 FR 58944-58948
[38] As defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1)
[39] Additional information for consideration of an offset percentage higher than the default can be submitted to outpatientpps@cms.hhs.gov. Additional information can be submitted prior to the issuance of an OPPS/ASC proposed rule or as a public comment to a proposed rule.

available for a new procedure requiring the implantation of a medical device, device-intensive status is applied to the code if the HCPCS code-level device offset is greater than 30 percent.

Beginning in 2025, for new HCPCS codes that describe a procedure that requires the implantation or insertion of a single-use device that meets the requirements of a device and that lacks claims data (from either the new HCPCS code or any predecessor code), 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 to both the OPPS and ASC payment systems and applies to new procedures assigned to clinical APCs, but not to new procedures assigned to New Technology APCs. Additionally, for procedures that cannot report modifier "CG" to bypass this claims processing edit, the device offset percentages calculated are based on hospital claims that reported a device code. Under this policy, CMS does not use claims data from procedures that had a status indicator of "E1" during the calendar year CMS is using for ratesetting and determining device offset percentages.

In the 2026 OPPS/ASC proposed rule, CMS proposed to continue these policies for 2026. If a device does not yet have associated claims data, information for CMS' consideration (such as pricing data or invoices) may be submitted to CMS prior to issuance of a proposed rule[40] or as a public comment in response to a proposed rule. Device offset percentages will be set in each year's final rule.

Comment/response: One commenter recommended CMS implement a nomination process for device-intensive procedures. In response, CMS indicates its belief that the current methodology is appropriate and does not see a need to create a nomination process at this time. Some commenters recommended that CMS modify its definition of device-intensive procedures to include non-insertable or implantable devices (such as histotripsy and skin substitute products). In response, CMS declines, noting its belief that the current ratesetting methodology adequately captures the costs for such items and services.

Commenters submitted a variety of comments related to specific codes. In response:

- CMS notes that CPT codes 0956T and 0960T were inadvertently omitted from the proposed list of device-intensive codes, although they were included in the ASC setting (in Addenda AA and FF), and **CMS is therefore accepting the commenter's recommendation** to include them.
- For CPT code 0202T, CMS notes it received one claim for 2026 OPPS/ASC ratesetting from 2024. Based on this one claim, CMS is assigning device-intensive status to the code. The final device offset percentage can be found in Addendum P to this final rule.
- For HCPCS code C9779, CMS notes that the device offset percentage is below the agency's threshold and therefore does not qualify for device-intensive for 2026.
- **CMS is establishing the device offset percentage for CPT codes 47384 and 55877** using the claims data from CPT code 0600T for 2026, as recommended by commenters. CMS

[40] Information should be directed to the Division of Outpatient Care, Mail Stop C4–01–26, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850, or electronically outpatientpps@cms.hhs.gov.

notes it inadvertently did not include the claims data from CPT code 0600T in the proposed rule.

- CMS is not accepting the commenters' recommendation to assign device-intensive status to CPT codes 52282 and 62287 for 2026 because the device offset percentages of the claims has not exceeded the device-intensive threshold of 30 percent.
- In response to commenter request, **CMS will assign a device offset percentage to the new lower extremity revascularization CPT codes** based on claims data from the predecessor codes. Mapping details are provided in the final rule preamble.

After consideration of the public comments, **CMS is finalizing** its proposed continued use of HCPCS code-level device-intensive determination and three criteria to designate device-intensive procedures. **CMS is also finalizing** its proposed continuation of the device-intensive procedure policy, proposed use of 2024 claims information for determining device offset percentages and assigning device-intensive status, and the agency's proposed default device offset policy for determining device offset percentages in the absence of claims data for device-intensive procedures.

The full listing of the final 2026 device-intensive procedures can be found in Addendum P to the final rule along with CMS' claims accounting narrative which contains a description of the agency's device offset percentage calculation; both can be found under supporting documentation for the final rule on CMS' website at https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.

3. Device Edit Policy

In this section of the preamble, CMS summarizes the historical development and modifications made to the agency's device edit policy. Beginning in 2015, CMS required any of the device codes used in device-to-procedure edits to be present on the claim whenever a procedure code assigned to any of the device-dependent APCs was reported on the claim. Beginning in 2017, CMS applies the device claims editing policy on a procedure level rather than APC level, consistent with its finalized policy to make device-intensive determinations at the HCPCS code level. In addition, CMS created HCPCS code C1889[41] to recognize devices furnished during a device intensive procedure that are not described by a specific Level II HCPCS Category C-code. Any device code, including C1889, when reported on a claim with a device-intensive procedure, will satisfy the edit requiring a device code to be reported on a claim with a device-intensive procedure.

In the 2025 OPPS/ASC final rule, CMS finalized a policy to apply its device edits policy permanently once a procedure is designated as a device-intensive procedure in a given year. Additionally, CMS finalized a policy to reinstate its device edits policy for procedures that have been device-intensive since CMS began assigning device-intensive status at the HCPCS code level on January 1, 2017. For 2026, under CMS' modified device edits policy, the agency's device edits

[41] Beginning in 2019, the description of HCPCS code C1889 is: "Implantable/insertable device, not otherwise classified."

requirement will apply to procedures that are designated as device-intensive in 2026 and will apply in subsequent years.

CMS proposed to continue its device edit policy for 2026.

Comment/response: Some commenters supported CMS' current policy. One recommended that CMS reinstate procedure-to-device edits, particularly for joint replacement procedures. In response, CMS declined to reinstate specific procedure-to-device edits for joint replacement procedures. Other commenters requested that CMS establish various C-codes. In response, CMS states it does not believe it would be appropriate to establish C-codes outside of the transitional pass-through approval process. Moreover, CMS believes that hospitals have sufficient experience in coding and reporting significant device costs correctly on hospital claims using the existing device category HCPCS C-codes and uncoded revenue codes. After consideration of comments, **CMS is finalizing its proposal to continue its device edits policy for 2026.**

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

CMS provides the history of policy development and modifications, beginning in 2007, related to OPPS payment when a hospital receives a device without cost or with full credit.

Currently, CMS reduces OPPS payment for device-intensive procedures by the full or partial credit a provider receives for a replaced device, when a hospital furnishes a specified device without cost or with a full or partial credit.[42] Hospitals report the amount of the credit in the amount portion for value code "FD" (credit received from the manufacturer for a replaced medical device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. CMS also 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.[43]

CMS proposed not to make any changes to its policies regarding payment for no cost/full credit and partial credit devices for 2026. The agency did not receive any public comment on this issue. Therefore, **CMS is finalizing its proposal to maintain its current policies regarding payment for no cost/full credit and partial credit devices for 2026.**

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.

[42] See: 2017 OPPS/ASC final rule (81 FR 79659 through 79660)
[43] See: 2014 OPPS/ASC final rule (78 FR 75005 through 75007)

Some drugs are policy packaged meaning they are always packaged into payment for the APC except when paid on pass-through. Policy packaged drugs and biologicals (as well as some medical supplies and devices furnished incident to a physician service) include:

- Anesthesia.
- Medical and surgical supplies and equipment.
- Surgical dressings.
- Devices used for external reduction of fractures and dislocations.
- Drugs, biologicals, radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure.
- Drugs and biologicals that function as supplies when used in a surgical procedure.

Other drugs are threshold packaged meaning that their per day costs must exceed a fixed threshold ($140 for drugs and biologicals other than radiopharmaceuticals and $630 for diagnostic radiopharmaceuticals in 2025) to be paid separately. For a separately payable drug that exceeds the packaging threshold, CMS will make payment at 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 using transitional pass-through payments.

A. Transitional Pass-Through Payment

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

Skin substitutes have been treated as devices and not drugs for transitional pass-through payment. However, in this final rule, CMS will treat skin substitutes that are approved under section 351 of the Public Health Service (PHS) Act as biologicals for Medicare payment purposes. Consistent with this policy, CMS will allow skin substitutes approved under section 351 of the PHS Act to be approved for pass-through payment as drugs. To effectuate this policy, CMS proposed to delete 42 CFR §419.64(a)(iv) that allowed transitional pass-through payment as a drug only for those biologicals that are not skin substitutes or similar products that aid wound healing. CMS is finalizing its proposal.

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 2026 and their designated APCs are assigned status indicator "G" in Addenda A and B of the final rule. For 2026, CMS is continuing to use ASP+6 percent as payment for transitional pass-through drugs and biologicals. CMS will be paying

for diagnostic and therapeutic radiopharmaceuticals receiving transitional pass-through payment at ASP+6 percent.

CMS approves transitional pass-through payments quarterly and expires pass-through payments in the calendar quarter that is not more than 3 years after payment was first made for the hospital outpatient service under Medicare. Table 104 of the final rule lists 28 drugs and biologicals where CMS will be expiring transitional pass-through payment by the end of 2025. Each of the products will have received the full 3 years of transitional pass-through payments once the additional payments expire. Table 105 of the final rule lists 52 drugs where CMS will end transitional pass-through payment status in 2026. Table 106 of the final rule lists 61 drugs and biologicals where CMS will continue transitional pass-through payment for all of 2026.

When policy-packaged or threshold drugs and biologicals are paid on transitional pass-through, CMS makes an offset to the APC payment for the cost of the predecessor drug products. For diagnostic radiopharmaceuticals that are paid on pass-through that would otherwise be packaged, CMS will apply a payment offset to the associated APC. No offset is required for a separately payable drug paid on transitional pass-through as there is no payment included in the APC for the drug.

In response to a comment, CMS clarified that diagnostic radiopharmaceuticals that would otherwise be packaged (e.g., per day costs below the diagnostic radiopharmaceutical packaging threshold) are not subject to coinsurance on their pass-through payments. However, radiopharmaceuticals that are separately paid (e.g., per day costs above the diagnostic radiopharmaceutical packaging threshold) and receiving transitional pass-through payment have a pass-through amount of $0. These products are not subject to any coinsurance on a pass-through payment of $0 but will be subject to coinsurance on the separately paid amount.

These commenters further indicated that MUC will be lower than ASP, WAC or AWP making it more likely that a beneficiary will have coinsurance on diagnostic radiopharmaceuticals without claims data as these products are more likely to have costs above the diagnostic radiopharmaceutical packaging threshold. The commenters requested that CMS treat all diagnostic radiopharmaceuticals as policy packaged for determining beneficiary coinsurance. CMS declined to adopt this suggestion indicating that its policy has been longstanding to use ASP, WAC or AWP to price drugs and biologicals and now diagnostic radiopharmaceuticals without claims data to determine a product's packaging and coinsurance status.

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 2026, 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 $630 and paying separately for diagnostic radiopharmaceuticals with per-day costs above $630. For 2026, CMS proposed to establish a packaging threshold of $655 for diagnostic radiopharmaceuticals.

The packaging threshold was initially set at $50 in 2005 for drugs, biologicals and therapeutic radiopharmaceuticals. To calculate the 2026 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 2026. CMS rounds the resulting amount ($141.67) to the nearest $5 increment ($140). Using the same methodology to trend the $630 threshold for diagnostic radiopharmaceuticals from the 3rd quarter of 2025 to the 3rd quarter of 2026, CMS determined a threshold of $654.23 rounded to the nearest $5 increment ($655).

Several commenters had concerns that the packaging threshold approach introduces financial and operational concerns when multiple packaged drugs are used during a procedure. Commenters recommended using a different inflation factor, maintaining the current threshold, or rolling back the threshold. CMS responded that the PPI update factor provides aggregate changes in the selling prices of pharmaceuticals making it appropriate for use to update the drug packaging threshold.

CMS proposed to continue using the following process to determine the 2026 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 2024 claims data processed through June 30, 2025, 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 2024 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 was used to pay for drugs and biologicals in physicians' offices during the 4th quarter of 2025. For products that do not have an ASP, other than diagnostic and therapeutic radiopharmaceuticals, CMS uses wholesale WAC or AWP pricing to determine the per-day cost. If neither of these is available, CMS uses MUC derived from 2024 hospital claims data.

For diagnostic and therapeutic radiopharmaceuticals that do not have pass-through status as of April 1, 2025, CMS is using mean unit cost derived from the 2024 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. For items other than diagnostic or therapeutic radiopharmaceuticals that did not have either an ASP-based payment rate, a payment rate based on WAC, or a payment rate based on AWP, CMS used the arithmetic mean unit cost of the items derived from the 2024 hospital claims data to determine their per day cost.

CMS proposed to package payment for products with a per-day cost of $140 or less ($655 for diagnostic radiopharmaceuticals) and pay separately for items with a per-day cost greater than $140 ($655 for diagnostic radiopharmaceuticals) in 2026.

CMS uses quarterly ASP updates as follows:

- 4th quarter of 2024: Per-day cost, budget neutrality estimates, packaging determinations, impact analyses, and Addenda A and B for the 2026 OPPS proposed rule.
- 2nd quarter of 2025: Per-day cost, budget neutrality estimates, packaging determinations, impact analyses, and Addenda A and B for the 2026 OPPS final rule.
- 3rd quarter of 2025: Payment rates effective January 1, 2026, for separately payable drugs and non-implantable biologicals (these are the same ASP data used to calculate payment rates effective January 1, 2026, for drugs and biologicals furnished in the physician office setting).

ASP-based payment rates for both the OPPS and physician office settings are updated quarterly using reported ASP data with a two-quarter lag, and these updates are available on the CMS website. CMS proposed to continue its policy of making an annual packaging determination for a HCPCS code in the OPPS final rule and not updating that code's packaging status during the year. Only HCPCS codes that are identified as separately payable in the 2026 final rule will be subject to quarterly updates.

As in past years, CMS proposed to apply the following policies to determine the 2026 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 2025 and were proposed for separate payment in 2026 are separately payable in 2026 even if the updated data used for the 2026 final rule indicates per-day costs equal to or less than the $140 threshold ($655 for diagnostic radiopharmaceuticals).
- HCPCS codes that are packaged in 2025, proposed for separate payment in 2026, and have per-day costs equal to or less than $140 ($655 for diagnostic radiopharmaceuticals) based on the updated data used for the 2026 final rule are packaged in 2026.
- HCPCS codes for which CMS proposed packaged payment in 2026 and have per-day costs greater than $140 ($655 for diagnostic radiopharmaceuticals) based on the updated data used for the 2026 final rule are separately payable in 2026.

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

For 2026, CMS proposed 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 107 of the final rule.

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

As indicated above, CMS proposed to pay for separately payable drugs and biologicals at ASP+6 percent in 2026. 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 on January 1, 2026. Payment rates effective January 2026 will be released near the end of December 2025 and will be based on ASP data submitted by manufacturers for the third quarter of 2025 (July 1, 2025, through September 30, 2025), or WAC+3 percent or 95 percent of AWP in that order 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, 2026.

Payment rates for drugs and biologicals in Addenda A and B of the final rule for which there was no ASP information available for the 2nd quarter of 2025 (used for payment in physicians' offices for the 4th quarter of 2025) are based on WAC, AWP or mean unit cost in the available 2024 claims data. If ASP information becomes available for the 3rd quarter of 2025 (used for payment in physicians' offices for the 1st quarter of 2026), CMS will pay for these drugs and biologicals based on the newly available ASP information. For diagnostic radiopharmaceuticals with a per-day cost over $655, the rate in Addenda A and B are based on mean unit cost in the 2024 data.

3. Biosimilar Biological Products

CMS pays for biosimilar biological products using policies that parallel those used for other drugs and biologicals with the 6 percent add-on to ASP based on the ASP of the reference product, not the ASP of the biosimilar. The 6 percent add-on is consistent with the statutory requirement in section 1847A of the Act that applies to drugs and biologicals furnished in physicians' offices. Beginning in 2024, CMS also adopted a policy to allow separate payment for a biosimilar when its per-day cost is below the packaging threshold if its reference product is paid separately.

Section 11403 of the Inflation Reduction Act establishes a temporary payment increase for qualifying biosimilars. Qualifying biosimilars are those with an ASP that is less than the ASP of their reference product. These biosimilars will be paid at their own ASP plus 8 percent of the reference product ASP for a 5-year period.

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

4. Invoice Drug Pricing Proposal for 2026

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 consistent with how these products are paid in physician offices. 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 for 2026 specifically for the purpose of this policy.

Before calculating an invoice-based payment amount, the Medicare Administrative Contractor (MAC) would use the provider invoice to determine that: (a) the drug is not policy-packaged and (b) the per-day cost of the drug, biological, therapeutic radiopharmaceutical or diagnostic radiopharmaceutical is above the threshold packaging amount. CMS proposed a minor change to the first criterion whereby CMS would make the determination that a drug is not policy packaged rather than the MAC.

One commenter indicated that by its very nature "invoice pricing" will not reflect post-sales price concessions. The commenter requested CMS clarify how to include post-sale price concessions in an invoice furnished to the MAC for payment. CMS provided a hypothetical numerical example for how a price concession would be offset from the full invoice cost of the drug. The response did not address the commenter's question of how to apply a price concession not yet received when submitting an invoice for payment to the MAC.

CMS is finalizing its proposal without change.

5. Payment Policy for Radiopharmaceuticals

Therapeutic Radiopharmaceuticals. For 2026, 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 2026 payment rates based on 2024 geometric mean unit cost. CMS does not use WAC or AWP to price therapeutic radiopharmaceuticals.

Diagnostic Radiopharmaceuticals. For 2026, CMS proposed to pay separately for diagnostic radiopharmaceuticals with a per-day cost above $655. CMS is basing the payment rate for separately payable non-pass-through diagnostic radiopharmaceuticals on mean unit cost data derived from hospital claims. CMS is considering pricing separately payable diagnostic radiopharmaceuticals using ASP in the future if valid ASP data is reported.

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

6. Payment for Blood Clotting Factors

CMS proposed to continue paying for blood clotting factors at ASP+6 percent and proposed to update the $0.258 per unit furnishing fee from 2025 by the Consumer Price Index for medical care for 2026. Following longstanding practice, CMS will announce the updated fee through program instructions once it is available and will post the updated rate on the CMS website at: https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price.

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

CMS proposed to continue the same payment policy in 2026 as in earlier years for non-pass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data. Because CMS has no claims data and must determine if these products exceed the per-day cost threshold, it estimates the average number of units of each product that would typically be furnished to a patient during one day in the hospital outpatient setting. CMS applies ASP+6 percent (or WAC or AWP as applicable) to determine their payment status indicators.

8. Reporting Discarded Amounts for Single-Use Package Drugs

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117-9, November 15, 2021) requires manufacturers to provide a refund to CMS for discarded amounts from a refundable single-dose container or single-use package drug. This provision may impact hospital outpatient departments and ASCs. CMS advises interested parties to review the 2026 PFS rule for any policies on this issue.

9. 340B Acquired Drugs Recoupment Adjustment

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 (GAO) 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 in 2018. This adjustment remained on the rates and was not updated for changes to utilization for 340B drugs.

- On December 27, 2018, the District Court concluded that the Secretary lacked authority to bring the default rate in line with average acquisition cost.[44] While the initial decision applied only to CMS' 2018 policy, the District Court later made the same finding for CMS' 2019 policy.[45] The policy continued while CMS pursued its appeal.
- On June 15, 2022, the Supreme Court held that the Secretary may not vary payment rates for drugs and biologicals among groups of hospitals in the absence of having conducted a survey of hospitals' acquisition costs.[46]
- On September 28, 2022, the District Court vacated CMS' 340B reimbursement rate for the remainder of 2022 without requiring any offset for budget neutrality.[47] In response to this order, CMS changed its 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.[48]

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.[49]

From January 1, 2018 through September 27, 2022, hospitals received $10.6 billion less in payment for 340B acquired drugs using 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 in 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 CMS to do so. The two periods of time do not correspond because the District Court vacated CMS' reduction to payment for 340B acquired drugs on September 27, 2022, but CMS could not accomplish

[44] American Hospital Association v. Azar, 348 F. Supp. 3d 62 (D.D.C. 2018)
[45] Am. Hosp. Ass'n v. Azar, 385 F. Supp. 3d 1 (D.D.C. 2019)
[46] 142 S. Ct. 1896 (2022)
[47] See Am. Hosp. Ass'n v. Becerra, 18-cv-2084 (RC), 2022 WL 4534617
[48] Am. Hospital Ass'n v. Becerra, 18-cv-2084 (RC), 2023 WL 143337
[49] See 87 FR 71975. The original adjustment multiplied the OPPS conversion factor by 1.0319 (3.19 percent) so 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.

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[50] 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 including the additional coinsurance amount that beneficiaries would have paid such that hospitals do not need to seek payment of coinsurance from the beneficiary.
- 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 OPPS services beginning January 1, 2026, until such time as the full amount of the additional payment is recouped (estimated at 16 years).

Hospitals that enrolled in Medicare after January 1, 2018 and did not 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 scheduled to begin in 2026.

In the proposed rule, CMS reconsidered whether a 0.5 percentage point annual reduction for approximately 16 years restores hospitals to as close to the financial position they would have been in had the 340B drug policy never been implemented. With a shorter recoupment period, CMS believed relative hospital utilization of non-drug items and services will 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.

By beginning the decrease to non-drug item and service payments in 2026, there is already an 8-year delay between the first year of the OPPS 340B payment policy and the first year of the prospective offset. In addition, 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 notes that $7.8 billion being recouped includes neither an adjustment for inflation nor interest costs.

Accordingly, effective January 1, 2026, CMS proposed to revise the annual reduction to the OPPS update used to determine the payment amounts for non-drug items and services from 0.5 percent to 2 percent beginning in 2026. With this revision to the recoupment schedule, CMS estimates the total offset of $7.8 billion would occur over 6 years rather than 16 years. CMS also presented an

[50] 88 FR 77150

alternative in the proposed rule where the annual reduction to the update would be 5 percent beginning in 2026 with recoupment occurring over 3 years.

Most commenters opposed CMS' proposal to apply a -2.0 percentage point adjustment to the OPPS update in place of the -0.5 percentage point adjustment finalized in the 340B Remedy Rule. Public comments were made in the following areas:

Same update required under the IPPS and OPPS. One commenter indicated that under section 1833(t)(3)(C)(iv) of the Act, CMS is required to update OPPS rates by the same update that applies under the IPPS. CMS disagrees and indicates that the statute authorizes the same payment update (market basket less productivity) as the IPPS but authorizes other adjustments for budget neutrality that will make the annual changes to the IPPS standardized amount and the OPPS conversion factor different. Such adjustments will include changes to wage index, outliers, etc., and section 1833(t)(3)(C)(iii) of the Act that authorizes an adjustment to the OPPS conversion factor for outpatient documentation and coding. Any of these factors result in the effective change to the OPPS conversion factor and the IPPS standard amounts being different annually.

No Authority for "temporal symmetry" or "administrative convenience" when applying the budget neutrality offset. This commenter argues CMS does not have the authority to compress the recoupment window to align with the additional 340B remedy payments. Further, CMS ignores the disproportionate impact that a 2 percent annual reduction will have on hospitals that did not receive full remedy payments, including those with high Medicare Advantage penetration or limited exposure to the original 340B cuts.

CMS disagrees, arguing that no statute requires a policy in place only from 2018 through 2022 to continue affecting payment rates until 2040. On the second comment, CMS indicates that hospitals received the 3.19 percent increase from 2018 through 2022 regardless of whether they also were paid less for 340B-acquired drugs. Therefore, all hospitals will be subject to the recoupment adjustment other than those that enrolled on or after January 1, 2018.

340 Remedy Rule already rejected annual reductions greater than 0.5 percent annually. Commenters noted that the 340B Remedy Rule "properly reverses the increased payments for non-drug items and services to comply with statutory budget neutrality requirements while at the same time accounting for any reliance interests and ensuring that the offset is not overly burdensome to impacted entities" (88 FR 77179).

CMS agreed with the point regarding reliance interests and will delay the change in the recoupment adjustment from -0.5 percent to -2.0 percent points for an additional year. However, hospitals should anticipate that CMS will implement a larger adjustment (such as 2 percent or another adjustment greater than 0.5 percent) beginning in 2027.

Impact on Vulnerable Hospitals and Patients. One commenter indicated that CMS selected the 0.5 percent adjustment considering the potential impact on vulnerable providers and their communities, standard remedial principles and basic fairness. The commenter stated that CMS fails to account for these concerns by increasing the recoupment adjustment to 2.0 percent. Various other

comments indicated that CMS did not adequately consider the financial strain the proposed increased reduction would impose on hospitals that are already operating on tight margins.

CMS responded that it did not cite any of those rationales as the basis for rejecting a higher reduction rate in the 340B Remedy rule. Instead, the policy turned on the fact that a 0.5 percent reduction complies with budget neutrality requirements while accounting for reliance interests and burden on providers.

The agency indicates that it continues to be sensitive to the potential impact on vulnerable patients, their communities, and providers. The statute includes other provisions such as transitional outpatient payments to cancer and children's hospitals that insulate them from the payment impact of policies like these (88 FR 77181).

However, CMS also responds that the first of the increased payment amounts occurred in 2018, whereas the last of the recoupment amounts may not be until after 2030—in effect a more than 10-year loan without any attached interest.

Not Recovering No Fault Overpayments. One commenter stated CMS should forgo recovery where the individual for whom the incorrect payment was made was without fault under section 1870 of the Act. The commenter further argued that recoupment removes an incentive for the agency to engage in thoughtful, judicious and textually grounded rulemaking in compliance with the law. If Congress is dissatisfied with the outcome, it may intervene to change future payments.

CMS responded to similar comments in the 340B remedy rule (88 FR 77178). In summary, CMS does not believe section 1870 of the Act applies while section 1833(t) of the Act remains applicable and requires budget neutrality for the additional 340B remedy payments. Recoupment of the additional payments does not excuse statutory non-compliance on the part of the agency or provide a disincentive to the agency from seeking the best reading of the statute.

Insufficient Information to Comment. One linked the proposed offset to current drug pricing and indicated that there is no information in the proposed rule to suggest that drug pricing information was set based on survey data or a default to ASP+6 percent to justify the 2.0 percentage point offset for budget neutrality. The commenter claimed that this lack of transparency prevents meaningful comment and does not adequately explain the agency's authority to apply a budget neutrality adjustment. Another commenter indicated that there is insufficient opportunity to comment because many of the figures in the rule are characterized as estimates and there are discrepancies between the amounts paid for 340B drugs and being recouped through future payment adjustments.

CMS responded that the rule is clear that the proposed 2.0 percentage point offset was for prior 340B remedy payments, not any changes to its drug payment policy in the 2026 proposed rule. Therefore, CMS disagrees that it has provided insufficient information for comment. In response to the other comment, CMS responds that the statute does not preclude recoupment because figures are described as estimates and that any discrepancies between the amount paid for 340B drugs and the amounts being recouped were explained in the 340B remedy rule. The final rule reiterates the

explanation from the 340B remedy rule in response to this comment.

Recoupment adjustment is a punitive response to unlawful actions by CMS. Many commenters characterized the offset as being unfair for hospitals, penalizing them for mistakes or past unlawful actions by CMS. CMS responded that the adjustment is not a penalty but a rate adjustment that accomplishes an incremental and interest-free recovery of "windfall" payments to hospitals.

Combined impact of the adjustment with sequestration. The 2 percent recoupment adjustment combined with a predicted new sequestration adjustment could reduce OPPS payments by as much as 8 percent in 2026. CMS responded that the commenters are referencing unrelated statutory policies. CMS rejects the comment that other unrelated statutory policies should interfere with CMS' obligation to implement the OPPS budget neutrality provisions more expeditiously.

Other Adjustments. Nearly all commenters rejected a higher offset while many suggested lower offsets including no larger than 0.25 percent. CMS rejected these suggestions including doing the recoupment adjustment over a 40-year timeframe.

Exempt New Procedures. CMS exempts hospitals that enrolled after January 1, 2018 from the recoupment adjustment. Many commenters suggested CMS should exempt new procedures as well. CMS rejected comments to exempt new procedures from the recoupment adjustment, arguing that it would distort providers' incentives to prescribe items and services based on whether they existed between 2018 and 2022.

Appeals. Some commenters were concerned that CMS does not outline how hospitals can appeal the payment reduction on individual claims if they are dissatisfied with the recoupment adjustment. CMS responds that the normal appeals process would apply following the procedures outlined under section 1869 of the Act and its implementing regulations.

Medicare Advantage (MA). Commenters expressed concern that MA organizations have not made additional remedy payments to hospitals but their payments to hospitals may be subject to prospective reductions in payments for the recoupment offset when their contracts require payment based on Medicare fee-for-service rates. CMS responded that it calculated and paid 2018-2022 MA rates under the Advance Notice and Rate Announcement and those MA rates reflected the FFS policies as of the time they were finalized.

CMS' response indicates that it further establishes payment policies and payment rates for services payable under FFS through a separate, distinct process that is not directly related to the terms of private contracting arrangements between MA organizations and providers. Additionally, 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.

CMS is finalizing a 340B recoupment adjustment of -0.5 percentage points to the OPPS update and not the proposed -2.0 percentage point adjustment. However, it plans to use notice and comment

rulemaking to propose a -2.0 percentage point adjustment beginning in 2027.

The proposed rule indicated that revisions to the OPPS conversion factor can have an indirect impact on the ASC payment system. The device related portion of a device intensive APC paid under the ASC system is a pass-through to the OPPS before adding the non-device related portion that will be a percentage of the OPPS payment. If the OPPS conversion factor is reduced, the device related portion passed through to the ASC payment system will be less. However, the system is budget neutral meaning the non-device related portion will increase. Payment will be redistributed from device intensive procedures to non-device intensive procedures under the ASC payment system absent any other policy intervention.

CMS proposed not to apply the 2 percent reduction to the OPPS conversion factor when determining ASC payments to avoid this payment redistribution. The reduction to the OPPS payment rate is intended to place hospitals in as close to the financial position they would have been in had the 340B drug payment policy never been implemented. By contrast, CMS is not under any statutory requirement to pass through the reduction to the OPPS conversion factor to ASCs. Even though such a reduction would be budget neutral under the ASC payment system, CMS does not believe any policy purpose would be served by redistributing payment from device intensive services to other services resulting from an issue that has nothing to do with ASC payment.

Public commenters supported CMS' proposal. The proposal is being finalized as proposed.

10. 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.[51] For 2025, the AIR is $718 for the lower 48 states and $1,193 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 2024 AIR in the lower 48 states ($667 x 2 = $1,334). 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.

Beginning January 1, 2025, Medicare makes payment to IHS and tribal facilities for drugs with per days costs above $1,334 at ASP without the 6 percent add-on (or WAC or 89.6 percent of AWP in that order if ASP is unavailable). For 2026, CMS is updating the packaging threshold to be twice the 2025 AIR for the lower 48 ($718 x 2 = $1,436). Addendum Q of the 2026 OPPS Final rule will list drugs paid separately above the packaging threshold. ASPs for qualifying drugs will be updated quarterly. Public commenters supported this proposal that CMS is finalizing without change.

51 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.

11. Payment for Skin Substitutes

a. Background

In the 2014 OPPS final rule, CMS described skin substitutes as "a category of products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers" (78 FR 74930 through 74931). When a procedure utilizing a skin substitute product is performed, providers bill one or more HCPCS codes to describe the preparation of the wound, the use of at least one skin substitute product, and application of the skin substitute product through suturing or various other techniques. CPT codes 15271 through 15278 describe the application of skin substitutes to various size wounds and anatomical locations.

According to Medicare claims data, Part B spending for skin substitute products rose from approximately $250 million in 2019 to over $10 billion in 2024, a nearly 40-fold increase, while the number of patients receiving these products only doubled. Increases in payment rates and launch prices for skin substitutes, especially newer products, account for most observed Medicare spending increases on these products. The U.S. Department of Health and Human Services' Office of the Inspector General announced in November 2024 plans to review Medicare Part B claims for skin substitutes.

On April 25, 2024, the MACs released proposed Local Coverage Determinations (LCD) to limit Medicare coverage for skin substitute grafts used for chronic non-healing diabetic foot and venous leg ulcers to those that are supported by evidence showing the product is reasonable and necessary. The LCDs were finalized in November 2024 with a February 12, 2025 effective date. The effective date of these LCDs was delayed by CMS until January 1, 2026 (see CMS Statement on Local Coverage Determination for Certain Skin Substitute Grafts | CMS).

In the 2023 PFS proposed rule (87 FR 46249), CMS established the following objectives for its skin substitute policy: (1) ensuring a consistent payment approach across settings; (2) ensuring appropriate HCPCS codes; (3) employing a uniform benefit category and consistent payment methodology for synthetic, human or animal-based material; and (4) promoting clarity for stakeholders. Stakeholders have expressed concern about inconsistencies in payment and coding for skin substitute products and across non-facility settings and the hospital outpatient department.

The high growth in spending and concern about program integrity has led CMS to believe its existing payment policies are unsatisfactory, unsustainable over the long term, and rooted in historical practice established two decades ago prior to significant evolutions in medical technology and practice. CMS has developed a proposal to address its stated objectives and the many comments on this topic it has received.

b. Medicare Part B Payment for Skin Substitutes

CMS has historically treated skin substitutes as biologicals for Part B payment in the non-facility setting. As these products are treated as biologicals, each product receives its own unique code and

is paid based on ASP+6 percent. In the 2022 PFS rule (86 FR 65120), CMS established a policy where synthetic skin substitute products would be assigned an A code and treated as a separately payable medical supply rather than a biological.

Under the OPPS, CMS has been packaging skin substitutes as drugs and biologicals that function as supplies when used in a surgical procedure since 2014. The packaging methodology divides skin substitutes into high- and low-cost groups to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures. Skin substitutes assigned to the high-cost group are billed with HCPCS codes 15271, 15273, 15275 and 15277. Skin substitutes assigned to the low-cost group are billed with HCPCS codes C5271, C5273, C5275 and C5277. HCPCS codes are assigned to APCs as follows in 2025:

APC	HCPCS	2025 Payment Rate
5053 (Level 3 Skin Procedures)	C5271, C5275, C5277	$612.13
5054 (Level 4 Skin Procedures)	C5273, 15271, 15275,15277	$1,829.23
5055 (Level 5 Skin Procedures)	15273	$3,660.97

CMS determines the high-cost/low-cost status for each skin substitute product based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold, or the product's per-day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold. Once a product has been assigned to the high-cost group, CMS has maintained that assignment in future years regardless of its MUC or PDC.

New skin substitutes without pricing information are typically assigned to the low cost group until pricing information is available to compare to the MUC and PDC thresholds. However, CMS has only applied this policy for new skin substitutes with J codes. New skin substitutes with A codes are always assigned to the high-cost group.

c. Current FDA Regulation of Products CMS Considers to be Skin Substitutes

The FDA regulates products that CMS considers to be skin substitutes based on a variety of factors, including product composition, mode of action, and intended use. The proposed rule described the various regulatory pathways under which a skin substitute may be approved: as human cells, tissues, and cellular and tissue-based products (HCT/Ps) regulated under section 361 of the PHS Act; as medical devices that receive a premarket approval (PMA); a De Novo classification or 510(k) approval; or biologicals licensed under section 351 of the PHS Act.

Of these, CMS proposed that only skin substitutes approved as biological under section 351 of the PHS Act would be treated as biologicals for Medicare Part B payment at ASP+6 percent (or WAC+6 percent or 95 percent of AWP if ASP is unavailable). Skin substitutes approved under other FDA regulatory pathways would be considered incident-to supplies.

Some commenters agreed with CMS' proposal to pay skin substitutes as incident-to supplies except for those that have BLA. Other commenters stated that CMS' proposal to narrow the definition of

"biological" to only include products licensed under section 351 of the PHS conflicts with section 1861(t)(1) of the Act. Section 1861(t)(1) of the Act defines drugs and biologicals to include products listed in the U.S. Pharmacopoeia or approved by hospital P&T committees. Skin substitutes, including section 361 products, meet this definition of "biological" according to the commenter.

CMS disagreed, indicating that section 1861(t)(1) of the Act does not require all "products" be included in the definition of drugs and biologicals but is narrower to include "only such drugs and biologicals" in its definition (implying that skin substitutes are supplies and not "such drugs and biologicals"). The response further indicates that the compendia referenced in the statute are outdated with only one continuing to be published. With some exceptions, the compendium no longer publishes product specific monographs. For this reason, CMS will rely on section 1847A of the Act to authorize payment for "products described therein" (*e.g.*, drugs and biologicals).

One commenter indicated that continuing to pay for the few BLA-approved products using ASP+6 percent while moving all others to a flat rate would create a perverse incentive for the manufacturers of biologicals to continue increasing prices. CMS responded that opportunities for rapidly increasing prices for BLA skin substitute products will be curtailed by the longer time required to bring these products to market, potential rebate requirements, and new ASP reporting requirements finalized in the 2026 PFS rule (see section III.A. 2 of the 2026 PFS final rule).

Many commenters reported various provider abuses of skin substitutes including use in clinically questionable circumstances by third-party mobile wound clinics that operate without coordination with the patient's primary care team, using higher-cost products regardless of patient need, launching clinically undifferentiated products at very high prices, and use on vulnerable and terminally ill patients, including those in hospice, where such treatment is inappropriate.

Other commenters indicated that the tremendous spending growth for skin substitutes can be attributed to a few providers. These commenters suggested CMS should focus on program integrity efforts rather than the broad policy change it has proposed. In addition to targeted enforcement, these commenters recommended site accreditation through a self-regulatory organization (SRO) to verify adherence to standard of care, documentation protocols, and product handling, analogous to durable medical equipment and Clinical Laboratory Improvement Act accreditation models. CMS agrees that not all increased use of skin substitutes is improper and is implementing a coordinated effort across the Center for Medicare, the Center for Clinical Standards and Quality, and the Center for Program Integrity to address this issue.

Several commenters raised concerns about ACOs being disproportionately impacted by skin substitute billing compared to the national trend. They recommended that CMS address this high utilization through the Significant, Anomalous, and Highly Suspect (SAHS) billing activity policy—when billing of one or more HCPCS or CPT codes represents significant, anomalous, and highly suspect billing activity for a calendar year that warrants adjustment to ACO calculations.

CMS assessed the impact of an increase in billing to Medicare for skin substitutes and determined

that the billing activity for these services does not represent SAHS billing activity for Performance Year 2024. Payments that are not excluded under the SAHS policy are also reviewable at the ACOs' request if improper payments are identified after the initial determination is made under the reopening policy (42 CFR 425.315). The response further indicates that the impact on ACOs of large growth in skin substitute expenditures is mitigated by CMS' truncation policy that minimizes variation in costs from catastrophically large claims.

CMS is finalizing its proposed policy to limit payment as a biological to those skin substitutes that are approved as a biological product under section 351 of the PHS Act.

d. Payment of Skin Substitute Products under the PFS and OPPS

(i) Separate Payment for Skin Substitute Products as Incident-To Supplies

Beginning January 1, 2026, CMS proposed to pay for skin substitutes as separately payable supplies under the OPPS when used during a covered application procedure. This policy would not apply to biologicals licensed under section 351 of the PHS Act which will continue to be threshold packaged or separately paid using ASP+6 percent.

CMS considered bundling payment for skin substitutes in both the PFS and OPPS but decided it would be premature before efforts are made to address improper utilization patterns. However, CMS may consider packaging skin substitute products with the related application procedures in both the hospital outpatient setting and non-facility setting in future rulemaking.

Under CMS' proposal, the payment for skin substitutes would no longer be packaged into the administration procedures under the OPPS, when performed in the outpatient hospital setting. CMS proposed to delete HCPCS codes C5271 through C5278 and retain HCPCS codes 15271 through 15278 for the application of all skin substitutes. As skin substitutes would no longer be packaged into HCPCS codes 15271 through 15278, the cost of these codes will be affected resulting in changes to their APC assignments. To make the APC assignments for HCPCS codes 15271 through 15278, CMS proposed to combine the existing claims data for these codes with HCPCS codes C5271 through C5278. HCPCS add-on administration codes 15272, 15274, 15276, and 15278 would still be packaged in the hospital outpatient setting.

CMS proposed analogous changes to its payments in the 2026 PFS proposed rule that will result in consistent payment across sites of service for skin substitutes. According to that proposed rule, this policy "would empower providers to make the best treatment decisions for their patients, ensure equitable access to needed services, and pay appropriately for these services."

One purpose of these proposals is to limit profiteering practices CMS has observed such as high launch prices, overuse of expensive skin substitute products, and waste resulting from use of more-expensive skin substitute products over clinically appropriate, less-expensive alternatives. The PFS and OPPS proposed rules indicated that it is unclear how high launch prices could be attached to realistic changes in resource costs as many of these new products are minimally manipulated

tissues. Further, CMS observes that payment growth under the OPPS has not been significant where payment is packaged with the application procedure as it has in the office setting where these products are paid separately as a biological.

Many commenters opposed classifying skin substitutes as supplies. They stated this classification is legally, clinically, and definitionally incorrect, as these products are the primary intervention, not an incidental part of a service.

CMS disagrees stating that because a skin substitute must be used to perform any of the application procedures described by a CPT code in the range 15271 through 15278, skin substitute products serve as a necessary supply for these surgical repair procedures. CMS is finalizing its proposal to pay separately for the provision of skin substitutes as incident-to supplies under the OPPS in the hospital outpatient department.

Many commenters expressed strong support for paying separately for skin substitutes under the OPPS rather than packaging them with the application codes. Other commenters opposed the move away from bundled payments. MedPAC, for example, did not support unbundling skin substitutes in the facility setting, arguing that paying for items separately undermines payment bundles, can lead to overuse, and shifts financial burden from providers to Medicare and its beneficiaries.

CMS acknowledges the concerns about unbundling but determined that it would be premature to bundle payment for skin substitute products with their administration procedures across both settings before efforts are made to address improper utilization patterns. Depending on the outcomes of this policy, CMS may consider packaging skin substitute products with the related application procedures in future rulemaking.

There were also comments concerned that a payment for the application procedure of approximately $150 in a non-facility setting and over $800 (combined facility and physician payment) will create a strong financial incentive to shift patient care to HOPDs. These commenters suggested CMS increase the application payment for clinicians in non-facility settings to close this gap. Other commenters were concerned about reassigning the application procedures to lower-paying APCs once the costs of skin substitutes are no longer packaged.

CMS acknowledged the disparities in the payment rates for the application codes between settings and is open to using OPPS data to set site-neutral payments in the non-facility sites. Regarding specific APC assignments for some of the skin substitute application procedures (HCPCS codes 15271-15278), these codes are now being assigned to lower paying APCs because they no longer include the cost of skin substitutes being paid separately. Table 113 illustrates that unpackaging the skin substitute results in costs for the application procedure being reduced by 47 percent to 53 percent.

CMS is finalizing its proposals to pay separately for skin substitute products under the OPPS and reassign the skin substitute application to APC 5054 and 5055 as shown in Table 113 of the final rule.

(ii) Payment Categories Based on FDA Regulatory Category

CMS proposed to group skin substitutes into one of three payment categories based on its FDA approval: section 361 HCT/Ps; devices requiring a 510(k) or De Novo approval; and devices requiring a PMA.

Section 361 HCT/Ps. These products are dressings intended only to cover and protect a wound. They are not intended to act on the wound to mediate, facilitate, or accelerate wound healing. Their activity is typically limited to that of a physical covering or wrap.

Devices with a 510(k) Clearance or De Novo Approval. A 510(k) clearance is for a device that is substantially equivalent to a legally marketed device and does not require premarket approval. Currently, 510(k)-cleared devices that CMS considered for this policy generally are dressings intended only to cover and protect a wound, to absorb exudate, and to maintain appropriate moisture balance within the wound. They are not intended to act on the wound to mediate, facilitate, or accelerate wound healing.

De Novo classification is a marketing pathway for medical devices for which there is a reasonable assurance of safety and effectiveness despite there being no legally marketed predicate device. CMS expects skin substitutes authorized through the De Novo pathway and a 510(k) clearance to be similar for purposes of its proposal.

Devices Requiring a PMA. Like BLA-approved wound care products, PMA-approved wound care products are intended to interact with the wound to facilitate, promote, or accelerate wound healing. Approval of these products requires demonstration of safety and efficacy for the intended use, which generally requires the performance of clinical studies. PMA-approved devices go through a much more rigorous review process before marketing compared to the substantial equivalence requirements for 510(k)s and lack of premarket review for registered section 361 HCT/Ps.

CMS proposed to create three new APCs:

1. APC 6000 (PMA Skin Substitute Products).
2. APC 6001 (510(k)/De Novo Pathway Skin Substitute Products).
3. APC 6002 (section 361 HCT/P Skin Substitute Products).

Three new unlisted C-codes were also proposed—one in each category—for new skin substitute products that have received FDA approval or clearance but do not yet have their own code. CMS has made a file available on the 2026 PFS final rule website that shows each skin substitute code and its FDA regulatory category at: https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices/cms-1832-f. The file is the listed at the end under "Downloads."

CMS proposed that new skin substitutes may continue to receive pass-through payment. Under CMS' proposal, skin substitutes with an approved BLA would be considered under the drug pass-

through payment criteria while skin substitutes with a PMA or 510(k) clearance would be evaluated under the device pass-through criteria.

Many commenters supported grouping skin substitutes based on their FDA regulatory categories while others opposed the proposal, stating that regulatory status does not correlate with clinical effectiveness, outcomes, or resource use. These commenters indicated that products approved under the PMA pathway are not necessarily superior to 510(k) products which may represent technological advancements, include improved materials and design, are evidence based on real-world data, and have improved usability and safety features. Other commenters stated that establishing payment based on regulatory pathways creates potential for instability over time because FDA pathway choice is not voluntary—the FDA determines which pathway is appropriate for which product.

CMS responded that the FDA's regulatory framework provides an objective and consistent basis on which to group these products for purposes of developing payment rates. Each regulatory pathway is distinct and provides a specific level/type of information regarding product content and activity that CMS can leverage to inform payment rate decisions. The agency indicates that 510(k) or HCT/P products do not act on the wound to mediate, facilitate, or accelerate wound healing. They are dressings intended only to act as a physical cover to protect a wound, to absorb exudate, and to maintain appropriate moisture balance within the wound. Wound care products intended to interact with the wound to facilitate, promote, or accelerate wound healing generally require a BLA or a PMA when it meets the statutory definition of a device. The FDA approval pathway is informed, in part, by a sponsor's desired indications and ability to prove them. For all these reasons, CMS believes the FDA regulatory category provides a sufficient basis for establishing different payment categories under the PFS.

Several commenters emphasized that CMS should acknowledge post-FDA clinical investment as a basis for changing a product's payment category. Such a policy would avoid disincentives to further develop clinical evidence and would incent innovation of improved skin substitute products. CMS encourages entities that have made investments in clinical research to work with the FDA to determine if these studies are sufficient to support approval or clearance through a different FDA regulatory pathway that a product initially received.

CMS is finalizing its proposals to:

- Group skin substitutes (other than those with a BLA approval) into three categories: PMA, 510(k) and section 361 HCT/Ps for purposes of developing Medicare payment rates and assigning them to one of three clinical APCs based on their FDA regulatory category.
- Approving transitional pass-through payment for skin substitutes (other than those with a PMA approval) under the device transitional pass-through payment pathway.
- Create three new unlisted codes (HCPCS codes Q4431-Q4433) to describe skin substitute products that are FDA authorized or cleared but have not yet received a specific individual HCPCS or CPT code.

(iii) Alternative Payment Categories

CMS considered aligning skin substitutes in payment groups based on their composition such as non-synthetic or synthetic. However, CMS indicated that skin substitutes are a heterogenous group with an increasing intersection between tissue, bioengineered, and synthetic components.

It also considered grouping all products together to set a single payment rate or creating two or more categories reflecting product cost. However, CMS rejected this idea because of the financial incentive to use the least expensive skin substitute or the product offering the greatest discount, which could negatively affect patient outcomes and discourage innovation and would still rely on pricing set by manufacturers.

CMS requested comments on adding subcategories to the three proposed FDA categories based on, for example, FDA device product codes, the number of tissue layers (for example, one layer, two layers, and three or more tissue layers) or if a product is entirely synthetic or non-synthetic. If significant clinical or resource differences were identified between products in one or more of these categories, CMS could create a separate payment grouping for these products for payment purposes.

Many commenters advocated establishing a single payment rate for all non-BLA skin substitutes to encourage product selection based on clinical evidence and patient need rather than on which category receives the highest reimbursement. CMS responded that differentiation of the products will better ensure access to products in each group. CMS also asserted that a flat payment rate also reduces the incentive to innovate, perform relevant studies, and seek an FDA approval requiring proof of wound treatment or healing.

Public commenters provided a variety of alternative payment categories to the ones proposed by CMS based on product technology, clinical evidence, composition, the availability of evidence from randomized clinical trials, and FDA label. CMS found these alternatives to be administratively difficult as well as finding it unclear if they were a basis for differentiating based on resource or clinical similarity. CMS maintained that the FDA approval pathway is a sufficient basis to determine payment category and CMS does not need to replicate the FDA's existing functions for purposes of Medicare payment determinations.

Products that are not in sheet form (gel, powder, ointment, foam, liquid, or injected products listed in the nontraditional units of cc, mL, mg, and cm^3) are not currently used in conjunction with the CPT administration codes in the range 15271 through 15278. CMS requested comments on whether other administration codes could be used to appropriately describe services performed using products with units other than cm^2.

One commenter recommended CMS include non-sheet product forms in the definition of skin substitutes eligible for separate payment as they offer additional treatment options for irregularly shaped or tunneling wounds. One commenter recommended that CMS not pay separately for non-sheet products as skin substitutes as that could introduce gaming opportunities if these products are paid differently than skin substitute products that can be billed per square centimeter.

CMS responded that it is important to maintain access to non-sheet products performing similar functions to sheet skin substitutes in cases where application of these products is part of reasonable and necessary care. These products have the potential to be payable as skin substitutes but present difficulties for product coding and standardizing for payment purposes. CMS will maintain the current coding mechanisms for these products and MAC pricing.

Several commenters requested that CMS formally define "skin substitutes" and provided suggested definitions. CMS responded that a formal definition of skin substitutes could prematurely and unnecessarily limit an evolving category of products.

(iv) Establishing Initial Payment Rates

The proposed payment for skin substitutes for each group wase based on the volume weighted per unit ASP from the 4th quarter of 2024 without the 6 percent add-on or mean unit cost when ASP was not available.

Some commenters requested prioritizing use of ASP as it is more reliable than MUC to determine payment rates. These commenters noted ASP is being reported but not used in some situations. CMS agreed that it is preferable to use ASP but did not include the ASP weighted average calculation for some products because of concerns that some manufacturers classified certain costs as bona fide service fees rather than price concessions, artificially inflating the ASP. The response indicates that CMS needs an alternative to ASP as it cannot expect that all manufacturers of skin substitute products will continue to report ASP data to CMS each quarter. CMS believes that MUC is a reasonable alternative to ASP that CMS has used in pricing in other situations. Application of cost-to-charge ratios to hospital charges will account for variations in hospital markup.

A few commenters expressed concern that using ASP without a 6 percent add-on removes appropriate overhead and handling costs. CMS noted that overhead costs related to application of these products are included in the facility fees or PE RVUs for the application procedures. The response notes that the 6 percent add-on could be excessive. A recent Office of the Inspector General report found that, in the third quarter of 2024, a typical beneficiary received 82 units of skin substitutes, meaning that the typical $74 add-on amount per unit alone was worth over $6,000 per patient. Hospitals have been managing these products without a separate markup for years through packaged payments.

Several commenters requested that CMS not use ASP from prior to the 4th quarter of 2024 as that data reflects dramatic price increases. Other commenters requested using more recent data that reflect real time market conditions. While CMS agreed with the first comment about using 4th quarter 2024 data including dramatic price increases, it is using more recent data to reflect many new products that might represent quality additions to the market.

CMS is finalizing its proposal to establish PE RVUs and initial payment rates for skin substitute products in each of the three FDA regulatory categories using ASP, or MUC when ASP is not available from the 4th of 2024 as proposed.

CMS initially determined the weighted average per unit ASP using utilization from both the hospital outpatient department and physician office settings. However, the result produced a rank order anomaly with the PMA category having the lowest average payment.

For this reason, CMS proposed to use data from the outpatient department only and establish a single payment rate for all three categories. CMS justified using only outpatient hospital data on the basis that non-facility utilization reflects problematic incentives and is not reflective of expected resource costs. As the outpatient hospital data is reflective of products grouped in either the high- or low-cost categories, hospitals have incentives to choose either the lowest-cost, clinically appropriate product in the low-cost group or the lowest-cost, clinically appropriate product in the high-cost group making it more reliable for pricing purposes.

While MedPAC and other commenters supported using data from the hospital outpatient department only to weight pricing, the majority of commenters strongly opposed the exclusion of physician office data on the basis that:

- It is unreasonable to exclude the majority of data from the predominant site of service,
- The OPPS data distorts utilization by creating disincentives to treat larger wounds,
- Hospitals can negotiate lower prices through group purchasing organizations unavailable to smaller physician purchasers, and
- Using data from one site only is inconsistent with the goal of a consistent payment approach across settings.

These commenters recommended CMS use data from both the physician office and hospital outpatient settings but that the agency trim outlier data or use data from an earlier year that does not reflect distorted utilization patterns.

CMS reiterated its proposed rule rationale for using data from the hospital setting only. Once updated data reflects CMS' pricing policy, CMS plans to use all relevant products and the combined product utilization patterns (OPPS and non-facility) to determine a weighted average per-unit cost by category to set separate payment rates for each of the three categories. CMS is finalizing its proposal to use hospital outpatient utilization data to weight ASP prices to determine the initial skin substitute rate.

CMS proposed to use the highest of the calculated volume-weighted average payment amounts in each category for the initial valuation. The initial payment will be based on the weighted per unit cost of the section 361 HCT/P category. In the future, CMS intends to update pricing using claims data and expects pricing in each of the categories to diverge.

The proposed calculation methodology resulted in an initial payment rate of $125.38 for all three proposed new APCs based on the FDA categories including PMA-approved devices, section 361 HCT/Ps, and 510(k) devices. For comparison, if CMS used the volume weighted per unit ASP for all four quarters of 2024 rather than just the fourth quarter, the rate would be $114.87. Using a

pooled payment rate across all three categories would result in a rate of approximately $65.85, while splitting the categories to pay the PMA category using the combined product utilization patterns and the 510(k) and section 361 HCT/P categories using the OPPS utilization patterns would result in rates of approximately $259.47 and $125.38 respectively.

As a possible alternative, CMS considered setting the payment rate for the PMA category using data for the facility and non-facility settings as there has not been as much growth in the number of products approved as PMA and this category may not have costs that are as distorted as the other two. Setting a separate payment rate for this category using combined product utilization patterns (from both OPPS and non-facility settings) would result in a higher initial payment rate for the PMA category. CMS believes this would rationally order the FDA regulatory categories based on clinical considerations and indicators of resource cost until aberrant financial incentives are removed from cost data and can be incorporated into the payment rates.

Many commenters stated that the proposed payment rate of $125.38 per square centimeter is well below most providers' acquisition and operational costs. They asserted that CMS' policy will result in access issues and result in amputations, infections, and hospitalizations. Public commenters suggested a variety of alternative methodologies that would result in rates between $478 to $973/cm². Other comments raised concerns about higher Medicare payments for placing amniotic membrane on ocular surfaces (65778 and 65779) than skin substitutes applied to other part of the patient's body arguing that the applications are clinically and resource similar.

CMS rejected changing the proposed payment rate based on these comments for a variety of reasons, including that manufacturers have demonstrated the ability to offer products well below current ASP levels and there are a significant number of products with current ASPs below $125.38. CMS further disagreed that amniotic products placed on patient's eye are comparable to those placed elsewhere.

Many commenters expressed concern that a low, uniform payment rate would stifle innovation. CMS welcomes continued dialogue on ways to differentiate a truly innovative product from others that offer no clinical advance.

Some commenters supported finalizing a single, standardized payment rate for all non-BLA products for one or two more years and moving to tiered payment rates in 2027. Other commenters suggested a tiered or differentiated payment system in 2026, rather than waiting until 2027 as reflective of product complexity and clinical evidence and avoiding treating all products as if they are the same. CMS responded that to address concerns about novel pricing in the past, it needs to establish initial uniform pricing but intends to update these rates once updated use patterns reflect its new policy.

Some commenters recommended phasing in payment reductions over several years. CMS responded that a transition was unnecessary given that the nearly 40-fold increase in spending on these products has been concentrated in just the past several years.

Several commenters opposed applying geographic adjustments under the PFS to skin substitute product payments, stating that product costs do not vary by location as manufacturer pricing remains consistent regardless of clinical site or geography. CMS responded to this comment in the 2026 PFS rule indicating that section 1848(e) of the Act requires that the PFS account for geographic variations in the costs of furnishing services. However, CMS recognizes that the variations in relative resource costs based on geography are not necessarily proportionately the same across all kinds of inputs and may consider adjustments for future rulemaking.

There were comments concerned about differential updates under the PFS and OPPS resulting in variation in payment between the two payment systems. CMS may consider the interaction between the update factors in future rulemaking.

CMS is finalizing rates consistent with the groupings illustrated in the proposed rule with changes based on comments. Final rates will be based on section 361 HCT/P volume-weighted average payment amount using utilization data only from Q4 2024 from the outpatient department and ASP data from the same period.

Given the volatility around skin substitute products, updating the regulatory categories of only 17 of over 200 skin substitute products can result in significant changes to the payment rate. Accordingly, CMS is maintaining the same framework for setting the payment rate that was used for the proposed rule and determined a final payment rate for 2026 of $\$127.28/cm^2$.

The initial assignment and payment rates are listed in the file titled "Skin Substitute Products by FDA Regulatory Category" on the CMS website under downloads for the 2026 PFS final rule at: PFS Federal Regulation Notices | CMS.

CMS proposed to create new status indicator "S1" to indicate that the skin substitute product is paid separately from other procedure codes under the OPPS. The status indicator "S1," along with its descriptor and payment status, is provided in Table 114 of the final rule.

As an alternative, CMS also considered whether or not to make the skin substitute products an add-on to the application procedure but continue to be paid separately unlike other add-on codes that are packaged. Some commenters supported add-on codes for skin substitutes that would eliminate the need for A codes for some skin substitutes and Q codes for others. MedPAC and other commenters supported add-on codes not having malpractice RVUs associated with a supply product. CMS agrees and has finalized a policy that all skin substitute products codes will be add-on codes.

CMS proposed to maintain the current structure of HCPCS codes for skin substitutes. Individual HCPCS coding remains necessary to provide identification on claims, track each product's cost, and apply coverage policies. Beginning January 1, 2026, CMS proposed to review HCPCS Level II coding applications for all skin substitutes marketed as section 361 HCT/Ps through the semiannual coding cycle for non-drugs and non-biological products, rather than on a quarterly basis. Skin substitutes that received a section 510(k) clearance, PMA approval, or a granted De Novo request

would continue to be evaluated in the semiannual HCPCS Level II coding cycles. Before a code is assigned, not otherwise classified (NOC) codes would be used and the MACs would assign the appropriate payment based on the product's FDA regulatory category.

Many commenters supported CMS' proposal to maintain the current structure of HCPCS codes for skin substitutes while others recommended CMS reassign all skin substitute products "Q" codes to reduce administrative burden and confusion for providers and MACs. CMS will take these comments into consideration for future rulemaking.

Several commenters opposed CMS' proposal to shift the HCPCS Level II coding application review for section 361 HCT/P products from a quarterly to a semi-annual cycle stating that it would create lengthy delays (18 months or more) for new products to get a code and be paid, creating a barrier to market entry. CMS disagrees stating that it posts coding decisions for all non-drug and non-biological products on a semiannual basis.

CMS is finalizing its proposal and will evaluate all complete HCPCS Level II applications for skin substitutes on a semiannual basis as proposed.

Skin substitutes not licensed under section 351 of the PHS Act would no longer be paid as biologicals under this proposal. Therefore, manufacturers of these products would no longer be required to report ASP data to CMS. However, when ASP data is reported, it may serve as a better estimate of resources across the hospital outpatient and non-facility settings than hospital outpatient MUC data.

CMS proposed to update the rates for the skin substitute categories annually through rulemaking using the most recently available calendar quarter of ASP data when available. Alternatively, CMS considered using the most recently available four calendar quarters of ASP data to set payment rates in future years. In the event ASP is not available for a particular product, CMS proposed to use the MUC, WAC, or 89.6 percent of AWP (the analog to ASP without the add-on) in that order.

Once updated use patterns reflecting this policy are available to calculate rates, CMS proposed using all relevant products and the combined product utilization patterns (OPPS and non-facility) to determine a weighted average per-unit cost by category to set separate payment rates for each of the three categories.

Most commenters recommended that CMS update the payment rates based on a price index like the Consumer Price Index for Urban Consumers (CPI-U) or the Producer Price Index (PPI), rather than recalculating them based on ASP data. The commenters stated that an inflationary update would provide stability and predictability for providers and manufacturers, avoiding the significant rate variability that would occur with annual ASP recalculations, and reduce the regulatory burden from reporting ASP that has led CMS to propose this policy.

CMS responded that, over time, the ASP data will more accurately reflect the market impacts of its policy to treat skin substitute products as incident-to supplies. By relying on ASP, payment updates

will be responsive to changes in the actual cost of skin substitute products resulting from market pressures rather than anchoring the cost to the initial payment rate for 2026 based on data collected prior to the implementation of this policy.

Several commenters expressed concern about using a single, scheduled quarter of ASP data and recommended using a longer timeframe, such as four calendar quarters, to mitigate the impact of pricing manipulation. CMS agrees and plans to use a longer timeframe for collection of ASP data that would reduce the opportunity for manipulation in future years.[52]

(v) Payment Impact

CMS states that the impact will be budget neutral under the OPPS, with any reduction in APCs from unbundling skin substitutes and paying for them separately being offset by an increase in the OPPS weight scalar.

12. Medicare Part B Drugs without a Medicaid National Drug Rebate Agreement (NDRA)

Under section 1927(a)(1) of the Act, Medicare may only make Part B payment for covered outpatient drugs where the drug's manufacturer has a Medicaid NDRA. CMS lists the single source drugs, biologicals, and radiopharmaceuticals where the manufacturer does not have an NDRA in Table 116 of the final rule. Medicare Part B payment will no longer be available for these products under the OPPS and ASC payment system. These HCPCS codes will be assigned non-payable status indicator E1 under the OPPS and B5 under the ASC payment system. No effective date was specified for this policy in the proposed rule.

Several commenters expressed concern that CMS' policy would reduce Medicare beneficiary access to drug therapies where patients have few, or inferior, clinical alternatives. A few commenters asked CMS to delay enforcement to allow manufacturers to be compliant with the rule. CMS responded that it is enforcing a statutory requirement and has no discretion in the matter.

For manufacturers not compliant with the regulation, CMS will cease payment for their products on April 1, 2026. Part B payment may resume once the manufacturer obtains an NDRA. The final rule indicates that three manufacturers not compliant with the NDRA requirement as of the proposed rule are now compliant. As a result, CMS will continue Medicare Part B payment for HCPCS code J2850 (Inj secretin synthetic human), HCPCS codes A9592 (Fluoroestradiol f 18), and J9248(Inj melphalan (hepzato) 1 mg).

If a manufacturer contacts CMS with intent to obtain an NDRA, CMS will aim to maintain their products' separate payment for January 1, 2026 pending prompt verification of compliance with the rule. If a manufacturer comes into compliance by obtaining an NDRA, Medicare Part B payment will be reinstated retroactive to the date that the signed and completed NDRA has been received and accepted by CMS.

[52] CMS' policy on this topic appears internally inconsistent. It will no longer require ASP reporting for the large majority of skin substitute products but will use ASP reported data to update the payment rates.

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

Beginning in 2013, CMS finalized a policy to provide an additional payment of $10 for the marginal cost for radioisotopes produced by non-HEU sources (77 FR 68323). CMS expected this additional payment would be needed for the duration of the industry's conversion to alternative methods to producing radioisotopes without HEU.

The Secretary of Energy issued a certification on January 2, 2022, stating that there is a sufficient global supply of molybdenum-99 (Mo-99) produced without the use of HEU available to meet the needs of patients in the United States.[53] In the 2023 rulemaking cycle, CMS indicated that the Department of Energy (DOE) expected that the last HEU reactor that produces Mo-99 for medical providers in the U.S. would finish its conversion to a non-HEU reactor by December 31, 2022, although it would be sometime into 2023 that hospitals would only be able to purchase Technetium-99m (Tc-99m) produced from non-HEU sources.

Therefore, CMS believed that the conversion to non-HEU sources of Tc-99m had reached a point where a reassessment of the policy of paying an add-on payment of $10 for non-HEU radioisotopes was necessary. CMS intended to end its policy on December 31, 2025—a date two years after using the 2023 data to set OPPS rates.

While CMS anticipated ending this additional $10 payment for non-HEU-sourced Tc-99m beginning in 2026, the DOE and other interested parties raised another issue affecting the domestic supply chain for Mo-99 and Tc-99. Mo-99 production has historically been subsidized by foreign governments, resulting in prices below the true cost of production. These artificially low, government-subsidized prices have created a disincentive for investments in Mo-99 production infrastructure, and they also created a barrier to entry for new producers, including U.S. companies.

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

To address the difference in costs between purchasing domestically produced Mo-99 and imported Mo-99, CMS established a new add-on payment of $10 per dose for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99 starting on January 1, 2026, using its equitable adjustment authority (section 1833(t)(2)(E) of the Act).

CMS used the 2026 OPPS proposed rule to establish criteria for when a Mo-99 and Tc-99 will be considered domestically produced and eligible for the add-on payment. The proposed criteria for

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

domestically produced Mo-99 and Tc-99 were provided to CMS by the DOE's National Nuclear Security Administration (NNSA). A domestically produced dose of Tc-99m is defined as:

- One generated from domestically produced Mo-99 that is irradiated and processed in the United States.
- "Irradiated" is defined as the process of bombarding a uranium or molybdenum target with radiation to produce Mo-99 typically performed with a nuclear reactor or particle accelerator.
- "Processed" is defined as the purification of Mo-99 from irradiated material.

CMS proposed to establish new HCPCS C-code C917X (Tc-99m from domestically produced non-HEU Mo-99, [minimum 50 percent], full cost recovery add-on, per study dose), effective January 1, 2026. Hospitals will be able to report new HCPCS C-code C917X once per dose, along with any diagnostic scan or scans furnished using Tc-99m derived from domestically produced Mo-99. Hospitals can bill this add-on code if the hospital can certify that at least 50 percent of the Mo-99 in the Tc-99m generator to produce the Tc-99m was domestically produced Mo-99. Internal records must support that the hospital billed the code eligible for the add-on payment.

The proposed rule also included an RFI asking for public comment on a variety of specific issues for how to incent the use of domestically produced Mo-99. Public commenters supported CMS' proposed policy while a few commenters indicated the policy should be delayed until domestic production of Mo-99 begins. CMS responded that it believes it is better to have a regulatory framework for this policy in place for when domestic production of Mo-99 begins.

CMS is finalizing the proposal without modification to define a domestically produced dose of Tc-99m as a dose generated from domestically produced Mo-99 that was both irradiated and processed in the U.S.

C. Notice of Intent to Conduct Medicare OPPS Drugs Acquisition Cost Survey

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, use the amount otherwise paid under various provisions of statute (generally using ASP+6 percent under section 1847A of the Act). Under section 1833(t)(14)(D)(ii) of the Act, CMS will be conducting 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. Based on this survey, CMS intends to propose Part B drug payment policies for setting 2027 OPPS rates.

The proposed rule indicated that hospitals have an obligation to respond to the survey. Despite this statement, CMS requested comment on whether to make responding to the survey a mandatory requirement of all hospitals paid under the OPPS.

CMS also requested comment on options for addressing non-response to the survey. Among the options presented were:

- Using the lowest acquisition cost reported among otherwise similar responding hospitals as a proxy for the non-respondent's cost.
- Using supplemental data sources such as the Federal Supply Schedule as the non-respondent's cost.
- Assume an ASP add-on percentage (0 percent, 6 percent or some other percent) as the hospital's cost.
- Assume that a non-respondent has insignificant drug costs and always package and never pay separately for the non-respondent's drug costs.

The survey will ask only about drugs that are separately paid under the OPPS. Hospitals will report total acquisition cost, net of all rebates and discounts, of each drug by NDC from July 1, 2024, through June 30, 2025. The survey will ask hospitals to distinguish drugs and discounts acquired under the 340B program from other drugs and discounts.

There are approximately 700 drug HCPCS codes that will be subject to the survey, with most HCPCS codes having multiple NDCs per HCPCS code. Only the total cost and the total units of the drug acquired need to be reported.

Comments were made in the following areas:

Regulatory Burden. Most commenters opposed CMS doing this survey as it will impose a significant burden on hospitals. Commenters indicated that CMS' estimate of that burden grossly underestimates the cost, time and resources that will be necessary to complete the survey. The survey responses will have to come from pharmacists and will require a concerted effort of multi-disciplinary teams, including pharmacy, supply chain, finance, legal, and reimbursement professionals—resources unaccounted for in CMS' estimate of regulatory burden.

CMS responded that it has created a survey instrument and process to minimize burden. The survey instrument consists of a streamlined online portal, where hospitals can either directly enter acquisition costs or download and upload an Excel template of acquisition costs. Technical assistance will be available to hospital staff for responding to the survey. CMS is further engaging in robust education and outreach efforts with hospitals to reduce the burden of completing the survey.

Regardless of the burden involved, CMS indicates that section 1833(t)(14)(D)(ii) of the Act requires "the Secretary to conduct periodic…surveys to determine the hospital acquisition cost for each specified covered outpatient drug for use in setting the payment rates." Therefore, CMS indicates it is following a statutory mandate.

Exclusion of Radiopharmaceuticals. CMS responded to comments about excluding radiopharmaceuticals, stating radiopharmaceuticals are unique products with various forms in

which they can be purchased as noted in a GAO study.[54]

Potential for Unreliable Results. Commenters indicated that when conducting the 2004 survey, the GAO worked with knowledgeable parties to develop a survey instrument before sending it to its sample population. GAO pretested the survey instrument, made adjustments based on hospital feedback, and engaged a data collection contractor to pilot the revised instrument with a larger group. As a result of the pilot, GAO adjusted the instructions and changed its procedures before engaging in a multifaceted effort to collect data from about half as many hospitals as CMS intends to survey. The commenters were concerned that CMS is not being as rigorous and the survey will produce unreliable results.

CMS responded that it is engaging with hospitals and experts within the hospital and drug purchasing industry, and incorporating the valuable feedback received through the notice and comment rulemaking process. The survey will go through extensive user testing, and there will be a thorough onboarding process once an OMB control number is received, which will involve webinars, user guides, fact sheets, additional communications as well as a dedicated email inbox, phone number, and website to ensure hospitals are able to respond to the survey.

Interaction with the 340B Drug Discount Program. This comment was detailed and complex alleging that the price discerned through a retrospective acquisition cost survey will not reflect the net cost to 340B covered entities for any drugs that, in the future, are subject to both the Medicare Drug Price Negotiation Program (DPNP) under Part B and HRSA's proposed 340B rebate pilot program. Survey respondents pay higher prices at the point of sale that do not reflect later discounts that will not be accounted for through a retrospective survey. The result will be an understatement of actual costs. CMS responded that HRSA's 340B pilot program is out of scope for purposes of this rulemaking and CMS defers to HRSA for specifics on this program. This pilot program has yet to go into effect, and the period of the survey does not overlap with the pilot program. CMS' response to incorporating discounts or price concessions not provided at the point of sale are addressed in the next paragraph.

Rebates. A commenter indicated that CMS has not accounted for GAO's concern that it "could not obtain data that would permit calculation of hospitals' acquisition costs, because, in general, hospitals were unable to report accurately or comprehensively on rebates." To the extent non-340B hospitals are more likely to receive discounts through rebates, the survey results will reflect higher than actual acquisition costs for this group as well as an overestimate of the difference from 340B hospital acquisition costs, according to this commenter.

CMS responded that it is asking hospitals to incorporate all rebates and discounts in their acquisition cost for each NDC—including discounts directly applicable to an individual NDC—but also those discounts that are not necessarily linked to a single NDC. That discount could be one linked to a certain invoice, or discounts linked to purchases made over a certain period such as prompt pay discounts, wholesaler discounts, or other discounts.

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54 Government Accountability Office. April 2006 at: Medicare Hospital Pharmaceuticals: Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS | U.S. GAO

CMS believes discounts should be readily available in hospitals' purchasing systems with technology advancing considerably in the 20 plus years since the GAO survey. Similarly to how there have been significant advances in technology over the past 20 years, there has also been large growth in 340B drug utilization and spending.

Obsolesence and Unrepresentative Survey Results. Commenters indicated that fluctuating prices and policy interventions like pharmacy benefit manager reform, the implementation of negotiated drug prices under the IRA, 340B drug pricing program rebate policies, most favored nation pricing and pharmaceutical tariffs will preclude the survey from serving as an accurate basis for future Medicare payment. CMS responded that if drug pricing changes significantly over time, it confirms CMS' decision to collect data instead of continuing to rely on drug pricing policies set based on GAO surveys from two decades ago. The response further indicates CMS does not need to rely solely on survey data to inform drug pricing policies. As discussed in the proposed rule (90 FR 33654), CMS could consider pricing from the Federal Supply Schedule, 340B ceiling pricing, ASP plus 6 percent, zero percent or another percentage, or other recognized drug pricing to inform future CMS payment policy.

Insufficiency of Using 1 Year of Survey Data. Many commenters stated that one year of data is an insufficient basis upon which to make drug pricing changes. CMS disagrees stating that the commenters provided no empirical support for their conclusion that one year of survey data is an insufficient basis upon which to make a conclusion about drug acquisition costs.

2026 is Too Soon to Begin a Survey and Hospitals Need More than 90 Days. Commenters indicated that hospitals need time to identify, validate and coordinate drug cost information across internal departments and that without additional advance notice and technical guidance hospitals may be unable to respond comprehensively within the proposed survey window. The commenter requested CMS delay the begin date of the survey. Several commenters expressed concern about the length of the survey window, arguing that 90 days was not enough time given that survey completion will require a multidisciplinary team at any hospital, including but not limited to pharmacy, supply chain, finance, and reimbursement. CMS disagrees stating that the survey has been designed to minimize the amount of effort required by hospitals to collect and report the information.

Transparency and Privacy. A commenter recommended that all four data fields (total units and net acquisition costs for 340B and non-340B drugs) be made available at the hospital level with pseudonymized provider numbers, but that all hospital identifiers (for example, state or location data, NPIs) be excluded from the data sets that can be accessed by the public or those with data use agreements. CMS responded that proposed payment rates and calculations with aggregate data could appear in notice and comment rulemaking to ensure transparency and replicability; however, the confidentiality of individual hospitals and proprietary information would be maintained to the extent permitted by law.

Limiting Data to Hospitals. Many commenters requested that CMS use data sources from other than hospitals and engage drug manufacturers, distributors and other entities. CMS responded that it has designed the survey to allow for the incorporation of information from supplemental data sources, including manufacturers and distributors.

Sampling. Several commenters suggested that CMS sample specific drugs and hospitals rather than collecting data from all institutions. For this initial survey, CMS responded that it will survey the universe of hospitals to obtain a comprehensive data set but will consider sampling for updated surveys.

Other Options. GAO's 2006 report indicated that CMS could audit manufacturers' price submissions or examine proprietary data as an alternative to surveying hospitals. Commenters asked whether CMS considered these alternatives. CMS did consider these alternatives but decided to proceed with conducting a survey because that is the rate-setting methodology prescribed by statute.

Hospital Characteristics. A commenter requested that CMS capture other hospital characteristics that might influence drug acquisition costs, rather than the singular focus on the difference between 340B and non-340B acquired drug costs. CMS responded that it intends to consider many different hospital characteristics when analyzing the results of the data, such as hospital size, location, urban/rural status, teaching hospital status, etc. These are all hospital characteristics that CMS routinely considers for various policies under the OPPS that do not need to be collected as they are already known to CMS. Therefore, to reduce burden on hospitals submitting data, CMS is not asking hospitals to submit information it already has.

Only Survey to Validate ASP Reporting. A commenter indicated that the GAO recommended that the survey be conducted only once or twice per decade and be used only to validate "ASP data that manufacturers report to CMS for developing specified covered outpatient drug rates." CMS responded that its proposal to conduct the survey every 4 years is consistent with the GAO's recommendation that the Secretary validate, "on an occasional basis—possibly every 5 or 10 years—average sales price (ASP) data that manufacturers report to CMS for developing SCOD payment rates."

Impact on Safety Net and Other Hospitals. Many commenters requested that various hospitals be exempted from payment reductions (e.g., safety net, SCHs, MDHs, low volume, small rural hospitals). CMS responded that it is premature to consider the payment consequences of the drug cost survey at this time for including or excluding any type of hospital from its results.

Making the Survey Mandatory. Many commenters stated that CMS lacks the statutory authority to make the survey mandatory and requested that CMS state in the final rule that the survey is voluntary. A commenter stated that when GAO previously conducted the survey it provided no incentives or penalties to encourage participation but received usable data from 83 percent of the hospitals. Other commenters supported making the survey mandatory, arguing that doing so was critical to ensuring that the wide range of hospital acquisition costs is appropriately accounted for

and reflected in the survey results.

CMS responded that the survey authority under section 1833(t)(14)(D) of the Act imposes obligations on both the Secretary to design a survey and hospitals to respond. However, CMS agrees that section 1833(t)(14)(D) of the Act does not mandate specific consequences on hospitals for failing to respond to that survey. Nevertheless, CMS states the lack of a response to this required survey is still meaningful data which can be taken into consideration to inform future payment rates in future rulemaking.

Consequences for Not Responding to the Survey. Most commenters opposed the actions that CMS presented in the proposed rule when hospitals do not respond to the survey stating the statute does not provide authority for CMS to adopt any of those options. CMS responded that it has made no final decision on how, if at all, it will address hospitals not responding to the survey. Any policies would be a subject for future rulemaking.

CMS is finalizing its proposal to conduct an OPPS drug acquisition cost survey of all hospitals paid under the OPPS, pending final approval from OMB. This new information collection request will be submitted to OMB for review under control number 0938-1487 (CMS-10931). The OMB control number will not be valid until formally approved by OMB.

The final rule indicates that the survey will apply to all hospitals paid under the OPPS, approximately 3,500 hospitals, and will take 80.5 hours to complete including the time to review instructions, gather data (including potentially from hospital wholesalers), perform basic addition calculations, and enter data. CMS revised the estimate from 73.5 hours in the proposed rule by changing a pharmacist's time for completing the survey from 1 to 8 hours.

VI. Estimate of Transitional Pass-Through Spending

CMS estimates 2026 transitional pass-through payments of approximately $307.0 million, or 0.30 percent of total OPPS spending, which is less than the applicable transitional pass-through payment percentage statutory limit of 2.0 percent.

A. Devices

CMS estimates transitional pass-through spending of $291.8 million in 2026 for devices—$251.9 million for those recently eligible for transitional pass-through payments that will continue for 2026 and $39.9 million for those CMS knows or projects could be approved for 2026.

B. Drugs and Biologicals

CMS estimates transitional pass-through spending of $15.2 million in 2026 for drugs and biologicals—$5.2 million for those recently eligible for transitional pass-through payments that will continue for 2025 and $10 million for those CMS knows or projects could be approved in 2026.

VII. Hospital Outpatient Visits and Critical Care Services

CMS did not propose any changes to the current clinic and emergency department hospital outpatient visits payment policies or to the payment policy for critical care services when these services are provided on the campus of a hospital for 2026. It also did not propose any changes to its policy for how it pays for clinic visits provided in off-campus provider-based departments. As discussed in section X.A, CMS is using its authority to control unnecessary increases in the volume of covered OPD services under section 1833(t)(2)(F) to expand its site neutral payment to drug administration services furnished in an off-campus provider-based department.

VIII. 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 cycles, it adopted policies to protect against significant reductions in payment rates for PHP services, and, in response to the COVID-19 pandemic, it provided greater flexibility for the delivery of PHP services by community mental health centers (CMHCs) and hospital-based providers.

In the 2023 OPPS/ASC final rule (87 FR 71995), CMS observed decreases in the number of hospital-based and CMHC PHP days due to the continued effects of COVID-19 though service volumes appeared to be returning to pre-pandemic levels. It used the latest available 2021 claims, but used the cost information from before the COVID-19 PHE for calculating the 2023 CMHC and hospital-based PHP APC per diem costs. Notwithstanding these changes, the final calculated CMHC PHP APC payment rate was lower than the 2022 final CMHC PHP APC rate; thus, CMS used its equitable adjustment authority[55] to pay for CMHC PHP services at the same payment rate as in effect for 2022. CMS also clarified that payment under the OPPS for new HCPCS codes that designate non-PHP services provided for diagnosis, evaluation or treatment of a mental health disorder and furnished to beneficiaries in their homes by clinical staff of the hospital would not be recognized as PHP services.

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

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

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 2025 OPPS/ASC final rule with comment period (89 FR 94266), CMS continued the coding and billing policies for PHP as established in the 2024 OPPS/ASC final rule without change.

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 less intensive than a PHP.

CMS established payment and program requirements for the IOP benefits furnished by a hospital to its outpatients or by a CMHC, an FQHC, or an RHC.[56] 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, CMS 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.

In the 2025 OPPS/ASC final rule with comment period (89 FR 94266-94268), CMS continued the coding and billing policies for IOP as established in the 2024 OPPS/ASC final rule without change.

[56] The 2026 payment policies for IOP services furnished by FQHCs and RHCs are found in the 2026 Physician Fee Schedule final rule.

B. Coding and Billing for PHP Services and Intensive Outpatient (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.[57] 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; no new services were proposed to be added in this rulemaking cycle.

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

C. Payment Rates for PHP and IOP

For 2026, CMS proposed maintaining the current payment rate methodology that used for calculating PHP and IOP payment rates for hospital-based providers. However, the agency proposed to revise the methodology for calculating PHP and IOP payment rates for CMHCs by applying the 40 percent MPFS Relativity Adjuster to calculate PHP and IOP payment rates for CMHCs. Under this proposed methodology, CMS would multiply the 2026 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. CMS finalizes its proposals 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:

[57] 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.

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

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

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 believed 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 the agency finalizes its proposal to continue that policy for 2026. However, it notes that if future data analysis supports calculating rates independently, it may do so.

2. 2026 Payment Rate Methodology for PHP and IOP

CMS uses data from cost reports beginning three fiscal years before the year that is the subject of the rulemaking, as well as 2024 OPPS claims, to update the payment rates for the four PHP APCs and the four IOP APCs finalized in the 2024 OPPS/ASC final rule. CMS calculates the PHP rates for CMHCs and hospital-based programs separately.

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

However, CMS notes that calculating the 2026 geometric mean per diem cost for CMHC PHP and IOP providers using its current methodology resulted in an inversion: CMHC 3-service geometric mean per diem costs equaled $191.83 and CMHC 4-service geometric mean per diem costs equaled $110.39. The agency believes the inversion may be 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. To address the inversion, CMS finalizes its proposal to change its

methodology for CMHCs; the 2026 geometric mean per diem costs are calculated for those CMHCs based on 40 percent of the corresponding hospital-based PHP and IOP APCs. CMS believes using 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. CMS sees several similarities between nonexcepted off-campus hospital outpatient departments and CMHCs, and it believes basing CMHC rates on hospital cost data will stabilize CMHC payment rates.

Comments/Responses: CMS reports that commenters were generally pleased with the proposal to maintain the structure of the payment rate methodology for 2026.

However, several commenters stated that the CMHC cost estimates do not reflect the actual costs of providing PHP and IOP services and that the resources involved are comparable to those required for hospital-based programs. They asserted that the policy of paying separate rates for hospitals and CMHCs creates arbitrary incentives for PHP and IOP services to be furnished in settings other than CMHCs. CMS disagrees that its payment methodology provides incentives for PHP and IOP services to be furnished in non-CMHC settings; it also disagrees that the final payment rates are inadequate. Some commenters argued that the 40 percent MPFS Relativity Adjuster is irrelevant for calculating the geometric mean per diem costs for the CMHC rates. CMS believes it is both relevant and appropriate, reiterating that it found similarities between CMHCs and nonexcepted off-campus hospital outpatient departments. CMS concludes that this methodology appropriately stabilizes CMHC payment rates by setting them relative to hospital-based rates, while avoiding cost inversions.

Some commenters encouraged CMS to set site-neutral payment rates for CMHCs and hospital-based providers for PHP and IOP services. Others suggested the statute (sections 1832(a)(2)(J) and 1833(a)(2)(B)(iii) of the Act) entitles CMHCs to receive payment for PHP and IOP services under the same methodology as hospital outpatient departments. Some commenters stated that while the agency may create APC codes for different classes of services, it may not create distinct APC codes based on the site of service. They further asserted that paying CMHCs the same rate as hospital-based providers would have a negligible impact on the Medicare program. CMS disagrees with all the points these commenters expressed.

The agency cites its longstanding practice of paying separately for these services and its authority to revise the groups and relative payment weights and to make other adjustments to the payment rates for PHP services, including basing rates on hospital-based PHP data only, combined hospital-based PHP and CMHC data, or CMHC data only. CMS also notes that it takes into account relevant information and factors that allow it to more appropriately pay providers for the resource costs associated with providing PHP services. CMS also disagrees that paying CMHCs the hospital-based payment rates would have no significant impact on Medicare spending, noting that a payment increase of 150 percent for these services when furnished by CMHCs would result in a significant increase in the total amount of PHP and IOP payments from the Medicare program and from Medicare beneficiary coinsurance payments.

The 2026 geometric mean per diem costs and payment rates are as follows:

2026 APC	Group Title	PHP and IOP APC Geometric Mean Per Diem Costs*	Payment Rates**
5851	Intensive Outpatient (3 services per day) for CMHCs	$128.73	$127.74
5852	Intensive Outpatient (4 or more services per day) for CMHCs	$168.67	$167.38
5853	Partial Hospitalization (3 services per day) for CMHCs	$128.73	$127.74
5854	Partial Hospitalization (4 or more services per day) for CMHCs	$168.67	$167.38
5861	Intensive Outpatient (3 services per day) for hospital-based IOPs	$321.83	$319.38
5862	Intensive Outpatient (4 or more services per day) for hospital-based IOPs	$421.67	$418.45
5863	Partial Hospitalization (3 per day) for hospital-based PHPs	$321.83	$319.38
5864	Partial Hospitalization (4 or more services per day) for hospital-based PHPs	$421.67	$418.45

* Table 118 of the final rule shows the 2026 PHP and IOP APC geometric mean per diem costs.
** The 2026 payment rates are from Addendum A to the proposed rule.

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.

D. Outlier Policy for Community Mental Health Centers (CMHCs)

For 2026, CMS finalizes its proposals to update the calculations of the CMHC outlier percentage, cutoff point and percentage payment amount, outlier reconciliation, outlier payment cap, and fixed-dollar threshold determined under established policies to include intensive outpatient services. CMS received no comments on its outlier policy proposals.

The methodology for calculating the CMHC outlier percentage was first established in the 2018 OPPS/ASC final rule (82 FR 59267), which is also applied to payments for IOP services as well as PHP services for 2026. CMS projects that CMHCs will receive 0.01 percent of total hospital outpatient payments in 2026 (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 2026 is set at 3.4 times the highest CMHC PHP APC payment rate, and CMS pays CMHCs 50 percent of the 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 2026, CMS uses its established outlier reconciliation policy to address charging aberrations related to OPPS outlier payments described in the 2023 OPPS/APC final rule (83 FR 58874) and extends 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 2026 and applies it to both PHP and IOP; this only impacts CMHCs.

CMS does not set a fixed-dollar threshold for CMHC outlier payments that it applies to other OPPS outlier payments; this is due to the relatively low cost of CMHC services. It continues this policy for 2026 and applies it to both PHP and IOP APCs.

E. Regulatory Impact

CMS estimates that payments to 34 CMHCs for PHP services will increase by 2.1 percent in 2026 relative to their 2025 payments. The estimate is derived by combining the OPD fee schedule increase factor, along with the changes in APC policy for 2026 and the FY 2026 wage index updates as shown in column 4 of Table 167.

IX. 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). Currently, the IPO list includes approximately 1,731 services.[58] Services on the IPO list 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

[58] CMS uses the word "approximately" despite using a very precise number to quantify the services on the IPO list.

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 believed the IPO list should be eliminated and deference given to the clinical judgment of physicians for selecting where to perform a service. 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 (65 FR 18455). 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 (76 FR 74354). Other stakeholders, however, 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 exempt from 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, over time 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, effective 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 CY 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 CY 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.

B. Current Methodology for Identifying Appropriate Changes to the IPO List

The criteria that CMS uses to evaluate procedures for removal from the IPO list are:

- Most outpatient departments are equipped to provide the service or procedure to the Medicare population.

- The simplest service or procedure described by the code may be performed in most outpatient departments.
- The service or procedure is related to codes that CMS has already removed from the Inpatient Only list.
- CMS determines that the service or procedure is being performed in numerous hospitals on an outpatient basis.
- CMS determines that the service or procedure can be appropriately and safely performed in an ambulatory surgical center and is specified as a covered ambulatory surgical procedure, or CMS has proposed to specify it as a covered ambulatory surgical procedure.

Given advances in technology and surgical technique, CMS has continuously evaluated services to determine whether they should be removed from the IPO list.

C. Changes to IPO List

In the 2026 OPPS proposed rule, CMS stated that while the agency agreed with commenters in previous rulemakings that the IPO list was necessary, and that it would be inappropriate for Medicare to establish payment rates for those services under the OPPS (78 FR 75055, 86 FR 63673), it subsequently reconsidered the various comments from interested parties requesting that CMS eliminate the IPO list. CMS asserted that this change would ensure maximum availability of services to beneficiaries in the outpatient setting. The agency argued that advances in medical technology have led to more services able to be safely performed in outpatient settings over time; such advances have led the agency to remove various individual services from the IPO list in previous rulemakings.59 CMS believed that the evolving nature of the practice of medicine has mitigated, and continues to mitigate, any potential patient safety and quality of care risks.

Thus, in the 2026 OPPS proposed rule CMS again proposed to eliminate the IPO list over a three-year transition period, beginning in CY 2026, with the elimination complete by January 1, 2029. The agency also proposed to eliminate the criteria for removing procedures from the IPO list currently codified at §419.23, as a conforming change. However, because the agency would need time to develop payment rates for services previously not payable under the OPPS, the agency proposed to eliminate the IPO list in stages, with musculoskeletal services being the first group of services that would be removed from the IPO list.

In conjunction with the proposed removal of these services from the IPO list, CMS also proposed to continue to exempt services that have been removed from the IPO list from certain medical review activities to assess compliance with the 2-midnight rule until the Secretary determines that the service or procedure is more commonly performed in the Medicare population in the outpatient setting, even after their removal. Specifically, the agency proposed to continue the indefinite exemption from site-of-service claim denials, referrals to Recovery Audit Contractors (RACs), and

[59] CMS notes that certain procedures have been removed from the IPO list multiple times. For example, CMS removed several maxillofacial procedures in CY 2023, after originally removing them from the IPO list in 2021 and adding them back in 2022 (87 FR 72009).

RAC reviews for "patient status" for procedures that are removed from the IPO list under the OPPS beginning on January 1, 2021, as part of the transition away from the IPO list (85 FR 86120).

As part of these proposals, CMS also sought comment on whether it should restructure or create any new APCs or C-APCs to allow for efficient OPPS payment for services that are removed from the IPO list.

Comment/Response: CMS indicates that many commenters supported its proposal to eliminate the IPO list, for the reasons CMS posed as the rationale for doing so in the proposed rule.

The agency notes, however, that "numerous" commenters, including hospitals and health systems, opposed the proposed IPO list elimination for patient safety reasons. CMS largely dismissed these concerns, arguing that "patient safety and quality of care will be safeguarded by the physician's assessment of the risk of a procedure or service to the individual beneficiary and their selection of the most appropriate setting of care based on this risk, in addition to State and local licensure requirements, accreditation requirements, hospital conditions of participation (CoPs), medical malpractice laws, and CMS quality and monitoring initiatives and programs."

Other commenters opposed the IPO list elimination out of financial concerns, asserting that less complex patients would migrate to outpatient settings, leaving hospital inpatient departments to treat more complex (and more costly) patients. Commenters also asserted that hospitals could experience more claims denials for inpatient admissions for procedures no longer on the IPO list. In response, CMS reasserted its position that physicians' medical judgment should determine where hospital procedures are performed, and generally did not address the financial considerations raised by these commenters.

Some commenters raised issues related to the potential APC assignments of procedures formerly on the IPO list, suggesting specific APC assignments, or that former IPO list procedures, be assigned to new technology APCs. CMS declined to act on the new technology APC assignment suggestion, and largely held to its proposed APC assignments from the proposed rule, but the agency did make changes to the APC assignments for five formerly IPO list procedures.

CMS indicates that "numerous" commenters raised concerns about the implications of the elimination of the IPO list for the requirement of a 3-day inpatient hospital stay as a prerequisite for coverage of post-discharge skilled nursing facility care. CMS dismissed these concerns, arguing that patients who have formerly IPO list procedures on an outpatient basis would be unlikely to need SNF post-acute care, but rather would be discharged to home health care or home with outpatient therapy.

Some commenters raised issues related to CMS' transitional device pass-through policy, asking if devices associated with procedures removed from the IPO list would be eligible for device pass-through status. CMS responded that "devices that are reported only with codes that are removed from the IPO list will not be precluded from applying for or receiving transitional device pass-through payment status."

CMS devotes a section of the comment/response discussion to the implications for beneficiary cost-sharing. Under current law, even though OPPS services are Part B services, the OPPS cost-sharing for a service is capped at the applicable Part A hospital inpatient deductible amount for that year for each service. This cap applies to individual services, and some commenters have expressed concern in prior rulemaking that if a Medicare beneficiary receives multiple separately payable OPPS services, it is possible that the aggregate cost-sharing for a beneficiary could be higher for services provided in the outpatient setting than it would be had the services been furnished during an inpatient stay. In response, CMS asserts that services previously included on the IPO list but subsequently performed in an outpatient setting would tend to be surgical procedures that would typically be the focus of a hospital outpatient encounter and would likely be assigned to a comprehensive APC (C-APC) when they are removed from the IPO list. Therefore, under the OPPS, these services would likely be considered a single episode of care with one payment rate and one copayment amount, instead of multiple copayments for each individual service.

CMS indicates that "a few" commenters supported the three-year transition period for the elimination of the IPO list, while "a few" commenters disagreed with this timeline.

With respect to its proposal to eliminate the IPO list criteria at §419.23, CMS indicates that it received comments suggesting alternatives to these criteria, and stated that it will take these suggestions into account in future rulemaking. The agency is silent, however, on whether or not it received comments in response to its solicitation for suggestions on the next round of services that could be eliminated from the IPO list.

After consideration of comments received, **CMS is finalizing its proposal to eliminate the IPO list over the course of the next three years, beginning with the 285 (mostly musculoskeletal) services listed in Table 119 of this final rule**.[60]

CMS indicates that the agency received several comments on its proposal to continue to exempt procedures that are being removed from the IPO list from certain medical review activities to assess compliance with the 2-midnight rule until the Secretary determines that the service or procedure is more commonly performed in the Medicare population in the outpatient setting. Services on the IPO list are not subject to the 2-midnight rule for purposes of determining whether payment is appropriate under Medicare Part A. However, once services have been removed from the IPO list, the 2-midnight rule would apply. To prevent this, in the 2026 OPPS proposed rule, CMS proposed to indefinitely exempt procedures formerly on the IPO list from review for compliance with the 2-midnight rule.[61]

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[60] Note that p. 888 of the display version of this final rule incorrectly identifies the completion date of the IPO list elimination as January 1, 2028; it should be January 1, 2029.

[61] CMS proposed to delete §412.3(d)(2)(i) and (ii) and revise §412.3(d)(2) to read

> "An inpatient admission for a surgical procedure specified by Medicare as inpatient only under § 419.22(n) of this chapter is generally appropriate for payment under Medicare Part A regardless of the expected duration of care. Procedures no longer specified as inpatient only under §419.22(n) of this chapter are appropriate for payment under Medicare Part A in accordance with paragraph (d)(1) or (3) of this section. Claims for services nd procedures removed from the inpatient only list under §419.22 of this chapter on or after January 1, 2021 are exempt from certain medical review activities until the Secretary determines that the service or procedure is more commonly performed in the outpatient setting."

CMS states that many commenters supported its proposed indefinite exemption from certain medical review activities for former IPO list services. CMS notes that several commenters asked CMS to clarify the proper application of the case-by-case exception to the 2-midnight rule under 42 CFR 412.3(d)(3), especially given the propensity of Medicare Advantage plans to "ignore" the 2-midnight rule. (CMS reiterates existing regulations require Medicare Advantage plans to comply with the 2-midnight rule.)

After consideration of the public comments received, **CMS is finalizing its proposal with a small modification. CMS will (1) continue the indefinite exemption from site-of-service claim denials, initial medical review contractor referrals to RACs, and RAC reviews for "patient status" (that is, site-of-service) finalized in the CY 2021 OPPS/ASC final rule with comment period for procedures that are removed from the IPO list in CY 2021 or later under the OPPS; and (2) remove §412.3(d)(2)(i) and (ii) and revise §412.3(d)(2) to clarify that claims for services and procedures removed from the IPO list on or after January 1, 2021 are exempt from certain medical review activities until the Secretary determines that the service or procedure is more commonly performed in the outpatient setting than the inpatient setting.** In response to public comments, CMS is not finalizing its proposal to announce in subregulatory guidance when an exemption is ending for a particular service or procedure. Instead, the first time that the Secretary determines that a service or procedure is more commonly performed in the outpatient setting than the inpatient setting, CMS will make the announcement that the exemption is ending for the service or procedure through notice and comment rulemaking.

X. Nonrecurring Policy Changes

A. Payment Reduction for Drug Administration 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.

The American Hospital Association 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)."[62]

[62] 964 F.3d 1230, 1245 (D.C. Cir. 2020)

2. Expanding the "Method" to Other Services

CMS expresses concern about the increasing share of chemotherapy administration services being performed in hospital outpatient departments. MedPAC stated that the share of chemotherapy services furnished in OPDs has grown from 35.2 percent in 2012 to 51.9 percent in 2021. HCPCS code 96413 – which describes chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug – pays $119 under the PFS and $341 under the OPPS, a difference of 186 percent. CMS further indicates that between 2012 and 2021, the OPD share of nuclear cardiography services has grown from 33.9 percent to 47.6 percent, and its share of echocardiography services has grown from 31.6 percent to 43.1 percent.[63]

The natural inference according to the proposed rule is that these changes result from financial incentives and therefore are unnecessary increases in the volume of OPD services. CMS believes that this problem is pervasive and exists across service families. For 2026, CMS proposed to address drug administration services provided in off-campus provider-based departments (PBDs). In future years, CMS plans to examine whether to expand its policy to other APC families of services, such as imaging without contrast, and other settings, specifically on-campus outpatient clinic visits.

3. Utilization of Drug Administration Services

CMS indicates that the high volume of drug administration services and the magnitude of rate differences between the physician office and OPD settings make it a family of services likely to migrate to a higher paying setting of care. The rule further indicates that drug administration can be performed in either physician offices or OPDs—68 percent of these services are performed in physician offices despite the increasing share being performed in hospital outpatient departments[64]— and the resource costs are not meaningfully different between the sites.

The number of beneficiaries enrolled in fee-for-service Medicare decreased by over 14 percent between 2018 and 2024[65] but CMS analysis of claims data and Medicare FFS enrollment shows an increase in the volume of drug administration services provided in OPDs utilized per beneficiary. CMS concluded from these statistics that the increase in off-campus PBD volume over a 10-year period was at least partially driven by the payment differential between the physician office and OPD setting.

CMS further expressed concern about beneficiaries who pay higher cost sharing because of the payment incentives driving them to OPDs—a small portion of the population with high utilization. One study found that:

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[63] https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch8_MedPAC_Report_To_Congress_SEC.pdf.
[64] https://craftmediabucket.s3.amazonaws.com/uploads/Drug-Admin-Off-Campus-Site-Neutrality-2023.10.18.pdf.
[65] https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/medicare-monthly-enrollment

> in 2021, approximately 74,000 Medicare FFS chemotherapy patients utilized excepted off-campus OPDs and would have had cost sharing expenses that were $292 lower per patient had site neutrality applied. For the highest utilizing 5,000 patients who received chemotherapy most frequently at excepted off-campus OPDs, cost sharing would have been $1,055 lower per patient if payments had been site neutral.[66]

MedPAC found that it would be reasonable to align the OPPS payment rates with the PFS payment rates for all four of the drug administration APCs as these services have a higher volume in freestanding facilities than in OPDs, indicating that these services can be safely provided to beneficiaries in a lower cost setting of care.[67]

4. Payment for Drug Administration Services at Provider-Based Departments

Under the Bipartisan Budget Act of 2015, off-campus PBDs within 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.

CMS examined the top twenty most frequently billed HCPCS codes in the drug administration APC family billed with a "PN" and "PO" modifier and found that they are the same with slight variations in the order based on volume. This finding indicates that the site neutral payment rate is sufficient to support the provision of these services in an off-campus PBD currently paid at the OPPS rate.

5. Patient Severity and Cost of Care

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. MedPAC found that, on average, OPD patients have higher risk scores but the difference in patient severity between settings is small and not statistically significant as the services, like drug administration, are generally of low complexity.[68]

6. Impact of Unnecessary Increases in Volume on the OPPS

CMS' concern with unnecessary increases in the volume of drug administration services is tied to the health and sustainability of the OPPS. The OPPS was originally designed to manage Medicare spending growth by replacing a cost-based system with a prospective payment system. Contrary to this purpose, the OPPS has continued to be the one of the fastest growing sectors of Medicare payments out of all payment systems under Medicare Parts A and B.[69] CMS believes that paying

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[66] https://craftmediabucket.s3.amazonaws.com/uploads/Drug-Admin-Off-Campus-Site-Neutrality-2023.10.18.pdf
[67] See footnote 16.
[68] https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch8_MedPAC_Report_To_Congress_SEC.pdf
[69] https://www.govinfo.gov/content/pkg/FR-2018-11-21/pdf/2018-24243.pdf

for drug administration services provided at excepted off-campus departments at the PFS-equivalent rate would be an effective method to control the volume of these unnecessary services because the payment differential that is driving the site-of-service decision will be removed.

The proposed policy would apply to APCs 5691-5694. While section 1833(t)(9)(B) of the Act requires that certain "adjustments" made under the OPPS be made in a budget neutral manner, this section does not apply to the volume control method under section 1833(t)(2)(F) of the Act according to CMS. A volume-control method under section 1833(t)(2)(F) of the Act is not an "adjustment" subject to budget neutrality. Section 1833(t)(2)(F) of the Act refers to a "method" for controlling unnecessary increases in the volume of covered OPD services, not an adjustment. Further, implementing a volume control method in a budget neutral manner would not appropriately reduce unnecessary spending—it would just redistribute the spending to other services.

After consideration of comments, CMS is finalizing its proposal to use its authority under section 1833(t)(2)(F) of the Act to pay 40 percent of the OPPS rate for drug administration services furnished in excepted off-campus PBDs without applying budget neutrality.

CMS requested comment on other services for which CMS should pay the PFS-equivalent rate at off-campus provider-based departments such as imaging without contrast. Commenters suggested many other services to make subject to site neutral payment. CMS responded that it will consider these suggestions in future notice and comment rulemaking.

Commenters in support of CMS' proposed policy included organizations representing private health insurance plans, physician associations, specialty medical associations, and individual Medicare beneficiaries. These commenters stated that aligning payment between OPPS and PFS services will discourage site-of-service shifts driven by financial incentives rather than clinical need. The commenters reiterated many of the same reasons for adopting the policy that CMS presented in the proposed rule.

MedPAC supports payment parity between the OPPS and PFS but stated it should be applied on a budget neutral basis to not adversely affect hospitals' ability to be available to provide 24/7 emergency care. Further, MedPAC requested CMS pay particular attention to safety-net and rural providers in considering this policy. CMS responded that it does not believe its volume control method will adversely impact hospitals' ability to provide 24/7 emergency care as the policy will only be applied to drug administration services billed with the "PO" modifier. CMS believes the policy should be applied budget neutral to reduce unnecessary volume of covered OPD services, rather than shift payment to other services. As noted elsewhere, CMS is exempting rural SCHs from the policy.

There were comments making highly technical legal arguments that the Circuit Court decision upholding CMS' site neutral policy in the 2019 rule is no longer applicable as the *Chevron* decision that it cited was overturned by *Loper Bright Enterprises v. Raimondo* (603 U.S. 369, 412 (2024)). Under *Chevron,* the courts were required to defer to a reasonable agency interpretation of an

ambiguous statute. Under *Loper Bright*, "courts need not and under the [Administrative Procedures Act (APA)] may not defer to an agency interpretation of the law simply because a statute is ambiguous". Commenters contend that the agency's reading of section 1833(t)(2)(F) of the Act is not the best interpretation of the law and will no longer receive court deference in future litigation.

CMS responded that it continues to believe that section 1833(t)(2)(F) of the Act gives the Secretary authority to develop its proposed policy. The D.C. Circuit previously held CMS' regulation was a reasonable interpretation of section 1833(t)(2)(F) of the Act. *Loper Bright* does not change that result. CMS believes that if the court had analyzed the matter under the new *Loper Bright* framework, the result would have been the same. As the D.C. Circuit already found, CMS' policy falls comfortably within the agency's delegated authority under the best reading of section 1833(t)(2)(F) of the Act.

Throughout the remainder of the section, comments and CMS' responses reiterated issues that were the subject of prior rulemaking and arguments made in litigation. For instance, commenters stated that the statute specifically grandfathers off-campus PBD from site neutral payment that were providing or in the process of providing OPPS services prior to the enactment of section 1833(t)(21) of the Act on November 2, 2015. CMS' policy violates this grandfathering provision by applying site neutral payment to off-campus PBDs already providing services prior to November 2015 or in the process of doing so. CMS responded that section 1833(t)(2)(F) of the Act and section 1833(t)(21) of the Act have different purposes—one is concern with unnecessary growth of hospital services while the other about the proliferation of off-campus PBDs. CMS does not believe it is violating the grandfathering provision in section 1833(t)(21) of the Act.

Similarly, the commenters argued that section 1833(t)(9) of the Act makes adjustments under the entirety of section 1833(t)(2) of the Act including section 1833(t)(2)(E) subject to the budget neutrality. CMS reiterates its position that the payment policy authorized by section 1833(t)(2)(E) of the Act is a "method" and not an "adjustment" subject to budget neutrality. Further, the D.C. Circuit has held that budget neutrality is not required under the section 1833(t)(2)(E) of the Act volume control method and making that method budget neutral would be contrary to the purpose and intent of the provision.

Many commenters requested that CMS use different timeframes for analyzing growth in drug administration services being furnished in hospitals on the basis that CMS' conclusion about volume growth would be different. CMS' responded that it does not believe it would matter for purposes of this provision as looking at a wider timeframe only further supports its analysis. CMS presented its proposed rule analysis in the response with different timeframes. The response indicates the analysis supports growth in drug administration services furnished in hospitals that CMS believes could just as easily be furnished in physician offices.

A few commenters suggested that, to control unnecessary volume increases, CMS would need to identify a necessary rate of increase for the volume of drug administration services above which any growth is unnecessary. CMS disagreed. Because site-of-service payment differentials are pervasive throughout the OPPS it would be extremely difficult, on a HCPCS or APC level, to

measure what volume should have been absent the influence of those payment differentials. CMS continues to believe shifts of services to the off-campus OPD setting are unnecessary if the beneficiary can safely receive the same services in a lower cost setting.

A few commenters noted that CMS declined to adopt a sustainable growth rate (SGR) like methodology under section 1833(t)(2)(F) of the Act in the 2008 OPPS/ASC final rule (72 FR 66580) stating "implementing such a system could have the potentially undesirable effect of escalating service volume as payment rates stagnate and hospital costs rise, thus actually resulting in a growth in volume rather than providing an incentive to control volume." Commenters concluded that subsection 1833 (t)(2)(F) of the Act only authorizes a method for controlling unnecessary increases in volume. Following CMS' logic, a policy that increases volume through price reductions would not be a permissible volume-control method.

CMS responded that in 2008 it was concerned about continued double digit increases in the expenditure growth under the OPPS from 2001-2008. The 2008 analysis suggested this expenditure growth could be addressed through greater packaging such that further volume controls would not be needed. However, CMS noted that if spending were to continue to escalate at the then current rates, even after increased packaging, it would consider the possibility of imposing external controls that could link growth in volume to reduced payments under the OPPS. As spending has continued to increase especially from 2011 through 2019, CMS stated it has done exactly what it said it would do.

Some commenters stated that the volume control method for clinic visits was not an effective method to control volume as the commenters data analysis indicated that volume did not decrease. CMS responded that its data indicates that clinic visit volume in excepted off-campus PBDs has decreased since 2021 both in absolute volume and in relative volume compared to the total of OPPS and PFS volume. Further, given that both on-campus and non-excepted PBDs have experienced increases in volume for the clinic visit, while excepted off-campus has experienced a decrease, CMS believes its policy has reduced the unnecessary increases in off-campus PBDs.

Several commenters indicated that growth in vertical consolidation of oncology practices with hospitals is driven by 340B discounts in addition to payment differentials between PFS and OPPS. The commenters indicated that hospitals profit by acquiring physician offices and converting them into PBDs. Commenters cited studies that found that hospitals newly participating in the 340B program shifted the site of cancer drug administration to OPDs and increased spending on other cancer care.[70] These commenters requested that these off-campus outpatient facilities not be able to benefit from 340B drug pricing.

CMS responded that this suggestion would have to be addressed by Congress through a statutory change. The response further notes that the commenter's comment raises concern that policies like the 340B program could be contributing to growth in the volume of drug administration services. But CMS' analysis of the study cited by the commenter does not show that the 340B program is

[70] https://pmc.ncbi.nlm.nih.gov/articles/PMC6153182/

responsible for the entire shift in volume from physician offices to OPDs. Instead, this information suggests that for drug administration services, the payment incentives might be layered.

Several commenters asserted that commercial insurers and private equity have invested heavily in physician practice acquisitions. Commenters cite one study that contends that private equity, physician groups, and health insurers, acquired the vast majority of physician practices from 2019 to 2023, while hospitals and health systems accounted for only 6 percent of acquisitions during this period. CMS responded while physician practices may be acquired by private equity or commercial insurers, only hospitals are able to move payments from the PFS to the OPPS as a result of the acquisition.

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. Commenters noted that hospitals must take steps to ensure that a licensed pharmacist supervises drug preparation, rooms are cleaned with positive air pressure to prevent microbial contamination, and employees are protected from exposure to hazardous drugs.

CMS acknowledges that off-campus hospitals outpatient departments sometimes incur costs that physician offices do not. However, a specific drug administration service provided in an off-campus provider-based department of a hospital is clinically similar to the provision of that same drug administration service when provided in a physician office indicating that higher payment is not warranted.

Further, physician offices also incur costs to adhere to regulatory and safety standards and ensure that they are fully equipped to provide drug administration services. While some hospital off-campus hospital outpatient departments may have additional costs that physician offices do not, hospitals may also have some efficiencies physician offices do not, such as greater purchasing power that may offset some of the additional costs identified by commenters.

Citing two studies prepared for the American Hospital Association71, 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 drug administration 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.

[71] The final rule did not provide a citation for these studies.

Some commenters state CMS does not consider that the decision to treat a patient in the outpatient department may be based on the patient's needs, the presence of comorbidities, or a desire for the resources available in an outpatient department. CMS responded that its policy does not prevent beneficiaries from receiving these services in an OPD if it is medically necessary but that argument does not support paying more for drug administration services in an OPD than a physician office. Further, studies examining the role of vertical integration on physicians' choice of care setting show that physicians are much more likely to admit a given patient to their acquiring hospital and that these same hospitals tend to be higher cost, less convenient, and lower quality than nearby options—suggesting negative patient welfare effects from vertical integration.72

Some commenters were concerned about the financial impact this proposal would have on providers. This reduction, commenters stated, threatens the financial viability of hospitals, particularly those serving underserved communities. CMS responded that it is finalizing its proposal to exempt rural SCHs from this policy.

Several commenters indicated CMS should phase-in the reduction over multiple years like it did when it adopted reduced payment for a clinic visit. CMS responded that it believes that the provider community can adapt to the change in payment for drug administration services, which affects a smaller portion of hospital revenues than clinic visits.

CMS is finalizing its proposal to use its authority under section 1833(t)(2)(F) of the Act to pay 40 percent of the OPPS rate for drug administration services furnished in excepted off-campus PBDs. This policy is being adopted without applying budget neutrality.

7. RFI: Expanding the Site Neutral Policy to On-Campus Clinic Visits

The clinic visit (G0463) is still the most utilized service across the OPPS and over 60 percent of clinic visits furnished under the OPPS are furnished on-campus. CMS requested comment on whether it would be appropriate to address unnecessary increases in the volume of covered OPD services in on-campus clinic visits.

CMS received a range of comments on expanding the method to the on-campus setting for clinic visits, imaging without contrast in off-campus PBDs, and other services that may have experienced unnecessary growth. CMS will take these comments into consideration as it develops proposals for future rulemaking.

8. Exemptions for Rural SCHs

In the 2023 OPPS/ASC final rule with comment period (87 FR 72047 through 72051), CMS exempted rural SCHs from receiving the PFS-equivalent rate for clinic visits. Rural SCHs have historically received special payment treatment to account for their higher costs and the disproportionately harmful impact that payment reductions could have on them.

[72] https://doi.org/10.1016/j.jhealeco.2016.08.006

For rural SCHs, CMS indicates that many rural providers, and rural SCHs in particular, are often the only source of care in their communities,[73] which means beneficiaries and providers are not choosing between a higher paying off-campus PBD of a hospital and a lower paying physician office setting. CMS has reviewed utilization data for drug administration services at rural SCHs and has not found strong evidence that drug administration services are being utilized at an unnecessary volume at off-campus PBDs of rural SCHs. For this reason, CMS proposed to exempt drug administration services from site neutral payment at rural SCHs. CMS estimated lost savings from exempting rural SCHs from the drug administration site neutrality policy would be $16 million for 2026.

Public commenters supported CMS proposal. One commenter stated that any exemptions to the volume control methodology should be targeted to independent hospitals. CMS disagrees that any exemptions should be limited to independent hospitals noting that rural SCHs can be part of a larger chain.

Several commenters suggested additional types of hospitals for which they believed further exemptions would be warranted. CMS responded that in each of these cases suggested by the commenters, Congress has not previously determined that any of these hospital types required additional payments for outpatient services. In response to a separate comment, CMS indicated that cancer hospitals are paid under a special methodology that involves targeting its outpatient payments based on the cancer hospital's payment to cost ratio. Site neutral payments may lower a cancer hospital's payment to cost ratio but result in an offsetting adjustment at cost report settlement.

CMS is finalizing its proposal to exempt rural SCHs from the drug administration site neutral policy.

9. Impact

The 2026 OPPS full payment rates for drug administration APCs 5691, 5692, 5693, and 5694 are shown in the below table. The site neutral payments are determined by applying the 40 percent relativity adjuster[74] to the full OPPS payment rates.

APC	Full OPPS Payment	OPPS Payment x 40% Relativity Adjuster
5691	$47.84	$19.14
5692	$73.56	$29.42
5693	$217.31	$86.92
5694	$337.46	$134.98

CMS estimated one year savings from this policy at $290 million, with $220 million of the savings

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

[74] Earlier in this discussion, CMS indicates that the volume control "method" is not an "adjustment" subject to budget neutrality yet in this discussion indicates that the site neutral payment is determined by applying an "adjuster" to full OPPS payment.

accruing to Medicare, and $70 million saved by Medicare beneficiaries and 10 year savings of $11.030 billion ($8,270 billion to Medicare and $2.810 billion to Medicare beneficiaries through reduced coinsurance).

Commenters indicated that CMS' impact table shows significantly greater savings from this proposal beginning in 2027 that appeared to be greater than the amount CMS spends on these services. CMS responded that beginning in 2027, the savings from this policy begin to flow into the baseline for Medicare Advantage rates, thus resulting in a significant increase in savings for 2027 compared to 2026. For 2026, the Medicare Advantage rates had already been calculated at the time of the 2026 OPPS proposed rule and are not impacted by the policy.

B. RFI: Reducing OPPS Payment for Services Performed in ASCs and Physician Offices

CMS sought feedback for future rulemaking on the development of a more systematic process for identifying ambulatory services at high risk of shifting to the hospital setting based on financial incentives rather than medical necessity. The proposed rule requested public comment on 11 categories of questions:

- Items and services paid under the OPPS that may have experienced unnecessary increases in volume.
- Limiting payment based on the site where the services is most performed.
- Whether to use the most recent data or older data to make policy (with a concern that new data may already reflect utilization shifts based on payment).
- How to account for the availability of OPDs, ASCs, and physician offices when determining the setting in which a service is most frequently performed.
- How to address different packaging and bundling policies across ambulatory payment systems.
- Whether to exempt emergent care, trauma-related care, or other care where the hospital is the most appropriate setting regardless of whether the item or service is typically furnished in a different setting.
- Whether to apply OPPS site neutral policies more broadly to all hospital OPDs or limit it only to only certain hospital OPDs, such as off-campus hospital PBDs
- Whether to exempt rural hospitals like SCHs, Medicare Dependent Hospitals, or Rural Emergency Hospitals.
- Other methods that may be warranted to control unnecessary increases in the volume of outpatient services beyond changes to payment rates.
- The impact of the proposed ambulatory payment adjustment on beneficiaries and health care innovations.

CMS received 43 comments on these RFI questions that it will consider for future rulemaking.

C. Virtual Direct Supervision of Certain Hospital Outpatient Services

During the COVID-19 PHE, CMS adopted policies to allow direct supervision of cardiac rehabilitation services (CR), intensive cardiac rehabilitation services (ICR), pulmonary rehabilitation services (PR) and diagnostic services to be furnished remotely via two-way, audio/visual communication technology (but not audio only) by physicians only. These flexibilities were extended through December 31, 2024 after the COVID-19 PHE ended. Beginning in 2024, CMS extended these flexibilities to allow supervision by nurse practitioner (NPs), physician assistants (PAs) and certified nurse specialists (CNSs) eligible to supervise these services in addition to physicians.

In the 2025 PFS rule, CMS revised the definition of direct supervision at §410.32(b)(3)(ii) to extend the availability of virtual direct supervision of CR, ICR, PR and diagnostic services under the PFS through December 31, 2025. Similarly, CMS extended the availability of virtual direct supervision (excluding audio only) for these same services under the OPPS through December 31, 2025.

CMS proposed to extend virtual supervision (excluding audio only) of CR, ICR, PR and diagnostic services under the PFS permanently in the 2026 PFS proposed rule except for services with a 10 or 90-day global period.[75] In the 2026 OPPS proposed rule, CMS proposed to extend virtual supervision (excluding audio only) under the OPPS permanently for these same services.

Nearly all commenters supported CMS' proposal. Commenters suggested a variety of modifications to operational aspects of CMS' policy that the agency will consider in future rulemaking.

One commenter opposed the proposal on the basis that it will increase incident to billing for services billed by physicians but performed by PAs and NPs, which would obscure the extent to which PAs and NPs are performing the services. This commenter suggested that CMS either only allow the supervision to be provided by physicians or establish a method through which CMS can identify incident to billing of services provided by non-physician practitioners.

CMS responded that PAs and NP as well as CNSs are authorized by statute to supervise these services either directly or under the incident to benefit. For this reason, CMS does not see a need to adopt this commenters suggestion.

Several commenters requested that CMS allow PAs, NPs and CNSs to order as well as supervise CR, ICR and PR. CMS responded that these services are "physician prescribed" by statute. The statute does not allow NAs, PAs and CNSs to order CR, ICR, and PR services.

[75] Services with a 10 global period are minor surgical procedures where payment includes preoperative services on the day of surgery and in the 10-day post operative period. Services with a 90-day global period are major surgical procedures with a 1-day pre-operative period and 90-day post-operative period where compensation for all services is made through a single bundled payment.

One commenter requested that CMS extend the definition of direct supervision to include real-time virtual presence via audio/video technology for all therapeutic radiation therapy services for sites of service paid under the OPPS and MPFS. CMS responded that ICR, CR and PR, are the only services that are subject to direct supervision requirements when furnished to hospital outpatients.

CMS is finalizing its proposal without modification.

D. Medical Review of Inpatient Hospital Admissions

Under the 2-midnight rule, services would generally be considered appropriate for inpatient hospital admission and Medicare Part A payment when the physician expects the patient to require at least 2 midnights of hospital care. Services on the IPO list continue to be appropriate for inpatient hospital admission and payment under Medicare Part A regardless of the expected length of stay.

In some cases, an inpatient admission may be appropriate even if the patient needs less than 2 midnights of hospital care based on the physician's judgment considering:

- Complex medical factors such as history and comorbidities.
- The severity of signs and symptoms.
- Current medical needs.
- The risk of an adverse event.

For the inpatient stay to be considered reasonable and necessary, documentation in the medical record must support either the admitting physician's reasonable expectation that the patient will require hospital care spanning at least 2 midnights, or the physician's determination based on factors identified above that the patient nonetheless requires care on an inpatient basis even though the patient's expected stay is less than 2 midnights. The decision to formally admit a patient to the hospital is subject to medical review.

In 2020, CMS finalized a policy to exempt procedures that have been removed from the IPO list from eligibility for referral to Recovery Audit Contractors (RACs) for noncompliance with the 2-midnight rule within the 2 calendar years following their removal from the IPO list. Procedures removed from the IPO list would not be considered by the Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs) in determining whether a provider exhibits persistent noncompliance with the 2-midnight rule for purposes of referral to the RAC nor would these procedures be reviewed by RACs for "patient status" (whether to treat the patient on an inpatient or outpatient basis). BFCC-QIOs could still review such claims to provide education for practitioners and providers regarding compliance with the 2-midnight rule during the 2-year period.

Beginning in 2021, CMS adopted a policy to eliminate the IPO list over a 3-year transitional period. The elimination of the IPO list meant that procedures currently on the IPO list would be subject to the 2-midnight rule. At that time, CMS finalized an indefinite exemption period rather

than the 2-year period for procedures removed from the IPO list after January 1, 2021. The exemption period would last until there is data indicating that the procedure removed from the IPO list is more commonly performed on an outpatient basis. "Commonly performed" would mean that the procedure would have to be performed more than 50 percent of the time in the outpatient setting. The end of the exemption period for each procedure removed from the IPO list on or after January 1, 2021 would be announced via rulemaking.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63736 through 63740), CMS reversed its decision to eliminate the IPO list and returned to the 2-year exemption period from the specified medical review activities for procedures removed from the IPO list.

In section IX of the proposed rule, CMS again proposed to eliminate the IPO list over a 3-year transition period beginning in 2026. While CMS proposed to eliminate the IPO list, it stresses that removal of a service from the IPO list has never meant that a beneficiary cannot receive the service as a hospital inpatient—as always, the physician should use his or her complex medical judgment to determine the appropriate setting on a case-by-case basis.

Consistent with its past policy when it previously eliminated the IPO list, CMS proposed to indefinitely exempt procedures currently on the IPO list from site-of-service claim denials under Medicare Part A, eligibility for referrals to RACs for noncompliance with the 2-midnight rule, and RAC reviews for "patient status" (that is, site-of-service). Procedures would be exempted from medical review for patient status until the procedure is more commonly performed in the outpatient setting, e.g. the claim data demonstrates that the procedure is being performed more than 50 percent of the time in the outpatient setting in a single calendar year. CMS proposed to announce the end of the exemption period for a procedure through sub-regulatory guidance.

During the exemption period, the medical review contractor[76] may still review such claims to provide education for practitioners and providers regarding compliance with the 2-midnight rule, but claims identified as noncompliant would not be denied with respect to the site-of-service under Medicare Part A. Again, information gathered by the medical review contractor when reviewing procedures as they are newly removed from the IPO list can be used for educational purposes but will not result in a claim denial during the exemption period.

CMS notes that there is an exemption period from certain medical review activities, not an exception to the 2-midnight rule. Providers are still required to comply with the 2-midnight rule during the exemption period, and CMS or its contractors may still conduct patient status medical review in cases in which there is evidence of systemic fraud or abuse occurring. Additionally, other types of medical review, unrelated to patient status, will not be impacted by the proposed exemption.

Public commenters generally supported CMS' proposal and its recognition of the physician's expertise in determining the most appropriate site of care. Another commenter was concerned that

[76] On May 22, 2025, CMS announced that responsibility for short-stay reviews will be transitioned from the BFCC-QIOs to the MACs, as of September 1, 2025. Inpatient Hospital Reviews | CMS.

when the exemption period ends, certain patients may continue to require an inpatient level care even though the majority of patients can receive service in a lower-acuity setting. CMS responded that the 2-midnight benchmark does not override the clinical judgment of the physician regarding the need to keep the beneficiary at the hospital, to order specific services, or to determine appropriate levels of nursing care or physical locations within the hospital.

Many commenters asked for additional clarification on the proper application of the case-by-case exceptions to the 2-midnight benchmark as Medicare Advantage plans historically ignore the 2-midnight rule. CMS indicated that providers should ensure that they clearly articulate in the medical record their rationale for admission to assist reviewers in understanding why admission for inpatient care is appropriate despite an expected length of stay that is less than two midnights. CMS emphasizes that Medicare Advantage plans are required to comply with the 2-midnight benchmark (88 FR 22191).

Several commenters offered suggestions about how CMS should provide notice that an exemption period is ending for a service. CMS responded that it will establish the process for ending the exemption period for a service through notice and comment rulemaking at a future date rather than use subregulatory guidance as it had proposed.

Three commenters requested CMS exempt hospitals that utilize certain clinical decision support tools from patient status review for the 2-midnight policy. CMS responded that it does not think clinical decision support tools are an appropriate substitute for patient status review by CMS or Medicare review contractors for compliance with the 2-midnight rule.

CMS is finalizing an indefinite exemption from site-of-service claim denials, initial medical review contractor referrals to RACs, and RAC reviews for "patient status" (that is, site-of-service) for procedures that are removed from the IPO list in 2021 until the service is more commonly performed in the outpatient setting than the inpatient setting.

E. Coding and Payment for Category B Investigational Device Exemption (IDE) Studies

In the 2025 OPPS final rule with comment period, CMS finalized a proposal to codify coding and payment policy for Category B IDE clinical trials with control arms through revisions to §419.47. CMS inadvertently deleted §419.47(a)(1) "The Medicare coverage IDE study criteria in §405.212 of this chapter are met" and paragraph (2) "A new or revised code is necessary to preserve the scientific validity of such a study, such as by preventing the unblinding of the study." Therefore, effective January 1, 2026, CMS proposed to amend the regulatory text at §419.47(a) to restore these two inadvertently removed paragraphs.

In the same final rule, CMS decided not to finalize a proposal to extend coding and payment policy to drugs and devices that are being studied in clinical trials under a Coverage with Evidence Development National Coverage Determinations for which the trial includes a treatment and control arm. However, the proposed revisions to §419.47 were made despite CMS' intent not to finalize this policy. CMS will delete "and devices/drugs studies" from the section heading at §419.47 consistent with its decision not to extend this policy.

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

XI. OPPS Payment Status and Comment Indicators

2026 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 2026, CMS proposed to create one new status indicator:

Status Indicator	Descriptor	OPPS Payment Status
S1	Skin substitute product paid separately	Paid under OPPS, separate APC payment. Subject to payment based on FDA regulatory pathway.

CMS proposed this new status indicator to identify skin substitutes that are paid separately under the OPPS according to their FDA regulatory pathway. CMS received no comments on this proposal. The proposal is being finalized without change. The complete list of 2026 payment status indicators and their definitions are in Addendum D1 of the final rule.

2026 Comment Indicator Definitions

For 2026, CMS proposed to continue to use the following comment indicators that are unchanged from 2025:

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 received no comments on this proposal. The proposal is being finalized without change. The definitions of the OPPS comment indicators for 2026 are in Addendum D2 of the final rule.

XII. Medicare Payment Advisory Commission (MedPAC) Recommendations

OPPS Update: In its March 2025 "Report to Congress: Medicare Payment Policy," MedPAC recommended that Congress update Medicare OPPS payment rates in 2026 by the amount specified in current law plus 1.0 percent. CMS is finalizing its proposal to update OPPS rates by a market basket of 3.3 percent less 0.7 percentage points for productivity or 2.6 percent for 2026 for hospitals that are compliant with the OQR. Hospitals non-compliant with OQR will receive an update that is reduced by 2.0 percentage points to 0.6 percent. CMS is further applying a reduction of 0.5 percentage points to the update for non-drug OPPS services for most hospitals as part of recouping past additional payments for 340B acquired drugs.

Medicare Safety Net Index: In its March 2025 "Report to Congress: Medicare Payment Policy," MedPAC recommended an update to IPPS and OPPS payment rates of current law plus 1.0 percent expressing concern that the statutory update will not ensure the financial viability of some Medicare safety-net hospitals with a poor payer mix.

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

The FY 2026 IPPS/LTCH proposed and final rule with comment period (90 FR 18002 and 90 FR 36536) provides additional information regarding statutory requirements for disproportionate share hospital and uncompensated care payments. CMS looks forward to working with Congress on these matters.

XIII. Ambulatory Surgical Center (ASC) Payment System

Summary of Selected Key Elements of ASC Payment Rates for 2026		
	ASCs reporting quality data	**ASCs not reporting quality data**
2025 ASC Conversion Factor	$54.895	
Wage index budget neutrality adjustment	1.0000	
2026 Update		
Hospital market basket update	3.3%	
Productivity adjustment	-0.7%	
Net MFP adjusted update	2.6%	
Penalty for not reporting quality data	0.0%	-2.0%
Net MFP and quality adjusted update	2.6%	0.6%
2026 Final ASC Conversion Factor	$56.322	$55.224

The ASC update is based on the finalized 2026 IPPS hospital market basket (3.3 percent), reduced by the multifactor productivity adjustment (-0.7 percentage points), and is estimated to be 2.6 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, and/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 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, revised, and become effective throughout the year. 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. In the 2026 OPPS proposed rule, 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 the proposed rule; and
- Codes for which it would seek comments in this final rule with comment period.

Table 126 in the final rule (reproduced below) provides the process and timeline for ASC list updates:

Comment and Finalization Timeframes for New and Revised ASC-Related HCPCS Codes				
ASC Quarterly Update CR	**Type of Code**	**Effective Date**	**Comments Sought**	**When Finalized**
April 2025	HCPCS (CPT and Level II codes)	April 1, 2025	2026 OPPS/ASC proposed rule	2026 OPPS/ASC final rule with comment period
July 2025	HCPCS (CPT and Level II codes)	July 1, 2025		
October 2025	HCPCS (CPT and Level II codes)	October 1, 2025	2026 OPPS/ASC final rule	2027 OPPS/ASC final rule with comment period
January 2026	CPT Codes	January 1, 2026	2026 OPPS/ASC proposed rule	2026 OPPS/ASC final rule with comment period
	Level II HCPCS Codes		2026 OPPS/ASC final rule with comment period	2027 OPPS/ASC final rule with comment period

2. April 2025 Codes

For the April 2025 ASC quarterly update, there were several new Level II HCPCS codes. Table 73 in the proposed rule displayed the new HCPCS codes and descriptors. CMS notes that the proposed payment indicators, comments 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 2025 OPPS/ASC final rule and invited public comment. **In this final rule,[77] CMS indicates it received no public comments on the April 2025 proposed Level II HCPCS payment indicator assignments, and is finalizing them as proposed**.[78]

3. July 2025 HCPCS Codes

In the July 2025 ASC quarterly update (Transmittal 13344, Change Request 14101, August 1, 2025), CMS added several separately payable CPT and Level II HCPCS codes to the list of covered surgical procedures and covered ancillary services, and solicited comments on these new

[77] This final rule is a final rule with comment period (FC). This summary uses the shorthand "final rule" for succinctness.

[78] CMS notes that in prior years the agency included the final ASC payment indicators in the coding tables in the preamble, but because CMS includes the same information in the ASC addenda, this year the agency has not included them in Table 123 in the preamble. Therefore, CMS advises readers to refer to the ASC addenda for the final ASC payment indicators and payment rates for all codes reported under the ASC payment system.

codes. **CMS did not receive any comments on the proposed interim ASC payment indicator assignments for the new CPT and Level II HCPCS codes that were added to the list of covered surgical procedures and ancillary services implemented in July 2025, and is finalizing the proposed ASC payment indicator assignments for the codes**. These codes appear in Table 124 of this final rule.

4. October 2025 - CMS Will Solicit Public Comments in the 2026 Final Rule

For 2026, consistent with CMS' established policy, CMS proposed in the CY 2026 OPPS/ASC proposed rule (90 FR 33704) that the Level II HCPCS codes that will be effective October 1, 2025, would be designated with "NI" in Addendum BB to the 2026 OPPS/ASC final rule to indicate that the codes have interim ASC payment status for 2025. CMS indicated that it would invite public comments on these codes in the 2026 OPPS/ASC final rule, and finalize them in the 2027 OPPS/ASC final rule. CMS carries through on that proposal here. **Table 125 lists the codes effective October 1, 2025 (Transmittal 1349, Change Request 14246, dated September 22, 2025), on which the agency now solicits comments**.

5. January 2026 HCPCS Codes

a. Level II HCPCS Codes Final Rule Comment Solicitation

CMS releases Level II HCPCS codes effective January 1, 2026 in this final rule, in the January 2026 ASC Update CR, and on the CMS HCPCS website. These codes are assigned comment indicator "NI" in Addendums AA and BB to the 2026 OPPS/ASC final rule to indicate an interim ASC payment status. **CMS solicits comments in this final rule on the interim payment indicators, which would then be finalized in the 2027 OPPS/ASC final rule**.

b. New CPT Codes Proposed Rule Comment Solicitation

In the proposed rule, CMS sought comment on proposed new and revised CPT codes effective January 1, 2026 that were received from the AMA in time to be included in the proposed rule. 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 codes are new or substantially revised for the next calendar year. CMS indicated that it would finalize the payment indicators in the CY 2026 OPPS/ASC final rule. **CMS did not receive any comments on the proposed ASC payment indicators for the new CPT codes effective January 1, 2026, and is finalizing these codes as proposed**.

6. 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), which provide payment information regarding covered surgical procedures and covered ancillary services, respectively, 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 CPL prior to CY 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 CY 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 2026

As noted above, proposed codes were included in ASC Addenda AA and BB to the proposed rule and labeled with comment indicator "NP" to indicate that the new and revised CPT and Level II HCPCS codes were open for comment as part of the 2026 OPPS/ASC proposed rule.

Under the ASC payment system, skin substitute products are currently packaged and assigned an ASC payment indicator of "N1" (Packaged service/item; no separate payment made). Under new policies, as finalized elsewhere in this final rule with comment period,[79] payment under the ASC

[79] In section III of the final rule (summarized above), CMS creates APC groups to pay separately for certain skin substitutes under the OPPS and, as discussed in section XIII.E. of this final rule (summarized below), CMS also finalizes a policy of paying separately for skin substitute supplies in the ASC payment system and adding such supplies

payment system for separately-payable skin substitute products would be based on the OPPS conversion factor, not on the ASC conversion factor. Additionally, payment for these skin substitute products would not be subject to the ASC wage index. Therefore, for 2026 and subsequent years, CMS proposed to create a new ASC payment indicator "S2" – (Skin substitute supply group; paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate) – to Addendum DD1 to this final rule to describe skin substitute products paid separately in an ASC. This "S2" payment indicator would indicate a separately payable ancillary skin substitute supply when provided integral to a separately payable ASC covered surgical procedure.

CMS indicates that it did not receive public comments on its proposal to create a new "S2" payment indicator. Therefore, **the agency is finalizing its proposal to indicate a separately payable ancillary skin substitute supply when provided integral to a separately payable ASC covered surgical procedure beginning CY 2026**.

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"[80] 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 nonfacility PE RVU-based amount or the amount calculated using the ASC standard rate setting 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.

In 2014, CMS finalized a policy of conditionally packaging 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

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to the ancillary items and services list for 2026.

[80] 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.

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 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 2026

CMS proposed to update the ASC payment rates for 2026 using the established rate calculation methodologies under §416.171, and using the definition of device-intensive procedures (discussed in section XIII.C.4 of this final rule). 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 using the methodology discussed in section XIII.C.4. of the proposed rule preamble. 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 2026 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") will be assigned the current ASC payment indicators associated with those procedures and will be paid separately under the ASC payment system. CMS does not discuss any comments received on these proposals that appear to be finalized without change.

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.[81] 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.

[81] A "J1" status indicator refers to a hospital outpatient service paid through a C-APC.

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 primary service and the primary service code reported with the add-on code is not reassigned to the next higher cost C-APC. CMS lists the finalized complexity adjustments for "J1" and add-on code combinations for 2026, along with all of the other proposed complexity adjustments, in Addendum J to this final rule.

(2) CY 2026 ASC Special Payment Policy Proposal for OPPS Complexity Adjusted C-APCs

For 2026, 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 claims data to calculate the code combination utilization and estimated payments for the ASC payment system budget neutrality calculations (discussed in section XIII.H2.a of this final rule).[82]

Interestingly, CMS indicates the agency received comments (plural) on "these" proposals (CMS does not indicate which specific proposals prompted public comments), but it only recounts a single comment recommending an adjustment to CMS' device-intensive determination for ASC complexity adjustment codes. CMS states the comment is out-of-scope of the current rule, but that it would consider the suggestion in future rulemaking.

After consideration of public comments received, CMS 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 Low-Volume Device-Intensive Procedures

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

Based on its analysis of claims data, in this year's proposed rule, CMS proposed to designate six brachytherapy APCs and four clinical APCs as Low-Volume APCs under the ASC payment

[82] The full list of the finalized ASC complexity adjustment codes for 2026 can be found in the 2026 ASC Addendum AA and the supplemental policy file, which also includes both the existing ASC complexity adjustment codes and finalized additions and published with the final rule on the CMS website at https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1834-fc.

system. These 10 APCs meet CMS' criterion of having fewer than 100 single claims in 2024. Table 127 in the final rule lists the 10 low-volume APCs and the number of 2024 claims used to set payment rates for them.

CMS indicates the agency received no comments on its proposal to designate these 10 APCs as low-volume APCs, and is thus finalizing the proposal without modification.

2. 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.[83]

Radiology services. CMS generally pays separately 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

[83] As determined by CMS under §416.174 (86 FR 63483).

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.

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[84] 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

In the OPPS/ASC notice of proposed rulemaking for 2026, 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. CMS also proposed to continue to set the 2026 ASC payment rates and subsequent year payment rates for brachytherapy sources and separately-payable drugs and biologicals equal to the OPPS payment rates for 2026 and subsequent year payment rates. For those covered ancillary services where the payment rate is the lower of the rate under the ASC standard rate setting methodology and the PFS proposed rates, the proposed

[84] 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.

payment indicators and rates were based on a comparison using the proposed PFS rates effective January 1, 2026.

CMS describes only a single comment related to this proposal, from a commenter arguing that MACs do not have sufficient guidance on how to establish separate payment for pass-through devices. CMS disagreed with the commenter, and is **finalizing its proposal to update the ASC payment rates and to make changes to ASC payment indicators, as necessary, to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the final CY 2026 OPPS and ASC payment rates and subsequent years' payment rates. CMS is also finalizing its proposal without modification to continue to set the CY 2026 ASC payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for CY 2026 and subsequent years**.

Covered ancillary services and their payment indicators for 2026 are listed in Addendum BB of this final rule (available on the CMS website).

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. CY 2026 Final Office-Based Procedures

For 2026, 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 2024 utilization of covered surgical procedures claims data, CMS identified

one surgical procedure that it proposed to permanently designate as office-based for 2026, specifically, CPT code 21930.[85]

CMS also reviewed the utilization for nine surgical procedures designated as temporarily office-based in the 2025 OPPS/ASC final rule. CMS proposed to remove two of the procedures, HCPCS codes G0564 and G0565, because they were deleted effective April 2025. Additionally, based on information submitted by interested parties, CMS has determined that the entirety of two of the remaining seven procedures, specifically, CPT code 15013 and its automated counterpart HCPCS C8002, are not expected to be performed in a physician office setting and that CPT code 11310 would not be an accurate crosswalk for site-of-service utilization. Therefore, CMS proposed to permanently remove the temporarily office-based designation for CPT code 15013 and HCPCS code C8002.

For the remaining five surgical procedures, CMS reviewed 2024 volume and utilization data. Based on these data, CMS determined that CPT code 0864T[86] is performed predominantly in the office setting. Therefore, CMS proposed to permanently designate this procedure as office-based and assign one of the office-based payment indicators, specifically "P2," "P3," or "R2."

For the remaining four procedures (0588T, 53866, 64598, and 67229), 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 2026 and assign one of the office-based payment indicators.

CMS did not propose to designate any new 2026 CPT codes for ASC covered surgical procedures as temporarily office-based.

CMS indicates it not receive any public comments on its proposed permanent office-based designations nor on its proposal to no longer designate the procedures in Table 129 as temporarily office-based; therefore, **the agency is finalizing its proposal to designate the procedures in Table 128 as permanently office-based beginning in 2026 and to no longer designate the procedures in Table 129 as temporarily office-based (tables reproduced below).**

[85] Excision, tumor, soft tissue of back or flank, subcutaneous; less than 3 cm. See Table 77 in the proposed rule.
[86] Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy.

TABLE 128: ASC COVERED SURGICAL PROCEDURES TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2026

CY 2026 CPT/HCPCS Code	Long Descriptor	Final CY 2025 ASC Payment Indicator	Final CY 2026 ASC Payment Indicator*
21930	Excision, tumor, soft tissue of back or flank, subcutaneous; less than 3 cm	G2	P3*
0864T	Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy	R2	R2*

* Payment indicators were based on a comparison of the final rates according to the ASC standard ratesetting methodology and the CY 2026 PFS final rates.

TABLE 129: ASC COVERED SURGICAL PROCEDURES TO BE NO LONGER DESIGNATED AS TEMPORARILY OFFICE-BASED FOR CY 2026

CY 2026 CPT/HCPCS Code	Long Descriptor	Final CY 2025 ASC Payment Indicator	Final CY 2026 ASC Payment Indicator*
0864T	Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy	R2	R2*
15013	Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin	R2	G2
C8002	Preparation of skin cell suspension autograft, automated, including all enzymatic processing and device components (do not report with manual suspension preparation)	R2	G2

* Payment indicators were based on a comparison of the final rates according to the ASC standard ratesetting methodology and the CY 2026 PFS final rates.

CMS also did not receive comments on its proposal to continue designating codes 0588T, 53866, 64598, and 67229 as temporarily office based, and is finalizing this proposal as well.

4. Device-Intensive ASC-Covered Surgical Procedures

a. CY 2026 Final Device-Intensive Procedures

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.[87]

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;[88] 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

[87] 83 FR 58944 through 58948.
[88] As defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1).

threshold under the standard ASC ratesetting methodology, the procedure will be assigned 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.

CMS refers to the implementation of the "Final Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022 rule" and expresses its belief that the remedy's proposed prospective offset to the OPPS conversion has a very limited impact on the ASC payment system. However, CMS states its belief 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.

Therefore, CMS proposed that the OPPS payment rates used for ratesetting under the ASC payment system for 2026 and subsequent years would not incorporate the two percent prospective offset to the OPPS conversion factor as a result of the 340B remedy offset that the agency proposed in that same proposed rule.[89] Please refer to Addendum FF of the final 2026 device offset percentages. Final 2026 device offset percentages may differ from the proposed percentages because CMS recalculates them using updated data for the 2026 OPPS/ASC final rule.

[89] CMS did not finalize the proposed 2.0 percent reduction in hospital payments, but instead continues the existing 0.5 percentage point reduction under the 340B remedy offset. See discussion in V.B.9 of this summary.

CMS received a number of comments in response to this proposal. Most of the comments were requests for CMS to assign device-intensive status to certain CPT codes or APCs or questioning CMS's removal of this status from other codes. CMS responded to these comments either agreeing or disagreeing with the commenters based on issues specific to each code raised. See preamble discussion starting here. After consideration of public comments received, **CMS is finalizing its proposal to not incorporate the prospective offset to the OPPS conversion factor or device-related portion as a result of the 340B remedy offset that CMS is finalizing elsewhere in this final rule**.

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.

CMS did not propose any changes to its policies related to no cost/full credit or partial credit devices for 2026. **CMS indicates it did not receive any comments on the agency's policies related to no cost/full credit or partial credit devices, and thus is finalizing the continuation of existing policies for CY 2026 without modification**.

5. Requirement in the PFS 2026 Proposed Rule for HOPDs and ASCs to Report Discarded Amounts of Certain Single-dose or Single-use Package Drugs

Section 1847A of the Act[90] requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug.

[90] Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117-9, November 15, 2021) ("the Infrastructure Act") amended section 1847A of the Act to re-designate subsection (h) as subsection (i) and insert a new subsection

The 2026 PFS proposed rule included proposals related to the discarded drug refund policy, including proposals that could impact hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs). CMS therefore included a notice in the 2026 OPPS/ASC proposed rule to ensure interested parties are aware of these proposals, and requested that interested parties submit their comments about these proposals to the 2026 PFS proposed rule. CMS advises interested parties to review the 2026 PFS rule for any policies on this issue..

D. Additions to ASC Covered Surgical Procedures and Covered Ancillary Services Lists

1. Current Review Process for the List of ASC Covered Surgical Procedures

Section 1833(i)(1) of the Act[91] 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 (ASC 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.

Currently, covered surgical procedures are those that meet the general standards specified in regulation and are not excluded. Specifically, covered surgical procedures are "surgical procedures specified by the Secretary and published in the *Federal Register* and/or via the internet on the CMS website that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure." (§416.166(b))

The general exclusion criteria (at §416.166(c)(1) to (8)) provide that covered surgical procedures do not include those surgical procedures that:

(1) Generally result in extensive blood loss;
(2) Require major or prolonged invasion of body cavities;
(3) Directly involve major blood vessels;
(4) Are generally emergent or life-threatening in nature;
(5) Commonly require systemic thrombolytic therapy;
(6) Are designated as requiring inpatient care under §419.22(n);
(7) Can only be reported using a CPT unlisted surgical procedure code; or
(8) Are otherwise excluded under §411.15.

Beginning in 2019,[92] 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

(h).
[91] Section 1833(i)(1) of the Act.
[92] See 2019 OPPS/ASC final rule (83 FR 59029 through 59030).

the CPT surgical range that CMS determines met the general standards established in previous years for addition to the ASC CPL.

2. Final Changes to the List of ASC Covered Surgical Procedures for 2026

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. CMS discusses the recent history of revisions to the agency's method for adding surgical procedures to the list. Specifically, in 2021, CMS finalized a policy that the general exclusions and general standard criteria would become "safety factors" for physicians to consider for a specific beneficiary when determining whether to perform a covered surgical procedure. Under this policy, CMS intended to add surgical procedures to the list when the agency determined a procedure met the criteria or when the agency was notified of a surgical procedure that could meet criteria and CMS confirmed that the procedure met requirements. This policy broadened the list for 2021.

In 2022, this policy was reversed when CMS reinstated the general standard and general exclusion criteria as part of its review process. The notification process became a "pre-rule recommendation process" in which an external party can recommend a surgical procedure by March 1 of a calendar year for the list of ASC covered surgical procedures for the following calendar year. Subsequently, CMS finalized the removal of 255 procedures that had been added to the ASC CPL in 2021.

a. ASC CPL Review Process for 2026

(1) Proposed Changes to General Standards and Exclusion Criteria for 2026

In this year's 2026 OPPS/ASC proposed rule, CMS proposed to again revise the regulatory criteria by removing certain general standard and general exclusion criteria at 42 CFR 416.166(b) and (c), moving them to a new section (§416.166(d)) as nonbinding "physician considerations for patient safety." Under the revised criteria, CMS would add certain surgical procedures to the ASC CPL, beginning in 2026, in order to expand access, while maintaining the safety for Medicare beneficiaries through the nonbinding physician considerations for patient safety. Specifically, CMS proposed the following:

Revising the general criteria (at existing §416.166(b)). CMS proposed to revise the general standard criteria for covered surgical procedures to be "surgical procedures specified by the Secretary that are published in the *Federal Register* and/or via the internet on the CMS website and that…are separately paid under the OPPS" at new §416.166(b)(2) and (b)(2)(i). This revision would remove two of the general criteria, specifically, that the procedure: (1) would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and (2) is one for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. These two criteria would be included in the new "physician consideration" section at new paragraph (d).

Revising the general exclusion criteria (at existing §416.166(c)). CMS also proposed to eliminate five of the current general exclusion criteria at §416.166(c)(1) through (c)(5) and move them to the new "physician considerations" section at new paragraph (d). They include surgical procedures that: (1) Generally result in extensive blood loss; (2) Required major or prolonged invasion of body

cavities; (3) Directly involve major blood vessels; (4) Are generally emergent or life-threatening in nature; and (5) Commonly require systemic thrombolytic therapy. Under this proposal, CMS would continue to exclude certain procedures from the ASC CPL based on the remaining three general exclusion criteria (§416.166(c)(6) through (c)(8)).

With respect to the existing general exclusion at §416.166(c)(6), which excludes procedures designated as requiring inpatient care under §419.22(n) from classification as covered surgical procedures, this proposal would modify this standard since the IPO list was proposed for elimination beginning in 2026 with a 3-year transition period.[93] CMS believes that maintaining this criterion for 2026 would allow for consistency between the two lists during the 3-year phaseout period and notes that if a service comes off the IPO list at any time, then the general exclusion at §416.166(c)(6) would cease to apply to the service. Specifically, CMS would revise the phrase at existing §416.166(c)(6) from "Are designated as requiring inpatient care under §419.22(n) of this chapter;" to indicate (under new §416.166(b)(2)) that such services are not "currently" designated as requiring inpatient care under §419.22(n).

CMS explains that given advances in the practice of medicine and the evolving nature of ASCs, CMS believes that ASCs are now better equipped to safely perform procedures that were once too complex or risky to be performed safely on Medicare beneficiaries in the ASC setting. Moreover, CMS believes that these procedures are safe to perform in an ASC setting because all procedures identified are already payable in the HOPD setting and, therefore, are already safely performed on an ambulatory basis, consistent with the statutory requirement under section 1833(i)(1) of the Act.

(2) ASC CPL Review Process for CY 2026

CMS will add surgical procedures to the ASC CPL in rulemaking as the agency becomes aware of new surgical procedures that meet the four requirements at new §416.166(b)(2), that is, the sole general criterion and the three remaining general exclusion criteria. The public may also notify CMS of a surgical procedure they believe meets the revised requirements through the pre-proposed rule recommendation process or the public comment period. Upon receiving the request, CMS will confirm that the procedure meets the requirements (as proposed) and if it does, add the procedure to the ASC CPL. In accordance with the new proposed regulatory text at §416.166(d), physicians would then assess whether their specific patients can or cannot safely receive such covered surgical procedure in the ASC setting based on patient-specific considerations.

b. Proposed Surgical Procedure Additions for 2026

For 2026, CMS proposed to update the ASC CPL by adding 276 potential surgery or surgery-like codes to the list that the agency believes would meet the proposed revised ASC CPL criteria under new §416.166(b)(2). Additionally, CMS proposed to add 271 surgery or surgery-like codes to the ASC CPL that are currently on the IPO list, if CMS were to finalize its proposal to remove these services from the IPO list for 2026.

CMS indicates that it received support from ASCs, ambulatory surgery associations, and professional societies for its proposals to revise the ASC CPL criteria, and add 547 surgery or

[93] CMS finalized its proposed elimination of the IPO List in this final rule. See section IX of this summary for a complete discussion.

surgery-like procedures to the ASC CPL for 2026. CMS states that many commenters, however, including hospital systems and hospital associations, were opposed to these proposals. These commenters argued that ASCs are not as well-regulated as hospitals, and that ASCs do not have the necessary resources on site to provide the higher level of care necessary to perform many of the surgical procedures proposed for addition to the ASC CPL. Commenters opposing these proposals were particularly concerned about procedures formerly on the IPO list, arguing that CMS should wait until the agency had data on the performance of such procedures in hospital OPDs before adding them to the ASC CPL. Lastly, commenters were concerned that allowing certain procedures to be performed in the ASC setting could increase the burden on hospitals if they face increased transfers from ASC facilities if there are increases in complications from ASCs performing procedures that are not safe in that setting. Commenters were also concerned that this proposal would allow certain higher paying procedures to move over to the ASC setting, negatively affecting hospitals and their ability to offset lower paying procedures.

CMS was generally unmoved by these concerns.

After consideration of the public comments, **CMS is finalizing its proposal, with modification, to revise the ASC CPL criteria under §416.166 by modifying the general standard criteria and eliminating five of the general exclusion criteria and to add the proposed 547 procedures to the ASC CPL for 2026.** In response to public comments, **CMS is also finalizing adding an additional 13 codes recommended by commenters to the ASC CPL for 2026. These codes, along with their long descriptors and final payment indicator assignments, are listed in Tables 131, 132, and 133.**

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 2025, but will be packaged under the 2026 OPPS, CMS would also package the ancillary service under the ASC payment system for 2026 to maintain consistency with the OPPS. New CPT and HCPCS codes for covered ancillary services for 2026 can be found in section XIII.B. of the 2026 OPPS/ASC proposed rule. All ASC covered ancillary services and their payment indicators for 2026 are included in Addendum BB to this final rule.

CMS received public comments requesting that 24 procedures be added to the list of covered ancillary services for 2026; in this final rule CMS is adding 22 of these procedures, along with 13 procedures recommended by commenters that did not qualify for addition to the ASC CPL, due to being nonsurgical in nature, but which could be appropriately placed on the list of ASC covered ancillary services. The full list of new covered ancillary services for 2026 appears in section XIII.B of this final rule.

E. Skin Substitute Changes to the List of ASC Covered Items and Services

CMS proposed to remove skin substitutes from the list of packaged items and services under the OPPS and ASC payment systems beginning in 2026. Therefore, similar to how ASCs are paid separately for brachytherapy sources provided integral to ASC covered surgical procedures at

prospective rates adopted under the OPPS, CMS proposed to pay for groups of skin substitute products at annual prospective rates adopted under the OPPS, effective January 1, 2026. In order to separately pay for the provision of certain groups of skin substitute products when used during a covered surgical procedure, **CMS proposed** to revise 42 CFR 416.164(b) to include groups of skin substitute products as covered ancillary items and services that are integral to a covered surgical procedure, and to identify separately payable HCPCS skin substitute codes with a payment indicator of "S2." Therefore, for existing skin substitute products for which CMS proposed to pay separately, CMS will revise the payment indicator from "N1" to "S2" for 2026. New skin substitute products that are proposed for addition to the list of ASC covered ancillary items and services would also be assigned an ASC payment indicator of "S2."

Fascinatingly, given the amount of attention given to the skin substitute payment policy changes finalized in this year's 2026 physician fee schedule final rule, CMS indicates that in response to the skin substitute proposals in the ASC payment system proposed rule, **the agency received no public comments, and is thus finalizing these proposals as proposed**.

F. Non-Opioid Policy for Pain Relief Under the OPPS and ASC Payment System

1. Background

Section 4135(a) and (b) of the CAA, 2023 directs CMS to unpackage and provide separate payment for three years beginning January 1, 2025 for non-opioid treatments for pain relief. CMS describes the policies finalized in the 2025 OPPS ASC final rule,[94] which outline payment for non-opioid pain management drugs, biologicals, and medical devices under both the ASC payment system and OPPS. CMS finalized several qualifying products for separate payment beginning January 1, 2025,[95] 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 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

[94] See 42 CFR 416.174 and 42 CFR 419.43(k).
[95] See Table 158 in the 2025 OPPS ASC final rule, beginning 89 FR 94358.

replace, reduce, or avoid opioids, the medical device will not meet the evidence criterion to qualify for separate payment.

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.[96]

Payment Amount. For a drug or biological that qualifies for separate payment, the statute sets payment at the methodology used under section 1847A (generally, ASP+6 percent) less the amount included in the OPPS or ASC payment for the product 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 is 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,[97] 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.

[96] 89 FR 94346 through 94347

[97] 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 CY 2026 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023

In the 2026 OPPS/ASC proposed rule, CMS proposed to continue to use the policies it finalized in the 2025 OPPS/ASC final rule without modification. It believes the zero-dollar offset policy is appropriate for all qualifying products. Additionally, the data used for the proposed rule was from 2024 claims, which preceded the effective date of the section 4135 policy. Accordingly, CMS proposed to remove the limiting phrase "which is determined to be zero dollars for calendar year 2025" from §416.174(c)(1).

CMS also sought comment on additional drugs or devices that stakeholders believe should qualify as non-opioid treatments for pain relief.

CMS indicates that commenters were generally supportive of Medicare paying for drugs paid under the ASC non-opioid treatment policy authorized by section 6082 of the SUPPORT Act under the policy authorized by section 4135 of the CAA, 2023 for the second year, including the C-APC exclusion of qualifying products. Commenters recommended that CMS begin to assess its authority for continuing a policy for the payment of non-opioid treatments for pain relief in future rulemaking, starting in 2028 and beyond, including making the current policy permanent. One commenter suggested that CMS approve products for this policy on an off-cycle basis in order to provide more timely access to non-opioid analgesic products. Other commenters expressed support for broader interpretations of products that could be covered under this policy (e.g., allowing products that have FDA-approved indications for "acute pain" or other pain indications to qualify under this policy, rather than only those with the FDA-approved label indications to "reduce postoperative pain" or to "produce postsurgical or regional analgesia" that is prescribed by the Congress. Overall, commenters did not think it was appropriate for CMS to require the indications specified in section 1833(t)(16)(G)(iv) of the Act strictly. (Perhaps unsurprisingly, given the broad implications of *Loper Bright*, CMS declined to act on such suggestions.)

CMS did concede that it may be reasonable to consider a pathway to approve new products or products newly meeting the statutory requirements on a quarterly basis, pursuant to public comment. After consideration of public comments, **CMS is finalizing its proposal to continue the policies finalized in the 2025 OPPS/ASC final rule with comment period with a minor modification to permit more timely consideration of payment requests**.

Table 134 in this final rule (summarized below) lists for 2026 the non-opioid alternatives finalized for separate payment as non-opioid pain management drugs or devices under section 4135 criteria.

TABLE 134: QUALIFYING PRODUCTS FOR SEPARATE PAYMENT IN CY 2026 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

Brand Name	HCPCS Code	Long Descriptor
Zynrelef	C9088	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg
Ketorolac tromethamine Injection	J1885	Injection, ketorolac tromethamine, per 15 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)

Table 136 lists the final qualifying products for separate payment under Section 4135 of the CAA, 2023. Table 137 lists the final payment limitations for qualifying products for 2026.

G. New Technology Intraocular Lenses (NTIOLs)

New Technology Intraocular Lenses (NTIOLs) are intraocular lenses that replace a patient's natural lens that has been removed in cataract surgery and that also meet the requirements listed in §416.195. CMS did not receive any requests for review to establish a new NTIOL class for 2026 by March 1, 2025, the due date published in the 2025 OPPS/ASC final rule (89 FR 94361). CMS did not propose to revise the current payment adjustment ($50 per lens) for NTIOLs. However, CMS received multiple comments asking the agency to increase the NTIOL add-on payment amount to $100 for 2026, arguing that the payment has not been adjusted for over two decades despite significant inflation and increased research and development costs associated with bringing new IOL technologies to market. The commenters noted that in real dollar terms, the flat rate payment for NTIOLs has significantly lagged the overall economic inflation rate, with consumer inflation increasing by 138.6 percent since 2010 and manufacturing costs rising due to labor inflation and

increased material costs. The commenters also requested that CMS update the NTIOL payment annually going forward.

Rather than respond to the comment on its face, CMS refers readers to its response to a similar comment in the 2024 OPPS/ASC final rule with comment period (88 FR 81955 through 81956), and does not reiterate its response in this final rule.

H. ASC Payment Rates and ASC Conversion Factor

In the OPPS/ASC proposed rule for 2026, CMS proposed to continue to update relative weights using the national OPPS relative weights and the PFS non-facility PE RVU-based amounts when applicable. CMS scales the relative weights as under prior policy. Holding ASC use, the ASC conversion factor, and mix of services constant from 2024,[98] CMS computes the ratio of:

- Estimated total payments using the 2025 relative payment rates, to
- Estimated total payments using the 2026 relative payment rates.

The proposed 2026 total payments would also include spending and utilization related to ASC complexity adjustment codes or C codes. CMS estimated the change in ASC spending related to these codes for 2026 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 estimated that the proposed 2026 payment limitations would not impact the ASC weight scalar.

As noted above, CMS proposed to unpackage and pay separately for groups of skin substitute products under the ASC payment system beginning January 1, 2026, and is finalizing that proposal in this final rule. To maintain budget neutrality, CMS multiplied the change in the geometric mean costs of covered surgical skin procedures in the ASC setting from unpackaging skin substitute products by the use of skin procedures in the ASC setting to approximate the estimated skin substitute payments in the ASC setting. The estimated separate payments for skin substitutes in the ASC setting did not impact the ASC weight scalar.

The resulting ratio, 0.872, was the proposed weight scalar for 2026. 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 scaler would not apply to ASC payments for separately payable covered ancillary services that have a predetermined national payment amount and are not based on OPPS relative payment weights (e.g., drugs and biologicals that are separately paid and services that are contractor-priced or paid at reasonable cost in ASCs).

As described above in section V.B.8.i., CMS proposed that the OPPS payment rates used for ratesetting under the ASC payment system for 2026 and subsequent years would not incorporate

[98] The supporting data file is posted on the CMS web site at: http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/ASCPaymentSystem.html.

the two percent (now finalized at 0.5 percentage points) prospective offset to the OPPS conversion factor, as a result of the 340B remedy offset that CMS proposed to implement in the proposed rule and finalizes in this final rule. The ASC payment system has generally adopted the OPPS conversion factor used for determining the proposed or final OPPS payment rates in determining the device portions for device-intensive procedures under the ASC payment system. However, a two percent reduction in the OPPS conversion factor would otherwise reduce ASC payments for device-intensive procedures by approximately one percent; the non-device portions for all covered surgical procedures would otherwise be increased to offset reduction to device portions for device-intensive procedures. CMS estimated that the reduction to device portions from the two percent prospective offset would have reduced proposed 2026 ASC expenditures for device-intensive procedures by approximately $42 million and would have otherwise increased the ASC weight scalar by 0.1 percent to offset such reduction.

CMS indicates that many commenters reiterated their longstanding recommendation that CMS discontinue the ASC weight scalar, stating that the secondary rescaling process applied to maintain budget neutrality has created an inappropriate and growing payment disparity between ASCs and HOPDs, with ASC reimbursement rates now averaging 50 percent less than HOPD rates for the same procedures despite no evidence of increased differences in capital and operating costs between settings. CMS declined positive action in response to these comments. Other comments were generally APC- or CPT-specific.

After consideration of public comments received, CMS is finalizing its proposal to use scaled OPPS relative weights to establish ASC relative payment weights and to use the ratio of 2025 to 2026 total payments (the weight scalar) to scale the ASC relative payment weights for 2026. The final 2026 ASC weight scalar is 0.872.

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)[99] 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 scaler, CMS computes the ratio of:

- ASC payments using the 2025 ASC wage indices, to
- ASC payments using the 2026 ASC wage indices.

The resulting ratio, 0.9999, was the proposed wage index budget neutrality adjustment to the

[99] Consistent with CMS's proposed changes to other FY and CY 2026 fee-for-service payment systems, CMS proposed to update the labor market definitions used to adjust ASC payments for geographic differences in wages using the most recent labor market definitions issued via OMB Bulletin No. 23-01 (86 FR 37770, July 21, 2023). Similarly, CMS proposed to limit reductions in the wage index values to 5 percent. All of these changes would be implemented in a budget-neutral manner.

conversion factor for 2026; in this final rule CMS has updated its estimate of the budget neutrality factor to 1.0000.

To update ASC rates, CMS finalizes the use of the hospital market basket update of 3.3 percent minus the productivity adjustment of 0.7 percent, yielding an update of 2.6 percent for ASCs meeting quality reporting requirements. CMS continues its policy of reducing the update by 2.0 percentage points for ASCs not meeting the quality reporting requirements, yielding an update of 0.6 percent for such ASCs. The resulting proposed 2026 ASC conversion factor is $56.206 for ASCs reporting quality data, and $55.109 for those that do not, computed as follows:

	ASCs reporting quality data	**ASCs not reporting quality data**
2025 ASC conversion factor	$54.895	
Wage adjustment for budget neutrality	x 1.0000	
Net MFP-adjusted update	x 1.026	x 1.006
2026 ASC conversion factor	$56.322	$55.224

I. Impact

CMS provides the estimated aggregate increases for the six specialty groups that account for the most ASC utilization and spending, assuming the same mix of services from the 2024 claims data. (Table 168 of the final rule is shown below.) The eye surgical specialty group remains the largest source of payments.

Table 168: Estimated Impact on Surgical Specialty Groups

Surgical Specialty Group	Estimated 2025 ASC Payments (in Millions)	Estimated 2026 Percent Change
Total	**$7,814**	**3**
Eye	$2,082	4
Musculoskeletal	$1,718	2
Nervous system	$1,588	2
Gastrointestinal	$1,066	3
Cardiovascular	$520	5
Genitourinary	$327	12

CMS provides estimated increases for 30 selected procedures in Table 169 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 5 percent decrease in payment. The second largest aggregate payment procedure, CPT code 27447 (total knee arthroplasty), is expected to see a 2 percent increase.

Excerpt from Table 114: Estimated Impact of the 2026 Update to the ASC Payment System on Aggregate Payments for the Top 10 Procedures			
CPT/ HCPS Code	Short Descriptor	Estimated 2025 ASC Payments (in Millions)	Estimated 2026 Percent Change
66984	Xcapsl ctrc rmvl w/o ecp	$1,371	4
27447	Total knee arthroplasty	$428	2
63685	Ins/rplc spi npg/rcvr pocket	$385	4
45385	Colonoscopy w/lesion removal	$265	4
45380	Colonoscopy and biopsy	$261	4
63650	Implant neuroelectrodes	$223	-1
27130	Total hip arthroplasty	$215	2
43239	Egd biopsy single/multiple	$182	-1
23472	Reconstruct shoulder joint	$150	-4
64590	Ins/rpl prph sac/gstr npg/r	$146	-18

As noted at the beginning of this ASC section, Addenda tables available only on the website provide additional details, at https://www.cms.gov/license/ama?file=/files/zip/2026-nfrm-addendum-aa-bb-dd1-dd2-ee-ff.zip. They include:

- AA: Final ASC Covered Surgical Procedures for 2026 (Including surgical procedures for which payment is packaged)
- BB: Final ASC Covered Ancillary Services Integral to Covered Surgical Procedures for 2026 (Including Ancillary Services for Which Payment is Packaged)
- DD1: Final ASC Payment Indicators for 2026
- DD2: Final ASC Comment Indicators for 2026
- EE: Final Surgical Procedures to be Excluded from Payment in ASCs for 2026
- FF: Final ASC Device Offset Percentages for 2026
- O: Long Descriptors for New Category I CPT Codes, Category III CPT Codes, C-codes, and G-Codes Effective January 1, 2026

XIV. Cross-Program Policies for Quality Reporting Programs

A. Background and Overview

Background information on each of the Hospital Outpatient Quality Reporting (HOQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) programs is under section XV.A, XVI.A, and XVII.A of this summary, respectively.

CMS finalizes, as proposed, the removal of the following measures from the HOQR, REHQR, and ASCQR programs measure sets: (1) the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure from the HOQR and ASCQR programs; (2) the Hospital Commitment to Health Equity (HCHE) measure from the HOQR and REHQR programs and the Facility Commitment to Health Equity (FCHE) Measure from the ASCQR program, (3) the Screening for

Social Drivers of Health (SDOH) measure from all three programs, and (4) the Screen Positive Rate for SDOH measures from all three programs. The agency also finalizes, with one modification, updates to the Extraordinary Circumstances Exception (ECE) policy under all three programs. In addition, CMS summarizes comments it received in response to its RFI on the future measure concepts of well-being and nutrition for the three programs.

B. Review of RFI Issued on Well-Being and Nutrition

In the 2026 OPPS/ASC PPS proposed rule CMS issued an RFI seeking comments on well-being and nutrition measures for consideration in future rulemaking for the HOQR, REHQR, and ASCQR programs. CMS describes well-being as a comprehensive approach to disease prevention and health promotion that emphasizes person-centered care and promotes the well-being of patients and their families. The agency sought input on tools and measures that assess overall health, happiness, and satisfaction in life, as well as on tools and measures that assess optimal nutrition and preventive care in the programs. In the final rule, CMS summarizes comments received, does not respond to specific comments, but states it intends to use the input to inform its future measure development.

Many commenters supported the inclusion of well-being and nutrition measures in the quality reporting programs and believed these measures would improve patient outcomes and management of chronic conditions, as well as advance health equity. Several commenters recommended inclusion of specific measures, such as a malnutrition quality measure, which is used in the Hospital Inpatient Quality Reporting (HIQR) program. Other commenters were concerned about the applicability of a well-being measure to the outpatient setting and noted the associated administrative burden on facilities and that facilities should not be held accountable for factors beyond their control. Many commenters were concerned about the removal of social determinants of health (SDOH) measures, some of whom recommended aligning any future well-being or nutrition measure with SDOH screening tools.

C. Program Measure Sets

1. Removal of COVID-19 Vaccination Coverage Among HCP measure from HOQR and ASCQR Programs Beginning with 2024 Reporting Period

The COVID-19 Vaccination Coverage Among HCP measure was adopted into the HOQR and ASCQR programs in the 2022 OPPS/ASC final rule[100] and updated in the 2024 OPPS/ASC final rule.

CMS finalizes, without modification, its proposal to remove the measure from both programs, beginning with the 2024 reporting period/2026 payment determination, under removal factor 8—that is, the costs associated with the measure outweigh the benefit of its continued use in the program. CMS describes the burden associated with reporting the required 1 week of data on the measure for every month. With the end of the PHE and decrease in COVID-19 deaths, the agency

[100]See 86 FR 63824-63833 and 86 FR 63875-63883.

believes the costs and burden to facilities of tracking and monthly reporting outweighs any benefit of continued information collection on the measure. Hospitals and ASCs that do not report 2024 reporting period data for the measure will not be penalized for 2026 payments due to the measure and any 2024 reporting data for the measure received by CMS will not be used for public reporting or payment purposes.

2. Removal of HCHE measure from HOQR and REHQR Programs and FCHE measure from ASQR Program Beginning with 2025 Reporting Period

The HCHE and FCHE measures are attestation-based structural measures that assess hospitals' and other facilities' commitment to health equity. In the 2025 OPPS/ASC final rule, the HCHE measure was adopted for the HOQR and REHQR programs and the FCHE measure for the ASCQR program beginning with the 2025 reporting period/2027 payment (or program) determination.[101]

CMS finalizes, without modification, its proposal to remove the measures from the respective programs beginning with the 2025 reporting period/2027 payment (or program) determination under removal factor 8—that is, the costs associated with the measure outweigh the benefit of its continued use in the respective program. CMS describes that it is refocusing on measurable clinical outcomes and identifying quality measures on topics of prevention, nutrition, and well-being. Hospitals, REHs, and ASCs that do not report 2025 reporting period data for the HCHE or FHCE measure will not be penalized for 2027 payments due to the applicable measure and any 2025 reporting period HCHE or FCHE measure data received will not be used for public reporting or payment purposes.

Selected Comments/Responses. Many commenters supported removal of the respective measure from the respective programs, noting the administrative burden and the limited impact of the measures on improving patient outcomes. Many other commenters opposed the removal of the measures because they believed they serve a critical role in advancing health equity and addressing disparities in care. CMS responds that the agency remains focused on identifying measures that balance feasibility, burden, and impact, as well as align with the administration's priorities. The agency also emphasizes that facilities will still be able to collect, on their own initiative, data that is important to their specific patient care and population, regardless of the removal of the measures. Several commenters suggested refining the measures, including to reduce burden, rather than removing the measures. CMS states it will consider feedback for potential future measures.

3. Removal of Two SDOH Measures from the HOQR, REHQR, and ASCQR Programs Beginning with 2025 Reporting Period

SDOH refers to community-level factors that impact health and well-being. HRSNs refer to social and economic needs that affect an individual's health and well-being. The Screening for SDOH measure is a process measure that assesses the total number of HRSNs for which a patent is screened (up to 5—food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety). The Screen Positive Rate for SDOH is a process measure that provides

[101]See 89 FR 94368-94381.

information on the percentage of patients who were screened for all 5 HRSNs and who screened positive for at least one of the 5 HRSNs. The measures were adopted into the three programs in the 2025 OPPS/ASC final rule[102] for voluntary reporting in the 2025 reporting period and mandatory reporting beginning with the 2026 reporting period/2028 payment or program determination.

CMS finalizes, without modification, its proposal to remove the 2 SDOH measures from the 3 quality reporting programs beginning with the 2025 reporting period under removal factor 8. CMS describes how the agency received feedback from facilities concerned with the costs associated with screening patients and manually storing the data, as well as staff training and workflow concerns. The agency believes removal of the measures will reduce administrative burden as well as alleviate patient burden associated with SDOH screenings. Further, CMS notes that the measures document an administrative process rather than show whether providers are connecting patients with needed resources.

D. Updates to the Extraordinary Circumstances Exception (ECE)

Under current ECE regulations, CMS has granted exceptions to data submission deadlines and requirements under the three quality reporting programs if there are extraordinary circumstances beyond the control of a hospital, REH, or ASC. Extraordinary circumstances include natural disasters or systemic problems with data collection systems.

CMS finalizes, with one modification, its proposal to update the HOQR, REHQR, and ASCQR program ECE policies under §§419.46(e), 419.95(g), and 416.310(d), respectively, to include an extension of reporting deadlines as a form of relief and to provide further clarifications. As finalized, CMS may grant an ECE with respect to reporting requirements in the event of an extraordinary circumstance (an event beyond the control of the respective facility, such as a natural disaster or terrorist attack, that affected the facility's ability to comply with reporting requirements). The steps for requesting or granting an ECE will mostly remain as they are currently,[103] except, as finalized, the hospital, REH, or ASC will need to request an ECE within 60 days of the date of occurrence of the extraordinary circumstance (whereas the current policy allows for 90 days). The 60-day deadline is a modification from the agency's proposal, which would have instead applied a 30-day period for ECE submission. CMS finalizes that it would notify the requestor with a written decision and if the request is granted the notification will indicate if the facility is exempted from one or more reporting requirements or is granted an extension of a deadline to comply with one or more of the requirements.

Under the finalized policy, the agency will be able to grant an ECE to one or more hospitals, REHs, or ASCs that have not requested an ECE if it determines that (i) a systemic problem with a CMS

[102]See 89 FR 94381-94398; 89 FR 94398-94403.
[103] The current steps for requesting an ECE can be found on QualityNet. Centers for Medicare & Medicaid Services. Hospital OQR Program Extraordinary Circumstances Exceptions (ECE) Policy*:* *https://qualitynet.cms.gov/outpatient/oqr/participation%23tab2#tab2;* REHQR Program Extraordinary Circumstances Exceptions (ECE) Policy: *https://qualitynet.cms.gov/reh/rehqr/participation#tab2;* and ASCQR Program Extraordinary Circumstances Exceptions (ECE) Policy: *https://qualitynet.cms.gov/asc/ascqr/participation%23tab3#tab2*.

data collection system directly impacted the ability of the hospital, REH, or ASC to comply with a reporting requirement or (ii) an extraordinary circumstance has affected the entire region/locale.

Selected Comments/Responses. Several commenters were concerned that the agency may overuse the extension option for ECE requests when a broader exception may be more appropriate relief, and cautioned the agency against defaulting to deadline extensions in these instances. A few commenters requested further information on how the determination would be made to apply an extension versus an exception. CMS responds that it will determine whether to grant an exception versus extension using the same evaluation approach currently used in ECE determinations, which is on a case-by-based basis and based on the specific circumstances.

Many commenters did not support the reduced timeframe for hospitals and facilities to request an ECE from the current 90-day period to 30 days following an extraordinary circumstance, noting the reduced timeframe is insufficient to respond to a crisis, assess its impact, and submit an ECE request. In response, CMS is modifying the timeframe to allow for 60 days to submit the ECE request from the date of the extraordinary circumstance. This timeframe aligns with the same policy recently finalized for the HIQR program and inpatient psychiatric facilities quality reporting (IPQR) program.

XV. Hospital Outpatient Quality Reporting (OQR) Program

A. Background and Overview

CMS provides references to the legislative and regulatory histories of the HOQR program.[104] Section 1833(t)(17)(A) of the Act provides a 2.0 percentage point reduction in the annual Outpatient Department (OPD) fee schedule increase factor (Annual Payment Update, APU) for each subsection (d) hospital that does not submit data as required for the HOQR program's measures. CMS will continue to implement the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements by applying a reporting factor of 0.9805 to the OPPS payments and copayments for all applicable services. The finalized reporting ratio, when multiplied by the finalized full conversion factor of $91.415, will equal a reduced conversion factor for hospitals that fail to meet the requirements of the HOQR program of $89.632, for application for the 2026 payment determination.

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

- Adoption of the Emergency Care Access & Timeliness electronic clinical quality measure (eCQM);
- Removal of the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients) measure and the Left Without Being Seen measure; and

[104] 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.

- Modification of the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level-Outpatient) measure (Excessive Radiation eCQM) from mandatory reporting to voluntary reporting.

For the 2025 payment determination, of the 3,014 eligible hospitals, 42 hospitals failed to meet the reporting requirements needed to receive the full annual OPD fee schedule increase factor and an additional 54 hospitals elected not to participate.[105]

B. Changes to the HOQR Program Measure Set

1. Adoption of Emergency Care Access & Timeliness eCQM

Background. Emergency department (ED) boarding is holding a patient in the ED after the patient is admitted or placed into observation status. CMS describes how ED boarding rates are increasing, which causes safety risks for patients and worsening working conditions for health care personnel. The agency further describes how ED wait times is one of the most cited reasons for leaving an ED without being evaluated for care, as well as growing concerns about the quality and timeliness of care in the ED.

CMS is finalizing, without modification, its proposal to adopt into the HOQR program measure set the Emergency Care Access & Timeliness eCQM beginning with voluntary reporting for the 2027 reporting period followed by mandatory reporting beginning with the 2028 reporting period/2030 payment determination. CMS will publicly report the overall measure score and rates for the four numerator components, as well as the criteria-specific results regarding the age and mental health strata (all described below) once the measure becomes mandatory. A similar measure is finalized for adoption for the REHQR program under section XVI.B.1.

Measure Overview. The overall score for the eCQM represents the proportion of ED encounters associated with patients of all ages, for all payers, that experience at least one of the numerator events described below during a 12-month performance period.

- Denominator: All ED encounters associated with patients of all ages, for all payers, during a 12-month performance period; patients can have multiple encounters during a performance period and each encounter would be eligible to contribute to the measure calculation.
- Numerator: Any ED encounter in the denominator where the patient experiences any of the following (an event can contribute only once to the numerator):
    - Patient wait time longer than 1 hour after arrival to the ED until placement in a treatment room or dedicated treatment area that allows for audiovisual privacy during history-taking and physical exam.
    - Patient left the ED without being evaluated.
    - Patient boarding time in the ED (measured from a decision to admit (order) to ED to ED departure for admitted patients) longer than 4 hours.

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

    - Patient ED length of stay (LOS) (time from ED arrival to ED physical departure, measured by the ED departure timestamp) longer than 8 hours.
- Exclusions: ED encounters with ED observation stays are excluded from components #3 and #4, but are included in the denominator; patients who have a "decision to admit" after an ED observation stay are excluded from criteria #3.

In addition to the eCQM's overall score, the measure provides HOPDs with data for each of the individual numerator components. The agency clarifies that those individual numerator components will NOT be added or combined to obtain the overall score because they are not each mutually exclusive.

CMS describes that the eCQM's numerator components overlap with 2 chart-abstracted measures already in the HOQR program: (1) the Median Time for Discharged ED Patients measure (which assesses the time spent in the ED before being sent home) overlaps with the proposed eCQM's numerator component #4, and (2) the Left Without Being Seen measure (which assess the percentage of patients who leave the ED without being evaluated by a physician, advanced practice nurse, or physician's assistant) overlaps with the proposed eCQM's numerator component #2. In addition, the eCQM will capture information (numerator components #1 and #3) that the current two measures do not capture. The current two measures are chart-abstracted and require manual intervention to retrieve data, while the eCQM allows for automated extraction of data directly from the electronic health record (EHR), which will reduce burden. As discussed below, CMS is finalizing removal of the two current chart-abstracted measures.

Measure Calculation.[106] The measure score is first calculated at the individual ED level as the proportion of ED encounters where *any* one of the four numerator outcomes occurred. The overall score is then standardized by ED case volume using z-scores (which indicates how many standard deviations a data point is from the mean of a normal distribution). The volume-adjusted z-score for the eCQM shows how an ED's performance compares to the average for similar-volume EDs. If a CMS Certification Number (CCN) has more than one ED, the volume-adjusted z-scores are combined as a weighted average for the CCN.

The results of the eCQM will also be stratified into 4 groups: 2 by age (18 and older and under 18) and 2 by mental health diagnoses (with and without).

Pre-Rulemaking. The Emergency Care Access & Timeliness eCQM was endorsed by the consensus-based entity (CBE) on February 12, 2025 with conditions for use in the HOQR program. The conditions include that the measure developer explore within 3 years unintended consequences to patients and providers (including burden) and data elements to identify and address where challenges persist.

Data Collection, Submission, Reporting. The eCQM uses data extracted electronically from EHRs.

[106] Measure specifications can be found on the QualityNet HOQR Program website https://qualitynet.cms.gov/outpatient.

Selected Comments/Responses. A few commenters requested clarification on how encounters that meet more than one numerator criteria would be included in the measure calculations. In response, CMS explains that if a single ED encounter meets the criteria for more than one numerator event then the encounter would be included in each of the appliable component score but once in the overall summary score. The overall measure score represents the proportion of ED visits where *any* component occurred.

Some commenters noted that delays in the ability to transfer patients are frequently out of the control of hospitals, particularly small, rural hospitals. Other commenters suggested risk adjusting the measure. CMS notes the measure is not risk-adjusted because the numerator events are considered access failure regardless of patient characteristics. The agency also states that the HOQR program is a pay-for-reporting program, thus hospitals are penalized for not *reporting* required data, not for their performance on the measure. In response to concerns raised about the potential for the measure leading to inappropriate use of observation status to circumvent the measure's intent, CMS states that it will consider monitoring whether observation status volumes increase with the measure adoption.

In response to a few commenters' requests for clarification on whether the measure includes transfer patients, CMS clarifies that transfer patients are included and assessed against all numerator criteria. The agency further notes that the two versions of the Emergency Care Access & Timeliness eCQM being finalized for the HOQR program and REHQR program in the rule, differ in numerator component #3, boarding. The HOQR program version captures inpatient boarding time, whereas the REHQR program version (discussed in section XVI.B.1) captures transfer boarding time in the ED because REHs do not provide inpatient services.

2. Removal of the Median Time for Discharged ED Patients Measure and Left Without Being Seen Measure

As discussed in further detail above, CMS is finalizing adoption of the Emergency Care Access & Timeliness eCQM. CMS is therefore also finalizing its proposal to remove from the HOQR program measure set the Median Time for Discharged ED Patients measure and the Left Without Being Seen Measure since the finalized eCQM will serve as a replacement for the 2 existing chart-abstracted measures.[107] CMS believes the proposed eCQM will capture what the 2 chart-abstracted measures assess (time patients spent in the ED before being sent home and the percentage of patients who leave the ED without being evaluated, respectively) as well as assess additional components of information. In addition, the 2 chart-based measures require human review and manual intervention to extract data whereas the proposed eCQM does not.

The two chart-abstracted measures are being removed under measure removal factor 4—that is, the availability of a more broadly applicable measure for the topic. They will be removed beginning with the 2028 reporting period/2030 payment determination, when the finalized eCQM becomes mandatory.

[107] The Median Time for Discharged ED Patients measure and Left Without Being Seen measure were adopted in the 2011 OPPS/ASC final rule (72 FR 72086 and 75 FR 72088-72089, respectively).

3. Modification of Excessive Radiation eCQM from Mandatory Reporting Beginning with 2027 Reporting Period/2029 Payment Determination to Continue Voluntary Reporting in 2027 Reporting Period and Subsequent Years

The Excessive Radiation eCQM was finalized for adoption in the HOQR program measure set in the 2024 OPPS/ASC final rule with voluntary beginning with the 2025 reporting period and mandatory reporting beginning with the 2027 reporting period/2029 payment determination.

CMS is finalizing, without modification its proposal to, beginning with the 2027 reporting period, maintain voluntary reporting of the measure and not begin mandatory reporting in response to continued feedback expressing concerns about burden and operational feasibility associated with the measure. The agency's policy is to allow HOPDs more time to integrate, adequately test, and gain experience with implementing the eCQM and give CMS more time to monitor implementation progress. CMS expects that it will propose a date to begin mandatory reporting in the 2027 OPPS/ASC proposed rule.

Selected Comments/Responses. Many commenters supported the extension of the voluntary period, noting the many difficulties and challenges with reporting on the measure. Many other commenters, including patients and providers, expressed concerns about the performance of CT scans using radiation doses that are higher than necessary, which could increase cancer risks. CMS reiterates that it remains committed to the use of the Excessive Radiation eCQM. It believes the extended voluntary reporting will support patient safety goals and also provide hospitals the time needed to improve their technical capacity before the measure becomes mandatory.

4. Summary of Previously Finalized and Newly Finalized Program Measure Set Updates

The table below (based on the information provided in Table 138 in the rule) summarizes the previously finalized measure set for the 2026 to 2031 payment determinations.

Previously Finalized and Newly Finalized HOQR Program Measure Sets for 2026 to 2031 Payment Determinations

CBE	Measure	Measure Type	2026	2027	2028	2029	2030	2031
	Abdomen CT – Use of Contrast Material	Claims-Based	X	X	X	X	X	X
	Median Time from ED Arrival to ED Departure for Discharged ED Patients	Chart-Abstracted	X	X	X	X	Removed	Removed
	Left Without Being Seen	Chart-Abstracted	X	X	X	X	Removed	Removed
4625e	Emergency Care Access &	eCQM				Voluntary	X	X

CBE	Measure	Measure Type	2026	2027	2028	2029	2030	2031
	Timeliness eCQM							
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	Chart-Abstracted	X	X	X	X	X	X
0658	Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients	Chart-Abstracted	X	X	X	X	X	X
	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Survey-Based	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary
2539	Facility 7-Day Risk Standardized Hospital Visit Rate After Outpatient Colonoscopy	Claims-Based	X	X	X	X	X	X
3490	Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	Claims-Based	X	X	X	X	X	X
2687	Risk-Standardized Hospital Visits 7 Days After Hospital Outpatient Surgery	Claims-Based	X	X	X	X	X	X

CBE	Measure	Measure Type	2026	2027	2028	2029	2030	2031
	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS-CAHPS)	Survey-Based	Voluntary	X	X	X	X	X
3636	COVID-19 Vaccination Coverage Health Care Personnel	National Healthcare Safety Network	Removed	Removed	Removed	Removed	Removed	Removed
	Breast Cancer Screening Recall Rates	Claims-Based	X	X	X	X	X	X
	ST-Segment Elevation Myocardial Infarction (STEMI) eCQM	eCQM	X	X	X	X	X	X
3663e	Excessive Radiation eCQM	eCQM		Voluntary	Voluntary	Voluntary	Voluntary	Voluntary
	Risk-Standardized PRO-PM Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty in the HOPD Setting (THA/TKA PRO-PM)	Reported Outcomes-Based Performanc e Measure (PRO-PM)			Voluntary	Voluntary	Voluntary	X
	Hospital Commitment to Health Equity	Structural		Removed	Removed	Removed	Removed	Removed
	Screening for Social Drivers of Health (SDOH)	Process		Removed	Removed	Removed	Removed	Removed
	Screen Positive Rate for SDOH	Process		Removed	Removed	Removed	Removed	Removed

CBE	Measure	Measure Type	2026	2027	2028	2029	2030	2031
4210	Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery PRO-PM (Information Transfer PRO-PM)	PRO-PM			Voluntary	X	X	X
x = Measure is mandatory for the payment determination year								

C. Form, Manner, and Timing of Data Submission[108]

Data Submission and Reporting Requirements for the Emergency Care Access & Timeliness eCQM. CMS finalizes, without modification, its proposal that for the voluntary 2027 reporting period for the newly finalized Emergency Care Access & Timeliness eCQM, hospitals could voluntarily submit data for any quarter (up to all 4 quarters). Beginning with the 2028 reporting period/2030 payment determination, hospitals will be required to report all 4 calendar quarters (full year) of data. Data will need to be submitted by May 15 of the year prior to the affected payment determination year (aligning with policies on eCQM submission deadlines).

D. Payment Reduction for Hospitals Failing OQR Requirements

CMS finalizes its proposal that existing policies with respect to computing and applying the payment reduction for hospitals that fail to meet the OQR program requirements will be continued for the 2026 update factor. The resulting reduction ratio for hospitals that fail to meet OQR Program requirements, called the "reporting ratio", for the 2026 payment determination will be 0.9805. CMS finalizes its proposal to continue calculating the reporting ratio to four decimals. The finalized reporting ratio, when multiplied by the final full conversion factor of $91.415, equals a final reduced conversion factor of $89.632. The reduced conversion factor is the conversion factor applied for hospitals that fail to meet the requirements of the HOQR program.

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

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

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 HOQR program's reporting requirements. All other applicable standard adjustments to the OPPS national unadjusted payment rates also will continue to apply, and OPPS outlier eligibility and outlier payments also will be based on the reduced payment rates.

XVI. Rural Emergency Hospital Quality Reporting (REHQR) Program

A. Background and Overview

Section 1861(kkk) of the Act establishes rural emergency hospitals (REHs) as a Medicare provider type that furnishes emergency department services and observation care. The REH must have a staffed emergency department 24 hours a day, 7 days a week and may elect to furnish other medical and health services on an outpatient basis. Payments specific to REHs began on January 1, 2023.

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

In addition to the cross-program proposals discussed in section XIV, for the REHQR program, CMS finalizes its proposal to adopt the Emergency Care Access & Timeliness eCQM into the measure set as an optional alternative to reporting the Median Time for Discharged ED Patients measure and finalizes eCQM submission and certification policies for the REHQR program.

CMS estimates that for the 2026 reporting period there will be 38 REHs required to report under the REHQR program based on hospital conversions as of April 11, 2025. It estimates that the REHQR measures adoptions and removals finalized in the rule will result in a total information collection and reporting burden reduction of 14,813 hours at a savings of $380,235 annually for those 38 REHs for each of the 2025 through 2027 reporting periods, as reflected in Tables 151 through 153 of the rule.

B. Changes to the REHQR Program Measure Set

1. Adoption of Emergency Care Access & Timeliness eCQM

CMS finalizes, without modification, its proposal to adopt the Emergency Care Access & Timeliness eCQM (as specified for the REH setting) beginning with the 2027 reporting period/2029 program determination as an alternative to reporting the Median Time for Discharged ED Patients measure in the REHQR program. A version of the eCQM (as specified for the HOPD setting) is also being finalized for the HOQR program, as discussed above in section XV.

Measure Overview. As with the eCQM finalized for the HOPD setting, the eCQM for the REH setting calculates the proportion of 4 outcome metrics that quantify access to and timeliness of care in an ED setting against specified thresholds.

- Denominator: All ED encounters associated with patients of all ages, for all payers, during a 12-month performance period; patients can have multiple encounters during a performance period and each encounter will be eligible to contribute to the measure calculation.
- Numerator: Any ED encounter in the denominator where the patient experiences any of the following (an event can contribute only once to the numerator):
    (1) Patient wait time longer than 1 hour after arrival to the ED until placement in a treatment room or dedicated treatment area that allows for audiovisual privacy during history-taking and physical exam.
    (2) Patient left the ED without being evaluated.
    (3) Patient, if transferred, boarded in the ED longer than 4 hours.
    (4) Patient ED length of stay (LOS) longer than 8 hours.
- Exclusions: ED encounters with ED observation stays are excluded from components #3 and #4.

The Median Time for Discharged ED Patients measure (which is already included in the REHQR program and assesses the time spent in the ED before being sent home) overlaps with the Emergency Care Access & Timeliness eCQM's numerator component #4 but CMS notes that the eCQM will capture other information that the current measure does not. To provide flexibility for REHs, CMS is finalizing its proposal to give REHs the option to report *either* the newly finalized Emergency Care Access & Timeliness eCQM or the Median Time for Discharged ED Patients measure to meet program requirements beginning with the 2027 reporting period/2029 payment determination.

Measure Calculation.[109] The measure score is calculated at the individual ED level as the proportion of ED encounters where any one of the four numerator outcomes occurred, divided by the number of encounters in a performance period. If a CMS CCN has more than one ED, individual ED scores are combined as a weighted average for the CCN.

The results of the eCQM will be stratified into 4 groups: 2 by age (18 and older and under 18) and 2 by mental health diagnoses (with and without).

Pre-Rulemaking. The Emergency Care Access & Timeliness eCQM was endorsed by the consensus-based entity (CBE) on February 12, 2025 with conditions for use in the REHQR program. The conditions include that the measure developer explore unintended consequences to patients and providers (including burden) and data elements to identify and address where challenges persist.

Data Collection, Submission, Reporting. The Emergency Care Access & Timeliness eCQM will be the first eCQM in the REHQR program measure set. The eCQM uses data extracted electronically

[109] Measure specifications can be found on the QualityNet REHQR Program website https://qualitynet.cms.gov/reh/rehqr.

from EHRs. The adoption of the measure will not change the number of mandatory quality measures required to be reported in the REHQR measure set since an REH will have the option of reporting on the newly finalized eCQM (which will be reported annually) or the Median Time for Discharged ED Patients measure currently in the measure set (which is reported quarterly). CMS intends to publicly report data submitted on the Emergency Care Access & Timeliness eCQM and the Median Time for Discharged ED Patients measure on the Compare tool on Medicare.gov or its successor website after a 30-day preview period.

2. Summary of Previously Finalized and Newly Finalized Program Measure Set

Table 139 of the rule shows the previously finalized measure set and newly finalized REHQR program measure set by data collection method and program determination (PD) for 2026 to 2031 PDs. The information is shown below.

Previously Finalized and Newly Finalized REHQR Program 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 for Discharged ED Patients*	X	X	X	Optional	Optional	Optional
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
* In section XVI.C.2 CMS finalizes that 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.

C. Form, Manner, and Timing of Data Submission

CMS finalizes its proposal that the technical specifications for eCQMs for the REHQR program will be contained in the CMS Annual Update for the Hospital Quality Reporting Programs (Annual Update).[110] This is in alignment with the HOQR program.

Since the newly finalized Emergency Care Access & Timeliness eCQM, will be the first eCQM in the REHQR measure set, CMS is finalizing eCQM reporting and submission policies and requirements for the REHQR program that align with those of the HOQR program, Hospital Inpatient Quality Reporting (HIQR) program, and Medicare Promoting Interoperability Program (PIP). These policies will be codified at §419.95(h) and will apply to an REH only if the REH opts to report an eCQM.

CMS finalizes its proposal to adopt in the REHQR program, beginning with the 2027 reporting period, the same eCQM certification requirements that were adopted into the HOQR program. REHs will be required to use technology certified by ONCHIT certification criteria, as adopted and updated in 45 CFR 170.315 for reporting eCQMs. Health IT used for eCQM reporting by REHs will need to be certified to all eCQMs (tested and validated on each eCQM) available to report under the program and REHs will be required to use the most recent version of the eCQM electronic measure specifications for the applicable reporting period available on https://ecqi.healthit.gov/ or another CMS-designated website. CEHRT will not need to be recertified each time the eCQM's specifications are updated to a more recent version.

REHs will be able to meet reporting requirements by (i) submitting data via QRDA I files, (ii) having a zero denominator declaration, or (iii) satisfying case threshold exemptions.

The Quality Reporting Document Architecture (QRDA) is a commonly used exchange standard that provides a document format and standard structure to electronically report quality measure data. CMS finalizes that, beginning with the 2027 reporting period/2029 program determination, REHs (i) must submit eCQMs data through the QRDA Category I (QRDA I) file format; (ii) may use third parties to submit QRDA I files; and (iii) may either use abstraction or pull the data from non-certified sources to input the data into CERHT for capture and reporting QRDA I.

If an REH's EHR is certified to an eCQM but does not have data to report for the eCQM (i.e., the REH does not have patients who meet the denominator criteria), the REH would submit a zero in the denominator for that eCQM. In that case, submission of zero in the denominator for an eCQM would qualify as a successful submission for that eCQM.

CMS also finalizes its proposal for a case threshold exemption. If an REH's EHR system is certified to report an eCQM but the REH has 5 or fewer outpatient encounters or discharges per quarter or 20 or fewer outpatient encounters or discharges per year (all payers – Medicare and non-Medicare combined), as defined by the eCQM's denominator population, the REH will be exempt from reporting that eCQM. In addition, CMS finalizes its policy to require eCMQ data submission

[110] The Annual update and implementation guidance documents are available at https://ecqi.healthit.gov/.

by May 15 of the year following the reporting period (for example, for the 2027 reporting period, the submission deadline would be May 15, 2028).

Specifically for the newly finalized Emergency Care Access & Timeliness eCQM, an REH will be required to elect to report either that eCQM or the Median Time for Discharged ED Patients measure currently in the measure set beginning with the 2027 reporting period/2029 program determination. The eCQM would need to be reported annually, if selected, whereas the existing measure would need to be reported quarterly (as currently) through the HQR system, if selected.

XVII. Ambulatory Surgery Center Quality Reporting (ASCQR) Program

A. Background and Overview

Under section 1833(i)(7) of the Act, an ambulatory surgical center (ASC) that does not submit for a year required data on quality measures specified by the Secretary receives a 2.0 percentage point reduction to the annual increase. Payment determinations are linked to a quality reporting period that occurs two years before the payment determination year (e.g., 2026 reporting is linked to 2028 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).[111] Many of the statutory provisions applied to the Hospital OQR program are applied by statute to the ASCQR program. CMS provides references to the legislative and regulatory histories of the program.[112]

CMS states that of 6,012 ASCs billing Medicare, 4,271 were required to participate in the ASCQR program for 2025 payment determinations. Of those not required, 319 ASCs chose to participate and met full requirements. Based on the 2025 payment determination data, CMS estimates that 4,590 ASCs will submit data for the program for the 2026 reporting period.[113]

B. ASCQR Program Measure Set

1. Not Finalized: Proposal to Adopt Information Transfer PRO-PM

In addition to the cross-program proposals for the ASCQR program (which CMS is finalizing, as discussed in section XIV), CMS had proposed in the 2026 OPPS ASC PPS proposed rule to adopt the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measures (Information Transfer PRO-PM) beginning with voluntary reporting for the 2027 and 2028 reporting periods followed by mandatory reporting beginning with the 2029 reporting period/2031

[111] See §416.305(c) of title 42, Code of Federal Regulations. 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.
[112] 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.
[113] CMS posts individual facility payment determination result lists on the website https://qualitynet.cms.gov/asc/ascqr/apu#tab1.

payment determination. The measure had been proposed to address the importance of communicating discharge information in order for patients to understand clinical care instructions after a procedure in an outpatient setting.

However, given a significant number of public comments received (discussed below) opposing the adoption of the measure for the ASCQR program CMS is not finalizing adoption of the measure at this time.

Measure Overview. The Information PRO-PM assesses (through a 9-item survey) patient understanding of provided discharge information for patients 18 years of age or older who had a procedure (surgical or non-surgical) at an ASC. The survey has three domains to assess patient reported understanding of information: (i) applicability to patient needs, (ii) medication, and (iii) daily activities.

The measure has not been CBE-endorsed for the ASC setting but was endorsed on January 29, 2024 for the HOQR program. In the 2026 OPPS/ASC PPS proposed rule CMS stated it plans to seek CBE endorsement for the ASC setting in a future endorsement cycle.

Measure Calculation.

- Numerator: Sum of all individual scores an ASC receives from eligible respondents (patients or their caregivers). Individual scores are calculated for each respondent by dividing (i) the sum of items for which the respondent gave the most positive possible response ("Yes" or "Very clear"); by (ii) the number of items (of the maximum nine) the respondent deemed applicable to their procedure.
- Denominator: Number of patients 18 years or older who had a procedure in the ASC, left the ASC alive, and responded to the survey.

Selected Comments/Responses. Many commenters supported the proposal, particularly agreeing with the goals of the proposed PRO-PM and the importance of communicating clear discharge instructions to enhance recovery. However, many other commenters expressed concerns with the adoption of the proposed measure in the ASCQR program, particularly related to survey fatigue, low response rates, and administrative burden on ASCs which may have less experience integrating surveys in clinical workflows than other settings. Several commenters raised concerns about administering two distinct surveys (the OAS CAHPS survey and the proposed survey) to the same patient cohort. Some of these commenters noted that the OAS CAHPS survey has had declining response rates and adding another survey could increase patient survey fatigue and further decrease response rates. There were suggestions for combining the surveys. Some commenters raised concerns about the measure's applicability to the ASC setting and the lack of testing of the measure specific to the ASC setting.

CMS continues to believe that the proposed PRO-PM could provide valuable feedback to facilities on the usefulness of their discharge materials and methods in providing those materials, and that the lack of a clear understanding of clinical care instructions after a procedure is connected to decreased patient safety and increased rates of adverse effects. However, in response to the many

concerns raised, especially regarding low response rates and increased survey fatigue, CMS is not finalizing its proposal at this time. CMS recognizes that survey fatigue may particularly present challenges for ASCs as compared to other settings, noting that ASCs may have fewer dedicated resources to manage patient outreach and survey processes and their patient population may be more prone to survey fatigue given patients often have fewer ongoing interactions with ASCs after discharge as compared to other settings. The agency states it may consider the suggestions to combine the information transfer PRO-PM with OAS CAHPS in the future. CMS further states that if it decides to propose the PRO-PM in the future it will review the measure specifications for any needed updates for applicability to ASCs, as well as take into consideration comments raised regarding aligning the measure with various aspects of the OAS CAHPs.

2. Summary of Previously Finalized and Newly Finalized Program Measure Set for 2026 to 2031 Payment Determinations

Table 140 in the rule lists the previously finalized and newly finalized measure set for the 2026 to 2031 payment determinations (PDs), including the newly finalized removal of the FCHE, Screening for SDOH, Screen Positive Rate for SDOH, and COVID-19 Vaccination Coverage Among HCP measures (discussed in section XIV.C). Information from the table is shown below.

ASCQR Program Measures by Payment Determination Year						
	2026	**2027**	**2028**	**2029**	**2030**	**2031**
Chart-Abstracted Measures						
Patient Burn	X	X	X	X	X	X
Patient Fall	X	X	X	X	X	X
Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant	X	X	X	X	X	X
All-Cause Hospital Transfer/Admission	X	X	X	X	X	X
Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (CBE #0658)	X	X	X	X	X	X
Normothermia Outcome	X	X	X	X	X	X
Unplanned Anterior Vitrectomy	X	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	X
Hospital Visits After Orthopedic ASC Procedure (CBE #3470)	X	X	X	X	X	X
Hospitals Visits After Urology ASC Procedure CBE #3366)	X	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	X
National Healthcare Safety Network Measures						
COVID-19 Vaccination Coverage Health Care Personnel (CBE #3636)	Removed	Removed	Removed	Removed	Removed	Removed
Patient-Reported Outcomes-Based Performance Measures						

ASCQR Program Measures by Payment Determination Year						
	2026	**2027**	**2028**	**2029**	**2030**	**2031**
Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PROPM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO–PM)**			Voluntary	Voluntary	Voluntary	X
Process Measures						
Screening for SDOH		Removed	Removed	Removed	Removed	Removed
Screen Positive Rate for SDOH		Removed	Removed	Removed	Removed	Removed
Structural Measure						
FCHE		Removed	Removed	Removed	Removed	Removed
Survey-Based Measures						
Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS-CAHPS) - 5 measures***	Voluntary	X	X	X	X	X
Cataracts Visual	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary
X Measure is mandatory for the payment determination year. *** Reporting on a set of OAS CAHPS measures: About Facilities and Staff; Communication About Procedure; Preparation for Discharge and Recovery; Overall Rating of Facility; and Recommendation of Facility. ** This measure begins with voluntary reporting for the 2025 reporting period, followed by mandatory reporting beginning with the 2028 reporting period/2031 payment determination, as discussed in the 2024 OPPS/ASC final rule (88 FR 82033 through 82036).						

C. Form, Manner and Timing of Data Submission

Not Finalized: Proposals for Data Submission and Reporting for Requirements for PRO-PMs. In the 2026 OPPS/ASC PPS proposed rule, CMS had proposed that ASCs would need to use the HQR system for data submission for any PRO-PM adopted into the ASCQR program measure set. For the proposed Information Transfer PRO-PM, CMS had proposed data submission and reporting period requirements. The agency also proposed that for facilities with large patient populations (expect at least 200 completed surveys in a reporting period) the ASC could select to randomly sample a sufficient number of patients to yield at least 200 completed surveys in the reporting period, or could survey and report on the entire population. ASCs unable to complete 200 surveys for the reporting period would be required to submit data on all completed surveys received.

However, since CMS is not finalizing its proposal to adopt the Information Transfer PRO-PM in the ASCQR program measure set, it is not finalizing the data submission and reporting requirements it had proposed to apply generally to PRO-PMs in the measure set nor that it had proposed specifically for the proposed measure.

D. Payment Reduction for ASCs Failing ASCQR

CMS finalizes its proposal to continue applying its policies for determining the payment reduction for ASCs that fail to meet the ASCQR Program requirements. The 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 and biologicals, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on OPPS payment rates, and certain office-based procedures, radiology services, and diagnostic tests for which payment is based on the PFS nonfacility PE RVU-based amount, as well as some others. All other applicable adjustments to the ASC national unadjusted payment rates apply (e.g., wage index adjustment). When the update reduction is applied to a facility, beneficiary copayments are based on the reduced payment rate.

XVIII. Hospital Quality Star Rating: Safety of Care Measure Group

A. Summary

CMS is finalizing, without modification its proposal to modify the Overall Hospital Quality Star Rating methodology by implementing (i) a 4-star cap for hospitals in the lowest-performing quartile of the Safety of Care measure group for the 2026 Overall Hospital Quality Star Rating, and (ii) a 1-star reduction for hospitals in the lowest-performing quartile of that measure group for the 2027 Overall Hospital Quality Star Rating and subsequently.

B. Background

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

C. Hospital Quality Star Rating Methodology

Under the current Overall Hospital Quality Star Rating methodology:

(1) Measures are selected from those publicly reported on Care Compare on Medicare.gov through specified hospital inpatient and outpatient quality programs.
(2) Scoring is structured so that higher scores indicate better performance for all measures and all measure scores are standardized to a single, common scale to account for differences in score units.
(3) Measures are arranged into 5 measure groups (the first 4 of which include outcome measures and the 5th of which includes process measures): (1) Safety of Care, (2) Mortality, (3) Readmission, (4) Patient Experience, and (5) Timely and Effective Care.
(4) Measure group scores are calculated as an average of measure scores and then standardized to a common scale.
(5) The hospital summary score is calculated as a weighted average of measure group scores. That is, the weighted measure group scores are summed to generate the hospital summary score. Each of the groups (other than Timely and Effective Care) are weighted 22 percent.

Timely and Effective Care is weighted 12 percent. In the case that a hospital has no scores in a group, the weight for that group is redistributed proportionally across the remaining groups.

(6) To receive a star rating, a hospital must reach the minimum reporting threshold—that is, the hospital must report at least three measures in at least three measure groups (one of which must be the Mortality or Safety of Care measure group).

(7) Based on the number of measure groups for which a hospital reported at least three measures, hospitals are grouped into one of the following peer groups: 3-measure peer group, 4-measure peer group, or 5-measure peer group.

(8) Within each peer group a clustering algorithm is applied to assign hospital summary scores to star ratings, with one star being the lowest and five stars the highest.

D. Modification to the Hospital Quality Star Rating Methodology

Internal Analysis. CMS explains that it is possible in the current Overall Star Rating methodology for a hospital to score very low in the Safety of Care measure group but still receive a high star rating by receiving high scores in the other measure groups. CMS reviews that for a hospital to receive an Overall Hospital Quality Star Rating it must have at least 3 measures in each of at least 3 measure groups, one of which must be Mortality or Safety of Care. However, since the application of minimum reporting thresholds and peer grouping assignment occur after calculation of measure group scores and overall summary scores, once the hospital meets the reporting threshold, all measure groups for which it has any measure score are included in its rating. If a hospital has, for example, one or two Safety of Care measures it can still receive an Overall Hospital Quality Star Rating if it has at least 3 measures in Mortality and 2 of the other measure groups, and the hospital would still receive a Safety of Care group score based on the one or two measures it had.

CMS describes an internal analysis conducted to determine correlations between the Safety of Care measure group and performance in the Overall Hospital Quality Star Rating. Results showed that hospitals that performed in the lowest quartile of the Safety of Care usually also performed lower on the overall Star Rating, but there were a few that performed in the bottom quartile of the Safety and Care group that still received a 5-star rating.[114]

Finalized Methodological Changes. To increase the importance of the Safety of Care measure group, CMS is finalizing its proposal for a 2-stage update to its 8-step methodology described above:

(9) A 4-star cap for hospitals in the lowest quartile of that measure group's performance for 2026 – Any hospital that would have been assigned 5 stars but is in the lowest quartile of the group's score (based on at least 3 Safety of Care measures) would instead receive 4 stars. Using 2024 data, CMS determined that implementing this cap would result in 14 of the 2,847 hospitals receiving a lower Overall Quality Star Rating.

(10) A blanket 1-star reduction for hospitals in the lowest quartile of Safety of Care measure group performance for the 2027 Overall Hospital Quality Star Ratings and later years – Any hospital in the lowest quartile of the Safety of Care measure group scores (based on at least 3

[114] Table 141 in the rule shows the results of the analysis.

measure scores) would have its overall star rating reduced by 1 star to a minimum 1-star rating. This would replace the 2026 cap. Using 2024 data, CMS determined that implementing this reduction would result in 459 out of 2,847 hospitals receiving a lower overall star rating.

Table 142 in the rule shows the agency's evaluation of the proportion of hospitals that would be impacted by the methodological changes, stratified by various hospital characteristics and using the July 2024 Overall Hospital Quality Star Rating data.

Selected Comments/Responses. Many commenters supported the proposal and agreed that patient safety should be emphasized in the Overall Hospital Quality Star Rating. Some commenters offered general suggestions, such as continued engagement with interested parties, additional testing or simulation of the methodological changes before full implementation, and early notification on hospital performance. Other commenters offered various modifications to specific aspects of the proposed policy, such as capping hospitals in the lowest quartile of Safety of Care at no more than two stars or prohibiting a 4-star or 5-star rating for such hospitals. CMS believes, however, that other measure groups are still important in providing insight into the overall quality and that its policy strikes a good balance. A few commenters raised specific concerns for small and rural hospitals, including resource constraints and the potential for exacerbating rural health disparities if such hospitals disproportionately do not perform well in the measure grouping. CMS notes that its analysis, using the 2024 simulation data show that there is not a strong association between hospital type and actual Safety of Care performance.

Several commenters raised concerns that the update would overvalue safety relative to other aspects of hospital quality, which are also important to patients. Other commenters raised concerns that the changes would not adequately represent patient safety and may be confusing to patients to understand. CMS notes that under its policy even hospitals in the lowest quartile of Safety of Care could still achieve ratings as high as 4 stars if they performed well in the other measure groups. Further, the agency believes the updates and further emphasis of patient safety would better align the Overall Hospital Quality Star Rating with other CMS initiatives and federal efforts that are reinforcing patient safety as a national priority. The agency will consider how to increase transparency by providing plain-language explanations of the changes for patients and their families as well as advocates.

XIX. Price Transparency

A. Introduction and Overview

1. Statutory Basis and Background

The Affordable Care Act[115] amended the Public Health Service Act (PHS Act) to add a new section 2718(e) requiring each hospital operating within the United States for each year to establish,

[115] Section 1001 of the Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by section 10101 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152)

update, and make public a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups. Section 2718(b)(3) of the PHS Act requires the HHS Secretary to issue regulations to enforce the provisions of section 2718 of the PHS Act, and, in so doing, the Secretary may provide for appropriate penalties.

The CY 2020 Hospital Price Transparency (HPT) final rule[116] established requirements at 45 CFR part 180 for hospitals to make public their standard charges in two ways: (1) as a comprehensive machine-readable file (MRF); and (2) in a consumer-friendly format. CMS also established an enforcement process and penalties that apply to hospitals which the agency determines are noncompliant. CMS summarizes updates it has made to the requirements through rulemaking since the initiative's effective date on January 1, 2021. CMS notes that it believes requiring public release of hospital standard charge information is a necessary and important first step in ensuring transparency in prices of healthcare services for consumers. CMS notes that the regulations are designed to address some of the barriers that limit price transparency, with a goal of requiring hospitals to make meaningful price information available to patients and employers to support a more competitive, innovative, affordable, and higher quality healthcare system.

On February 25, 2025, the White House issued Executive Order 14221 (EO 14221)[117] to empower patients with clear, accurate, and actionable healthcare pricing information. EO 14221 requires the Departments of the Treasury, Labor, and HHS to: require disclosure of actual prices of items and services, not estimates; ensure pricing information is standardized and easily comparable across hospitals and health plans; and update their enforcement policies designed to ensure compliance with transparent reporting of complete, accurate, and meaningful data. Accordingly, CMS proposed and is finalizing several updates to the regulations at 45 CFR part 180.

2. Summary of Final Policies

In this section, CMS summarizes the final policy changes the agency is making to the HPT requirements. CMS is finalizing most requirements as proposed with some modification in response to comment. Additionally, while the policies will become effective January 1, 2026, CMS states it will delay enforcement of the requirements until April 1, 2026. The final policies include:

- Adding definitions for three new data elements, the "median allowed amount," the "tenth (10th) percentile allowed amount," and the "ninetieth (90th) percentile allowed amount" with modification of the proposal to revise the phrase, "no longer than the 12 months" to state, "no less than 12 months and no longer than 15 months."
- Requiring hospitals to encode in the MRF the 10th, median, and 90th percentile allowed amounts when the payer-specific negotiated charges are based on percentages or algorithms.

[116] CY 2020 Hospital Price Transparency (HPT) final rule (84 FR 65524)
[117] Executive Order 14221, "Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information"

- For calculating the 10th, median, and 90th percentile allowed amounts, a requirement to use EDI 835 ERA transaction data or an alternative, equivalent source of remittance data that includes the same information as EDI 835 ERA transaction data would include, to calculate and encode the allowed amounts.
- Replacing the currently required "good faith effort" and affirmation statement in the MRF with a new and expanded attestation. The final attestation language has been revised to include the phrase "to the best of the hospital's knowledge and belief".
- Requiring hospitals to encode additional hospital information in the MRF including: the name of the hospital chief executive officer, president, or senior official designated to oversee the encoding of true, accurate, and complete data; and the hospital's organizational National Provider Identifier (NPI).
- If CMS issues a penalty to a hospital it determines is noncompliant, permitting CMS to reduce the amount of a penalty by 35 percent, under certain conditions, when a hospital waives its right to appeal.

B. Modified Regulatory Requirements

1. Background

This section of the preamble recites relevant history from the CY 2024 OPPS/ASC final rule with comment period.[118] CMS highlights methods that hospitals and payers use to establish payer-specific negotiated charges and reiterates its stance that not all hospitals can produce a payer-specific negotiated charge in dollars that would meet the definition of a "standard charge." Thus, CMS finalized a requirement for hospitals to display an "estimated allowed amount" which would provide needed context, in dollars, for instances where the hospital's standard charge is based on a percentage or algorithm for a specified payer's plan. This new data element was defined as the average reimbursement in dollars that the hospital had received from the payer in the past and should reflect the amount the hospital expects to be reimbursed for the item or service (or service package), on average. As such, it is not the final exact amount in dollars that an individual would pay for an item or service. Even so, CMS stated its belief that this information, when paired with the algorithm encoded in the MRF, would promote greater transparency of hospital standard charges that can be useful to MRF users.

Since the CY2024 OPPS/ASC final rule, CMS has continued to gain experience with the implementation of the estimated allowed amount data element and received public feedback and questions requesting that the agency further clarify calculation of the estimated allowed amount. In light of these inquiries, and consistent with EO 14221, CMS revisited the "estimated allowed amount" data element requirement.

2. General Comments

In this section, CMS summarizes the general comments it received, which can be viewed in more detail in the preamble of the final rule. Briefly, while many commenters expressed support for the

[118] 88 FR 82098

goals of price transparency, generally, several suggested that CMS should focus on policies that directly help individual patients understand the costs of their care rather than increasing administrative requirements on hospitals. A few expressed appreciation for CMS' efforts to standardize and streamline requirements, while one commenter noted that the MRF data are insufficient on their own and must work in tandem and be coordinated with Transparency in Coverage (TiC) and No Surprises Act (NSA) policies. Many commenters generally opposed CMS' proposals, highlighting the operational and data complexities which they view as particularly burdensome for small and rural and/or safety-net hospitals. Many commenters provided additional recommendations and suggestions for improving HPT requirements, which are outlined in detail in the final rule preamble.

In response, CMS reiterates its goals and reminds the reader that CMS views the release of hospital charge information to be foundational but not sufficient to help drive market competition and consumer shopping. CMS goes on to provide examples of how these data are being used effectively in a variety of settings. CMS continues to believe that a healthcare consumers' more complete understanding of real prices would come in tandem with other price transparency policies, including TiC and NSA. CMS believes that HPT, TiC, and the NSA are complementary efforts and notes that it is considering comments receive from the 2024 OPPS/ASC rulemaking RFI. CMS encourages hospitals to provide consumers with cost information in a consumer-friendly manner. CMS also believes that the benefits of these proposals to the public outweigh the burden on hospitals, and the agency intends to provide technical guidance and examples of how to encode the new data elements finalized in this rule on the CMS Hospital Price Transparency – Data Dictionary GitHub Repository, as well as in guidance on the HPT resources page on the CMS website. Finally, CMS thanked commenters for the additional out-of-scope suggestions and indicates it may consider them for future rulemaking and process improvement.

3. Definitions

In the proposed rule, CMS proposed to add definitions for three new data elements, the "median allowed amount," the "tenth (10th) percentile allowed amount," and the "ninetieth (90th) percentile allowed amount" as follows:

- "Median allowed amount" is defined as the median of the total allowed amounts the hospital has historically received from a third-party payer for an item or service for a time period no longer than the 12 months prior to posting the machine-readable file. Should the calculated median fall between two observed allowed amounts, the median allowed amount is the next highest observed value.
- "Tenth (10th) percentile allowed amount" is defined as the 10th percentile of the total allowed amounts the hospital has historically received from a third-party payer for an item or service for a time period no longer than the 12 months prior to posting the machine-readable file. Should the calculated percentile fall between two observed allowed amounts, the 10th percentile allowed amount is the next highest observed value.
- "Ninetieth (90th) percentile allowed amount" is defined as the 90th percentile of total allowed amounts the hospital has historically received from a third-party payer for an item or service for a time period no longer than the 12 months prior to posting the machine-

readable file. Should the calculated percentile fall between two observed allowed amounts, the 90th percentile allowed amount is the next highest observed value.

Comment/response: A few commenters supported these definitions, noting that more precise definitions will ensure that hospitals are interpreting the specifications correctly and patients will have more accurate data to allow them to make more informed decisions. Many commenters expressed concerns with certain aspects of the definition (such as the lookback period), which CMS addresses in conjunction with policy proposals discussed in more detail below.

Final Action: After a review of comments, CMS is finalizing its proposed definitions for three new data elements, the "median allowed amount," the "tenth (10th) percentile allowed amount," and the "ninetieth (90th) percentile allowed amount" with modification to revise the phrase, "no longer than the 12 months" in each definition to state, "no less than 12 months and no longer than 15 months."

4. Replacing the Estimated Allowed Amount with the Allowed Amounts Data Elements and the Count of Allowed Amounts Data Element

a. Background on Encoding Payer-Specific Negotiated Charges As Dollar Amounts

CMS expects that, for most contracting scenarios, a hospital's payer-specific negotiated charges can be expressed as a dollar amount. CMS notes that there may be situations where the payer-specific negotiated charge cannot easily be expressed as a dollar amount. In the proposed rule, CMS clarified its current policies for displaying an estimated allowed amount (which CMS stated would be replaced with the median allowed amount should CMS' proposals be finalized).

b. Replacing the Estimated Allowed Amount with the Median Allowed Amount

Beginning in 2024, CMS established a policy that if the payer-specific negotiated charge is based on a percentage or algorithm, the MRF must also describe the percentage or algorithm that determines the dollar amount for the item or service and calculate and encode an estimated allowed amount in dollars for that item or service.[119] The "estimated allowed amount" was defined as the average dollar amount that the hospital has historically received from a third-party payer for an item or service.

However, in light of feedback from stakeholders and EO 14221, CMS proposed to require hospitals to encode, beginning January 1, 2026, the "median allowed amount", rather than the estimated allowed amount, if a payer-specific negotiated charge is based on an algorithm or percentage. CMS also proposed to require hospitals to calculate and encode the 10th and 90th percentile allowed amounts in dollars for that item or service. Under this proposal, the "median allowed amount", "tenth (10th) percentile allowed amount", and "ninetieth (90th) percentile allowed amount" would be defined as the median, 10th, or 90th (respectively) of the total allowed amounts the hospital has historically received from a third-party payer for an item or service for a time

[119] §180.50(b)(2)(ii)(C)

period no longer than the 12 months prior to posting the MRF. CMS noted that in many cases, the 10th percentile allowed amount, median allowed amount, and 90th percentile allowed amount could fall between two actual prices; in other words, where the total count of data points would be an even number. In such instances, CMS proposed the hospital should identify and display the next highest value.

In the proposed rule, CMS discussed and considered alternatives (such as using the 80th percentile or requiring display of maximum allowed amounts); however, CMS stated its belief that the 10th and 90th percentiles, along with the median (which is the 50th percentile), would convey sufficient information about the allowed amounts that the hospital has actually received for an item or service.

Comment/response: Response to CMS' proposals were mixed. Some commenters agreed that the 10th, median, and 90th percentile allowed amounts would improve information available to the public about hospital payer-specific negotiated charges while others questioned their value, especially their value for patients, and suggested alternatives such as displaying the average reimbursement amount. In response, CMS continues to believe the proposed information will benefit the public and reiterates that the MRF is designed to be used by innovators, employers and researchers and to be ingested into machines for further processing of the data. Additionally, CMS believes that the information contained in the MRF is critical for driving competition and directly beneficial for patients.

Many commenters objected to the burden these proposals would create for hospitals, particularly for small and rural hospitals, and expressed concerns about deviating from statistical best practices for determining the median when it would fall between two observed amounts. Commenters expressed concerns related to the burden created by the short timeline for complying with these new requirements in light of the recently implemented "estimated allowed amount". In response, CMS states that the agency understands that these revisions may create burden. However, by displaying the "next highest value" as the median when the median falls between two allowed amounts, the hospital will be displaying an actual dollar value the hospital has received, as required by EO 14221. CMS notes that, as with previous rulemaking, the agency will provide technical guidance and examples of how to encode the new data elements on the CMS Hospital Price Transparency – Data Dictionary GitHub Repository (https://github.com/CMSgov/hospital-price-transparency), as well as guidance on the HPT resources page on the CMS website (https://www.cms.gov/priorities/key-initiatives/hospital-price-transparency/resources).

Several commenters requested that CMS require hospitals to make public all their payer-specific negotiated charges "in dollars and cents," thus eliminating the need for the currently required estimated allowed amount or the proposed median, 10th percentile, and 90th percentile allowed amounts. One commenter suggested CMS should prohibit hospitals from charging patients more than a payer-specific negotiated charge dollar amount and presume that any MRF that has payer-specific negotiated charges represented as percentages and algorithms is automatically non-compliant. In response, CMS reminds readers that, although critical for determining an individual's out-of-pocket obligation, hospital standard charges do not represent either an

individual's out-of-pocket obligation or a "real, guaranteed price." CMS continues to strongly encourage individual consumers to avail themselves of hospital and payer price estimator and comparison tools, and to seek out "good faith estimates" from hospitals under the NSA, which may provide up-front pricing that can be used to dispute final charges that are substantially in excess of the up-front amounts. CMS reiterates that, as discussed in prior rulemaking, the agency believes that section 2718(e) of the PHS Act directs the Secretary to tell hospitals how to display their standard charges, not how to establish them or that they must establish them.

Final Action: After consideration of public comments, **CMS is finalizing its proposal to replace the estimated allowed amount** with the median allowed amount and to add the 10th and 90th percentile allowed amounts. **CMS is also finalizing** that, should the calculated percentile fall between two observed allowed amounts (in other words, where the total count is an even number), the allowed amount will be the next highest observed value. Enforcement of these requirements will be delayed until April 1, 2026.

c. Calculation of Allowed Amounts

(1) Determining the "Total Allowed Amount." In the proposed rule, CMS states that the new definitions of 10th, median and 90th percentile allowed charges would require hospitals to identify the "total allowed amounts" that the hospital has historically received for an item or service. CMS proposed that the "total allowed amount" dollar figure would be derived from the gross charge minus contractual adjustments and consist of the portion billed to a payer for a particular plan and the portion, if any, billed to the patient. **CMS states it received no comments on this proposal and is therefore finalizing it as proposed.**

(2) Data Source for Calculating the Allowed Amounts. Currently, hospitals have flexibility, in the interest of reducing burden, to determine the best data source(s) for calculating the estimated allowed amount data element. In the proposed rule, CMS proposed to require that hospitals only use EDI 835 ERA transaction data to calculate and encode the allowed amounts.

Comment/response: Commenters were mixed on their support for this proposal. Several commenters noted that EDI 835 ERA transaction data is sent by many payers and thus requiring its use to calculate and encode the allowed amounts would enhance the consistency of hospital standard charge information and the comparability of the median allowed amount, and the 10th percentile and the 90th percentile allowed amounts. Others indicated that it would be difficult to only use EDI 835 ERA transaction data to calculate and encode the allowed amounts because some hospitals do not have it, the data is not standardized, the data may not capture item or service level detail or reflect the full reimbursement amount, payers use claim adjustment reason codes (CARC) and remittance advice reason codes (RARC) inconsistently, and payers frequently deviate from Health Insurance Portability and Accountability Act (HIPAA) standard transaction requirements. A few commenters suggested that using EDI 835 ERA transaction data to calculate and encode the allowed amounts may be particularly difficult for small and rural hospitals with limited technical capacity. In response, CMS acknowledges the merits of the concerns raised by the commenters and is finalizing its proposal with modification. Specifically, **CMS is finalizing that hospitals will**

be required to use EDI 835 ERA transaction data or an alternative or equivalent source of remittance data that includes the same information as EDI 835 ERA transaction data would include. If a hospital chooses to use an alternative or equivalent source of remittance data, the alternative or equivalent source must allow the hospital to calculate the "total allowed amount" as defined by CMS.

(3) Lookback Period for Calculating the Allowed Amounts. In the proposed rule, in order to help ensure that all hospitals calculate the allowed amount data elements consistently and calculate them based on the most recent reimbursements, CMS proposed the following:

- Hospitals would be required to base the 10th, median, and 90th allowed amount and the count of allowed amounts (discussed in a later section) on EDI 835 ERA transaction data from no longer than 12 months prior to posting the MRF.
- If the negotiated percentage or algorithm associated with the allowed amounts was only used for a portion of the 12-month time period prior to posting the MRF, the hospital would be required to encode the median allowed amount (and 10th and 90th percentile allowed amounts, and count of allowed amounts) from the EDI 835 ERA transaction data for the portion of time that the percentage or algorithm was used.
- If the negotiated percentage or algorithm associated with the allowed amounts was used for the entire 12-month time period prior to posting the MRF, the hospital would encode the median allowed amount (and 10th and 90th percentile allowed amounts, and count of allowed amounts) from the EDI 835 ERA transaction data for the entire 12-month time period prior to posting the MRF.

CMS stated its belief that limiting the lookback period to no more than 12 months prior to posting the MRF would be consistent with section 2718(e) of the PHS Act that refers to "for each year," and the current requirement that hospitals must update the MRF at least annually (42 CFR 180.50(e) and 180.60(e)). CMS noted that under its proposal, a hospital may need to use different lookback periods to calculate the allowed amounts for each payer, depending on when a contract was negotiated. Additionally, CMS clarified that the allowed amounts would be based on the EDI 835 ERA transaction data available at the time the hospital updates its MRF, in recognition that there may be situations where the EDI 835 ERA transaction data is not yet final or may change after the allowed amounts are encoded in the MRF due to additional adjustments being applied to a claim(s).

CMS summarizes various alternative lookback periods it considered, but did not propose, including a 3- or 6-month lookback, or requiring hospitals to use a rolling 12-month period prior to posting the MRF.

Comment/response: Many commenters supported establishing a standardized lookback period, but expressed concerns related to the 12-month timeframe indicating that 12 months would not be sufficient because hospitals typically pull the data several months before posting their MRFs. Due to claims adjudication lags, this would mean that hospitals would only be able to use 6 to 8 months of data. Commenters made alternative suggestions to address this issue, such as extending the

lookback period to 18 or 24 months. In response, CMS recognizes commenter concerns and is modifying its proposal to expand the lookback period.

Commenters sought clarification on how to address situations in which renegotiations take place, expressing concerns that only including data from the most recent contract negotiation date would limit the amount of data used to encode allowed amounts. In response, CMS clarifies that in the event that hospitals renegotiate a contract during the lookback period, hospitals should use data from both prior to and after the negotiation date and encode one figure for each of the allowed amount data elements. Regardless of how many times a contract was modified or the amount changed, the hospital should use all data available over the lookback period.

A few commenters requested that CMS require the hospital to indicate in the MRF the number of months the hospital used as its lookback period and/or encode the effective date of each contract. Another commenter suggested CMS allow hospitals to leave the fields blank if the hospital has less than 6 months of data available. In response, CMS thanks the commenters, declines to require anything additional at this time, and reminds them that nothing precludes hospitals from making additional clarifying notes in the "Additional Notes" field in the MRF.

Final action: After consideration of public comments, **CMS is finalizing its proposal with modification**. Specifically, CMS is finalizing that the lookback period for the 10th, median, and 90th allowed amounts, and count of allowed amounts (discussed below) is a time period of no less than 12 months and no longer than 15 months prior to posting the MRF. CMS is making corresponding modifications to the definitions (as finalized and discussed above). CMS expects hospitals to use at least the most recent 12 months of data that is available to them. However, in the case where hospitals need additional time to pull or prepare the data before posting the MRF, hospitals may use data from up to 15 months prior to the date the MRF is posted to help ensure they have an adequate number of data points to encode the allowed amounts. The 12 to 15 months of data must be contiguous. In the event that a hospital renegotiates a contract during the 12- to 15-month span, the hospital must include data from both prior to and after the negotiation date.

d. *Encoding the Count of Allowed Amounts*

As part of its proposal to require hospitals to encode the 10th, median, and 90th percentile allowed amounts if a hospital's payer-specific negotiated charge is based on an algorithm or percentage, CMS proposed to require hospitals to encode the count of allowed amounts used to calculate the 10th, median, and 90th percentile allowed amounts. Under this proposal, hospitals would be required to encode the actual number of allowed amounts within the EDI 835 ERA transaction data utilized to calculate the allowed amount data elements, excluding zero-dollar claims from the count of allowed amounts.

Related to this, CMS also proposed that hospitals would be required to use the same count of allowed amounts to calculate the 10th, median, and 90th percentile allowed amounts. In the event that a hospital has a "0" count of allowed amounts from the most recent 12-month time period from which to derive the allowed amounts, the hospital would be required to encode "0" as the value for

the count of allowed amounts for a specific payer and may leave the 10th, median, and 90th percentile allowed amounts in the MRF blank. In the event a hospital must encode a "0" as the value for the count of allowed amounts for a specific payer, the hospital would be required to encode information to explain the hospital's insufficient claim remittance history in the "additional notes" field. If the reason for a "0" value is due to a new or revised payer contract, the hospital should encode "new or recently revised payer contract". CMS noted that nothing would preclude a hospital from updating its MRF once it has generated one or more remittances for an item or service under a new contract.

CMS discussed and sought comment on an alternative approach it considered that would require hospitals to provide the range, or categories, of the count of allowed amounts, rather than a precise count.

Comment/response: Commenters were mixed in their response to this proposal. Several expressed support, stating that the count would help users of the MRF establish the credibility of the 10th, median, and 90th percentile allowed amounts that are displayed in it. Others raised concerns related to burden. Others stated that a low claims volume could violate patient health information protections under HIPAA, and that CMS' proposal conflicts with long-standing CMS and Federal data suppression standards.

In response, CMS continues to believe that the count is necessary to bring context to the 10th, median, and 90th percentile allowed amounts and that this need outweighs the burden it presents. CMS notes that, as a result of comments, the agency has increased the burden estimate in the final rule and is also delaying enforcement to April 1, 2026 as discussed in a section below. Additionally, CMS was persuaded by comments to modify its proposal with respect to encoding the count of allowed amounts for low-volume services, in particular, for counts of remittances greater than zero but less than eleven.

Final action: After consideration of the comments received, **CMS is finalizing its proposals with modification**. Specifically, the hospital must calculate and encode the total number of allowed amount remittances from the EDI 835 ERA transaction data (or an alternative, equivalent source of remittance data) used to calculate the 10th, median, and 90th percentile allowed amounts. Should the total count of allowed amount remittances be greater than 0 but less than 11, the hospital must indicate that at least 1 but no more than 10 allowed amount remittances were used in the calculation, using the valid value described in the CMS Hospital Price Transparency – Data Dictionary GitHub Repository website.

Additionally, **CMS is finalizing** that should a hospital have a "0" count of allowed amounts within their remittance data from the 12- to 15-month lookback period from which to derive the allowed amounts for a particular item or service, the hospital must:

- Encode "0" as the value for the count of allowed amounts for a specific payer and plan;
- Leave the 10th, median, and 90th percentile allowed amounts in the MRF blank as there is no data to encode; and

- Encode information to explain the hospital's insufficient claim remittance history in the "Additional Notes" field.

CMS notes it is also finalizing a requirement that hospitals exclude zero-dollar claims from the count of allowed amounts.

5. Modification to the MRF Affirmation Statement

Currently, the existing regulation at §180.50(a)(3)(i) and (ii) requires each hospital to: make a good faith effort to ensure that the standard charge information encoded in the MRF is true, accurate, and complete as of the date indicated in the MRF; and affirm in its MRF that, to the best of its knowledge and belief, the hospital has included all applicable standard charge information in accordance with the requirements of this section, and that the information encoded is true, accurate, and complete as of the date indicated in the MRF.

In light of concerns raised by users of hospital MRFs, and for reasons expressed more fully in the proposed rule preamble, CMS proposed to supplant the existing affirmation and good faith effort requirements by, instead, specifying at new §180.50(a)(3)(iii) that, beginning January 1, 2026, each hospital would be required to attest in its MRF to the following:

> *"The hospital has included all applicable standard charge information in accordance with the requirements of § 180.50, and the information encoded is true, accurate, and complete as of the date in the file. The hospital has included all payer-specific negotiated charges in dollars that can be expressed as a dollar amount. For payer-specific negotiated charges that cannot be expressed as a dollar amount in the machine-readable file or not knowable in advance, the hospital attests that the payer-specific negotiated charge is based on a contractual algorithm, percentage or formula that precludes the provision of a dollar amount and has provided all necessary information available to the hospital for the public to be able to derive the dollar amount, including, but not limited to, the specific fee schedule or components referenced in such percentage, algorithm or formula."*

Additionally, CMS proposed at new §180.50(a)(3)(iv) that, beginning January 1, 2026, the hospital must encode within the MRF the name of the hospital chief executive officer, president, or senior official designated to oversee the encoding of true, accurate and complete data as directed in §180.50(a)(3)(iii). To implement this requirement, CMS proposed to add a new general data element, specifically "attester name" to the MRF.

Finally, in the proposed rule, CMS sought comment on two alternative approaches the agency considered but did not propose, specifically, a requirement for hospitals to submit an MRF attestation directly to CMS and/or a requirement for hospitals to post a standalone attestation document on the hospital website that would be signed by a hospital senior official.

Comment/response: Commenters were mixed in their support of this proposal. Several commenters supported the revisions to the attestation, which they believe strengthen the current

requirement and demonstrate that the Federal government and hospitals take seriously their obligation to provide "accurate, reliable, actionable prices". In response, CMS expresses appreciation for the comment that patients will use the MRF to be able to understand the dollar amount for an item or service, but cautions that the standard charge information encoded within the MRF reflects the standard charge, or the regular rate established by the hospital for an item or service provided to a specific group of paying patients, which is not necessarily reflective of an individualized charge for an episode of care.

Many commenters opposed the proposed attestation language, in particular, the phrase "has provided all necessary information available to the hospital for the public to be able to derive the dollar amount." Commenters stated this phrase is overbroad and fails to take into account the realities and complexities of hospital billing practices. Commenters pointed out that the phrase appears to incorrectly assume that members of the public are capable of anticipating their healthcare needs and have the specialized knowledge and understanding necessary to appropriately apply the algorithms displayed. A few commenters stated that, because it would be impossible for hospitals to unilaterally provide sufficient information to enable patients to undertake these calculations on their own, the proposed attestation requirement would be arbitrary and capricious. Other commenters expressed concern that the proposed language appears to require hospitals to guarantee absolute flawlessness of complex data and apply a strict liability standard. A few commenters requested that CMS reassure hospitals that these new attestation requirements do not generate False Claims Act (FCA) challenges. In response, CMS reiterates its commitment to requiring hospitals to display meaningful standard charge information for public use. CMS disagrees that it is 'impossible' for hospitals to comply with the requirements and reminds commenters that the MRF represents the data available at a point in time. Moreover, CMS expresses an understanding that hospitals cannot provide everything that everyone might need to know, but it is the agency's expectation that hospitals provide "sufficient and necessary information that is available to them for a reasonable objective person to derive the price for an item or service." In the final rule preamble, CMS provides several examples of acceptable and unacceptable algorithm descriptions and states that additional examples will be made available in the CMS Hospital Price Transparency Data Dictionary GitHub Repository. Additionally, CMS "forcefully" states that this final rule falls outside the scope of the FCA. CMS states that it is not expecting hospitals to vouch for the accuracy and completeness of the remittance data (which is provided by a third-party payer) but that it is expecting hospitals to certify to the completeness and accuracy of the calculations of the allowed amounts. However, in response to these and other concerns raised by commenters, CMS has elected not to finalize the removal of the phrase "to the best of the hospital's knowledge and belief" from the attestation statement to reflect that CMS does not view the attestation as an absolute guarantee of perfection, to acknowledge that there may be varied interpretations of contract calculations that could lead to variation in price when used by the public, and to reflect other reasons that may hinder an MRF user from being able to derive a price prior to services being performed.

Several commenters expressed concern that the new requirements could expose hospitals to significant legal challenges because many pricing algorithms rely on proprietary groupers or logic developed and owned by payers or third-party vendors that are often protected under intellectual

property agreements or confidentiality clauses in hospital contracts. In response, CMS notes that hospitals have had 4 years to comply with the requirements and yet CMS has had to issue thousands of warning notices and corrective actions plans as well as 27 civil monetary penalties (CMPs). CMS does not discount commenters' assertions that various confidentiality provisions may generally protect the terms of various contracts or products that intersect with price transparency, but reiterates, as it did in prior rulemaking,[120] that such contracts typically include exceptions where Federal law requires such a disclosure.

A few commenters supported CMS' proposal to encode within the MRF the name of the hospital chief executive officer, president, or other senior official designated to oversee the encoding of true accurate and complete data. However, many commenters disagreed for a variety of reasons including their belief that the requirement would be unnecessarily burdensome and that it would be unreasonable to expect the CEO to personally validate the data and expose himself or herself to legal risks and security concerns. Commenters stated that absent actual support for this proposal, the agency should not add to the burdens of hospital leaders. In response, CMS reiterates its rationale for the proposal, including its belief that this disclosure would strengthen accountability. CMS points to other Medicare programs that require hospital executives to attest to complex financial information, for example, when submitting hospital cost reports. CMS further notes that hospital executives are frequently included on the hospital's own website and in press releases. CMS notes that in the proposed rule it did not include the applicable burden level for CEO review of the MRF and is therefore adding 2 hours to both the one time and annual burden estimates. CMS declined to implement additional suggestions that were proffered by commenters.

Final Action: After consideration of public comments, **CMS is finalizing, effective January 1, 2026, its proposal to supplant the existing affirmation requirement with the proposed attestation statement, with modification.** CMS will add back the phrase "To the best of its knowledge and belief,". The finalized language reads as follows:

> *"To the best of its knowledge and belief, this hospital has included all applicable standard charge information in accordance with the requirements of 45 CFR 180.50, and the information encoded is true, accurate, and complete as of the date in the file. This hospital has included all payer-specific negotiated charges in dollars that can be expressed as a dollar amount. For payer-specific negotiated charges that cannot be expressed as a dollar amount in the machine-readable file or not knowable in advance, the hospital attests that the payer-specific negotiated charge is based on a contractual algorithm, percentage or formula that precludes the provision of a dollar amount and has provided all necessary information available to the hospital for the public to be able to derive the dollar amount, including, but not limited to, the specific fee schedule or components referenced in such percentage, algorithm or formula."*

In addition, **CMS is finalizing** that, beginning January 1, 2026, the hospital must encode within the MRF the name of the hospital chief executive officer, president, or senior official designated to

[120] See the CY 2020 HPT Final Rule (84 FR 65544) for a more complete discussion related to the Defend Trade Secrets Act of 2016 (18 U.S.C. 1905).

oversee the encoding of true, accurate and complete data. CMS has made updates to the burden estimate to reflect the hospital executive's time in review. Finally, as discussed below, CMS states that although these revisions to the attestation requirements will be effective January 1, 2026, CMS will delay enforcement until April 1, 2026.

6. Requirement to Report Hospital National Provider Identifier (NPI) Information in the Machine-Readable File

Currently, hospitals must encode in their MRFs certain general information including the hospital's name, license number, and location name(s) and address(es). Additionally, CMS' MRF naming convention requires hospitals to include the Employer Identification Number (EIN). While these elements help to identify the hospital, interested parties have told CMS that they are inadequate to facilitate comparing hospital MRF data with other datasets that include hospital-related information and that a standard identifier would bolster these efforts. As a result, and for reasons discussed more fully in the preamble of the proposed rule, CMS proposed to require hospitals to report a unique identifier, specifically their Type 2 (organizational) NPI(s), in their MRFs. CMS also proposed the following:

- Hospitals would specifically be required to include in their MRFs any Type 2 NPI(s) that has a primary taxonomy code starting with '28' (indicating hospital) or '27' (indicating hospital unit) and that is active as of the date of the most recent update to the standard charge information.
- Type 2 NPI(s) display would be limited to only those that meet the taxonomy criteria proposed above.
- In cases where hospitals have more than one NPI that meet the proposed criteria above, hospitals would be required to report all active Type 2 NPIs meeting the criteria.
- Hospitals would have to conform with additional technical instructions in the CMS data dictionary and JSON schema in the Hospital Price Transparency – Data Dictionary GitHub Repository.[121]

CMS also sought comment on alternative approaches it considered, such as a requirement for hospitals to report only one NPI, inclusion of a Place of Service code and the Taxpayer Identification Number (TIN), or inclusion of a CMS Certification Number (CCN) in the MRF.

Comment/response: Many commenters supported CMS' proposal citing its alignment with TiC and how it would improve MRF user ability to crosswalk information. Some commenters, however, did not support CMS' proposal citing burden concerns. CMS received several comments on the alternative approaches the agency considered but did not propose. In response, CMS states that a review of the publicly available CMS enrollment system information found that only approximately 10 percent of hospital enrollment applications reported multiple NPIs. Moreover, a hospital would only be required to list the information one time in the file. For these reasons, CMS does not believe that this requirement would present an undue burden. CMS clarifies that this

[121] Available at https://github.com/CMSgov/hospital-price-transparency

requirement will require hospitals to report their Type 2 NPIs that are associated with a primary taxonomy code starting with '28' or '27' and not the taxonomy codes themselves.

Final action: After consideration of public comments, **CMS is finalizing, without modification**, the requirement that hospitals must report, in a newly created general data element in the MRF, any Type 2 NPI(s) that are associated with a primary taxonomy code starting with '28' (indicating hospital) or '27' (indicating hospital unit) and that is active as of the date of the most recent update to the standard charge information. This regulation will become effective January 1, 2026; however, as noted below, CMS will delay enforcement to April 1, 2026.

7. Effective Date

CMS proposed that the revisions to §180.50 would become effective January 1, 2026.

Comment/response: CMS received many comments stating that CMS' proposed timeline was aggressive and that it would be unreasonable to require hospitals to update the data elements and implement the changes by January 1, 2026. Commenters recommended alternative effective dates ranging from 60 days to 2 years. A few commenters requested that CMS delay enforcement of the final policies, rather than delay the implementation date. In response, CMS states its belief that hospitals should implement the new policies as soon as possible; however, in light of comments, while CMS is finalizing the January 1, 2026 effective date, CMS will delay its enforcement.

Final Action: After consideration of public comments, **CMS is finalizing** that the effective date of the revisions at §180.50 (which include: removal of the estimated allowed amount; disclosure of the 10th, median, and 90th percentile allowed amounts; disclosure of the count of allowed amounts; the attestation requirement; and the NPIs) will be January 1, 2026. However**, CMS will delay enforcement of these finalized revisions until April 1, 2026.**

C. Improving and Enhancing Enforcement

In the proposed rule, CMS summarized its HPT enforcement activity and actions to date. CMS notes that the agency has authority to issue a CMP when a noncompliant hospital fails to respond to CMS' request to submit a corrective action plan (CAP) or comply with the requirements of the CAP.[122] The HPT regulations set forth the criteria CMS uses to determine the CMP amount[123] and permits hospitals to appeal the CMP within 30 days of issuance of the notice of imposition of a CMP.[124] As of May 2025, CMS has issued CMP notices to 27 hospitals, 20 of which have exercised their right to appeal the CMP to an administrative law judge (ALJ).[125] In the proposed rule, CMS noted that some other CMS enforcement programs offer entities subject to CMPs the ability to waive appeal rights in exchange for a 35 percent discount in the amount of the CMP

[122] §180.90(a)
[123] §180.90(c)
[124] §§180.100 and 180.110
[125] CMS posts the CMP notices on its website at: Enforcement Actions | CMS Hospitals designated as "Under Review" have exercised their right of appeal.

owed.[126] Given this, CMS considered whether offering hospitals the opportunity to receive a reduced penalty—in some circumstances, and in exchange for their acknowledging their HPT noncompliance—could expedite timely payment of CMPs.

CMS therefore proposed to establish, at new §180.90(c)(4), and subject to the exceptions discussed below, that the amount of a CMP would be reduced by 35 percent should a hospital submit to CMS a written notice requesting to waive its right to a hearing under §180.100 within 30 calendar days of the date of the notice of imposition of the CMP. CMS noted that its proposal would not preclude a hospital, so long as it did not seek a waiver, from requesting a hearing, nor would waiving the right to a hearing remove from the hospital's record the fact of its HPT noncompliance. Rather, under this proposal, should a hospital choose to waive its right to a hearing, it would accept CMS' determination that it was noncompliant. Significantly, whether or not a hospital would elect to waive the right to a hearing, it would still be required to achieve compliance to avoid the potential imposition of additional CMPs pursuant to existing regulations.[127]

Under this proposal, if a hospital waives its right to appeal a CMP and receives a 35 percent reduction in accordance with new §180.90(c)(4), the hospital would: 1) not be eligible to receive a 35 percent reduction on any CMPs issued under §180.90(f) that result from the same instance(s) of noncompliance (that is, continuing violations), and 2) waive its right to appeal CMPs for any such continuing violations. CMS also proposed that a hospital would not be eligible to request that CMS reduce the amount of a CMP if: 1) the hospital does not request to waive its right to a hearing within 30 calendar days of the date of the notice of imposition of the CMP, or 2) CMS imposed the CMP because the hospital failed to make public either an MRF or a consumer-friendly list of standard charges.[128] Finally, CMS proposed to make conforming revisions to §180.90 that are detailed in the preamble of the final rule.

Comment/response: Several commenters expressed general support for CMS' prior changes to its enforcement rules and processes and provided suggestions on future improvements. In response, CMS thanks the commenters and summarizes its enforcement efforts to date. CMS noted it would take the recommendations into consideration for future rulemaking.

A few commenters expressed support for the proposal stating that it strikes a fair balance between accountability and administrative efficiency. A few commenters expressed concerns that CMS' proposal puts undue pressure on hospitals to waive their rights and that CMS already has authority to reduce penalties. A few commenters suggested that this policy is unnecessary due to the high rate of compliance among hospitals. One commenter stated their belief that the proposal would incentivize noncompliant hospitals to pay and remain noncompliant. In response, CMS disagrees that the policy would put undue pressure on hospitals to waive their rights or that it would encourage continued noncompliance. CMS explains that under the regulation, hospitals that remain out of compliance would continue to be subject to issuance of CMPs, and under the proposal, a hospital could not continue to avail itself of the penalty reduction if it is found to be out

[126] See: FY 2024 Skilled Nursing Facility Prospective Payment System final rule (88 FR 53200, 53326)
[127] At §180.90(f)
[128] As required at §180.40(a) and (b).

of compliance for the same violations. CMS also notes that those hospitals found to not have an MRF or consumer-friendly display of shoppable services would not be eligible for this CMP reduction in the first instance. CMS agrees that hospitals have achieved high levels of compliance but believes the policy is necessary as it would benefit both CMS and the hospital by reducing or eliminating the time, resources, expenses, and other potential burden otherwise attributable to the administrative appeals processes.

Final Action: After consideration of the public comments, **CMS is finalizing its proposal with clarifying edits, with an effective date of January 1, 2026.** Specifically, CMS is adding new §180.90(c)(4) to state that: the amount of a civil monetary penalty is reduced by 35 percent if the hospital submits a written notice to CMS requesting to waive its right to a hearing within 30-calendar days of the date of the notice of imposition of the civil monetary penalty. A hospital that receives a 35 percent reduction in a civil monetary penalty is not eligible to receive a 35 percent reduction for any subsequent civil monetary penalties imposed pursuant to continuing violations and also waives its right to appeal any subsequent civil monetary penalties imposed for such continuing violations.

Additionally, CMS is finalizing, as proposed, that a hospital is not eligible to request that CMS reduce the amount of a civil monetary penalty by 35 percent if: 1) the hospital does not request to waive its right to a hearing, or 2) CMS imposed the CMP because the hospital failed to make public the MRF or failed to make public a consumer-friendly list of standard charges as required.

Finally, CMS is finalizing conforming revisions to §180.90 that are detailed in the preamble of the final rule.

D. Burden Estimate

In the proposed rule, CMS estimated that, as a result of these proposals, hospitals would incur an additional one-time burden with a total national cost of $3,545,441 across 7,416 hospitals. In the final rule, in response to comments, CMS increased the final burden estimate. Specifically, CMS estimates that these new policies include a one-time burden of $1,461.80 per hospital, and a total national cost of $10,840,708.80 ($1,461.80 × 7,416 hospitals).

XX. Market Based Weights for the Inpatient Prospective Payment System (IPPS)

A. Overview

In the FY 2021 IPPS final rule (85 FR 58873 through 58892), CMS required hospitals to report the median payer-specific charge negotiated by MS-DRG with Medicare Advantage Organizations (MAOs) on its Medicare cost report effective for cost reporting periods ending on or after January 1, 2021. This information was intended to be used to set the IPPS relative weights beginning in FY 2024. These policies were repealed one year later. For cost reporting periods ending on or after January 1, 2026, CMS is reinstating the reporting requirement with modifications and plans to use the submitted information to set IPPS relative weights beginning in FY 2029.

B. Factors Considered

CMS' purpose in requiring the median payer-specific charge and using it to set the MS-DRG relative weights is to reduce Medicare's reliance on the hospital chargemaster. In the FY 2021 IPPS rule, CMS described research that chargemasters are usually highly inflated and have been used to secure higher payments from Medicare and private payers (85 FR 32790). By reducing reliance on the hospital chargemaster, CMS could make the Medicare payment rates reflect the relative market value for inpatient items and services. CMS updates its analysis with more recent research it says supports prior conclusions.

CMS' literature review indicates that MAOs nominally pay only 100 to 105 percent of traditional Medicare rates and, in real economic terms, possibly less.[129] Another study found that MAOs paid 5.6 percent less for hospital services compared to FFS Medicare.[130] A third study found MAO prices to be roughly equal to Medicare FFS prices, on average, but commercial prices were 89 percent higher than FFS prices. In addition, commercial prices varied greatly across and within metropolitan areas, but MAO prices varied much less. Further, "there were some DRGs where the average MA[O] price was much higher than FFS and there were some DRGs where the average MA[O] price was a bit lower than FFS."[131]

Recent research by Linde and Egede concluded that higher chargemaster markups are associated with higher hospital profitability.132 Meiselbach et al. used 2022 price information disclosed by hospitals to examine the ratio of commercial-to-MAO prices negotiated by the same insurer and found that median prices were two to three times higher for commercial plans than MAOs in the same hospital for the same service.133 Randall and Duffy found that, for a market basket of inpatient services, prices for health insurance exchange plans were 143.3 percent of those for MAOs and about 89 percent of those for commercial group insurance plans.134

Taken as a whole, CMS believes research suggests that payer-specific charges negotiated between hospitals and MAOs are generally well-correlated with Medicare IPPS payment rates, and payer-specific charges negotiated between hospitals and other commercial payers are not as well-correlated with Medicare IPPS payment rates. Considering the public availability of payer-specific negotiated charges starting in 2021 and its desire to reduce the Medicare program's reliance on the hospital chargemaster, CMS believes it could change the methodology for calculating the MS-DRG

[129] Berenson RA, Sunshine JH, Helms D, Lawton E. Why Medicare Advantage plans pay hospitals traditional Medicare prices. Health Aff (Millwood). 2015;34(8):1289-1295.
[130] Baker LC, Bundorf MK, Devlin AM, Kessler DP. Medicare Advantage plans pay less than traditional Medicare pays. Health Aff (Millwood). 2016;35(8):1444-1451.
[131] Maeda JLK, Nelson L. How Do the Hospital Prices Paid by Medicare Advantage Plans and Commercial Plans Compare with Medicare Fee-for-Service Prices? The Journal of Health Care Organization, Provision, and Financing. 2018;55(1-8)
[132] Linde S, Egede LE. Do Chargemaster Prices Matter?: An Examination of Acute Care Hospital Profitability. Med Care. 2022 Aug 1;60(8):623-630.
[133] Meiselbach MK, Wang Y, Xu Jianhui, Bai G, Anderson GF. Hospital Prices for Commercial Plans Are Twice Those For Medicare Advantage Plans When Negotiated By The Same Insurer. Health Aff. 2023;42(8):1110-1118
[134] Randall S, Duffy EL. Insurers Negotiate Lower Hospital Prices for HIX Than for Commercial Groups. The American Journal of Managed Care. 2022;28(9): e347-e350.

relative weights to reflect a more market-based approach.

Another factor CMS considered is the experience hospitals have gained through the process of disclosing the payer-specific negotiated charge information for the purpose of the hospital price transparency requirements. Over the last four years, hospitals have become increasingly familiar with the hospital price transparency requirements and procedures necessary to disclose payer-specific negotiated charges. CMS intends to make its analysis of market-based data available for public review prior to the effective date of the market-based relative weight methodology in FY 2029.

C. Market-Based IPPS Relative Weight Estimation

CMS proposed to collect market-based payment rate data on the Medicare cost report for cost reporting periods ending on or after January 1, 2026 with modification to the FY 2021 requirement to use the payer-specific negotiated charges from the hospital's most recent machine readable file (MRF) published prior to the submission of its cost report. The modification reflects revisions to the hospital price transparency regulations and better addresses when the payer-specific negotiated charge is based on a percentage or algorithm.

The policy requires that hospitals report on their cost report the median of the payer-specific negotiated charge that the hospital negotiated with its MAOs. CMS cites the requirements in sections 1815(a) and 1833(e) of the Act as the authority under which it is requiring this information to be furnished. These provisions provide that no Medicare payments will be made to a provider unless it has furnished the information, as may be requested by the Secretary, to determine the amount of payments due to the provider under the Medicare program.

The proposed rule provides a 4-step process for determining a weighted median MAO payer-specific negotiated charge by MS-DRG from the hospital's most recent MRF. If the payer-specific negotiated charge is based on a percentage or algorithm, the hospital would substitute the dollar amount for the percentage or algorithm as required under the price transparency regulations. Negotiated charges that represent capitated payment are excluded. If the payer-specific negotiated charge is not by MS-DRG, the hospital would reclassify the case to an MS-DRG rate using the MS-DRG Grouper—software that uses information on each claim to classify or group a case to an MS-DRG.

These requirements would apply to subsection (d) hospitals (those paid under the IPPS) in the 50 states and Puerto Rico and would not include IHS hospitals, CAHs or REHs which are not IPPS hospitals. (Not stated but inpatient psychiatric facilities, inpatient rehabilitation facilities, long term care hospitals, children's hospitals and cancer hospitals are not IPPS hospitals either and would not be subject to these requirements). Maryland hospitals would be subject to these reporting requirements once the Maryland Total Cost of Care Model ends.

Terms such as "payer-specific negotiated charge" and "items and services" will have the same meaning as for the price transparency regulations. Further instructions for reporting market-based

data on the Medicare cost report will be discussed in a forthcoming information collection request, which is currently under development.

The proposed rule outlined the following steps for incorporating this data into the relative weight calculation:

- Step One: Standardize the median MAO payer-specific negotiated charges. Remove the effects of differences in area wage levels and cost-of living adjustments for hospital claims from Alaska and Hawaii in the same manner as under the current MS-DRG relative weight calculation.
- Step Two: Create a single weighted average standardized median MAO payer-specific negotiated charge by MS-DRG across hospitals. For each MS-DRG, CMS would use each hospital's transfer-adjusted case count to weight the standardized payer-specific negotiated charge as it does under the current MS-DRG relative weight methodology (84 FR 42621). CMS would further consider whether to use unadjusted Medicare case counts, or other alternative approaches based on the review of public comments.
- Step Three: Create a single national weighted average standardized payer specific negotiated charge across all MS-DRGs. CMS would create a single national weighted average across MS-DRGs of the results of Step Two, where the weights are the national Medicare transfer adjusted case counts by MS-DRG (or the unadjusted case counts if that is what is used for Step 2).
- Step Four: Calculate the market-based relative weights. For each MS-DRG, the result from Step 2 for each MS-DRG would be divided by the result from Step 3 across all MS-DRGs to create each MS-DRG's relative weight.
- Step Five: Normalize the market-based relative weights. As under the current cost-based MS-DRG relative weight methodology, the market-based relative weights would be normalized by an adjustment factor so that the average case weight after recalibration would be equal to the average case weight before recalibration such that aggregate payments neither increase nor decrease as required by section 1886(d)(4)(C)(iii) of the Act.

CMS believes there would be minimal initial impacts from this change because of correlation between the MAO rates and Medicare FFS rates. If finalized, CMS would expect to continue providing the MS-DRG relative weights based on the current methodology for some period for informational purposes.

The vast majority of commenters opposed CMS' proposals. Commenters indicated that the statute requires the MS-DRG weights reflect "the relative hospital resources used," not market rates negotiated with MA plans. Negotiated rates are not resource-based as they reflect market conditions not relative hospital resource use at the MS-DRG level.

Commenters stated that sections 1815(a) and 1833(e) of the Act require providers to furnish information necessary to determine amounts due but do not authorize the collection of third party negotiated rates. They further indicated that CMS' focus on inflated charges is misplaced because the MS-DRG relative weights are cost-based. There were also comments raising concerns that CMS' proposal risked being circular and having destabilizing effects across both FFS and MA.

CMS agrees with commenters that section 1886(d)(4)(B) of the Act requires that each MS-DRG have a relative weight which reflects relative hospital resources. However, CMS believes that the charges hospitals negotiate with MA organizations capture the relative resources used to provide services to patients according to market conditions (supply and demand, community benefit requirements, etc.) and are compliant with section 1886(d)(4)(B) of the Act.

CMS disagrees that it only has authority to collect data to make payments to hospitals, not collect third party negotiated rates to set Medicare rates. The response states that CMS is collecting negotiated charge data so that it may be used in determining relative weights for purposes of determining and making payment to hospitals under the IPPS. CMS also cited its reasonable cost authority (section 1861(v)(1)(A) of the Act) as requiring data elements beyond just cost to determine the cost of services.

The agency acknowledged that the MS-DRG relative weights are cost-based and not charge-based, but the weights still rely on hospital charges as its starting point. CMS' purpose for adopting this policy is to reduce reliance on hospital charges to set Medicare rates.

In response to the concern that the proposed approach risks being circular and having destabilizing effects, CMS indicates that initially there will be limited impact on the relative weights given the current similarity between MAO and Medicare FFS rates but rates may diverge over time as they become market-based. Further, CMS will adopt changes to the relative weights through notice and comment rulemaking so the public will know of the changes before they occur minimizing the potential risk of the policy being destabilizing.

Commenters stated that the research CMS cited in the 2026 proposed rule does not analyze relative hospital resource utilization at the MS-DRG level. CMS responded that the primary focus of the literature is the correlation between payer-specific charges negotiated between hospitals and MAOs and Medicare IPPS payment rates. By using MAO negotiated rates, CMS will be reducing reliance on hospital charges to set IPPS relative weights that are inflated and used to secure higher payments. To the extent hospitals and MAOs over time negotiate different relative relationships for some services than the well correlated relationships that currently exist under the IPPS, this information adds value to the IPPS.

Commenters stated that because MA rates are often based on Medicare FFS rates, market-based weights will maintain relative relationships that existed at a point in the past. This circularity in the calculation of the weights would contradict the statutory requirement to update weights to annually reflect changes in resource use. Further, CMS would not have cost data at the case level to evaluate MS-DRG reassignments as MA negotiated rates do not provide information on resource use variations within an MS-DRG.

There were also public comments on variety of issues that CMS has not addressed:

- Policy adjustments like disproportionate share, uncompensated care, wage index, etc., and how they would be affected by CMS' market-based weights policy.
- MAOs that pay hospitals based on a percentage of charges or completely based on capitation.
- Accounting for risk-sharing or value-based payment methodologies.

CMS responded that it remains open to adjusting its finalized policy through future rulemaking prior to the effective date if appropriate. The agency did not propose modifications to the process for adjusting the MS-DRG classification system or other policies issues like new technology add-on or outlier payments but may revisit these issues in future rulemaking.

Commenters indicated that the proposed rule does not provide information about how a provider would determine an MS-DRG rate for an MAO that pays for an inpatient stay based on a per-diem rate. These commenters believe CMS has understated the burden associated with these and other issues where there is not a straightforward rate per MS-DRG in the contract between the MAO and the hospital. There were additional comments that found it unclear whether weighted inpatient discharges are counted as (1) all inpatient discharges for the MAO's members, (2) those inpatient discharges where the MAO made payment (whether inpatient or otherwise), or (3) those inpatient discharges where the MAO paid for the care at the inpatient rate.

CMS responded that hospitals should include the actual price paid by the MAO but assign the MS-DRG based on using the publicly available CMS GROUPER and associated definitions manual. This software and associated definitions manual can be used to crosswalk the code(s) in the MRF to classify the discharge to an MS-DRG code. It is unclear what CMS means by "codes in the MRF." To use the CMS GROUPER to assign a case to an MS-DRG would require the hospital to have a fully coded inpatient Part A claim (age, discharge disposition, diagnosis and procedure codes, etc.) This information is not on the MRF. For the weighted average, CMS responded that hospitals should use inpatient discharges where the MAO paid for the care at the inpatient rate.

CMS continues to believe that hospitals have the capacity, based on the instructions provided within this final rule with comment period, and the forthcoming revision of the Information Collection Request under OMB control number 0938–0050 to report this data on the Medicare cost report for cost reporting periods ending on or after January 1, 2026. CMS may provide additional guidance as necessary.

There were comments expressing concern about proposing an IPPS policy in the OPPS rule. These commenters indicated the amount or kind of interested party feedback necessary to properly evaluate the proposal would not be received due to proposing an inpatient policy in the OPPS rule. CMS responded that there is substantial overlap between hospitals paid under the IPPS and OPPS to inform affected parties of the proposal.

CMS is finalizing its proposed market-based data collection requirement as proposed along with the following:

- If the hospital disclosed the payer-specific negotiated charge as a percentage or algorithm on the MRF, the hospital would use the "median allowed amount" to calculate the median of the payer-specific negotiated charges.
- Definitions of "payer-specific negotiated charge," "MA organization" and "items and services," are the same as those used for the hospital transparency requirements.
- Definition of an MA organization as a public entity or private entity organized and licensed by a State as a risk-bearing entity (with the exception of provider-sponsored organizations receiving waivers) that is certified by CMS as meeting the MA contract requirements.
- The reporting requirements apply to IPPS hospitals in the United States, DC and Puerto Rico.
- Hospitals that do not negotiate payment rates and only receive non-negotiated payments for service would be exempted from this data collection.

This data collection requirement is effective for cost reporting periods ending on or after January 1, 2026. Further instructions for reporting information on the Medicare cost report will be discussed in a forthcoming new Information Collection Request which will be submitted to OMB for review under control number 0938-1486 (CMS-10935). The OMB control number will not be valid until formally approved by OMB. CMS is also finalizing the adoption of a market-based MS-DRG relative weight methodology effective for FY 2029 without a transition period.

D. Information Collection

CMS proposes to collect this market-based information on new worksheet "Supplemental to Form CMS-2552-10, Weighted Median MAO Payer-Specific Negotiated Charge Data Worksheet." The proposed rule indicated that the administrative burden of this proposal will be minimized by using data already compiled for the hospital price transparency requirements.

Approximately 3,038 hospitals will be subject to the new reporting requirements. CMS estimated an average annual burden per hospital of 20 hours (5 hours for recordkeeping and 15 hours for reporting) for the Supplemental to Form CMS-2552-10: Weighted Median MAO Payer-Specific Negotiated Charge Data Worksheet. The cost per response is estimated at $1,599. CMS estimated total burden hours at 60,760 and aggregate costs of $4.86 million.

Public commenters believe CMS underestimates the data collection burden associated with these additional reporting requirements for the following reasons:

- A health system operating in numerous States will have multiple contracts for each individual hospital, within each State, and with each payer or hundreds of discharges for a given MS-DRG across hundreds of different payer contracts.
- The estimate does not take into the burden associated with MA organizations that do not pay based on MS-DRGs where hospitals will need to calculate an MS-DRG based on the same or similar package of services.

- The task of tabulating the data required for complying with this proposed policy could encompass reviewing data from thousands of patients from a single hospital taking well over the estimated 20 hours.
- Each hospital would be required to ensure its chargemaster team, contracting department, and finance staff coordinate to correctly identify all negotiated rates for each MS-DRG across potentially dozens of contracts, then calculate medians (with volume-weighting for each payer's discharges).

CMS responded that it continues to believe that the burden estimates are accurate as hospitals are already required to publicly report the payer-specific negotiated charge information that they will use to calculate median payer-specific negotiated charges by MS-DRG for payers that are MAOs. CMS is not revising its burden estimates.

XXI. Graduate Medical Education Accreditation

To receive direct graduate medical education and indirect medical education payments from Medicare, a hospital's training program must be an "Approved medical residency training program." Under 42 CFR §415.152, a graduate medical education program may be an approved medical residency training program if it is accredited by the Accreditation Council on Graduate Medical Education (ACGME).

In the proposed rule, CMS indicated that ACGME identified "diversity, equity, and inclusion" as a primary value of the organization and a central component of its vision for graduate medical education. In practice, the proposed rule stated that many such diversity, equity, and inclusion programs unlawfully discriminate against Americans based on race.

CMS stated that to ensure compliance with federal law, it proposed that accreditors may not require as part of accreditation, or otherwise encourage institutions to have diversity, equity, and inclusion programs that encourage unlawful discrimination based on race effective January 1, 2026. The proposed rule indicated that CMS may recognize other organizations—presumably other than the ACGME—that meet or exceed Medicare's requirements as accreditors to increase the potential for competition in the accreditation space and improve the quality of the accreditation process.

Many public commenters supported CMS' proposals, including recognizing organizations other than ACGME as accreditors of graduate medical education programs. Commenters in support of the policy recommended expanding it in various ways such that programs would not need to perform any of the following activities to be accredited: abortions, in vitro fertilization, surrogacy, certain forms of family planning, sterilization, sex-rejecting procedures, assisted suicide, euthanasia, medical aid in dying, voluntary stopping of eating and drinking, and inducing death for organ harvesting. A commenter also urged CMS to require that abortion training be offered under an opt-in only model, as opposed to the ACGME's current opt-out requirement. A commenter also recommended that CMS include similar language in other sections of the regulations.

CMS will consider expanding the policy in future rulemaking. Regardless of the explicit language in the GME regulations, CMS responded that no entity or individual may be forced to act contrary to objections protected by Federal conscience and nondiscrimination statutes.

Several commenters opposed CMS' proposal emphasizing the importance of a diverse physician workforce in achieving positive health outcomes, addressing upstream drivers of health (such as housing and food insecurity), and reducing health disparities. The commenters further indicated that the shift away from training informed by diverse American experiences risks eroding trust in healthcare institutions, especially among underserved groups.

A commenter stated that the proposed policy is unnecessary as the ACGME has removed its DEI-related accreditation requirements and closed its Department of DEI. Another commenter requested that, if the proposed policy were to be finalized, CMS should explicitly specify what sort of activities remain permissible for accreditors under the regulations.

CMS disagreed with these commenters stating that race-conscious elements of diversity, equity and inclusion policies such as those historically required by the ACGME are generally impermissible under Federal law. While ACGME has removed its DEI-related accreditation standards, CMS stated the rule remains necessary to preclude ACGME from reinstating the accreditation standard or another body from adopting them. Regarding what activities would remain permissible, accreditation criteria that promote or encourage discrimination based on race, color, national origin, sex, age, disability, or religion, including use of those characteristics or intentional proxies for those characteristics as a selection criterion for employment, program participation, resource allocation, or similar activities, opportunities, or benefits are prohibited.

Several commenters objected to recognizing new accrediting bodies beyond ACGME as that could result in divergent standards, create uncertainty for hospitals, undermine the rigor of the accreditation process, and jeopardize patient care by diminishing the quality of residency training. CMS disagrees observing that the existence of multiple accreditors for various specialties of nursing and allied health education programs has not undermined the quality of training or patient care in those specialties.

CMS is finalizing its proposal to specify that accrediting organizations must not use accreditation criteria that promote or encourage discrimination based on race, color, national origin, sex, age, disability, or religion, including use of those characteristics or intentional proxies for those characteristics as a selection criterion for employment, program participation, resource allocation, or similar activities, opportunities, or benefits. In addition, CMS is considering for future rulemaking how best to encourage accrediting bodies to incorporate nutrition education requirements into the accreditation standards for graduate medical education programs consistent with the Administration's commitment to preventing and reducing chronic disease through improved diet and public health measures.

XXII. Notice of a Closure of a 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 Pontiac General Hospital, located in Pontiac, MI:

Available Resident Cap FTEs

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME Resident Cap	DGME Resident Cap
23003	Pontiac General Hospital	Pontiac, MI	47664	November 24, 2024	33.75	30.44

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 by February 19, 2026 to be eligible to receive slots from this closed hospital.

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 reviews all applications received by the deadline and will notify applicants of its determinations as soon as possible.

Table 167: Estimated Impact 2026 OPPS Final Rule

	(1)	(2)	(3)	(4)	(5)	(6)	(7)
	Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 & 3) with Market Basket Update**	**Payment Adjustment for Drug Admin Off Campus Providers**	**All Changes with Outlier Final CY 2026 Update**	***Reduction for Providers Subject to the 340B Remedy Offset***
ALL PROVIDERS *	3,543	0.0	0.1	2.7	-0.3	**2.4**	-0.5
ALL HOSPITALS	3,439	0.0	0.1	2.8	-0.3	**2.5**	-0.5
(excludes hospitals held harmless and CMHCs)							
URBAN HOSPITALS	2,755	0.1	0.1	2.8	-0.3	**2.6**	-0.5
LARGE URBAN	1,298	0.1	0.0	2.7	-0.3	**2.5**	-0.5
(GT 1 MILL.)							
OTHER URBAN	1,457	0.1	0.2	2.9	-0.2	**2.6**	-0.5
(LE 1 MILL.)							
RURAL HOSPITALS	684	-0.4	0.2	2.4	-0.1	**2.3**	-0.5
SOLE COMMUNITY	333	-0.3	0.6	2.8	0.0	**2.7**	-0.5
OTHER RURAL	351	-0.4	-0.3	1.8	-0.2	**1.6**	-0.5
BEDS (URBAN)							
0 - 99 BEDS	971	0.0	0.3	2.9	-0.2	**2.6**	-0.5
100-199 BEDS	748	0.1	0.1	2.8	-0.1	**2.7**	-0.5
200-299 BEDS	425	0.2	-0.1	2.6	-0.1	**2.6**	-0.5
300-499 BEDS	380	0.2	0.1	2.9	-0.3	**2.6**	-0.5
500 + BEDS	231	0.0	0.2	2.8	-0.4	**2.4**	-0.5
BEDS (RURAL)							

		(1)	(2)	(3)	(4)	(5)	(6)	(7)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 & 3) with Market Basket Update**	**Payment Adjustment for Drug Admin Off Campus Providers**	**All Changes with Outlier Final CY 2026 Update**	***Reduction for Providers Subject to the 340B Remedy Offset***
	0 - 49 BEDS	331	-0.6	0.4	2.4	0.0	**2.3**	-0.5
	50- 100 BEDS	195	-0.4	0.5	2.7	-0.1	**2.5**	-0.5
	101- 149 BEDS	89	-0.5	0.2	2.3	-0.1	**2.3**	-0.5
	150- 199 BEDS	39	-0.2	0.1	2.6	-0.3	**2.1**	-0.5
	200 + BEDS	30	-0.1	-0.4	2.0	-0.1	**2.0**	-0.5
	REGION (URBAN)							
	NEW ENGLAND	122	-0.1	-0.8	1.7	-0.4	**1.5**	-0.5
	MIDDLE ATLANTIC	292	0.0	0.7	3.4	-0.3	**3.2**	-0.5
	SOUTH ATLANTIC	450	0.2	0.2	3.0	-0.3	**2.9**	-0.5
	EAST NORTH CENT.	421	0.0	-0.1	2.5	-0.4	**2.2**	-0.5
	EAST SOUTH CENT.	170	0.0	-1.1	1.5	-0.3	**1.3**	-0.5
	WEST NORTH CENT.	178	0.0	2.1	4.7	-0.3	**3.7**	-0.5
	WEST SOUTH CENT.	461	0.2	0.3	3.1	-0.1	**3.1**	-0.5
	MOUNTAIN	231	0.2	0.5	3.3	-0.2	**2.8**	-0.5
	PACIFIC	380	0.2	-0.9	1.9	-0.3	**1.8**	-0.5
	PUERTO RICO	50	-0.4	-4.1	-2.0	0.0	**-1.9**	0.0
	NEW ENGLAND	20	0.1	0.1	2.8	0.0	**3.1**	-0.5
	MIDDLE ATLANTIC	47	-0.2	0.7	3.1	-0.1	**3.1**	-0.5
	SOUTH ATLANTIC	109	-0.6	-0.5	1.4	-0.2	**1.3**	-0.5

		(1)	(2)	(3)	(4)	(5)	(6)	(7)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 & 3) with Market Basket Update**	**Payment Adjustment for Drug Admin Off Campus Providers**	**All Changes with Outlier Final CY 2026 Update**	***Reduction for Providers Subject to the 340B Remedy Offset***
	EAST NORTH CENT.	112	-0.5	-0.4	1.8	-0.2	**1.7**	-0.5
	EAST SOUTH CENT.	132	-0.6	-2.0	0.0	-0.1	**-0.1**	-0.5
	WEST NORTH CENT.	75	-0.1	2.7	5.2	0.0	**4.6**	-0.5
	WEST SOUTH CENT.	124	-0.3	0.1	2.4	0.0	**2.5**	-0.5
	MOUNTAIN	39	-0.4	2.2	4.4	0.0	**3.1**	-0.5
	PACIFIC	24	-0.7	-0.3	1.6	0.0	**1.8**	-0.5
	PUERTO RICO	2	-1.4	-2.7	-1.6	0.0	**-1.5**	0.0
TEACHING STATUS								
	NON-TEACHING	2,058	0.0	0.2	2.7	-0.1	**2.6**	-0.5
	MINOR	920	0.1	0.2	2.9	-0.2	**2.7**	-0.5
	MAJOR	461	0.0	0.0	2.6	-0.4	**2.4**	-0.5
DSH PATIENT PERCENT								
	0	11	1.6	-1.3	2.9	0.0	**2.1**	-0.3
	GT 0 - 0.10	225	0.2	0.7	3.5	-0.1	**3.2**	-0.5
	0.10 - 0.16	240	0.2	0.2	3.0	-0.2	**2.8**	-0.5
	0.16 - 0.23	527	0.2	0.3	3.1	-0.1	**3.0**	-0.5
	0.23 - 0.35	1,134	0.0	0.2	2.8	-0.2	**2.6**	-0.5
	GE 0.35	844	-0.1	-0.1	2.4	-0.4	**2.1**	-0.5

		(1)	(2)	(3)	(4)	(5)	(6)	(7)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 & 3) with Market Basket Update**	**Payment Adjustment for Drug Admin Off Campus Providers**	**All Changes with Outlier Final CY 2026 Update**	***Reduction for Providers Subject to the 340B Remedy Offset***
	DSH NOT AVAILABLE **	458	3.5	-0.8	5.3	0.0	**5.5**	-0.4
URBAN TEACHING/DSH								
	TEACHING & DSH	1,212	0.1	0.1	2.8	-0.3	**2.5**	-0.5
	NO TEACHING/DSH	1,103	0.0	0.1	2.7	-0.1	**2.6**	-0.5
	NO TEACHING/NO DSH	11	1.6	-1.3	2.9	0.0	**2.1**	-0.3
	DSH NOT AVAILABLE2	429	3.4	-0.8	5.3	0.0	**5.5**	-0.4
TYPE OF OWNERSHIP								
	VOLUNTARY	1,981	0.0	0.2	2.8	-0.3	**2.5**	-0.5
	PROPRIETARY	1,047	0.6	0.2	3.4	0.0	**3.3**	-0.5
	GOVERNMENT	411	-0.1	-0.2	2.3	-0.3	**2.1**	-0.5
CMHCs		34	-0.7	0.2	2.1	0.0	**2.2**	0.0

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

Column (2) includes all CY 2026 OPPS policies and compares those to the CY 2025 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the FY 2026 hospital inpatient wage index. The rural SCH adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The final budget neutrality adjustment for the cancer hospital adjustment is 1.0000 because the CY 2026 target payment-to-cost ratio is the same as the CY 2025 PCR target.

Column (4) shows the impact of all budget neutrality adjustments and the addition of the final 2.6 percent OPD fee schedule update factor (3.3 percent reduced by 0.7 percentage points for the productivity adjustment).
Column (5) shows the separate impact of the final payment adjustment for drug administration services furnished at excepted off campus providers.
Column (6) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate and adding estimated outlier payments. Note that previous years included the frontier adjustment in this column, but we have included the frontier adjustment to Column 3 in this table.
The column for the 340B Providers shows the separate impact of applying the 0.5 percentage point reduction to the OPPS conversion factor update in CY 2026 as part of the 340B Remedy Offset.
These 3,543 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.
We estimate that 3,229 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.