

Medicare Program: 2027 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs Proposed Rule Summary

The Centers for Medicare & Medicaid Services (CMS) released the calendar year 2027¹ proposed rule for Medicare's hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system (CMS-1850-P) on July 2, 2026. Policies in the proposed rule will generally go into effect on January 1, 2027, unless otherwise specified. The proposed rule was published on July 7, 2026 in the *Federal Register*. **The public comment period will close on August 31, 2026.**

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

Among other provisions, CMS proposes:

- To reduce the otherwise applicable update for non-drug OPPS services by 3 percent as part of a recouping additional spending resulting from adverse litigation against the Secretary for 340B acquired drugs.
- Change the payment for 340B acquired drugs from ASP+6 percent to ASP-33.4 percent based on a drug cost survey done earlier this year. This proposed reduction in payments for 340B acquired drugs will be offset by an 8.4 percent increase to non-drug OPPS services.
- Reduce payments for imaging services without contrast furnished in off-campus provider-based departments to a physician equivalent rate.
- Continue elimination of the inpatient only (IPO) list by pricing 638 additional procedures under the OPPS.
- Consistent with its FY 2027 inpatient prospective payment system (IPPS) proposal, eliminate the alternative pathway for pass-through beginning with applications submitted on or after October 1, 2026.

CMS also includes several requests for information (RFIs) in the 2027 OPPS proposed rule. 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-notice/cms-1850-p>.

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

TABLE OF CONTENTS

	Topic	Page
I.	Overview	4
	A. Estimated Impact on Hospitals	4
	B. Estimated Impact on Beneficiaries	6
II.	Updates Affecting OPPS Payments	6
	A. Ambulatory Payment Classification (APC) Relative Payment Weights	6
	B. Conversion Factor Update	11
	C. Wage Index Changes	12
	D. Statewide Average Default Cost-to-Charge Ratios (CCRs)	13
	E. Sole Community Hospital (SCH) Adjustment	14
	F. Cancer Hospital Adjustment	14
	G. Outpatient Outlier Payments	14
III.	APC Group Policies	15
	A. Treatment of New and Revised HCPCS Codes	15
	B. Variations Within APCs	17
	C. New Technology APCs	20
	D. Universal Low Volume APC Policy for Clinical and Brachytherapy APCs	26
	E. APC-Specific Policies	26
IV.	Payment for Devices	29
	A. Pass-Through Payments for Devices	29
	B. Device-Intensive Procedures	40
V.	Payment for Drugs, Biologicals, and Radiopharmaceuticals	42
	A. Transitional Pass-Through Payment	43
	B. Payment for Non-Pass-Through Drugs, Biologicals, and Radiopharmaceuticals	44
	C. Payment for 340B Purchased Drugs	52
	D. Payment for Skin Substitutes	56
VI.	Estimate of Transitional Pass-Through Spending	57
VII.	Hospital Outpatient Visits and Critical Care Services	57
VIII.	Partial Hospitalization (PHP) Services	58
	A. Background	58
	B. Coding and Billing for PHP Services and IOP Services	59
	C. Payment Rates for PHP and IOP	60
	D. Outlier Policy for CMHCs	62
	E. Regulatory Impact	63
IX.	Inpatient Only (IPO) List	63
X.	Nonrecurring Changes	65
	A. Payment Reduction for Imaging without Contrast Services	65
	B. Payment for Software as a Medical Service (SaMS)	69
	C. Adjustment for Cost-of-Living Adjustment (COLA) in Alaska and Hawaii	71
	D. Payment for Cardiac and Pulmonary Rehabilitation in a Patient's Home	71
XI.	OPPS Payment Status and Comment Indicators	72
XII.	Medicare Payment Advisory Commission (MedPAC) Recommendations	72
XIII.	Ambulatory Surgical Center (ASC) Payment System	73
	A. Background	73
	B. ASC Treatment of New and Revised Codes	74
	C. Payment Policies under the ASC Payment System	77
	D. Additions to ASC Covered Surgical Procedures and Covered Ancillary Services Lists	85
	E. Non-Opioid Post-Surgery Pain Management Drugs, Biologicals, and Devices	87

	Topic	Page
	F. New Technology Intraocular Lenses (NTIOLs)	91
	G. ASC Payment Rates and the ASC Conversion Factor	91
	H. Regulatory Impact	93
XIV.	Measure Removal: Follow-Up for Normal Colonoscopy in Average Risk Patients	94
	A. Background	94
	B. Remove Measure: Follow-Up for Normal Colonoscopy in Average Risk Patients	94
XV.	Hospital Outpatient Quality Reporting Program (HOQRP)	95
	A. Background	95
	B. Program Measure Set	95
	C. RFI: Advance Care Planning Electronic Clinical Quality Measure	97
	D. Updates to the Validation of HOQRP Data	98
	E. Validation Reconsiderations and Appeals Procedures	101
	F. Payment Reduction for Failing OQR Program Requirements	101
XVI.	Rural Emergency Hospital Quality Reporting Program (REH QRP)	102
XVII.	Ambulatory Surgical Center Quality Reporting Program (ASC QRP)	103
	A. Background	103
	B. Program Measure Set	103
	C. RFI on Stratification of the All-Cause Transfer/Admission Measure	104
	D. Form, Manner, and Timing of Data Submission	105
	E. Payment Reduction for ASCs Failing ASC QRP	105
XVIII.	Accrediting Organizations and the Emergency Medical Treatment and Labor Act	105
	A. Background	105
	B. Proposals	106
XIX.	Prior Authorization Botulinum Toxin Injection Codes	107
	A. Background	107
	B. Controlling Unnecessary Increases in the Volume of Covered OPD Services	107
XX.	Provider-Based Requirements	108
	A. Background	108
	B. Section 6225 of the Consolidated Appropriations Act (CAA), 2026	108
	C. Modifications to Implement the Provisions of Section 6225 of the CAA, 2026	108
	D. Documentation Requirements for Provider-Based Attestations	109
	E. CMS Verification and Oversight Activities	110
	F. Information Collection Requirements	111
XXI.	Notice of Closure of Teaching Hospital	111
XXII.	Separate IPPS Payment: Personal Protective Equipment and Essential Medicines	112
	A. Overview	112
	B. Prior Rulemaking	113
	C. Potential Eligible Domestic PPE Products and Cost Differentials	113
	D. Potential Eligible Domestic Essential Medicines and Cost Differentials	114
	E. Public File of Potential Eligible Products	115
	F. IPPS Payment Adjustments for Domestically Purchased PPE and Essential Medicines	115
	G. Maximum Annual Amount of Aggregate Payments	115
	H. Solicitation of Additional Options: Domestic PPE and Essential Medicines	116
XXIII.	RFI: Standardization and Comparability of Hospital Price Transparency Data	116
	A. Background	116
	B. Machine Readable File	116
	C. Consumer-Friendly Display	118
	2027 Proposed Rule Impact Table	120

I. Overview

A. Estimated Impact on Hospitals

The increase in spending due only to changes in the 2027 OPPS proposed rule is estimated to be approximately \$1.82 billion. Considering estimated changes in enrollment, utilization and case-mix for 2027, CMS estimates that OPPS expenditures, including beneficiary cost-sharing, will be approximately \$110.9 billion, which is approximately \$9.5 billion higher than estimated expenditures in 2025. CMS estimates a 3.0 percentage point reduction to the OPPS payment update—the 340B recoupment payment adjustment—for non-drug OPPS services for most hospitals will reduce OPPS payments by \$2.3 billion. The reduction in payment for imaging without contrast in off-campus provider-based department will reduce payment \$260 million (\$190 million in Medicare spending and \$70 million in reduced beneficiary copayments).

CMS estimates that the update to the conversion factor net of the productivity will increase payments 2.4 percent in 2027 (market basket of 3.2 percent less 0.8 percentage points for productivity). Including this update, all budget neutral changes, changes to proposed outlier payment, application of the frontier State wage adjustment, the proposed payment adjustment for imaging without contrast and the reduction to the quality update for hospitals that do not meet the OQR requirements to receive the full update, CMS estimates a 1.9 percent increase in payments between 2026 and 2027 before application of the 3.0 percent reduction in payment for non-drug OPPS services for recoupment of past additional spending for 340B acquired drugs.

Hospitals that satisfactorily report quality data will qualify for the full update of 2.4 percent update (before application of the 340B recoupment payment adjustment) while hospitals that do not will be subject to a 2.0 percentage point reduction in the applicable update or 0.4 percent. All other adjustments are the same for the two sets of hospitals. An additional 3.0 percentage points will reduce these updates to -0.6 percent and -2.6 percent respectively. Of the 3,362 hospitals included in modeling the payment impacts, CMS determined that 64 hospitals will not receive the full OPPS increase factor.

CMS' impact table indicates that Medicare makes payments under the OPPS to approximately 3,471 facilities (3,362 hospitals excluding CMHCs, cancer and children's hospitals held harmless to their pre-OPPS payment to cost ratios). Table 88 of the proposed rule (reproduced in the Appendix to this summary) includes the estimated impact of the proposed rule by provider type. It shows a 1.9 percent increase in Medicare spending for all facilities and all hospitals after accounting for all factors excluding the 340B recoupment adjustment. The table shows an additional reduction of -2.9 percent across all facilities and hospitals. The following table shows components of the payment change:

	% Change All Facilities
Fee schedule increase factor, Wage and Provider Adjustments	2.40
Imaging without Contrast Reduction	-0.40
Difference from 2026 outlier payments (1.19% vs. 1.0%)	-0.19
Difference in Pass-Through Payments	+0.12

	% Change All Facilities
Subtotal	1.93
340B Acquired Drugs Recoupment Adjustment	-2.90
All changes	-0.97

For 2026, CMS estimated that pass-through will be 0.30 percent of OPPS spending. For 2027, CMS estimates that pass-through spending for drugs, biologicals and devices will be \$195.3 million, or 0.18 percent of OPPS spending. The difference between these figures (0.30 – 0.18) = 0.12 percentage point) is the required adjustment to ensure that pass-through spending remains budget neutral from one year to the next. In addition, CMS estimates that actual outlier payments in 2026 will represent 1.19 percent of total OPPS payments compared to the 1.0 percent set aside for 2027, a -0.19 percentage point change in 2027 payments. Taken together, these factors produce a total decrease in 2027 OPPS payments of approximately 1 percent.

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

Although CMS projects an estimated decrease of just under 1 percent for all facilities, the rule's impacts vary depending on the type of facility. Impacts will differ for each hospital category based on the mix of services provided, location and other factors. Impacts for selected categories of hospitals are shown in the table below:

Facility Type	2027 Impact
All Hospitals	-1.0
All Facilities (including CMHCs and cancer and children's hospitals)	-1.0
Urban	-1.6
Large Urban	-2.9
Other Urban	-1.3
Rural	2.9
Beds	
0-99 (Urban)	4.8
0-49 (Rural)	4.5
500+ (Urban)	-6.9
200+ (Rural)	2.2
Major Teaching	-6.0
Type of ownership	
Voluntary	-1.5
Proprietary	7.4
Government	-4.2

An increase or decrease larger than the average will be accounted for by CMS' policy to pay for 340B acquired drugs at ASP-33.4 percent and apply a budget neutrality adjustment to non-drug OPPS services of 8.4 percent. The resulting impacts are large reductions in payment for 340B hospitals and large increases for hospitals that do not acquire drugs through the 340B program.

B. Estimated Impact on Beneficiaries

CMS estimates that the aggregate beneficiary coinsurance percentage will be 18.0 percent for all services paid under the OPSS in 2027. The coinsurance percentage reflects the requirement for beneficiaries to pay a 20 percent coinsurance after meeting the annual deductible. Coinsurance is the lesser of 20 percent of Medicare's payment amount or the Part A inpatient deductible (\$1,736 in 2026), which accounts for the aggregate coinsurance percentage being less than 20 percent.

II. Updates Affecting OPSS Payments

A. Ambulatory Payment Classification (APC) Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

For 2027, CMS is using 2025 hospital final action claims for services furnished from January 1, 2025, through December 31, 2025, processed through the Common Working File as of December 31, 2025 (approximately 74 million claims). CMS is using Medicare cost reports beginning in 2024 in most cases to develop the cost-to-charge ratios (CCR) that are used to convert hospital charges to cost.

In a separate document available on the CMS website, CMS provides a detailed description of the claims preparation process and an accounting of claims used in the development of the proposed rule payment rates, including the number of claims available at each stage of the process: <https://www.cms.gov/files/document/2027-nprm-ops-claims-accounting.pdf>.

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

For the 2027 proposed rule, CMS is bypassing the 177 HCPCS codes identified in Addendum N. There are 2 new bypass codes identified with an asterisk in column D. CMS indicates that the list of bypass codes may include codes that were reported on claims in 2025 but were deleted for 2026.

b. Calculation and Use of CCRs

To convert billed charges on outpatient claims to costs, CMS is multiplying the charges on the claim by a hospital-specific CCR associated with each revenue code and cost center. To calculate CCRs for 2027, CMS is employing the same basic approach used for APC rate construction since 2007. CMS applies the relevant hospital-specific CCR to the hospital's charges at the most detailed level possible based on a revenue code-to-cost center crosswalk containing a hierarchy

of CCRs for each revenue code. The current crosswalk is available for review and continuous comment on the CMS website at the link provided at the beginning of this summary.

CCRs are calculated for the standard and nonstandard cost centers accepted by the electronic cost report data at its most detailed level. Generally, the most detailed level will be the hospital-specific departmental level. CMS does not use nonstandard cost centers on cost report lines that do not correspond to the cost center number because of concerns about the accuracy of data reported in these cost centers.

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

In past years, to determine each APC's relative weight, CMS takes single procedure claims and adjusts charges to costs for each procedure within an APC and then calculates the APC's geometric mean cost. The relative weight is the geometric mean cost of the APC divided by the geometric mean cost across all APCs. CMS standardizes the relative weights to the APC for G0463, an outpatient hospital visit—the most furnished service billed under the OPPS. CMS proposes to continue following this basic process for 2027. CMS eliminates 2025 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 proposing to continue determining the relative weights for blood and blood product APCs by converting charges to costs using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific simulated blood-specific CCR for hospitals that did not. CMS is also proposing to continue including blood and blood products in the comprehensive APCs, which provide all-inclusive payments covering all services on the claim. HCPCS codes and their associated APCs for blood and blood products are identified with a status indicator of “R” (Blood and Blood Products) in Addendum B of the proposed rule.

(ii) Brachytherapy sources

The statute requires the Secretary to create APCs for brachytherapy consisting of a seed or seeds (or radioactive source)—i.e., “brachytherapy sources”—separately from other services or groups of services, to reflect the number, isotope, and radioactive intensity of the brachytherapy sources furnished. Since 2010, CMS has used the standard OPPS payment methodology for brachytherapy sources, with payment rates based on source-specific costs as required by statute. CMS proposed no changes to its brachytherapy policy for 2027.

If CMS does not have billing data to set the payment rates, it may use external data to set prices for brachytherapy sources. For 2018 through 2026, CMS used external data to set a payment rate for HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) at \$4.69 per mm². CMS has no claims for HCPCS code C2645 in the 2025 utilization data. For this reason, CMS proposes to use its equitable adjustment authority under section 1833(t)(2)(E) to continue the rate of \$4.69 per mm² for 2027 for HCPCS code C2645.

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

Beginning in 2022, CMS adopted a low volume APC policy to use up to four years of claims data for APCs with fewer than 100 single procedure claims in a year that can be used for rate-setting. For these APCs, CMS will determine the relative weight based on the higher of the arithmetic mean cost, median cost, or geometric mean cost. For 2027, CMS proposes to price five low volume brachytherapy APCs under this policy (excluding those that are priced using external data).

Recommendations for HCPCS codes that describe new brachytherapy sources should be directed to: outpatientpps@cms.hhs.gov. CMS will continue to add new brachytherapy source codes and descriptors to its payment systems on a quarterly basis through program transmittals.

b. Comprehensive APCs (C-APCs) for 2027

A C-APC is defined as a classification for a primary service and all adjunctive services provided to support its delivery. When such a primary service is reported on a hospital outpatient claim, Medicare makes a single payment for that service and all other items and services reported on the hospital outpatient claim that are integral, ancillary, supportive, dependent, and adjunctive. A single prospective payment is made for the comprehensive service based on the costs of all reported services on the claim. A HCPCS code assigned to a C-APC has a status indicator of “J1” and is referred to as a “J1 code.”

Certain combinations of comprehensive services are recognized for higher payment through complexity adjustments. Qualifying services are reassigned from the originating C-APC to a higher paying C-APC in the same clinical family of comprehensive APCs. Currently, code combinations satisfying the complexity criteria are moved to the next higher cost C-APC within the clinical family, unless (1) the APC reassignment is not clinically appropriate, or (2) the primary service is already assigned to the highest cost APC within the C-APC clinical family. CMS does not create a new APC for claims with a geometric mean cost that is higher than the highest cost C-APC in a clinical family just to accommodate potential complexity adjustments. CMS did not propose any changes to its criteria for making a complexity adjustment but requested public comment on these and other issues.

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. CMS is proposing to continue this policy without change.

Beginning in 2023, CMS adopted a new policy to exclude HCPCS Code C9399 (Unclassified drugs or biologicals) from being packaged into a C-APC. Consistent with section 1833(t)(15) of the Social Security Act (the Act), this code allows for pricing at 95 percent of average wholesale price (AWP) before a specific HCPCS code is assigned to the new drug or biological. Excluding HCPCS code C9399 from the C-APC policy will ensure that drugs that do not yet have a specific HCPCS code will be priced at 95 percent of AWP consistent with section 1833(t)(15) of the Act.

Beginning with 2025, CMS excluded specific gene therapies listed in Table 1 of the proposed rule from the C-APC policy. If HCPCS codes for cell and gene therapies appear on the same claim as a HCPCS code that is subject to the C-APC policy, CMS’ policy is to pay separately for the cell and gene therapy and not package payment into the C-APC. The rationale underlying CMS’ policy is that when these products are administered, they are the primary treatment being administered to a patient and are not integral, ancillary, supportive, dependent, or adjunctive to any primary C-APC services. CMS adopted this policy on a permanent basis in 2025 and is not proposing any changes for 2027.

As a result of its annual review of the services and APC assignments under the OPPTS, 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 2 of the proposed rule and Addendum J with a status indicator of “J1” or “J2” (only for the Comprehensive Observation Services C-APC).

c. Calculation of Composite APC Criteria-Based Costs

Since 2008, CMS has used composite APCs to make a single payment for groups of services that are typically performed together during a single clinical encounter and result in the provision of a complete service. Currently, CMS’ composite APC policy applies for mental health services and multiple imaging services. CMS is not proposing any changes to its composite APC policies for 2027.

For the mental health composite APC 8010, CMS does not believe the mental health composite APC payment should be higher than the highest partial hospitalization payment. APC 5864 is the highest paid partial hospitalization APC which is for 4 or more partial hospitalization services per day. Beginning with 2024, CMS has been capping the mental health composite APC 8010 to APC 5864. For 2027, CMS is proposing to continue this policy.

3. Changes to Packaged Items and Services

The Consolidated Appropriations Act (CAA), 2023 includes a provision that requires separate payment under the OPPTS for three years beginning January 1, 2025, for non-opioid drugs and devices that treat pain. Accordingly, CMS excludes non-opioid treatments for pain relief that meet the criteria for separate payment from APCs. This policy is discussed in more detail in section XIII. E. of this summary. CMS did not propose any other changes to its overall packaging policy.

4. Separate OPPTS Payment for Diagnostic Radiopharmaceuticals

Beginning with 2025, CMS adopted a policy to pay separately for diagnostic radiopharmaceutical with per days costs above \$630. Below this threshold, diagnostic radiopharmaceuticals remain packaged. Starting in 2026, CMS adopted a policy to update the \$630 threshold amount by the Producer Price Index (PPI) for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from IHS Global, Inc (IGI). This is the same as the update factor used for the OPPTS drug packaging threshold.

CMS uses the most recently available four-quarter moving average PPI levels to trend the 2025 threshold forward from the third quarter of 2025 to the third quarter of 2027 and rounds the resulting dollar amount to the nearest \$5 increment. Based on this methodology, CMS determined an updated threshold of \$667.44 rounded to the nearest \$5 increment or a proposed threshold of \$665 per day for 2027.

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 sought comment on this guidance in the 2026 OPPTS rule: *Submission of OPPTS ASP Data for Nonpass-Through Separately Payable Therapeutic Radiopharmaceuticals and Radiopharmaceuticals with Pass-Through Status*. Based on its analysis and input from interested parties, CMS will be publishing an ASP reporting *Framework for Diagnostic Radiopharmaceuticals* on the Medicare Hospital Outpatient PPS website: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>.

CMS proposes to base the initial payment for new diagnostic radiopharmaceuticals with HCPCS codes, but which do not have pass-through status and are without claims data, on ASP or wholesale acquisition cost (WAC) if ASP data is not available. If the WAC also is unavailable, CMS proposes to make payment at 95 percent of the products' most recent AWP. Payment based on these drug pricing methodologies would be temporary until a MUC is available.

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 proposes to pay separately are listed in Table 4 of the proposed 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 (2025) to determine budget neutrality for changes in the OPPS relative weights for the payment rule year (2027). Holding all other variables constant, CMS multiplies the 2026 final relative weights and the 2027 proposed relative weights respectively for each APC by its associated volume from 2025. It sums the 2026 final relative weights and the 2027 proposed relative weights respectively and divides the 2026 aggregate relative weights by the 2027 proposed aggregate unscaled relative weights to determine the weight scaler. Using this process, CMS proposes a weight scaler of 1.4582. The unscaled proposed 2027 relative payments are multiplied by 1.4582 to determine the 2027 scaled relative weights that are shown in Addenda A and B of the proposed 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 2026 and 2027 do not increase or decrease expenditures. However, separately payable drugs and diagnostic radiopharmaceuticals are not affected by the budget neutrality adjustment.

B. Conversion Factor Update

The proposed 2027 conversion factor will be \$99.015 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 \$102.004. The components of the update are shown below:

	Full Update	
2026 Conversion Factor (CF)	\$89.1690	Resulting CF
Remove pass-through & outliers from prior year CF	1.0133	\$92.6280
Wage Index Budget Neutrality	1.0098	\$93.5360
Cap on Wage Index Reductions	0.9951	\$93.0780
COLA for Alaska and Hawaii	0.9993	\$93.0130
Cancer Hospital Adjustment	0.9994	\$92.9570

	Full Update	
2026 Conversion Factor (CF)	\$89.1690	Resulting CF
Rural Hospital Adjustment	1.0000	\$92.9570
340B Adjustment	1.0844	\$100.8030
Update	1.0240	\$103.2220
Pass-Through/Outlier	0.9882	\$102.0040
2027 Conversion Factor (Pre 340B Recoup)	\$102.004	\$102.0040
340B Recoupment Adjustment	0.9707	\$99.0150

CMS removes the prior year's pass-through (0.0031) and outlier adjustment (0.0100) from the 2026 conversion factor, which equals 1.0133 (1.33 percent).² Wage index budget neutrality is 1.0098 (0.98 percent). The cap on reductions to the wage index requires a budget neutrality adjustment of 0.9951 (-0.49 percent). The budget neutrality adjustment for the Alaska and Hawaii cost of living allowance (COLA) is 0.9930 (-0.07 percent). The cancer hospital adjustment is 0.9994 (-0.06 percent). The rural sole community hospital adjustment is 1.0000 (0.0 percent).

The update of 1.024 (2.4 percent) equals the market basket of 3.2 percent less 0.8 percentage points for productivity for 2027. This update is the same as was included in the FY 2027 IPPS proposed rule and is based on the IGI fourth quarter 2025 forecast of the FY 2027 hospital market basket with historical data through the 3rd quarter of 2025. The productivity estimates are from the same period.

CMS estimates that pass-through spending for drugs, biologicals and devices for 2027 will be \$195.3 million, or 0.30 percent of OPPI spending. The outlier adjustment is 0.99 (-1.0 percent). The combined adjustment for pass-through and outliers is 0.9982 (-1.18 percent).

The 2027 conversion factor for hospitals that submit quality data before application of the 340B recoupment adjustment will be \$102.004. CMS will apply a 340B recoupment adjustment of 0.9707 (-2.93 percent that is the equivalent of reducing the applicable update from 2.4 percent by 3.0 percentage points) that would equal a conversion factor of \$99.015.

The conversion factor for hospitals that do not submit quality data is subject to all the same adjustments except the update is 1.004 (0.4 percent) instead of 1.024 (2.4 percent). CMS applies this reduction by applying a "reporting ratio" of 0.9805 (-1.95 percent which is the equivalent of reducing the applicable update of 2.4 percent by 2.0 percentage points). The resulting conversion factor would be \$100.015. Applying the 340B adjustment of 0.9707 (-2.93 percent) would further reduce this conversion factor to \$97.084.

C. Wage Index Changes

CMS proposes to continue using a labor share of 60 percent, the FY IPPS post-reclassified wage index and all the other adjustments that apply to IPPS hospitals for hospitals paid under the OPPI in 2027. These other adjustments include the rural floor, imputed floor, occupational mix

² Removing the budget neutrality adjustment from the prior year requires division so the factor equals 1.0/(1-0.01-0.0013) or 1.33 percent.

adjustment, adjustment based on commuting patterns of employees and a 5 percent cap on a decrease to hospital's wage index.

For FY 2020, CMS adopted a low-wage index policy under the IPPS where it increased wage indexes below the 25th percentile by one-half the difference between the hospital's otherwise applicable wage index and the 25th percentile wage index value. CMS applied a budget neutrality adjustment for the low wage index policy such that increasing the wage index for the affected hospitals did not increase Medicare spending. This policy was in place every year under the IPPS from FY 2020 through FY 2024.

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

Under the transition policy, CMS will compare the hospital's wage index proposed for FY 2027 to its wage index under the low-wage index policy in FY 2024 under the IPPS. If the hospital's wage index decreases by more than 5 percent annually (or 14.26 percent over three years),³ the hospital would be eligible for the transitional policy. The limit on the reduction in the wage index would be 5 percent from the otherwise applicable policy that would apply in FY 2027 if the low-wage index policy continued. As CMS is proposing to align the 2027 OPPS wage index with the FY 2027 IPPS wage index, it proposed to apply this same transition policy to 2027 OPPS wage indexes.

For non-IPPS hospitals paid under the OPPS for 2027, CMS proposes to continue its past policies of assigning the wage index that would be applicable if the hospital were paid under the IPPS and allowing the hospital to qualify for the out-migration adjustment—an adjustment that a hospital may qualify for if a high proportion of its workers commute to adjacent higher wage areas. For CMHCs, CMS proposes to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. CMS notes that, consistent with its current policy, the wage index that applies to CMHCs includes the rural floor adjustment but not the out-migration adjustment, which only applies to hospitals.

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

In cases where there 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

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

payments for hospitals that have a CCR falling outside the predetermined ceiling threshold for a valid CCR or for hospitals in which the most recent cost report reflects an all-inclusive rate status. CMS indicates that the table of statewide average CCRs can be found at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/annual-policy-files>. However, this file is not yet available for 2027.

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 OPSS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs. The adjustment is budget neutral and is applied before calculating outliers and copayments.

F. Cancer Hospital Adjustment

Eleven cancer hospitals meeting specific statutory classification criteria are exempt from the IPPS. Medicare pays these hospitals under the OPSS 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 OPSS budget neutrality. The cancer hospital adjustment is applied at cost report settlement rather than on a claim-by-claim basis although CMS adjusts claims payment to approximate the amount the cancer hospital is due at settlement.

To calculate the 2027 target PCR, CMS uses the same extract of cost report data from the Hospital Cost Report Information System used to estimate costs to determine the 2027 OPSS relative weights which, in most cases, would be the most recently available hospital cost reports. The cost reporting periods were predominantly from fiscal years ending in 2024 and 2025. CMS estimated a PCR of 0.89 (or 88 percent) for non-cancer hospitals. After reducing this PCR by 1.0 percentage point, the proposed target PCR would be 0.88 (or 88 percent).

Table 7 in the proposed rule shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals, with increases in OPSS payments for 2026 ranging from 5.3 percent to 52.9 percent. Other information in the proposed rule indicates the cancer hospital adjustment requires a budget neutrality adjustment of -0.06 percent to the OPSS conversion factor.

G. Outpatient Outlier Payments

CMS makes OPSS outlier payments on a service-by-service basis when the cost of a service exceeds the outlier threshold. For 2027, CMS proposes to continue setting aside 1.0 percent of the estimated aggregate total payments for OPSS outlier payments. It proposes calculating the fixed-dollar threshold using the same methodology that was used to set the threshold for 2026 and previous years. For 2027, CMS proposes to continue setting the outlier payment equal to 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC

payment amount when both the 1.75 multiple payment threshold and the fixed-dollar threshold are met.

CMS proposes to set aside a portion of the 1.0 percent outlier pool—specifically, an amount equal to less than 0.01 percent of outlier payments—for CMHCs’ partial hospitalization program outlier payments. If a CMHC’s cost for partial hospitalization services paid 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 OPSS annual payment update factor, resulting in reduced OPSS 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 2025 Medicare claims data to set the proposed 2027 outlier threshold. To model hospital outlier payments and set the outlier threshold, CMS applied a charge inflation factor of 1.15154 to approximate 2027 charges from 2025 claims.

The proposed rule indicates that CMS is using hospital-specific overall ancillary CCRs from the April 2026 update to the Outpatient Provider-Specific File to determine the 2027 proposed rule outlier threshold. CMS adjusted the April 2026 CCRs by 0.977497 to approximate the 2027 CCRs.

For 2027, CMS is adopting a fixed dollar threshold of \$7,100 (compared to \$6,225 in 2026). 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 OPSS payments to outlier payments.

For 2025, CMS estimates that it paid 0.93 percent of total OPSS payments as outliers, or 0.07 percentage points more than the 1.0 percent target. Using 2025 Medicare utilization, CMS estimates that it will pay 1.19 percent of total OPSS payments as outliers in 2026, or 0.19 percentage points more than the 1.0 percent target. CMS does not make any revisions to past or future payments if the amount paid as outliers differs from the 1.0 percent of payment set aside to fund outliers.

III. APC Group Policies

A. Treatment of New and Revised HCPCS Codes

Payments for OPSS procedures, services, and items are generally based on medical billing codes, specifically, Healthcare Common Procedure Coding System (HCPCS) codes, that are reported on hospital outpatient department (HOPD) claims. Code changes that affect the OPSS are published through the annual rulemaking cycle and through the OPSS quarterly update Change Requests (CRs). Generally, these code changes are effective January 1, April 1, July 1, or

October 1. CMS assigns the new codes to interim status indicators (SIs) and APCs and annually finalizes these interim assignments in the OPPTS/ASC final rule. Addenda related to these codes can be found on the CMS website.⁴

1. April 2026 HCPCS Codes Proposed Rule Comment Solicitation

For the April 2026 update, CMS established 61 new HCPCS codes that became effective on April 1, 2026. CMS seeks comment on the proposed APC and status indicator assignments for the codes listed in Table 9 (New HCPCS Codes Effective April 1, 2026) in the proposed rule. In Addendum B, these codes are marked with “NP” to indicate that the codes are assigned to an interim APC assignment and comments will be accepted on their interim APC assignments.

2. July 2026 HCPCS Codes Proposed Rule Comment Solicitation

For the July 2026 update, CMS established 98 new HCPCS codes that became effective July 1, 2026. CMS seeks comment on the proposed APC and status indicator assignments for the codes listed in Table 10 (New HCPCS Codes Effective July 1, 2026) in the proposed rule. In Addendum B, these codes are marked with “NP” to indicate that the codes are assigned to an interim APC assignment and comments will be accepted on their interim APC assignments.

3. October 2026 HCPCS Codes Proposed Rule Comment Solicitation

CMS will solicit comments on the new CPT and Level II HCPCS codes that will be effective October 1, 2026, in the 2027 OPPTS final rule, which allows the agency to finalize the status indicators and APC assignments for the codes in the 2027 OPPTS final rule. The new codes will be released through the October 2026 OPPTS Update CR. CMS proposes to assign indicator “N1” in Addendum B to these new codes to indicate that CMS is assigning them an interim status indicator, which is subject to public comment. CMS will invite public comments in the 2027 OPPTS final rule on the status indicator and APC assignments, which would then be finalized in the 2028 OPPTS final rule with comment period.

4. January 2027 HCPCS Codes Proposed Rule Comment Solicitation

a. New Level II HCPCS Codes Final Rule Comment Solicitation

CMS will solicit comments on the new Level II HCPCS codes that will be effective January 1, 2027, in the 2027 OPPTS final rule which will allow the agency to finalize the status indicators and APC assignments for the codes in the 2028 OPPTS final rule. Unlike the CPT codes that are effective January 1 and are included in the OPPTS proposed rules, and except for the proposed new C- codes and G-codes listed in Addendum O, most Level II HCPCS codes are not released

⁴ The proposed status indicator, APC assignment, and payment rate for each HCPCS code can be found in Addendum B. The complete list of proposed status indicators and corresponding definitions used under the OPPTS can be found in Addendum D1, while the complete list of proposed comment indicators and definitions can be found in Addendum D2. <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice/cms-1850-p>

until sometime around November to be effective January 1. Because these codes are not available until November, CMS is unable to include them in the OPPTS proposed rules.

For 2027, CMS proposes to continue its established policy of assigning comment indicator “N1” in Addendum B to the OPPTS 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 will invite comments in the 2027 OPPTS final rule on the status indicator and APC assignments, which would then be finalized in the 2028 OPPTS final rule.

b. New CPT Codes Proposed Rule Comment Solicitation

In this section of the proposed rule preamble, CMS describes its policies for addressing timely and untimely receipt of new/revised CPT codes from the AMA’s CPT Editorial Panel. For the 2027 OPPTS update, CMS timely received the CPT codes that will be effective January 1, 2027, from the AMA. The new and revised CPT codes are assigned to comment indicator “NP” in Addendum B to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year with a proposed APC assignment, and that comments will be accepted on the proposed APC assignment and status indicator. Long descriptors for the new and revised CPT codes are available in Addendum O. CMS notes that these new and revised CPT procedure codes have a placeholder for the fifth character and the final code numbers will be included in the final rule. CMS solicits public comments on the proposed CY 2027 status indicators and APC assignments for the new and revised CPT codes that will be effective January 1, 2027. Additionally, CMS proposes to finalize the status indicator and APC assignments for these codes (with their final CPT code numbers) in the 2027 OPPTS final rule as displayed in Addendum B.

Table 11 (reproduced below) summarizes CMS’ current process for updating codes through the OPPTS quarterly update CRs, seeking public comments, and finalizing the treatment of these codes under the OPPTS.

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

B. Variations Within APCs

1. Background

In accordance with statute,⁵ CMS developed a grouping classification system referred to as Ambulatory Payment Classifications (APCs) which is codified at 42 CFR 419.31. CMS uses Level I and Level II HCPCS codes to identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, CMS has established distinct groups of similar services. CMS has also developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices that are not packaged into the payment for the procedure. Into the payment 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 OPPTS, CMS generally pays for covered hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. For 2027, CMS proposes 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,⁶ CMS annually reviews the items and services within an APC group to determine, with respect to resource comparability, if the highest cost item or service within an APC group is more than 2 times greater than the lowest cost item or service within that same group (the “2 times rule”). In making this determination, CMS considers only those HCPCS codes that are significant based on the number of claims. Specifically, CMS considers significant only those HCPCS codes that either (i) have more than 1,000 single major claims or (ii) have both greater than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost. For CY 2027, CMS proposes to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as for certain low-volume items and services.

The Secretary is also required to consult with an expert outside advisory panel composed of appropriate representatives of providers to review the clinical integrity of the APC groups and the relative payment weights and advise the Secretary about any issues. The Advisory Panel on Hospital Outpatient Payment (also known as the HOP Panel or the Panel) provides recommendations for specific services for the 2027 OPPTS and CMS’ responses will be discussed in relevant sections in the 2027 OPPTS final rule.

For 2027, CMS has identified APCs with violations of the 2 times rule and proposes changes to the procedure codes assigned to these APCs in Addendum B (identified with comment indicator “CH”) other than those for which CMS is proposing an exception to the 2 times rule. CMS notes

⁵ Sections 1833(t)(2)(A) and (B) of the Act.

⁶ Section 1833(t)(9)(A) of the Act.

that in many cases, the proposed procedure code reassignments and associated APC configurations for 2027 are related to changes in costs of services that were observed in the 2025 claims data.

3. Proposed APC Exceptions to the 2 Times Rule

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

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

Table 12 (reproduced below from the proposed rule) lists the 27 APCs for which CMS proposes to make an exception under the 2 times rule for 2027 based on the criteria cited above and claims data submitted between January 1, 2025, and December 31, 2025, and processed on or before December 31, 2025, and CCRs, if available.

Table 12: Proposed 2026 APC Exceptions to the 2 Times Rule	
APC	APC Group Title
5012	Clinic Visits and Related Services
5054	Level 4 Skin Procedures
5071	Level 1 Excision/Biopsy/Incision and Drainage
5301	Level 1 Upper GI Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5572	Level 2 Imaging with Contrast
5573	Level 3 Imaging with Contrast
5611	Level 1 Therapeutic Radiation Treatment Preparation
5612	Level 2 Therapeutic Radiation Treatment Preparation
5613	Level 3 Therapeutic Radiation Treatment Preparation
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
5731	Level 1 Minor Procedures
5734	Level 4 Minor Procedures
5735	Level 5 Minor Procedures
5741	Level 1 Electronic Analysis of Devices
5742	Level 2 Electronic Analysis of Devices
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 and is reasonable and necessary.

For 2026, there were 52 levels of New Technology APC groups with two parallel status indicators; one set with a status indicator of “S” (S = Significant procedure, not discounted when multiple) and the other set with a status indicator of “T” (T = Significant procedure, multiple reduction applies). The New Technology APC levels range from the cost band assigned to APC 1491 (New Technology – Level 1A (\$0 - \$10)) through the highest cost band assigned to APC 1908 (New Technology – Level 52 (\$145,001 - \$160,000)).

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

Some services assigned to New Technology APCs have low annual volume, which CMS considers to be fewer than 100 claims in the year of claims data used for ratesetting. 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 to 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 for New Technology APCs under which CMS calculated and presented the results of each statistical methodology (arithmetic mean, geometric mean, and median) based on up to 4 years of claims data and solicited public comment on which methodology should be used to establish the payment rate for the low-volume new technology service. Since 2022, CMS replaced and expanded this low-volume New Technology APC policy to universally apply to clinical APCs and brachytherapy APCs. Under its “universal low volume APC 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.

To further mitigate payment instability for services assigned to New Technology APCs with very low volume claims, beginning 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. Instead of assigning these services to a different New Technology APC based on the very few claims available, CMS maintains the New Technology APC assignment for each service from the prior year.

Finally, consistent with CMS' policy to maintain the New Technology APC assignment for services with zero claims in the claims year used for rulemaking, if a service has no CY 2025 claims, CMS proposes to maintain the same New Technology APC assignment for CY 2027.

The proposed payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 are in Addendum A.

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

For CY 2027, there are nine services that have either zero claims for CY 2027 rulemaking (based on CY 2025 claims) or fewer than 10 claims in the previous 4-year lookback period. For CY 2027, CMS proposes to maintain the New Technology APC assignments (shown in parentheses) for these services:

Blinded Procedure for NYHA Class III/IV Heart Failure - C9758 (1590, T)	Magnetic Resonance Imaging With Inhaled Hyperpolarized Xenon-129 Contrast Agent - C9791 (1551, T)	DARI Motion Procedure - 0693T (1505, S)
Implantable Glucose Monitoring System - 0446T (1563, T)	Implantable Glucose Monitoring System - 0448T (1563, T)	Transcatheter Atrial Shunt System (TASS) - C9792 (1537, S)
Corvia Medical Interatrial Shunt - C9760 (1592, T)	Surfacer Inside-Out Access Catheter - C9780 (1534, S)	CardiAMP - C9782 (1590, T)

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

As noted previously, 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 where 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), if CMS obtains new information that was not available at the time of its initial New Technology APC assignment, or if 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.

Based on the policies described above, the below table reflects CMS' proposed New Technology APC assignments for 2027:

Proposed 2027 New Technology APC and Status Indicator Assignments				
HCPCS	Long Descriptor	Proposed 2027 SI	Proposed 2027 APC	Notes and Proposals
0810T	Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies	T	1564	Established in 2024 after HCPCS code C9770 was deleted. <100 claims using both codes in 4yr lookback. Proposal to assign based on the arithmetic mean and to reassess final payment using updated claims data for the final rule.
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	1518	This G code replaced CPT code C9794 in 2025. <100 claims using both codes in 4yr lookback. Proposal to assign based on the median cost. Proposed payment rate of \$2,644 for 2027.
G0563	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance and real-time positron emissions-based delivery adjustments to 1 or more lesions, entire course not to exceed 5 fractions	S	1523	This G code replaced CPT code C9795 in 2025. <100 claims using both codes in 4yr lookback. Proposal to base assignment using the arithmetic mean. Proposed payment rate of \$2750.50 for 2027.
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	1594	CMS' proposed assignment is a result of changes CMS proposes for APCs 5591-5594 (see section III.E).
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability)	S	1594	CMS' proposed assignment is a result of changes CMS proposes for APCs 5591-5594 (see section III.E).
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability); with concurrently acquired computed tomography transmission scan	S	1594	CMS' proposed assignment is a result of changes CMS proposes for APCs 5591-5594 (see section III.E).
C9789	Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed	T	1550	Sufficient 2025 claims data to reassign from APC 1551 to 1550 with a payment rate of \$1,150.50 for 2027.
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	S	1581	Proposed APC assignment based on low volume using the arithmetic mean with a payment rate of \$55,000.50 for 2027.

Proposed 2027 New Technology APC and Status Indicator Assignments				
HCPCS	Long Descriptor	Proposed 2027 SI	Proposed 2027 APC	Notes and Proposals
	radiological supervision and interpretation, when performed			
0686T	Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance	S	1575	Sufficient 2025 claims data to reassign from APC 1576 to 1575 with a payment rate of \$12,500.50 for 2027.
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	1513	Sufficient claims to determine a geometric mean cost. Proposed assignment to APC 1513 with a payment rate of \$1,150.50 in 2027.
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation	S	1518	Proposal to maintain assignment to APC 1518 with a payment rate of \$1,650.50 for 2027 based on 2025 claims data.
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	Sufficient claims data. Based on the median cost, CMS proposes to assign to APC 1511 with a 2027 payment rate of \$950.50
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	Based on the arithmetic mean, CMS proposes to assign to APC 1521 with a payment rate of \$1,950.50 for 2027.
0891T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent treatment day	S	1520	Based on the geometric mean, CMS proposed to assign to APC 1520 with a payment rate of \$1,850.50 for 2027.
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	1523	Based on the arithmetic mean, CMS proposes to assign to APC 1523 with a payment rate of \$2,750.50 for 2027
15X19	Skin cell suspension autograft (SCSA), trunk, arms, and/or legs; first 100 sq cm or less, or 1% of body area of infants and children	S	1575	In light of recent coding changes, CMS proposes to maintain overall payment rates for the SCSA procedure and to delete HCPCS code C8002.
15X20	each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)	N	N/A	In light of recent coding changes, CMS proposes to maintain overall payment rates for the SCSA procedure and to delete HCPCS code C8002.

Proposed 2027 New Technology APC and Status Indicator Assignments				
HCPCS	Long Descriptor	Proposed 2027 SI	Proposed 2027 APC	Notes and Proposals
15X21	Skin cell suspension autograft (SCSA), face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children	S	1575	In light of recent coding changes, CMS proposes to maintain overall payment rates for the SCSA procedure and to delete HCPCS code C8002.
15X22	Skin cell suspension autograft (SCSA), face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)	N	N/A	In light of recent coding changes, CMS proposes to maintain overall payment rates for the SCSA procedure and to delete HCPCS code C8002.
0888T	Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including image guidance	S	1534	Low volume in 2025 claims. CMS proposes to assign to APC 1534 with a payment rate of \$8,250.50 in 2027.

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

As discussed in section X.B. of the proposed rule, CMS is proposing an interim payment policy for software-based medical services with algorithmic analyses. The proposed interim policy would impact certain services assigned to New Technology APCs. In section X.B., CMS proposes to:

- Change the agency’s terminology from Software as a Service (SaaS) to Software as a Medical Service (SaMS).
- Maintain the current new technology APC assignments under its section 1833(t)(2)(E) equitable adjustment authority for CY 2027. This policy would be a transitional step as the agency continues to refine a more comprehensive payment framework for SaMS services.
- Assign a proposed new status indicator “O1” (Software as a Medical Service, paid under OPPS; separate APC payment) to SaMS that are assigned to new technology APCs.

The table below(prepared by HPA) summarizes the new technology APCs procedures CMS proposes to designate as SaMS procedures and for which CMS proposes to maintain current new technology APC assignments under its equitable adjustment authority for 2027. CMS expresses hope that its interim policy will minimize potential disruptions in payment for these services while the agency continues to evaluate longer-term payment approaches. Each procedure would be assigned status indicator “O1”.

HCPCS	Long Descriptor	Proposed 2027 APC, SI	Proposed 2027 Payment Rate
75577 (previously 0625T)	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; data preparation and transmission, computerized analysis of data, with review of	1511, O1	\$950.50

HCPCS	Long Descriptor	Proposed 2027 APC, SI	Proposed 2027 Payment Rate
	computerized analysis output to reconcile discordant data, interpretation and report		
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	1511, OI	\$950.50
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)	1511, OI	\$950.50
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	1508, OI	\$650.50
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)	1508, OI	\$650.50
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	1511, OI	\$950.50
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)	1511, OI	\$950.50
0723T	Quantitative magnetic resonance cholangiopancreatography (QMRCF) 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	1511, OI	\$950.50
0724T	Quantitative magnetic resonance cholangiopancreatography (QMRCF), 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)	1511, OI	\$950.50
0877T	Augmentative analysis of chest CT imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging	1508, OI	\$650.50
0878T	Augmentative analysis of chest CT imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; obtained with concurrent CT examination of the same structure.	1508, OI	\$650.50

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

Beginning in 2022, CMS designates 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. 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 CMS' current methodology for determining payment rates for non-specified brachytherapy sources is appropriate. For 2027, CMS proposes to designate five brachytherapy APCs and four clinical APCs as low volume APCs, displayed in Table 23 in the preamble. They include APC 2635, 2642, 2643, 2645, 2647, 5244, 5495, 5496, and 5881.

E. APC-Specific Policies

1. Nuclear Medicine and Related Services APC Series (APC 5591 through 5594)

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

Given the relative proximity of the APC geometric mean costs and the clinical and cost similarities of the services between the APCs in the Nuclear Medicine and Related Services series, CMS believes that it is appropriate to reorganize the Nuclear Medicine and Related Services APC series for 2027 and reassign a number of services to revised levels. CMS refers readers to Addendum B to view the Nuclear Medicine APC CMS has proposed to assign each HCPCS code in the series. Additionally, CMS proposes to assign CPT codes 78431, 78432, and 78433 to APC 5594 for 2027.

2. Breast/Lymphatic Surgery and Related Procedures APC Series (APC 5091 through 5093)

In the 2026 OPPS/ASC final rule, CMS recalibrated the four-level Breast/Lymphatic Surgery and Related Procedures APC series to address concerns related to a data anomaly that occurred as a combined result of: (1) the APC levels having cost ranges that were not sufficiently distinct, and (2) the contribution of the complexity adjustment claims data contributing to the APC geometric means.

In reviewing the claims data available for ratesetting for 2027, CMS has continued to observe data anomalies due to the APC cost ranges not being sufficiently distinct, in particular between the Level 2 and 3 APCs in this series. As a result, CMS is proposing, to establish a three-level Breast/Lymphatic Surgery and Related Procedures APC series by consolidating the current Level 2 and 3 APCs into a single Level 2 APC, and remapping the current Level 4 APC as the Level 3 APC.

3. Hypoglossal Nerve Neurostimulator (HGNS) Procedures (APCs 5465, 5463, and 5432)

Effective January 1, 2022, the AMA's CPT Editorial Panel created three new codes to describe the open implantation of hypoglossal nerve neurostimulator (HGNS) array, including CPT codes 64582, 64583, and 64584. As the technology has evolved, CMS realizes that these HGNS CPT codes do not accurately describe newer hypoglossal nerve neurostimulators that are on the market.

To address the questions and concerns regarding coding and billing for the implantation, revision or replacement, or removal of hypoglossal nerve neurostimulators that are not described by existing coding, CMS created six new C-codes that describe the implantation, revision or replacement, and removal of hypoglossal nerve neurostimulators that do not contain a separate implantable respiratory sensor electrode or electrode array, and systems that do not contain an implanted battery or pulse generator. CMS used the current HGNS CPT codes as the crosswalk codes for the new C-codes. These new HCPCS codes and their APC and status indicator assignments were published in the April 2026 quarterly update CR and are retroactive to January 1, 2026. The proposed APC and status indicator assignments for HCPCS codes C8007 – C8009 and C8011 – C8013, along with their long descriptors are shown in Table 24 in the proposed rule preamble. The proposed 2027 rates for these codes can be found in Addendum B on the CMS website.

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

For 2026, CMS assigned CPT code 52282 (describing insertion of a permanent prostatic urethral stent procedure) to APC 5374 (Level 4) based on its geometric mean cost. For 2027, CMS reviewed 2025 claims used for ratesetting and the claims report for CPT code 52282. In its review, CMS notes that there had not been an FDA approved permanent prostatic urethral stent on the US market for approximately 9 years until a permanent prostatic urethral stent received their FDA PMA approval in late 2025. Therefore, CMS believes the report claims for CPT code 52282 do not accurately represent the device and service cost associated with inserting a permanent prostatic urethral stent.

CMS examined the device and service costs associated with a permanent prostatic urethral stent and noted that CPT code 52282 shares resource and clinical homogeneity with HCPCS code C9739 (Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants). As a result, CMS proposes to reassign CPT code 52282 to APC 5375 (Level 5).

5. Integrated Sacral Neurostimulator, CPT Code 0786T (APC 5464)

Effective January 1, 2024, the CPT Editorial Panel separated integrated from nonintegrated (i.e., traditional) sacral neurostimulator procedures by establishing new CPT code 0786T to report procedures using integrated sacral neurostimulator devices, while CPT code 64590 was updated to reflect the use of traditional technology. CMS assigned CPT code 0786T to status indicator “E1” (Not covered by any outpatient benefit category) because the device associated with this CPT code did not have FDA approval.

For 2026, CMS initially assigned CPT code 0786T to APC 5463 (Level 3) and status indicator “J1” based on the costs and resources the agency believed were required to perform the procedure with an integrated device. For 2027, the agency has revisited its initial assignment and proposes to reassign CPT code 0786T from APC 5463 (Level 3) to APC 5464 (Level 4). CMS explains that because 0786T was not assigned to a clinical APC before January 1, 2026, CMS does not have any ratesetting claims data with which to base a cost calculation. However, because CPT code 0786T shares more resource cost and clinical homogeneity with procedures in APC 5464, CMS believes the reassignment is appropriate.

6. C-Codes Describing Percutaneous Coronary Intervention (PCI) With Drug-Eluting Stents, C-codes C9601, C9603, C9605, and C9608

Effective January 1, 2013, CMS created several HCPCS C-codes to describe certain percutaneous coronary intervention (PCI) procedures utilizing drug eluting stents to mirror PCI CPT codes that do not utilize drug eluting stents. The AMA CPT Editorial Board deleted several of those CPT codes effective January 1, 2026. For 2027, CMS proposes to delete the C-codes that mirrored the deleted CPT codes, specifically revising the status indicators for C9601, C9603, C9605, and C9608 to “D” (Discontinued Codes) indicating that they are no longer active codes. The C-codes, long descriptors, status indicators, and their corresponding CPT code are shown in Table 26 in the proposed rule preamble.

7. Electrophysiologic Evaluation of Cardiac Contractility Modulation Systems, CPT Code 0930T

CPT code 0930T describing electrophysiologic evaluation of cardiac contractility modulation defibrillator leads became effective January 1, 2025, and is currently assigned to APC 5211 (Level 1) and status indicator “J1”. There are currently no claims data for CPT 0930T. After review of the service and other like services, CMS believes this service is always performed with the initial implantation or replacement of the system. As such, CMS believes the service is integral, ancillary, supportive, dependent, and adjunctive to the primary service and should therefore be packaged into the CPT code describing the initial implantation or replacement of the cardiac contractility modulation-defibrillator pulse generator. Therefore, for 2027, CMS proposes to revise the status indicator for CPT 0930T to “N”.

8. Endovenous Femoral-Popliteal Arterial Revascularization with Placement of Stent Graft, CPT Code 0505T

CPT code 0505T became effective January 1, 2018, and is used to treat patients with advanced peripheral vascular disease, specifically those with long complex femoropopliteal artery stenoses and occlusions resulting in lifestyle limiting claudication or severe lower limb threatening

ischemia. CPT code 0505T is currently assigned to APC 5193 (Level 3 Endovascular Procedures) with a payment of approximately \$11,800. Based on CMS' analysis of 2025 claims data, CMS noted that CPT code 0505T has a geometric mean cost of \$41,123 based on 46 single frequency claims. CMS therefore considered reassigning CPT 0505T to APC 5194 (Level 4) with a payment of approximately \$18,700 but CMS does not believe this APC would be appropriate due to the impending expiration of a device pass-through payment for the DETOUR™ System and the incorporation of its costs.⁷

Given the low volume of claims data for this procedure and the absence of a clinical APC in terms of clinical and resource similarity, CMS proposes to reassign CPT 0505T to APC 1580 (New Technology - Level 43) with a payment of \$45,000.50. As the agency gathers adequate claims data on this code, it invites public comment on the appropriate clinical APC for CPT code 0505T.

IV. Payment for Devices

A. Pass-Through Payment for Devices

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

a. Background

As implemented at 42 CFR 419.66, transitional device pass-through payments are intended for beneficiaries to have access to new and innovative devices by providing for adequate payments for new devices while the necessary cost data is collected to incorporate the device costs into the procedure APC rate. In accordance with statute, a category of devices is eligible for transitional pass-through payments for at least two, but not more than three years.⁸ Since 2017, the pass-through eligibility period for a device category begins on the first date on which pass-through payment is made under the OPPS and, to allow a pass-through payment period that is as close to a full three years as possible, this pass-through status expires quarterly. Once devices are no longer eligible for pass-through payments, CMS packages the costs of the devices into the procedures with which the devices are reported in the claims data.

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

Currently, 21 device categories are eligible for pass-through payment. These devices are listed in Table 29 (reproduced from the preamble below) which includes the expiration dates of pass-through payment status for each.

⁷ CMS created HCPCS code C1604 (Graft, transmural transvenous arterial bypass (implantable), with all delivery system components) when the DETOUR™ System was approved for transitional device pass-through payment under the OPPS effective January 1, 2024. The pass-through payment for this device expires December 31, 2026. Once the pass-through payment period expires, payment for the device is packaged into the OPPS payment rate for the associated procedure(s).

⁸ Section 1833(t)(6)(B)(iii) of the Act

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

HCPCS Code	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1600	Catheter, transluminal intravascular lesion preparation device, bladed, sheathed (insertable)	01/01/2024	12/31/2026
C1601	Endoscope, single-use (<i>i.e.</i> 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>i.e.</i> disposable), for attaching ultrasound system to upper gastrointestinal endoscope	07/01/2024	06/30/2027
C8000	Support device, extravascular, for arteriovenous fistula (implantable)	10/01/2024	09/30/2027
C1735	Catheter(s), intravascular for renal denervation, radiofrequency, including all single use system components	01/01/2025	12/31/2027
C1736	Catheter(s), intravascular for renal denervation, ultrasound, including all single use system components	01/01/2025	12/31/2027
C1737	Joint fusion and fixation device(s), sacroiliac and pelvis, including all system components (implantable)	01/01/2025	12/31/2027
C1738	Powered, single-use (<i>i.e.</i> disposable) endoscopic ultrasound-guided biopsy device	01/01/2025	12/31/2027
C1739	Tissue marker, uniquely detectable and identifiable with probe/sensor, any method (implantable), with delivery system	01/01/2025	12/31/2027
C9610	Catheter, transluminal drug delivery with or without angioplasty, coronary, non-laser (insertable)	01/01/2025	12/31/2027
C1740	Leadless electrode, transmitter, battery (all implantable), for sequential left ventricular pacing	10/01/2025	09/30/2028
C1741	Anchor/screw for bone fixation, absorbable (implantable)	10/01/2025	09/30/2028
C1742	Pressure monitoring system, compartmental intramuscular (implantable), continuous, including all components (e.g., introducer, sensor), excludes mobile (wireless) software application	10/01/2025	09/30/2028
C1607	Neurostimulator, integrated (implantable), rechargeable with all implantable and external components including charging system	01/01/2026	12/31/2028
C1608	Prosthesis, total, dual mobility, first carpometacarpal joint (implantable)	01/01/2026	12/31/2028
C1743	Scaffold, endovascular non-coronary, resorbable drug eluting, with delivery system (implantable)	04/01/2026	03/31/2029
C1609	Vertebral device, motion-preserving, with screw fixation	07/01/2026	06/30/2029

2. New Device Pass-Through Applications for CY 2027

a. Background

The statute provides for pass-through payments for devices and requires CMS to use categories in determining eligibility.⁹ The specific requirements are established at 42 CFR 419.66. The agency believes that pass-through payments for devices that offer substantial clinical improvement are important for ensuring hospitals can provide Medicare beneficiaries with access to the advantages of the new technologies.

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

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

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

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

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

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

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

⁹ Section 1833(t)(6) of the Act

amount for the related service by at least 25 percent, and (3) the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service.

Device pass-through applications are submitted through the quarterly subregulatory process to allow for timely pass-through status. The applications are subject to notice-and-comment rulemaking in the next applicable OPPS/ASC annual rulemaking cycle to allow for a transparent, public review. All applications that are preliminarily approved during the quarterly review are automatically included in the next rulemaking cycle and are granted access to pass-through payment at the beginning of the next quarter following approval. Submitters of applications that are not approved during the quarterly review have the option of being included in the next rulemaking cycle or withdrawing their application. Applicants may submit new evidence for consideration during the public comment period. Applications are publicly posted on a CMS website.

In the 2020 OPPS/ASC final rule, CMS 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 (§419.66(c)(2)) 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.

However, as discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19457 to 19459), CMS has proposed to repeal the alternative pathway for new technology add-on payment and OPPS device pass-through applications and require all applicants for new technology add-on payments and OPPS device pass-through payments to demonstrate that they meet the same eligibility requirements to receive add-on payments and/or pass-through payments. If finalized, this policy would apply to all applications received for OPPS device pass-through payment status on or after October 1, 2026, including all applications received through the remainder of the CY 2028 OPPS application cycle ending on March 1, 2027. Previously existing device category codes would continue to be eligible for device pass-through payment status and would remain in effect for at least 2 years, but no more than 3 years, consistent with § 419.66(g). CMS has proposed to revise paragraph §419.66(c)(2)(ii) to reflect this proposed policy. If finalized as proposed, the change would go into effect on October 1, 2026 (91 FR 19458).

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

CMS received 19 complete applications by March 2, 2026, which was the last quarterly deadline for applications to be received in time to be included in the 2027 proposed rule. Six applications subsequently withdrew. Of the remaining 13 applications, 10 were submitted under the alternative pathway and 3 were submitted under the traditional pathway. The applications are discussed in the sections below.

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

(1) Alternative Pathway Device Pass-Through Applications

CMS received 10 eligible device pass-through applications under the alternative pathway by the March 2026 application deadline. HPA has provided a summary table of these technologies and CMS' preliminary assessment. CMS invites public comment on each aspect of each application as to whether the device meets criteria. Only the three technologies that CMS proposes to deny (designated as (a), (d), and (g) to align with the proposed rule preamble) are discussed in more detail below the table. For details on the seven applications which CMS proposes to approve, please refer to the proposed rule preamble.

Summary of Technologies Evaluated under the Alternative Pathway for Device Pass-Through Payments (Received by March 2, 2026)

Technology	FDA Approval Date	Preliminary CMS Assessment and Application Link
(a) Altius® Direct Electrical Nerve Stimulation System	August 26, 2024	Proposes to deny. See discussion below. MEARIS™ Publication device-ntp DEP250530FMCYD
(b) Esprit™ BTK Everolimus Eluting Resorbable Scaffold System	April 26, 2024	Preliminarily approved for device pass-through effective April 1, 2026. CMS proposes to finalize approval for 2027. MEARIS™ Publication device-ntp DEP250829XYFGP
(c) MY01 Continuous Compartmental Pressure Monitor	March 13, 2025	Preliminarily approved for device pass-through effective October 1, 2025. CMS proposes to finalize approval for 2027. MEARIS™ Publication device-ntp DEP250602XAAW9
(d) ProSense® Cryoablation System	October 3, 2025	Proposes to deny. See discussion below. MEARIS™ Publication device-ntp DEP251226K6A1C
(e) RemeOs™ Screw LAG Solid	March 29, 2023	Preliminarily approved for device pass-through effective October 1, 2025. CMS proposes to finalize approval for 2027. MEARIS™ Publication device-ntp DEP2506023YUR4
(f) SetPoint System	July 30, 2025	Preliminarily approved for device pass-through effective January 1, 2026. CMS proposes to finalize approval for 2027. MEARIS™ Publication device-ntp DEP2508042W2C1
(g) TIDAL™ Fusion Cage System (Ossera™ AFX)	March 24, 2025	Proposes to deny. See discussion below. MEARIS™ Publication device-ntp DEP250529B0B27
(h) TOPS™ System	June 15, 2023	Preliminarily approved for device pass-through effective July 1, 2026. CMS proposes to finalize approval for 2027. MEARIS™ Publication device-ntp DEP2602261DX3J
(i) TOUCH® CMC 1 Prosthesis	July 10, 2025	Preliminarily approved for device pass-through effective January 1, 2026. CMS proposes to finalize approval for 2027. MEARIS™ Publication device-ntp DEP250829G4VEC
(j) WiSE® CRT System	April 11, 2025	Preliminarily approved for device pass-through effective October 1, 2025. CMS proposes to finalize approval for 2027. MEARIS™ Publication device-ntp DEP250429663YG

(a) Altius® Direct Electrical Nerve Stimulation System

The Altius® System is an implantable neuromodulation system that provides continuous, high frequency, high amplitude nerve stimulation to either the sciatic nerve or both the tibial and common peroneal nerves by directly stimulating targeted nerves via implanted cuff electrode

leads that are wrapped circumferentially around target nerves in the amputated leg. While the system is composed of several components, the applicant is seeking a new device category for transitional pass-through payment status for only the Altius® IPG and the Altius® Cuff Electrode Lead components of the Altius® System. Table 30 in the proposed rule preamble summarizes this product's application information and CMS' preliminary assessment.

Eligibility criteria at §419.66(b). CMS does not express concerns about whether the device meets the newness or eligibility criteria; however, CMS invites public comment specifically on whether the Altius® System meets the newness criterion at §419.66(b)(1) or whether the Altius® IPG and the Altius® Cuff Electrode Lead components meet the eligibility criteria at §419.66(b)(3) and (b)(4).

Device category eligibility criterion at §419.66(c). Under §419.66(c)(1), CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect. CMS notes that the agency does not establish passthrough device categories for the purpose of describing specific devices, but rather, device categories are intended to encompass all devices that can be appropriately described by a category. In this context, CMS believes that the Altius® IPG and the Altius® Cuff Electrode Lead components may be appropriately described by C1778 and C1822.

CMS notes that the applicant has stated that no existing device pass-through payment categories appropriately describe the nominated device components and summarizes the reasons provided by the applicant as to why they do not believe that C1778 and C1822 describe the nominated device components. CMS disagrees, stating that, based on the description the applicant provided, the Altius® IPG is a rechargeable neurotransmitter device that generates a continuous high frequency, high amplitude alternating electrical stimulus (5kHz and 10kHz) via the Altius® Cuff Electrode Leads, which are circumferentially wrapped, anchored, and implanted around the nerve(s), and therefore, CMS believes these could be appropriately described by C1778 (Lead, neurostimulator (implantable) and C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), respectively. Specifically, CMS believes that the pass-through payment category C1778 may appropriately describe the Altius® Cuff Electrode Lead component because the pass-through payment category describes any device that is an implantable neurostimulator lead. Additionally, CMS believes the pass-through payment category C1822 may appropriately describe the Altius® IPG because the category includes implantable neurostimulator pulse generators that deliver high-frequency stimulation (including approximately 10 kHz) and are rechargeable using an external charging system. Further, C1822 does not describe the amplitude, pulse frequency, or waveform of the stimulation generated by the device. CMS invites public comment on whether the Altius® IPG and the Altius® Cuff Electrode Lead components meet the device category eligibility criterion at §419.66(c)(1).

Cost criterion at §419.66(d). CMS does not express concerns related to the cost criterion; however, the agency seeks public comment on this issue.

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

(d) ProSense® Cryoablation System

The ProSense® Cryoablation System is designed to destroy tissue by the application of extreme cold temperatures utilizing liquid nitrogen for the treatment of breast cancer for patients with low-risk tumors. The applicant is seeking a new device category for transitional passthrough payment status for only the ProSense® Cryoprobe component of the ProSense® Cryoablation System. Per the applicant, the ProSense® Cryoprobe is a rigid probe with a tip that creates ice balls to destroy target tissue through cycles of freezing and thawing. Table 33 in the proposed rule preamble provides an overview of the application and CMS' preliminary assessment.

Eligibility criteria at §419.66(b). With respect to the newness criterion at §419.66(b)(1), the device must have received FDA approval or clearance (that is, FDA marketing authorization), and the pass-through payment application must be submitted within 3 years from the date of the initial FDA marketing authorization. While the October 3, 2025, FDA decision summary for De Novo classification for the ProSense® Cryoablation System includes a new indication for use in the treatment of patients with T1 invasive breast cancer and/or patients not suitable for surgical alternatives for the treatment of breast cancer, CMS believes that the initial FDA marketing authorization date for the ProSense® Cryoablation System, inclusive of the nominated ProSense® Cryoprobe component, may be December 20, 2019 or earlier. The applicant submitted the pass-through payment application on December 26, 2025, which is more than 3 years after December 20, 2019; therefore, CMS does not believe that the ProSense® Cryoablation System, inclusive of the nominated ProSense® Cryoprobe, meets the newness criterion.

Device category eligibility criterion at §419.66(c). Under §419.66(c)(1), CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect. CMS notes that the agency does not establish pass-through device categories for the purpose of describing specific devices; rather, device categories are intended to encompass all devices that can be appropriately described by a given category. Therefore, in this context, CMS believes the ProSense® Cryoprobe may be appropriately described by C2618.

CMS summarizes the reasons provided by the applicant as to why they do not believe that the existing pass-through code C2618 (Probe, cryoablation) would appropriately describe the ProSense® Cryoprobe. However, based on the description the applicant provided, the ProSense® Cryoprobe is a probe used for cryoablation, and therefore, CMS believes it could be appropriately described by C2618. Specifically, CMS believes that the pass-through payment category C2618 may appropriately describe the ProSense® Cryoprobe because C2618 describes any probe used for cryoablation and is not specific to an anatomical location.

Cost criterion at §419.66(d). CMS does not express concerns related to the cost criterion; however, the agency seeks public comment on this issue.

In summary, because CMS is unable to determine that the ProSense® Cryoablation System, inclusive of the ProSense® Cryoprobe, meets the new device category eligibility criteria, CMS proposes to deny transitional pass-through payment status for CY 2027.

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

The TIDAL™ Fusion Cage is a single, continuous, porous piece of titanium alloy containing a circular window for an intramedullary nail used during salvage procedures to restore bone length due to bone void, absent bone or surgical resection. The TIDAL™ Fusion System is not for standalone use and is intended for use as an accessory to the DynaNail® TTC Fusion System and with an autograft and/or allogenic bone graft. Table 36 in the proposed rule preamble provides an overview of the application and CMS' preliminary assessment.

Eligibility criteria at §419.66(b). CMS does not express concerns about whether the device meets the newness or eligibility criteria; however, CMS invites public comment on whether the TIDAL™ Fusion Cage meets the newness criterion at §419.66(b)(1) and the eligibility criteria at §419.66(b)(3) and (b)(4).

Device category eligibility criterion at §419.66(c). Regarding §419.66(c)(1), CMS believes that the TIDAL™ Fusion Cage may be appropriately described by C1713. Per the applicant, the existing pass-through code C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)) does not appropriately describe the TIDAL™ Fusion Cage because C1713 is typically used to represent fixation components, such as an intramedullary nail or other fixation screws, but does not represent the TIDAL™ Fusion Cage. CMS disagrees, stating that, based on the description the applicant provided, the TIDAL™ Fusion Cage is a porous cage used as part of a limb salvage arthrodesis construct to bridge bone loss or a critical bone defect in the ankle and restore length due to bone void, absent bone, or surgical resection and therefore, could be described by C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)). Specifically, CMS believes that the pass-through payment category C1713 may appropriately describe the TIDAL™ Fusion Cage because C1713 is defined as implantable pins and/or screws inserted or drilled into bone, principally with the intent to facilitate stabilization or oppose bone-to-bone contact and may include orthopedic plates with accompanying washers or nuts as well as synthetic bone substitutes that may be used to fill bony voids or gaps.

Cost criterion at §419.66(d). CMS does not express concerns related to the cost criterion; however, the agency seeks public comment on this issue.

In summary, CMS is unable to determine that the TIDAL™ Fusion Cage meets the new device category eligibility criteria, and therefore proposes to deny transitional pass-through payment status for CY 2027.

(2) Traditional Device Pass-Through Applications

CMS received three eligible device pass-through applications under the traditional pathway by the March 2026 application deadline. HPA has provided a summary table of these technologies

and CMS’ preliminary assessment. CMS invites public comment on each aspect of each application as to whether the device meets criteria. All three are discussed in more detail below the table.

Summary of Technologies Evaluated under the Traditional Pathway for Device Pass-Through Payments (Received by March 2, 2026)

Technology	FDA Approval Date	Preliminary CMS Assessment and Application Link
(a) EndoForce™ Connector for Endovascular Venous Anastomosis	May 15, 2025	Proposes to deny. See discussion below. MEARIS™ Publication device-ftp DEP260228AHPFT
(b) LINK™ External Fixator	May 29, 2024	Proposes to deny. See discussion below. MEARIS™ Publication device-ftp DEP250902M814F
(c) Santreva™-ATK Endovascular Revascularization Catheter	September 22, 2025	Proposes to deny. See discussion below. MEARIS™ Publication device-ftp DEP260302QH9AE

(a) EndoForce™ Connector for Endovascular Venous Anastomosis

The EndoForce™ System provides an endovascular method for attachment of a non-autogenous arteriovenous graft (AVG) to a vein in the upper arm in patients with end stage renal disease (ESRD) requiring hemodialysis. The System is provided as a sterile, single-use EndoForce™ Connector Delivery System with a pre-mounted EndoForce™ Connector that is attached endovascularly at the venous anastomosis, in conjunction with a standard 6mm expanded polytetrafluoroethylene (ePTFE) vascular access graft, to establish an end-to-end endovascular anastomotic conduit designed to help absorb the shear forces of blood flow at the AVG-vein junction and to provide a physical barrier to the ingress of neointimal hyperplasia. Table 40 in the proposed rule preamble provides an overview of the application and CMS’ preliminary assessment.

Eligibility criteria at §419.66(b). CMS does not express concerns about whether the device meets the newness or eligibility criteria.

Device category eligibility criterion at §419.66(c). CMS does not express concerns related to the device category eligibility criterion at §419.66(c)(1). CMS raises several concerns related to the substantial clinical improvement criterion at §419.66(c)(2), including the following:

- Concerns related to the single published study submitted (Burgess et al. (2024)),¹⁰ specifically:
 - The study may limit generalizability of results to the Medicare population.
 - What extent any improvement in cumulative patency is due to use of the EndoForce™ Connector versus the less invasive endovascular procedure used for implantation.
 - Validity of comparisons between Burgess study patient population, vascular location, and outcomes to those in the submitted unpublished studies.

¹⁰ Burgess, J. S., Beaver, J. D., London, M., Rohan, V., Orland, P., Yevzlin, A., Setum, C., Ross, J., & InterGraft Study Investigators. (2024). Prospective multicenter study of a novel endovascular venous anastomotic procedure and device for implantation of an arteriovenous graft for hemodialysis. The Journal of Vascular Access, 25(4), 1244–1251. <https://doi.org/10.1177/11297298231159691>.

- Concerns related to the claim that the EndoForce™ System improves patency and reduces AVG abandonment.
- Concerns related to the claim that the EndoForce™ System sustains patency and requires fewer interventions to maintain patency.
- CMS questions whether Kramer et al. (n.d.)¹¹ conclusively demonstrates that the EndoForce™ System provides a substantial clinical improvement compared to other available treatments. CMS questions comparisons made between this study and other studies submitted.
- CMS questions whether the EndoForce™ System improves cumulative (secondary) patency compared to mature AV fistulas (AVFs), and existing devices used for AVF creation, including WaveLinQ™, and Ellipsys™.

Cost criterion at §419.66(d). CMS does not express concerns related to the cost criterion; however, CMS seeks public comment on this issue.

In summary, CMS is unable to determine that the EndoForce™ System meets the new device category eligibility criteria, and therefore proposes to deny transitional pass-through payment status for CY 2027.

(b) LINK™ External Fixator

The LINK™ External Fixator is a dynamic percutaneous bone external fixator that provides continuous compression during the healing of bony fractures, fusions, and osteotomies. Table 41 in the proposed rule preamble provides an overview of the application and CMS' preliminary assessment.

Eligibility criteria at §419.66(b). CMS expresses concerns regarding whether the LINK™ External Fixator meets the eligibility criterion at §419.66(b)(3). For reasons described more fully in the preamble, CMS believes the LINK™ External Fixator components may not be integral to the service furnished, come in contact with human tissue, or be surgically inserted or implanted.

Regarding the eligibility criterion at §419.66(b)(4), CMS questions whether the LINK™ Bone Pins could be considered a supply furnished incident to a service. Specifically, CMS is unclear if the LINK™ Bone Pins (or other bone fixation pins or wires) are placed through a previously created surgical opening or if they are directly inserted through skin and soft tissue to access bone; items used to create incisions are considered by CMS to be supplies. CMS also questions whether the LINK™ Bone Pins may be replaced with other commercially available bone fixation pins or wires.

Device category eligibility criterion at §419.66(c). Regarding §419.66(c)(1), CMS believes that the pass-through payment category C1713 may appropriately describe the LINK™ External Fixator because C1713 describes implantable pins and/or screws inserted or drilled into bone, principally with the intent to facilitate stabilization or oppose bone-to-bone contact, which is consistent with the LINK™ External Fixator description.

¹¹ Kramer, A., Moorthi, K., Grant, L., Litchfield, T. (Pre-publication). Extended Follow-Up of an Endovascular Venous Anastomotic Connector for Arteriovenous Graft Creation in Hemodialysis: A Multicenter Study.

Regarding the substantial clinical improvement criterion at §419.66(c)(2), CMS outlines a number of concerns. Specifically, CMS is concerned that the applicant did not (1) clearly identify the patient population that is unresponsive to, or ineligible for, currently available treatments that can only be treated with the LINK™ External Fixator and provide corresponding supporting evidence; (2) provide sufficient evidence of the LINK™ External Fixator's effect on recovery time, adverse events, pain, or any other clinical outcomes; or (3) submit evidence that the LINK™ External Fixator substantially improves the diagnosis or treatment of an illness when compared to other available treatments.

Cost criterion at §419.66(d). CMS does not express concerns about whether the LINK™ External Fixator meets the cost criterion.

In summary, CMS is unable to determine that the LINK™ External Fixator meets the new device category eligibility criteria, and therefore proposes to deny transitional pass-through payment status for CY 2027.

(c) Santreva™-ATK Endovascular Revascularization Catheter

The Santreva™-ATK Catheter is an energy and wire-free platform for simultaneous intraplaque crossing and revascularization of complex occlusive peripheral artery disease, intended for facilitating intraluminal placement of guidewires beyond stenotic lesions. Table 42 in the proposed rule preamble provides an overview of the application and CMS' preliminary assessment.

Eligibility criteria at §419.66(b). CMS does not express concerns about whether the device meets the newness or eligibility criteria.

Device category eligibility criterion at §419.66(c). Under §419.66(c)(1), CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect. CMS believes the pass-through payment category C1887 may describe the Santreva™-ATK Catheter because the pass-through payment category includes guiding catheters and the Santreva™-ATK Catheter's primary function of crossing peripheral stenotic lesions to establish a revascularization pathway appears to be the same function performed by device described in C1887.

Regarding the substantial clinical improvement criterion at §419.66(c)(2), after reviewing the information provided by the applicant, CMS raises several concerns regarding whether the Santreva™-ATK Catheter meets the substantial clinical improvement criterion and the application materials submitted, including:

- CMS does not believe that the single Banerjee et al. (2026) study¹² submitted directly supports claims of improved mechanism compared to other existing devices or

¹² Banerjee, S., Metzger, C., Thatipelli, M., Ramaiah, V. G., Sayfo, S., Das, T., Tsai, S., Hyder, O., Shamma, N. W., Bunte, M., Nseir, G., Thomas, A., Beasley, R., Bosarge, C., Gagne, P., Kwolek, C., Rao, S., Novak, S., Pershad, A., Walker, C., & Soukas, P. (2026). Safety and effectiveness of the Santreva™-ATK endovascular revascularization catheter in the RESTOR-1 peripheral CTO crossing pivotal study. The American Journal of

techniques that facilitate wire crossing and questions whether the results of the study are generalizable to the Medicare population. Specifically, CMS expresses concerns related to: (1) small sample size, (2) lack of comparator group, (3) short follow up period, and (4) focus on safety and effectiveness without isolating the contribution of simultaneous crossing from that of revascularization to patient outcomes.

- CMS believes that the Santreva™-ATK Catheter may not demonstrate that it substantially improves the diagnosis or treatment of an illness when compared to other available treatments, given the availability of other currently available treatments, including the Crosser™ Catheter S6 and the Viance™ Crossing Catheter.
- Comparator tables submitted do not identify the specific studies or datasets from which the comparator values originated, which are necessary for CMS' evaluation.
- Lack of sufficient supporting evidence for the claim that the Santreva™-ATK Catheter is a substantial clinical improvement over current crossing devices and algorithms.
- Lack of sufficient supporting evidence that the Santreva™-ATK Catheter substantially improves the clinical condition and quality of life of patients. CMS expresses interest in receiving additional information to determine whether the Santreva™-ATK Catheter independently contributes to downstream, patient-level clinical outcomes independent of the overall revascularization procedure.
- Regarding the claim that the Santreva™-ATK Catheter offers a substantial improvement for physicians in day-to-day clinical practice, CMS notes that this is a matter of physician workflow rather than measurable clinical outcomes for patients. CMS requests clarification on how the evidence provided directly relates to the applicant's claims of improved clinical outcomes.
- Supplemental materials provided were not linked to specific claims of substantial clinical improvement, and CMS was therefore unable to evaluate that content under the substantial clinical improvement criteria.

Cost criterion at §419.66(d). CMS does not express concerns related to whether the Santreva™-ATK Catheter meets the cost criterion at §419.66(d)(3); however, the agency seeks public comment on this issue.

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

B. Device-Intensive Procedures

1. Background

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

Cardiology. Advance online publication. <https://doi.org/10.1016/j.amjcard.2026.01.007>.

intensive status regardless of their APC assignment, rather than at the APC-level as it did prior to 2017.

2. Proposed Device-Intensive Procedure Policy

Beginning in 2019, device-intensive procedures are subject to the following criteria:

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

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

- Has received FDA marketing authorization, has received an FDA IDE and has been classified as a Category B device by the FDA in accordance with 42 CFR 405.203 – 405.207 and 405.211 – 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not any of the following:
 - Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or
 - A material or supply furnished incident to a service (e.g., a suture, customized surgical kit, or a clip, other than a radiological site marker).

Beginning in 2025, for new CPT/HCPCS codes that both describe a procedure that requires the surgical implantation or insertion of a single-use device that exceeds 30 percent of the procedure's cost and lack claims data (from either the new HCPCS code or any predecessor code or clinically-similar code that uses the same device), CMS applies a default device offset percentage that is the greater of 31 percent or the device offset percentage of the APC to which the procedure has been assigned. This policy applies for both the OPPS and ASC Payment System and applies to new procedures assigned to clinical APCs, but not to new procedures assigned to New Technology APCs.

Additionally, for procedures subject to CMS' device edits policy that cannot report modifier "CG" to bypass the claims processing edit, the device offset percentages calculated (for the CPT/HCPCS code or its predecessor code) are based on hospital claims that reported a device code. For purposes of determining device offset percentages, CMS will not use claims data from procedures that have a status indicator of "E1" during the calendar year CMS is using for ratesetting and determining device offset percentages. Lastly, CMS uses available claims data

from predecessor codes annually until the agency has available claims data from the successor code.

CMS proposes to continue these policies for CY 2027. Additional information for CMS' consideration of an offset percentage higher than the default of 31 percent (or the APC-wide default offset percentage) for new HCPCS codes describing procedures requiring the implantation (or, in some cases, the insertion) of a device that do not yet have associated claims data, such as pricing data or invoices from a device manufacturer, should be submitted to the Division of Outpatient Care electronically at outpatientpps@cms.hhs.gov. Such additional information can be submitted prior to issuance of an OPPTS/ASC proposed rule or as a public comment in response to an issued OPPTS/ASC proposed rule. Device offset percentages will be set in each year's final rule.

The full listing of the proposed CY 2027 device-intensive procedures can be found in Addendum P. Further, CMS' claims accounting narrative, which contains a description of the agency's device offset percentage calculation, can be found under supporting documentation for the CY 2027 OPPTS/ASC proposed rule 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 of its device edit policy. Beginning in 2025, CMS applies its device edits policy permanently once a procedure is designated as a device-intensive procedure in a given year. CMS is not proposing any changes to its device edit policy for 2027.

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

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

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 OPPTS payment rate for the associated procedure or service.

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

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

Other drugs are threshold packaged meaning that their per day costs must exceed a fixed threshold (proposed \$140 for drugs and biologicals other than radiopharmaceuticals and \$665 for diagnostic radiopharmaceuticals in 2027) to be paid separately. For a separately payable drug that exceeds the packaging threshold, CMS will make payment at average sales price (ASP)+6 percent (unless ASP is unavailable as explained below).

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

A. Transitional Pass-Through Payment

Section 1833(t)(6) of the Act provides for temporary additional payments or transitional pass-through payments for certain drugs and biologicals. For transitional pass-through payment purposes, radiopharmaceuticals are “drugs.” As required by statute, transitional pass-through payments for a drug or biological can be made for at least 2 years, but not more than 3 years, after payment was first made under the OPPS. Transitional pass-through drugs and biologicals for 2027 and their designated APCs are assigned status indicator “G” in Addenda A and B of the proposed rule. For 2027, CMS is continuing to use ASP+6 percent as payment for transitional pass-through drugs and biologicals. CMS will be paying for diagnostic and therapeutic radiopharmaceuticals receiving transitional pass-through payment at 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 43 of the proposed rule lists 49 drugs and biologicals where CMS will be expiring transitional pass-through payment by the end of 2026. Each of the products will have received the full 3 years of transitional pass-through payments once the additional payments expire. Table 44 of the proposed rule lists 28 drugs where CMS will end transitional pass-through payment status in 2027. Table 45 of the proposed rule lists 45 drugs and biologicals where CMS will continue transitional pass-through payment for all of 2027.

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

separately payable drug paid on transitional pass-through as there is no payment included in the APC for the drug.

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

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

a. Cost Threshold for Packaging of “Threshold-Packaged Drugs”

For 2027, CMS proposes to maintain a packaging threshold of \$140 for drugs, biologicals, and therapeutic radiopharmaceuticals that are not new and do not have pass-through status. Prior to 2025, diagnostic radiopharmaceuticals were policy-packaged and not paid separately except when receiving transitional pass-through payments. Beginning with 2025, CMS is packaging diagnostic radiopharmaceuticals with per-day costs equal to or below the packaging threshold and paying separately for diagnostic radiopharmaceuticals above the packaging threshold initially set at \$630. For 2027, CMS proposes to establish a packaging threshold of \$665 for diagnostic radiopharmaceuticals.

The packaging threshold was initially set at \$50 in 2005 for drugs, biologicals and therapeutic radiopharmaceuticals. To calculate the 2027 threshold, CMS used the most recently available four quarter moving average Producer Price Index forecast levels for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) to trend the \$50 threshold forward from the third quarter of 2005 to the third quarter of 2027. CMS rounds the resulting amount (\$142.40) 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 2027, CMS determine a threshold of \$667.44 round to the nearest \$5 increment (\$665).

CMS proposes to continue using the following process to determine the 2027 packaging status for all non-transitional pass-through drugs, biologicals and therapeutic radiopharmaceuticals that are not policy packaged (except for those drugs and biologicals with multiple HCPCS codes that include different dosages as described below). Using 2025 claims data processed through December 31, 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 2025 and were paid (either as packaged or separate payment) under the OPPS.

To calculate the per-day cost for the proposed rule, CMS used ASP+6 percent for each HCPCS code with manufacturer-submitted ASP data from the 4th quarter of 2025 (data that was used to pay for drugs and biologicals in physicians’ offices effective April 1, 2026). For products that do not have an ASP, other than diagnostic and therapeutic radiopharmaceuticals, CMS uses wholesale acquisition cost (WAC) or average wholesale price (AWP) pricing to determine the per-day cost. If neither of these is available, CMS uses mean unit cost derived from 2025 hospital claims data.

For diagnostic and therapeutic radiopharmaceuticals that do not have pass-through status as of April 1, 2026, CMS is using mean unit cost derived from the 2025 hospital claims data to

determine their per-day cost. CMS does not use an ASP-based, WAC-based, or AWP-based payment rate for those items unless there is no mean unit cost reported for the product.

CMS proposes to package payment for products with a per-day cost of \$140 or less (\$665 or less for diagnostic radiopharmaceuticals) and pay separately for items with a per-day cost greater than \$140 (\$665 for diagnostic radiopharmaceuticals) in 2027.

CMS uses quarterly ASP updates as follows:

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

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

As in past years, CMS proposes to apply the following policies to determine the 2027 packaging status of a threshold-packaged drug when the drug's packaging status, as calculated for the final rule using more current data, differs from its status in the proposed rule.

- HCPCS codes that are separately payable in 2026 and were proposed for separate payment in 2027 are separately payable in 2027 even if the updated data used for the 2027 final rule indicates per-day costs equal to or less than the \$140 threshold (\$665 for diagnostic radiopharmaceuticals).
- HCPCS codes that are packaged in 2026, proposed for separate payment in 2027, and have per-day costs equal to or less than \$140 (\$665 for diagnostic radiopharmaceuticals) based on the updated data used for the 2027 final rule are packaged in 2027.
- HCPCS codes for which CMS proposed packaged payment in 2027 and have per-day costs greater than \$140 (\$665 for diagnostic radiopharmaceuticals) based on the updated data used for the 2027 final rule are separately payable in 2027.

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

For 2027, CMS proposes 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 46 of the proposed rule.

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

a. Payment for Separately Payable Drugs and Biologicals

As indicated above, CMS proposes to pay for separately payable drugs and biologicals at ASP+6 percent in 2027. Consistent with policy in the PFS, CMS will pay for drugs and biologicals under the OPPS during an initial sales period (2 quarters) for which ASP pricing data are not yet available from the manufacturer at WAC+3 percent. The WAC+3 percent payment under the OPPS will only apply to new drugs and biologicals in an initial sales period. Other drugs and biologicals where ASP data are not available will continue to be paid at WAC+6 percent as required by statute. If ASP and WAC are unavailable, Medicare will pay 95 percent of AWP.

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

The payment rates shown for drugs and biologicals in Addenda A and B of the proposed rule are not the payment rates that Medicare will pay beginning on January 1, 2027. Payment rates effective January 2027 will be released near the end of December 2026 and will be based on ASP data submitted by manufacturers for the third quarter of 2026 (July 1, 2026, through September 30, 2026), or WAC+3 percent or 95 percent of AWP if ASP is unavailable. These will be the same payment rates that are used to pay for drugs and biologicals in a physician's office effective January 1, 2027.

Payment rates for drugs and biologicals in Addenda A and B of the proposed rule for which there was no ASP information available for the 4th quarter of 2025 (used for payment in physicians' offices for the 2nd quarter of 2026) are based on WAC, AWP or mean unit cost in the available 2025 claims data. If ASP information becomes available for the 3rd quarter of 2026 (used for payment in physicians' offices for the 1st quarter of 2027), CMS will pay for these drugs and biologicals based on the newly available ASP information. For diagnostic radiopharmaceuticals with a per-day cost over \$665, the rates in Addenda A and B are based on mean unit cost in the 2025 data.

b. Biosimilar Biological Products

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

a biosimilar when its per-day cost is below the packaging threshold if its reference product is paid separately.

Section 1847A(b)(8)(B) of the Act provides for a temporary payment increase for qualifying biosimilars. Qualifying biosimilars are those with an ASP that is less than the ASP of their reference product. These biosimilars will be paid at their own ASP plus 8 percent of the reference product ASP for a 5-year period.

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

c. Invoice Drug Pricing for 2027

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

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

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

3. Payment Policy for Radiopharmaceuticals

a. Therapeutic Radiopharmaceuticals.

For 2027, CMS proposes to continue paying for therapeutic radiopharmaceuticals at ASP+6 percent. For therapeutic radiopharmaceuticals for which ASP data are unavailable, CMS will continue its past policy of determining 2027 payment rates based on 2025 geometric mean unit cost. CMS does not use WAC or AWP to price therapeutic radiopharmaceuticals.

b. Diagnostic Radiopharmaceuticals.

For 2027, CMS proposes to pay separately for diagnostic radiopharmaceuticals with a per-day cost above \$665. CMS is basing the payment rate for separately payable non-pass-through

diagnostic radiopharmaceuticals on mean unit cost data derived from hospital claims. CMS is considering pricing separately payable diagnostic radiopharmaceuticals using ASP in the future if valid ASP data is reported.

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

4. Payment for Blood Clotting Factors

CMS proposes to continue paying for blood clotting factors at ASP+6 percent and proposes to update the \$0.265 per unit furnishing fee from 2026 by the Consumer Price Index for medical care for 2027. 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>.

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

CMS proposes to continue the same payment policy in 2027 as in earlier years for non-pass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPI hospital claims data. Because CMS has no claims data and must determine if these products exceed the per-day cost threshold, it estimates the average number of units of each product that would typically be furnished to a patient during one day in the hospital outpatient setting. CMS applies ASP+6 percent (or WAC or AWP as applicable) to determine their payment status indicators.

6. 340B Acquired Drugs Recoupment Adjustment

a. Background and History

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

- Beginning in 2018, CMS adopted a policy to pay for drugs acquired under the 340B program at ASP-22.5 percent to approximate a minimum average discount for 340B drugs based on findings of the Government Accountability Office and the Medicare Payment Advisory Commission (MedPAC) that hospitals acquire drugs at a significant discount under the 340B program. CMS made the reduction in payment for drugs acquired under the 340B program budget neutral by increasing payments for non-drug OPPI services by 3.19 percent or approximately \$1.6 billion. This adjustment remained on the rates paid for non-drug OPPI services through September 27, 2022 and was not updated for changes to utilization of 340B drugs.
- On December 27, 2018, the U.S. District Court for the District Court of Columbia concluded that the Secretary lacked authority to bring the default rate in line with

average acquisition cost.¹³ While the initial decision applied only to CMS' 2018 policy, the District Court later made the same finding for CMS' 2019 policy.¹⁴ 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.¹⁵
- On September 28, 2022, the District Court vacated CMS' 340B reimbursement rate for the remainder of 2022 without requiring any offset for budget neutrality.¹⁶ In response to this order, CMS changed its payment systems to make payment at ASP+6 percent for claims received shortly after the District Court's order with a date of service after September 27, 2022. Some of CMS' contractors allowed for reprocessing of *all* 2022 claims at the revised ASP+6 percent rate.
- On January 10, 2023, the District Court issued a remand to CMS giving it the opportunity to determine the proper remedy for the reduced payment amounts to 340B hospitals under the payment rates in the final OPPS rules for 2018 through 2022.¹⁷

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.¹⁸

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 for 340B acquired drugs, it was a lesser amount because CMS did not update the budget neutrality adjustment after 2018 for increases in the utilization of 340B acquired drugs despite repeated public comments asking 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 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 rule¹⁹ 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

¹³ American Hospital Association v. Azar, 348 F. Supp. 3d 62 (D.D.C. 2018)

¹⁴ Am. Hosp. Ass'n v. Azar, 385 F. Supp. 3d 1 (D.D.C. 2019)

¹⁵ 142 S. Ct. 1896 (2022)

¹⁶ See Am. Hosp. Ass'n v. Becerra, 18-cv-2084 (RC), 2022 WL 4534617

¹⁷ Am. Hospital Ass'n v. Becerra, 18-cv-2084 (RC), 2023 WL 143337

¹⁸ See 87 FR 71975. The original adjustment multiplied the OPPS conversion factor by 1.0319 (3.19 percent). Reversing the adjustment requires dividing the OPPS conversion factor by 1.0319 or 1/1.0319 or 0.9691 which equals a reduction of 3.09 percent.

¹⁹ 88 FR 77150

occurred for services furnished between January 1, 2022, through September 27, 2022. These one-time lump sum payments were issued in early 2024.

- Provide the repayment amount to hospitals inclusive of any additional beneficiary coinsurance and not allowing hospitals to collect additional coinsurance.
- Maintain budget neutrality for these additional payments to 340B hospitals through a -0.5 percentage point adjustment to the annual OPPS payment rate update that applies to non-drug 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 that began in 2026.

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

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

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

b. 2027 Prospective Adjustment

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

- The timeframe for recouping the additional 340B payments will be more closely aligned to the period during which these payments were made.

- A 3 percentage point payment reduction is the most logical and appropriate percentage to apply as it closely approximates the 3.19 percent payment increase hospitals received for non-drug items and services from 2018 through 2022.
- Hospitals were on notice in the 2026 OPPS rule that CMS planned to increase the reduction to the update from 0.5 percentage points to a higher amount beginning in 2027.

CMS presents its proposed 3 percentage points reduction to the update relative to an alternative 2 percentage points reduction in table 48 reproduced below. The proposed 3.0 percentage points reduction would fulfill CMS’ goal of recouping the additional \$7.769 billion over three years rather than five years as would occur with a 2 percentage points reduction.

Table 48: Illustration of Alternative Recoupment Reductions

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

7. 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.²⁰ For 2026, the AIR is \$733 for the lower 48 states and \$1,233 for Alaska. The AIR is intended to cover the cost of hospital outpatient services, including drugs and biologicals that are separately paid under the OPPS.

²⁰ 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.

In the 2025 OPPS/ASC final rule, CMS adopted a policy to separately pay IHS and tribal facilities for drugs furnished in hospital outpatient departments with per day costs that exceed twice the AIR in the lower 48 states. CMS follows its existing methodology to calculate per-day costs for OPPS drugs to determine whether a drug's cost is above the IHS/Tribal facility packaging threshold.

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

C. Payment for 340B Purchased Drugs

1. Background and History

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

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

2. Drug Acquisition Cost Survey Design and Implementation

CMS identified approximately 4,500 entities for inclusion in the survey study population. The survey collected acquisition cost data for separately payable outpatient drugs for 1,843 National Drug Code (NDCs), which correspond to 519 drug HCPCS codes. The survey captured acquisition data for drugs purchased between July 1, 2024 and June 30, 2025. The 6 month lag between June 30, 2025 and the beginning of the survey period on January 1, 2026 allowed adequate time for all rebates, discounts, and price concessions to be incorporated into the NDC acquisition cost submitted by hospitals. The survey period closed on April 7, 2026.

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

3. Data Analysis and Methodology

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

these two values, termed the acquisition cost margin.

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

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

In addition to eliminating potential outliers, CMS eliminated data:

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

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

4. Survey Results

Approximately 41.4 percent of the 4,494 entities eligible for OPPS payment responded to the survey and reported they had acquisition costs during the survey period that included 53.3 percent of non-340B hospitals and approximately 28.6 percent of 340B hospitals. Compared to the overall survey-eligible population, hospitals that responded to the survey and reported acquisition cost data were slightly more likely to have lower claims billing volume, be smaller, in a rural area, and not major teaching hospitals.

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

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

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

CMS undertook various statistical methodologies demonstrating the response rate was sufficient to be statistically valid and respondents' data yielded statistically representative estimates of hospital outpatient drug acquisition costs. These methodologies are described with some degree of detail in the proposed rule and in complete detail in the *2026 Outpatient Prospective Payment System Drug Acquisition Cost Survey Technical Report* to be posted on the CMS OPPS website: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/outpatient-prospective-payment-system-opps-drug-acquisition-cost-survey>.

5. Proposal

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

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

For 340B acquired drugs that do not have an ASP, CMS is establishing a parallel policy as all other drugs that do not have an ASP pricing them using WAC minus 33.4 percent and 59.69²¹ percent of AWP if WAC is unavailable. For 340B drugs paid based on MUC, CMS proposes to continue payment based on 100 percent of MUC that will already reflect any 340B discounts.

The proposed payment policy would not apply to vaccines, drugs with transitional pass-through payment status, and non-opioid pain management drugs. CMS may continue to validate the results of this survey on a periodic basis; for example, perhaps as often as every 4 years.

²¹ This percent was calculated by first reducing the original 95 percent of AWP price by 6 percent to generate a value that is similar to WAC with no percentage markup. Then CMS applied the 33.4 percent reduction WAC-similar AWP value to obtain the 59.69 percent of AWP.

6. Beneficiary Coinsurance

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

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

7. Exemptions

CMS proposes to exempt children’s hospitals and PPS-exempt cancer hospitals from the proposed policy to adjust OPPI payments for drugs acquired under the 340B Program. As these hospitals are held harmless under the OPPI to their “pre-BBA” payments and receive hold harmless payments known as “transitional outpatient payments” (TOPS), the reduction in payment for 340B acquired drugs would be replaced by TOPS. CMS is also proposing to exempt rural SCHs from the policy to recognize unique needs and financial challenges these hospitals face.

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

Non-excepted off campus provider-based departments are those hospital outpatient departments that are off the campus of the main hospital and have opened since November 2, 2015. These departments are not paid under the OPPI and are paid at 40 percent of the OPPI and based on ASP+6 percent for drugs (or WAC+6 percent or 95 percent of where ASP is unavailable).

While the statutory authority for CMS 340B policy applies to the OPPI, CMS indicates that it has broad authority for setting payment rates in non-excepted off-campus provider-based departments under section 1833(t)(21) of the Act. To avoid perverse incentives that would result from paying non-excepted off-campus provider based departments more for 340B acquired drugs than other hospital outpatient services, CMS proposes to pay ASP-33.4 percent, or equivalent, for drugs, biologicals, biosimilars, and radiopharmaceuticals acquired under the 340B Program in these sites.

As non-excepted off campus provider-based departments are not paid under the OPPI, this proposal would not be subject to the OPPI budget neutrality requirements. CMS estimates that this aspect of its proposal would result in savings of approximately \$735 million to the Medicare Part B Trust Fund and would collectively reduce beneficiary copayments by an estimated \$185 million.

9. Billing Modifiers

Consistent with its prior and current policy regarding billing for 340B acquired drugs, CMS will require hospitals subject to the 340B payment policy to use the JG modifier to indicate the drug was acquired under the 340B program and is subject to a payment of ASP-33.4 percent. For providers and drugs exempted from the 340B payment policy but acquired under the 340B program, hospitals are required to use the TB modifier. Beginning January 1, 2027, CMS proposes to require a new modifier to be specified (placeholder modifier “XX” - Drug or biological not acquired under the 340B Drug Pricing Program) to be reported on a claim for all separately payable drugs that were purchased outside of the 340B Program.

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

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

10. Budget Neutrality

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

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

D. Payment for Skin Substitutes

In the 2026 OPSS rule, CMS finalized a policy to separately pay for skin substitute products as incident-to supplies in the physician office, hospital outpatient, and ambulatory surgical center settings effective January 1, 2026 (90 FR 53729 through 53748). CMS assigned sheet-form skin substitute products to one of three clinical APCs based on their FDA regulatory category: APC 6000 (PMA Skin Substitute Products), APC 6001 (510(k) Skin Substitute Products), and APC 6002 (361 HCT/P Skin Substitute Products).

CMS set an initial payment rate of \$127.14/cm² for all three APCs and said it intended to update payment rates for each category based on the ASP or MUC if ASP is unavailable. However, as

skin substitutes would no longer be paid as a drug biological, manufacturers of skin substitutes are no longer required to report ASP effective January 1, 2026.

The proposed rule indicates that CMS does not have sufficient data upon which to propose a revised payment rate for all three skin substitute product APCs. Further, CMS would like more utilization data to evaluate use patterns reflecting the 2026 policy changes before making additional pricing changes for skin substitutes. For this reason, CMS is proposing to maintain a payment rate of \$127.14/cm² for all three skin substitute APCs.

VI. Estimate of Transitional Pass-Through Spending

CMS estimates 2027 proposed rule transitional pass-through payments of approximately \$195.3 million, or 0.18 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 \$183.1 million in 2026 for devices—\$177.6 million for those recently eligible for transitional pass-through payments that will continue for 2027 and \$5.6 million for those CMS knows or projects could be approved for 2027.

B. Drugs and Biologicals

CMS estimates transitional pass-through spending of \$12.2 million in 2027 for drugs and biologicals—\$2.2 million for those recently eligible for transitional pass-through payments that will continue for 2027 and \$10 million for those CMS knows or projects could be approved in 2027.

VII. Hospital Outpatient Visits and Critical Care Services

MS is not proposing for 2027 any changes to the current clinic and emergency department hospital outpatient visits payment policies or to the payment policy for critical care services when these services are provided on the campus of a hospital. The agency also is not proposing any changes to its policy for how it pays for clinic visits provided in off-campus provider-based departments. As discussed in section X.A., CMS points to its authority to control unnecessary increases in the volume of covered OPD services under section 1833(t)(2)(F) of the Act to expand its site neutral payment policy to imaging services without contrast furnished in an off-campus provider-based department.

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, 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 OPPTS/ASC final rule (87 FR 71995), CMS clarified that payment under the OPPTS for new HCPCS codes that designate non-PHP services provided for diagnosis, evaluation or treatment of a mental health disorder and furnished to beneficiaries in their homes by clinical staff of the hospital would not be recognized as PHP services. However, it noted that none of the PHP regulations would preclude a patient that is under a PHP plan of care from receiving other reasonable and medically necessary non-PHP services from a hospital.

In the 2024 OPPTS/ASC final rule (87 FR 71995), CMS established separate payment rates for PHP days with 3 services and days with 4 or more services, which resulted in four separate PHP APC per diem payment rates: one for CMHCs for 3-service days and another for CMHCs for 4-service days (APC 5853 and APC 5854, respectively), and one for hospital-based PHPs for 3-service days and another for hospital-based PHPs for 4-service days (APC 5863 and APC 5864, respectively). It also finalized a policy to use the separate CMHC rates for 3-service and 4-service PHP days as the Medicare Physician Fee Schedule (MPFS) rates, depending upon whether a nonexcepted off-campus hospital outpatient department furnishes 3 or 4 PHP services in a day. That final rule required a physician certification for PHP services to include a determination that the patient requires such services for a minimum of 20 hours per week, as required by section 1861(ff)(1) of the Act; that determination must be made at least monthly. CMS also finalized changes to align coding, billing, and payment between PHPs and intensive outpatient programs.

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

2. Intensive Outpatient Program Services

Section 4124(b) of the CAA, 2023 established Medicare coverage for intensive outpatient services effective for items and services furnished on or after January 1, 2024. CMS implemented this requirement in the 2024 OPPTS/ASC final rule. Thus, effective for items and

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

In the 2024 OPPS/ASC final rule, CMS established payment and program requirements for the IOP benefits furnished by a hospital to its outpatients, or by a CMHC, an FQHC, or an RHC.²² Additionally, it established Part B coverage for IOP services furnished by Opioid Treatment Programs (OTPs) for the treatment of opioid use disorder (OUD). Section 410.44 sets forth conditions and exclusions for intensive outpatient services, §410.111 establishes conditions for coverage of IOP services furnished in CMHCs, and §410.173 lists the conditions for payment for IOP services furnished in CMHCs. Of note, the outpatient mental health treatment limitation does not apply to IOP services.

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

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

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

B. Coding and Billing for PHP and IOP Services

Because the statutory definitions of both IOP and PHP generally include the same types of covered items and services, CMS aligns the programs using a consistent list of services; the only differentiating factor between partial hospitalization services and intensive outpatient services is the level of intensity. To differentiate between IOP and PHP for billing purposes, CMS requires hospitals and CMHCs to report condition code 92 on IOP claims; hospitals and CMHCs report condition code 41 on their PHP claims.

The Partial Hospitalization and Intensive Outpatient Primary list contains the HCPCS codes recognized under the PHP and IOP benefit categories that are used to determine the number of

²² The 2027 payment policies for IOP services furnished by FQHCs and RHCs are proposed in the 2027 Physician Fee Schedule proposed rule.

services per PHP or IOP day, which also determine the APC per diem payment amount for each day.²³ To qualify for payment for the PHP APC or the IOP APC, one service must be from this list. If CMS needs to add more codes to the list, it does so through sub-regulatory guidance. However, CMS goes through notice and comment ruling to add new items and services to the scope of partial hospitalization and intensive outpatient services under section 1861(ff)(2)(I) of the Act; it does not propose adding any new services in this rulemaking cycle.

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

C. Payment Rates for PHP and IOP

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

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

1. Background

In 2024, CMS established four separate PHP APC per diem payment rates and four separate IOP per diem payment rates as follows:

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

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

For hospital-based PHPs, CMS calculates payment rates using the broader OPPS data set instead of hospital-based PHP data only. The broader OPPS data set allows the agency to capture data

²³ 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>.

from claims not identified as PHP, but that include the service codes and intensity required for a PHP day. CMS considers all OPPS data for PHP days and non-PHP days that include 3 or more of the same service codes. Because CMS uses the broader OPPS data set, it does not apply PHP-specific trims and data exclusions; instead, it applies the same trims and data exclusions consistent with the OPPS.

CMS calculated the 2026 geometric mean per diem cost for CMHC PHP and IOP providers for the 2026 OPPS/ASC proposed rule using its previous methodology, which resulted in an inversion. The agency believed the inversion was due to the small number of CMHCs that bill Medicare for PHP and IOP services and to CMHCs with low costs that first began billing Medicare for services in 2024. As noted above, CMS changed its methodology for CMHCs to address the inversion and calculated the 2026 geometric mean per diem costs for those facilities based on 40 percent of the corresponding hospital-based PHP and IOP APCs. It believes that the use of the 40 percent MPFS Relativity Adjuster is generally appropriate for estimating CMHC costs and notes that using the adjuster aligns with the methodology applied to other nonexcepted OPPS services furnished by nonexcepted off-campus hospital outpatient departments.

2. 2027 Payment Rate Methodology for PHP and IOP

CMS proposes to use data from cost reports beginning three fiscal years before the year that is the subject of the rulemaking, as well as 2025 OPPS claims to update the payment rates for the four PHP APCs and the four IOP APCs finalized in the 2024 OPPS/ASC final rule. CMS proposes to calculate the PHP rates for CMHCs and hospital-based programs separately.

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

CMS notes that the typical PHP day is typically four services or more per day and that payment for days of 3 services is currently limited to extenuating circumstances, such as when the patient transitions to discharge. Even though it pays for days with three or fewer services to accommodate occasional instances when a patient is unable to complete a full day of PHP or IOP, CMS expects that days with fewer than three services would be “very infrequent” and will monitor claims accordingly.

The proposed 2027 geometric mean per diem costs and payment rates are as follows:

2027 APC	Group Title	Proposed PHP and IOP APC Geometric Mean Per Diem Costs*	Proposed Payment Rates**
5851	Intensive Outpatient (3 services per day) for CMHCs	\$130.63	\$139.81
5852	Intensive Outpatient (4 or more services per day) for CMHCs	\$173.78	\$185.98

2027 APC	Group Title	Proposed PHP and IOP APC Geometric Mean Per Diem Costs*	Proposed Payment Rates**
5853	Partial Hospitalization (3 services per day) for CMHCs	\$130.63	\$139.81
5854	Partial Hospitalization (4 or more services per day) for CMHCs	\$173.78	\$185.98
5861	Intensive Outpatient (3 services per day) for hospital-based IOPs	\$326.57	\$349.52
5862	Intensive Outpatient (4 or more services per day) for hospital-based IOPs	\$434.46	\$464.99
5863	Partial Hospitalization (3 per day) for hospital-based PHPs	\$326.57	\$349.52
5864	Partial Hospitalization (4 or more services per day) for hospital-based PHPs	\$434.46	\$464.99

* Table 57 of the proposed rule shows the proposed 2027 PHP and IOP APC geometric mean per diem costs.

** The 2027 proposed payment rates are from Addendum A to the proposed rule.

D. Outlier Policy for CMHCs

For 2027, CMS proposes to update the calculations of the CMHC outlier percentage, cutoff point and percentage payment amount, outlier reconciliation, outlier payment cap, and fixed-dollar threshold determined under established policies to include intensive outpatient services. No changes are proposed to any of the methodologies used for purposes of the outlier policy for CMHCs for 2027.

The methodology for calculating the CMHC outlier percentage was first established in the 2018 OPPTS/ASC final rule (82 FR 59267), and it will be applied to payments for IOP services as well as PHP services for 2027. CMS projects that CMHCs will receive 0.01 percent of total hospital outpatient payments in 2027 (excluding outlier payments), and it proposes to designate less than 0.01 percent of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHC outliers.

The cutoff point for outlier payments for CMHCs for 2027 would be set at 3.4 times the highest CMHC PHP APC payment rate, and CMS would pay CMHCs 50 percent of CMHC geometric mean per diem costs over that threshold. Specifically, CMS calculates a CMHC outlier payment equal to 50 percent of the difference between the CMHC's cost for the services and the product of 3.4 times the APC 5853 or 5854 payment rate. The same policies would apply to intensive outpatient services paid under the CMHC IOP APCs.

For 2027, CMS proposes to continue to use its established outlier reconciliation policy to address charging aberrations related to OPPTS outlier payments described in the 2023 OPPTS/APC final rule (83 FR 58874) and to extend it to intensive outpatient services. The policy requires outlier reconciliation for providers whose outlier payments meet a specified threshold (\$500,000 for hospitals and any outlier payments for CMHCs) and whose overall ancillary CCRs change by ± 10 percentage points or more, pending approval of the CMS Central Office and Regional Office.

In the 2017 OPPS/ASC final rule (81 FR 79692), CMS implemented an outlier payment cap of 8 percent; thus, an individual CMHC may not receive more than 8 percent of its total per diem payments in outlier payments. CMS proposes to continue this policy for 2027 and to apply it to both PHP and IOP; this only impacts CMHCs.

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

E. Regulatory Impact

CMS estimates that payments to 39 CMHCs for PHP services will increase by 8.1 percent in 2027 relative to their 2026 payments. The estimate is derived by combining the proposed OPD fee schedule increase factor, along with the proposed changes in APC policy for 2027, the proposed FY 2027 wage index updates, and the proposed 340B payment policy.

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).

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

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

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

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

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

CMS subsequently halted the phase-out of the IPO list in the November 16, 2021 CY 2022 OPPTS 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 CY 2025.

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

B. Proposed CY 2027 Changes to IPO List

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

would require a lengthier review process; nevertheless the agency signals that these services would be removed in CY 2028.

CMS does not discuss issues relating to assigning these services to APCs in this proposed rule's preamble. CMS simply notes that these services and their proposed status indicators and APC assignments (if applicable) are listed in the public use file titled "Proposed Procedures for Removal from the IPO List for CY 2027," available on the CMS website. The services proposed for removal from the IPO list for CY 2027 and their proposed status indicators and APC assignments (if applicable) are also included in Addendum B of this proposed rule. The complete list of services that would remain on the Inpatient Only List is included as Addendum E to this proposed rule.

In short, in this proposed rule, CMS proposes to eliminate 637 services from the clinical families listed above from the IPO list in CY 2027. In contrast to the 2026 rulemaking cycle, in which CMS solicited comment on its proposal to eliminate the IPO list and the corresponding criteria for adding to or subtracting from that list, CMS does not explicitly seek comments on its proposal to eliminate additional services in 2027.

X. Nonrecurring Policy Changes

A. Payment Reduction for Imaging without Contrast Services

1. Background

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

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)."²⁴

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

²⁴ 964 F.3d 1230, 1245 (D.C. Cir. 2020)

2. Expanding the “Method” to Other Services

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

That payment differential creates an incentive for providers to shift the care of beneficiaries to an OPD rather than a physician office or ASC, even if the services can be safely performed in the physician office or an ASC according to CMS. CMS has found correlation among the increasing volume of OPD clinic visits, vertical integration, and the higher OPPS payment rates for clinic visits.^{25, 26}

The impact of vertical integration and the increases in volume of outpatient services extends to multiple clinical families. Studies have shown that after vertical integration, the number of imaging tests performed in hospital sites of care increased while the number of procedures performed in nonhospital sites of care decreased.²⁷

3. Utilization of Imaging without Contrast Services

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

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

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

CMS indicates that 70 HCPCS codes account for over 95 percent of the volume of imaging without contrast services provided in excepted PBDs. From 2016 to 2025, the provision of these

²⁵ <https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0830>

²⁶ <https://onlinelibrary.wiley.com/doi/10.1111/1475-6773.13613>

²⁷ <https://pmc.ncbi.nlm.nih.gov/articles/PMC9924392/>

services grew over 38 percent. From 2016 to 2025, these increases in volume have resulted in a 33 percent increase in spending, corresponding to approximately \$126 million additional spending in 2025.

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

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

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

4. Payment for Imaging without Contrast Services at PBDs

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

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

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

5. Patient Severity and Cost of Care

Public comments on prior rules have indicated that the higher payments for services in hospital outpatient settings are justified by the level of care patients need, the higher costs of providing care in hospitals, and the costs of maintaining emergency care and standby capacity. CMS believes imaging without contrast services are generally low- to moderate-complexity diagnostic procedures, such as standard CT, MRI, ultrasound, radiography, and bone density testing, that do

not require the administration of contrast agents or the associated monitoring and infrastructure. These services can be safely and effectively furnished in multiple settings, including physician offices, without compromising quality or patient safety.

A 2023 literature review found no peer-reviewed evidence that shows differences in the quality of services delivered across hospital OPDs and physicians' offices.²⁸ Further, MedPAC found that, on average, while OPD patients have higher risk scores, the difference in patient severity between settings is small and not statistically significant as the services, like imaging without contrast, are generally of low complexity.²⁹

6. Impact of Unnecessary Increases in Volume on the OPPS

CMS' concern with unnecessary increases in the volume of imaging services without contrast is tied to the health and sustainability of the OPPS. The OPPS was originally designed to manage Medicare spending growth by replacing a cost-based system with a prospective payment system. Contrary to this purpose, OPPS has continued to be one of the fastest growing Medicare payment systems under Medicare Parts A and B.³⁰ CMS believes that paying for imaging services without contrast provided at excepted off-campus departments at a site-neutral rate would be an effective method to control the volume of these unnecessary services because the payment differential that is driving the site-of-service decision will be removed.

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

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

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

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

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

²⁸ [Search | Tobin Center for Economic Policy](#)

²⁹ https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch8_MedPAC_Report_To_Congress_SEC.pdf

³⁰ <https://www.govinfo.gov/content/pkg/FR-2018-11-21/pdf/2018-24243.pdf>

The proposed rule indicates that CMS will apply its proposal non-budget neutral reiterating legal arguments made in past rulemaking that the adjustment under section 1833(t)(2)(F) is not subject to budget neutrality. While budget neutrality applies to the entirety of section 1833(t)(2), CMS argues it only applies to “adjustments” not the volume control method under section 1833(t)(2)(F) which is a “method” and not an “adjustment.”³¹

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

8. Exemptions for Rural Sole Community Hospitals

In the 2023 OPPS final rule (87 FR 72047 through 72051), CMS exempted rural SCHs from its site-neutral policy on the basis that rural SCHs have historically received special payment treatment to account for their higher costs and exempted from the disproportionately harmful impact that payment reductions could have on them. For rural SCHs, CMS indicates that many rural providers, and rural SCHs in particular, are often the only source of care in their communities,³² which means beneficiaries and providers are not choosing between a higher paying off-campus PBD of a hospital and a lower paying physicians’ office setting. For this reason, CMS is proposing to exempt imaging services without contrast from site-neutral payment at rural SCHs.

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

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

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

CMS has had challenges with pricing SaMS services under Medicare Part B. Current Medicare Part B payment systems for SaMS, including in the OPPS, are primarily designed to pay for services that rely on material resources, rather than technologies whose value is driven by proprietary algorithms and scalable, non-material costs. To address this issue, CMS proposes to

³¹ To determine the OPPS payment under section 1833(t)(2)(F), CMS multiplies the full OPPS payment by the PFS relativity adjustor. Therefore, CMS is arguing that the result of applying an adjustor is not an “adjustment.”

Nevertheless, the budget neutrality issue was adjudicated *American Hospital Assoc. v. Azar* and CMS’ policy was upheld by the courts irrespective of whether the reduction in payment is considered a “method” or an “adjustment.”

³² https://www.shepscenter.unc.edu/wp-content/uploads/dlm_uploads/2017/11/SCHs_Differences_in_Community_Characteristics.pdf

reassign 36 HCPCS codes designated as SaMS services that are currently separately paid to new technology APCs that closely align with their current 2026 payment rates.

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

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

2. SaMS Analyses Performed on Laboratory Tests

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

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

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

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

CMS believes SaMS analyses performed on laboratory tests are substantively similar to other SaMS technologies that are currently paid under the OPPS like algorithmic analysis of an

imaging test. For 2027, CMS proposes to assign 10 HCPCS codes describing various SaMS analysis performed on laboratory tests to new technology APCs under the OPPTS. CMS will use the latest available CLFS data to crosswalk to new technology APCs with payment rates that closely approximate the current 2026 CLFS payment rates. These codes will be assigned to new technology APCs with the newly proposed status indicator “O1” (Software as a Medical Service, Paid under OPPTS; separate APC payment) for 2027.

Table 62 shows the list of SaMS analyses affected by this policy and their proposed APC assignments. If there were no laboratory methods included in the code descriptor, and only an algorithmic analysis was described, CMS identified the code as a SaMS laboratory analysis. The proposed policy will also be applied to any new SaMS analyses performed on laboratory test codes. Based on public comment, CMS may apply the proposed policy to additional codes in the final rule.

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

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

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

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

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

Section 6211 of the Consolidated Appropriations Act, 2026 authorized Medicare payment under the OPPTS for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation to hospital outpatients in their homes via audio and video real-time communications technology (excluding audio-only) through December 31, 2027. The law allowed CMS to implement this provision via sub-regulatory guidance which can be found at:

<https://www.cms.gov/medicare/coverage/telehealth>. CMS is using this OPPTS rule to inform readers of this new policy.

XI. OPPS Payment Status and Comment Indicators

A. 2027 OPPS Payment Status Indicator Definitions

Each status indicator will identify whether a given code is payable under the OPPS or another payment system, and the OPPS policies that apply to the code.

For 2027, CMS proposes two status indicator changes:

Proposed Status Indicator	Proposed Descriptor	Proposed OPPS Payment Status
O1	Software as a Medical Service, paid under OPPS; separate APC payment.	Paid under OPPS; separate APC payment.
E2	Items and Services: For which pricing information and claims data are not available.	Not paid by Medicare when submitted on outpatient claims (any outpatient bill type). Exception: claims under drug invoice pricing policy are contractor priced.

CMS proposes new status indicator O1 for software as a medical service that is paid separately under the OPPS. CMS proposes to revise the definition of status indicator “E2” to comply with the drug invoice policy. The complete list of 2026 payment status indicators and their definitions are in Addendum D1 of the proposed rule.

B. 2027 Comment Indicator Definitions

For 2027, CMS proposes to continue to use the following comment indicators that are unchanged from 2026:

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

XII. Medicare Payment Advisory Commission (MedPAC) Recommendations

OPPS Payment Rates Update: In its March 2026 “Report to Congress: Medicare Payment Policy,” MedPAC recommended that Congress update Medicare OPPS payment rates in 2026 by

the amount specified in current law. CMS indicated that it appreciates MedPAC’s recommendation and, as discussed further in section II.B. of this proposed rule, it proposed to increase the OPPS payment rates by the amount specified in current law. Not stated, CMS further proposes to apply a reduction to the update of 3.0 percentage points for the 340B recoupment adjustment to the otherwise applicable OPPS update.

Medicare Safety Net Index: In its March 2026 “Report to Congress: Medicare Payment Policy,” MedPAC stated that its recommended update to IPPS and OPPS payment rates of current law plus 1.0 percent may not be sufficient to ensure the financial viability of some Medicare safety-net hospitals with a poor payer mix. MedPAC recommended that Congress should begin a transition to redistribute disproportionate share hospital and uncompensated care payments through a new Medicare Safety-Net Index (MSNI). Additionally, MedPAC recommended that Congress add \$1 billion to the MSNI pool of funds to help maintain the financial viability of Medicare safety-net hospitals and recommended to the Congress transitional approaches for an MSNI policy.

Any CMS action on this recommendation would require legislation. CMS indicates that the agency looks forward to working with Congress on these matters were it to explore adopting the MSNI proposal.

XIII. Ambulatory Surgical Center (ASC) Payment System

Summary of Selected Key Elements of ASC Payment Rates for 2027		
	ASCs reporting quality data	ASCs not reporting quality data
2026 ASC Conversion Factor	\$56.322	
Wage index budget neutrality adjustment	1.0016	
2027 Update		
Hospital market basket update	3.2%	
Productivity adjustment	-0.8%	
Net MFP adjusted update	2.4%	
Penalty for not reporting quality data	0.0%	-2.0%
Net MFP and quality adjusted update	2.4%	0.4%
2027 Proposed ASC Conversion Factor	\$57.766	\$56.638

The ASC update is based on the proposed 2027 IPPS hospital market basket (3.2 percent), reduced by the multifactor productivity adjustment (-0.8 percentage points), and is estimated to be 2.4 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, require an overnight stay or active medical monitoring and care at midnight following the procedure. Payment for ancillary items and services (with some exceptions) are packaged into the ASC payment. The OPPS relative payment weights and, in some cases, payment rates are used as the basis for the payment of many covered surgical procedures and covered ancillary services under the revised ASC payment system. The ASC payment is generally a percentage of the OPPS payment rate unless the service is “office-based.” Payment for office-based services is capped based on the PFS non-facility payment.

CMS recognizes Category I and III CPT codes and Level II HCPCS codes for reporting procedures, services, items, and supplies under the ASC payment system. Similar to the OPPS, CMS provides quarterly update change requests (CRs) for ASC services throughout the year and makes new codes effective outside the formal rulemaking process via these quarterly updates. The annual rulemaking process is used to solicit comments and finalize decisions.

CMS also undertakes annually a review of excluded surgical procedures, new codes, and codes with revised descriptors, to identify any that the agency believes meet the criteria for designation as ASC covered surgical procedures or covered ancillary services.

B. ASC Treatment of New and Revised Codes

1. Background on Process for New and Revised HCPCS Codes

On a quarterly basis, Level II HCPCS codes are released and revised throughout the year and become effective. New and revised Category III CPT codes are recognized by CMS in the July and January CRs. New and revised Category I CPT codes, except vaccine codes, are released only once a year, and are implemented only through the January quarterly CR update. New and revised Category I CPT vaccine codes are released twice a year and are implemented through the January and July quarterly CR updates.

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

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

Table 66 in the proposed rule (reproduced below) provides the process and timeline for ASC list updates:

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

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

2. April 2026 HCPCS Codes Proposed Rule Comment Solicitation

For the April 2026 ASC quarterly update, there were several new Level II HCPCS codes added to the list of covered ancillary services (but no new CPT codes). Table 64 displays 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 proposes to finalize the payment indicators in the 2027 OPPS/ASC final rule with comment period and invites public comment.

3. July 2026 HCPCS Codes Proposed Rule Comment Solicitation

In the July 2026 ASC quarterly update (Transmittal R13836, Change Request 14522, June 24, 2026), CMS added several separately payable CPT and Level II HCPCS codes to the list of covered surgical procedures and covered ancillary services. Table 65 of this proposed rule lists the new HCPCS codes that are effective July 1, 2026.

As with the April 2026 codes, 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 proposes to finalize the payment indicators in the 2027 OPPS/ASC final rule with comment period.

4. October 2026 HCPCS Codes Final Rule Comment Solicitation

For 2027, consistent with CMS' established policy, CMS proposes that the Level II HCPCS codes that will be effective October 1, 2026, would be designated with "NI" in Addendum BB to the 2027 OPPS/ASC final rule to indicate that the codes have interim ASC payment status for

2026. CMS will invite public comments in the 2027 OPPS/ASC final rule with comment period and finalize the codes in the 2028 OPPS/ASC final rule with comment period.

5. January 2027 HCPCS Codes

a. Level II HCPCS Codes Final Rule Comment Solicitation

Level II HCPCS codes will be released to the public through the 2027 OPPS/ASC final rule with comment period, the January 2027 ASC Update CR, and the CMS HCPCS website. CMS proposes to continue to assign comment indicator “NI” in Addendums AA and BB to the 2027 OPPS/ASC final rule with comment period for those new and revised Level II HCPCS codes that are effective January 1, 2027. This indicates that CMS has assigned the codes an interim ASC payment status. CMS will invite comments in the 2027 OPPS/ASC final rule with comment period on the interim payment indicator assignments, which would then be finalized in the 2028 OPPS/ASC final rule.

b. CPT Codes Proposed Rule Comment Solicitation

CMS seeks comment on proposed new and revised CPT codes effective January 1, 2027 that were received from the AMA in time to be included in this 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 code is new or substantially revised for the next calendar year. CMS will accept comments and finalize the payment indicators in the CY 2027 OPPS/ASC final rule with comment period. Additionally, CMS includes the 5-digit placeholder codes and their long descriptors for the new 2026 CPT codes in Addendum O to this proposed rule so that the public can comment on the agency’s proposed payment indicator assignments. CMS intends to include the final CPT code numbers in the 2027 OPPS/ASC final rule with comment period.

6. Proposed ASC Payment and Comment Indicators

a. Background

For Addenda AA and BB, CMS has created payment and comment indicators as follows:

(1) Payment indicators (see Addendum DD1) to provide payment information regarding covered surgical procedures and covered ancillary services, 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 covered procedures list (CPL) prior to 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services, including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, NTIOLs, or qualifying non-opioid devices.

- The payment indicator “K5” (Items, Codes, and Services for which pricing information and claims data are not available. No payment made) indicates services and procedures

that CMS anticipates will become payable when claims data or payment information becomes available.

- The payment indicators, “D1” (Ancillary dental service/item; no separate payment made) and “D2” (Non office-based dental procedure added in 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. Proposed ASC Payment and Comment Indicators for 2027

As noted above, proposed codes are included in ASC Addenda AA and BB to this proposed rule and labeled with comment indicator “NP” to indicate that the new and revised CPT and Level II HCPCS codes are open for comment as part of the 2027 OPPS/ASC proposed rule.

C. Payment Policies Under the ASC Payment System

1. Proposed ASC Payment for Covered Surgical Procedures

a. Background

Currently, for procedures with payment indicators “G2” and “A2”³³ 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 ratesetting methodology for the procedure. CMS updates the payment amounts for these office-based procedures using the most recent available PFS and OPPS data.

³³ 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.

The rate calculation established for device-intensive procedures (payment indicator “J8”) is structured so only the service (non-device) portion of the rate is subject to the ASC conversion factor. CMS updates the payment rates for device-intensive procedures to incorporate the most recent device offset percentages calculated under the ASC standard ratesetting methodology.

Beginning in 2014, CMS conditionally packages payment for device removal procedures under the OPPS. Under the OPPS, a conditionally packaged procedure (status indicators “Q1” and “Q2”) describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a covered surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indicator “N1”) under the ASC payment system. Under the OPPS, device removal procedures are conditionally packaged and, therefore, would be packaged under the ASC payment system. There is no Medicare payment made when a device removal procedure is performed in an ASC without another surgical procedure included on the claim; therefore, no Medicare payment would be made if a device was removed but not replaced. To ensure that the ASC payment system provides separate payment for surgical procedures that only involve device removal, CMS has continued to provide separate payment since 2014 and assign the current ASC payment indicators associated with these procedures.

b. Update to the ASC Covered Surgical Procedure Payment Rates for 2027

CMS proposes to update the ASC payment rates for 2027 using the established rate calculation methodologies and using the definition of device-intensive procedures (discussed in section XIII.C.4 of the proposed rule). **CMS proposes** 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 proposes 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. **CMS proposes** to update the payment amount for the service portion (the non-device portion) of the device-intensive procedures using the standard ASC ratesetting methodology and the payment amount for the device portion based on the proposed 2027 device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. Under this proposal, that payment for office-based procedures would be the lesser of the proposed 2027 PFS nonfacility PE RVU-based amount or the proposed 2027 ASC payment amount calculated according to the ASC standard ratesetting methodology.

Finally, **CMS proposes** 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.

c. Proposed Payment for ASC Add-on Procedures Eligible for Complexity Adjustments under the OPPTS

(1) OPPTS 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.³⁴ CMS notes that the highest payment for any claim including a code combination for services assigned to a C-APC would be the highest paying C-APC in the clinical family, even if the calculated cost is higher than the highest cost C-APC in the family.

CMS packages payment for add-on codes into the C-APC payment rate. If any add-on code reported in conjunction with the “J1” primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the 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 proposed complexity adjustments for “J1” and add-on code combinations for 2027, along with all of the other proposed complexity adjustments, in Addendum J to the proposed rule.³⁵

(2) CY 2027 ASC Special Payment Policy Proposal for OPPTS Complexity Adjusted C-APCs

For 2027, **CMS proposes** to continue its current special payment policy and methodology for OPPTS complexity-adjusted C-APCs. For those ASC complexity adjustment codes for which CMS has claims data, **CMS proposes** to use the claims data to calculate the code combination utilization and estimated payments for the ASC payment system budget neutrality calculations (discussed in section XIII.H of the proposed rule).³⁶

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

In the 2022 OPPTS/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

³⁴ A “J1” status indicator refers to a hospital outpatient service paid through a C-APC.

³⁵ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>

³⁶ The full list of the proposed ASC complexity adjustment codes for 2027 can be found in the 2027 proposed ASC Addendum AA and the supplemental policy file, which also includes both the existing ASC complexity adjustment codes and proposed additions and published with the proposed rule on the CMS website at <https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/asc-regulations-and-notice>

does for low-volume services assigned to New Technology APCs. The payment rate for a low-volume APC would be based on the highest of the median cost, arithmetic mean cost, or geometric mean cost calculated using multiple years of claims data.

Based on its analysis of claims data, **CMS proposes** to designate APC 2645 (Brachytx, non-stranded, gold-198) as Low-Volume APCs under the ASC payment system. This APC met CMS' criteria of having fewer than 100 single claims in 2025. CMS also proposes to continue the low-volume APC designation for four brachytherapy and four clinical APCs that had met the low-volume in the 2026 rulemaking cycle. The relative weight for these APCs would be based on the greater of the median cost, arithmetic mean cost, or geometric mean cost using up to four years of claims data. Tables 3 and 67 in the proposed rule list the nine current low-volume APCs and the number of 2025 claims used to set payment rates for them.

2. Proposed 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.³⁷

Radiology services. CMS generally pays separately for radiology services at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to

³⁷ As determined by CMS under §416.174 (86 FR 63483).

the ASC standard ratesetting methodology. However, payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services (including radiology services that use contrast agents) that are paid separately when provided integral to a surgical procedure on the ASC list are set to “Z2” so that payment is made based on the ASC standard ratesetting methodology rather than the PFS nonfacility PE RVU amount (“Z3”), regardless of which is lower.

Brachytherapy sources. ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at contractor-priced rates.

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 range³⁸ 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. Proposed payment for covered ancillary items and services

CMS proposes to update payments and make changes necessary to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services. It also proposes to continue to set the 2027 ASC payment rates and subsequent year payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for 2027 and subsequent year payment rates. For those covered ancillary services where the payment rate is the lower of the rate under the ASC standard ratesetting

³⁸ 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.

methodology and the PFS proposed rates, the proposed payment indicators and rates are based on a comparison using the proposed PFS rates effective January 1, 2027. Covered ancillary services and their proposed payment indicators for 2027 are listed in Addendum BB of this proposed 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. Proposed Office-Based Procedures for 2027

For 2027, **CMS proposes** 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 CY 2025 utilization of covered surgical procedures claims data, CMS identified two surgical procedures that it proposes to permanently designate as office-based for 2027, specifically, CPT code 0102T (Extracorporeal shock wave performed by a physician, requiring anesthesia other than local, and involving the lateral humeral epicondyle), and 60660 (Ablation of 1 or more thyroid nodule(s), one lobe or the isthmus, percutaneous, including imaging guidance, radiofrequency). These procedures are performed more than 50 percent of the time in physicians’ offices and CMS believes they are of a level of complexity consistent with other procedures performed routinely in physicians’ offices.

CMS also reviewed the utilization for four surgical procedures designated as temporarily office-based in the 2026 OPPS/ASC final rule. **CMS proposes** to remove one of the procedures, HCPCS codes 53866 (Catheterization with removal of temporary device for ischemic remodeling (*i.e.*, pressure necrosis) of bladder neck and prostate), because there were more than 50 claims for this service available for CY 2025, and the service was not predominantly performed in offices in that year.

For the remaining three procedures (0588T, 53866, 64598, and 67229) temporarily designated as office-based in 2026, there was an insufficient number of claims to determine if the office setting was the predominant setting of care for these procedures. Therefore, **CMS proposes** to continue to designate such procedures as temporarily office-based for 2027 and assign one of the office-based payment indicators. These codes are listed and described in Table 70 in the proposed rule.

CMS is not proposing to designate any new 2027 CPT codes for ASC covered surgical procedures as temporarily office-based.

4. Proposed Device-Intensive ASC-Covered Surgical Procedures

a. Proposed Device-Intensive Procedures for 2027

In 2019, CMS adopted a policy to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. CMS also lowered the device offset percentage threshold from 40 percent to 30 percent. Device-intensive procedures are subject to the following criteria:

- All procedures must involve implantable or insertable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost. The default device offset for new codes that describe procedures that involve the implantation of medical devices is 31 percent and is applied in the same manner as the policy CMS adopted for device pass-through status.³⁹

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;⁴⁰ 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).

³⁹ 83 FR 58944 through 58948.

⁴⁰ As defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1).

In 2022, CMS adopted a policy of assigning device-intensive status to procedures that involve surgically inserted or implanted, high-cost, single-use devices if their device offset percentage exceeds 30 percent under the ASC standard ratesetting methodology, even if the procedure is not designated as device-intensive under the OPPS. Additionally, if a procedure is assigned device-intensive status under the OPPS, but has a device offset percentage below the device-intensive threshold under the standard ASC ratesetting methodology, the procedure will be assigned device-intensive status under the ASC payment system with a default device offset percentage of 31 percent. The policies were adopted to provide consistency between the OPPS and ASC payment system and provide a more appropriate payment rate for surgical procedures with significant device costs under the ASC payment system.

In 2023, CMS created certain C-codes, or ASC complexity adjustment codes that describe certain combinations of a primary covered surgical procedure as well as a packaged (payment indicator “N1”) procedure that are otherwise eligible for a complexity adjustment under the OPPS (as listed in Addendum J). Each ASC complexity adjustment code’s APC assignment is based on its corresponding OPPS complexity adjustment code’s APC assignment. Under CMS’ current policy, the ASC complexity adjustment code retains the device portion of the primary procedure (also called the “device offset amount”) and not the device offset percentage. Therefore, for device-intensive ASC complexity adjustment codes, CMS sets the device portion of the combined procedure equal to the device portion of the primary procedure and calculates the device offset percentage by dividing the device portion by the ASC complexity adjustment code’s APC payment rate. Further, CMS multiplies the OPPS relative weight by the ASC budget neutrality adjustment and the ASC conversion factor and sums that amount with the device portion to calculate the ASC payment rate.

Beginning in 2025, CMS modified the default device offset percentages for new codes that meet CMS’ criteria for device-intensive status. Under both the OPPS and ASC payment system, for new device-intensive procedures that lack claims data, CMS applies the greater of the APC-wide device offset percentage or 31 percent (the previous default device offset percentage). CMS believes that an APC-wide average device offset percentage is, in most cases, a better reflection of device costs when the typical device costs of procedures assigned to such APC are significantly greater than 31 percent. This policy does not apply to new device-intensive procedures assigned to New Technology APCs.

In the 2026 OPPS/ASC final rule, CMS discussed the implementation of the “Final Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022 rule” and expressed its belief that the remedy’s proposed prospective offset to the OPPS conversion would have had a very limited impact on the ASC payment system. At the time, the agency believed that it would be inaccurate and inappropriate to use OPPS payment rates that have been reduced by the remedy’s prospective offset since this could accumulate to have a potentially noticeable impact on ASC payment rates for certain device-intensive procedures over time. Thus, CMS finalized a policy that the OPPS payment rates used for ratesetting under the ASC payment system for CY 2026 and subsequent years would not incorporate the prospective offset to the OPPS conversion factor as a result of the 340B remedy offset that the agency proposed to implement in the CY 2026 OPPS/ASC proposed rule.

In this proposed rule, CMS is not proposing any changes to our device-intensive procedure policies under the ASC payment system for CY 2027, but we are soliciting comment on whether our device-intensive calculation methodology should continue to exclude device portions from the ASC weight scaler or whether device portions should represent scalable prospective expenditures. The reader should refer to Addendum FF of the proposed rule for proposed 2027 device offset percentages. Final 2026 device offset percentages may differ from the proposed percentages because CMS recalculates them using updated data for the 2027 OPPS/ASC 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 is not proposing any changes to its policies related to no cost/full credit or partial credit devices for 2027.

D. Additions to ASC Covered Surgical Procedures and Covered Ancillary Services Lists

1. Proposed Additions to the List of ASC Covered Surgical Procedures

The statute⁴¹ 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 CPL each year to determine whether procedures should be added to or

⁴¹ Section 1833(i)(1) of the Act.

removed from this list, and changes to the list are often made in response to specific concerns raised by interested parties.

Beginning in 2019,⁴² CMS defined a surgical procedure under the ASC payment system as any procedure described within the range of surgical Category I CPT codes (CPT codes 10000 through 69999), as well as procedures that are described by Level II HCPCS codes or by Category I CPT codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that CMS determines met the general standards established in previous years for addition to the ASC CPL.

CMS substantially changed its regulations governing the list of ASC covered surgical procedures in the CY 2026 rulemaking cycle. Under the revised regulations at §§416.2 and 416.166, covered surgical procedures furnished on or after January 1, 2026, are surgical procedures that meet the criteria specified in §416.166(b)(2). In the CY 2026 OPPS/ASC final rule with comment period, the agency expanded the ASC CPL by revising the criteria for adding surgical procedures to the ASC CPL (90 FR 53855 through 53886). Under the revised criteria, procedures added to the ASC CPL must be separately paid under the OPPS and are not

- (1) currently designated as requiring inpatient care under § 419.22(n),
- (2) only able to be reported using a CPT unlisted surgical procedure code, or
- (3) otherwise excluded under § 411.15.

Additionally, CMS moved certain general standards and exclusions used to evaluate services for addition to the ASC CPL prior to January 1, 2026, to a new section of the following *non-binding physician considerations*:

- (1) Is not expected to pose a significant safety risk when performed in an ASC;
- (2) Is one of which standard medical practice dictates the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure;
- (3) Generally results in extensive blood loss;
- (4) Requires major or prolonged invasion of body cavities;
- (5) Directly involves major blood vessels;
- (6) Is generally emergent or life-threatening in nature; and
- (7) commonly requires systemic thrombolytic therapy.

2. Proposed Changes to the List of ASC Covered Surgical Procedures for 2027

Historically, CMS has reviewed the clinical characteristics of procedures and consulted with appropriate medical organizations, other interested parties, and the agency's clinical advisors to determine if those procedures would meet the agency's existing regulatory criteria. As part of the agency's evaluation process to add procedures to the CPL, CMS assesses potential procedures against the revised ASC CPL criteria at §416.166(b)(2). For CY 2027, CMS reviewed interested parties' nominations received in the pre-proposed rule nominations process. Additionally, CMS reviewed procedures that are proposed to be removed from the IPO list for CY 2027, as part of the continuation of the elimination of the IPO list, as described in section IX of this proposed rule. Based upon this review, **CMS proposes to update the ASC CPL by adding 618**

⁴² See: 2019 OPPS/ASC final rule (83 FR 59029 through 59030).

procedures that are proposed to be removed from the IPO list for CY 2027. These procedures include four procedures that were recommended by interested parties for addition to the ASC CPL:

- CPT code 49596 (Repair of anterior abdominal hernia(s) (*i.e.*, epigastric, incisional, ventral, umbilical, spigelian), any approach (*i.e.*, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated),
- CPT code 49616 (Repair of anterior abdominal hernia(s) (*i.e.*, epigastric, incisional, ventral, umbilical, spigelian), any approach (*i.e.*, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated),
- CPT code 40617 (Repair of anterior abdominal hernia(s) (*i.e.*, epigastric, incisional, ventral, umbilical, spigelian), any approach (*i.e.*, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible), and
- CPT code 40618 (Repair of anterior abdominal hernia(s) (*i.e.*, epigastric, incisional, ventral, umbilical, spigelian), any approach (*i.e.*, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated).

These procedures are listed in the public use file titled “Proposed Additions to the List of ASC Covered Procedures for CY 2027,” which is available on the CMS website.

3. Covered Ancillary Services

Beginning in 2019, CMS updates the ASC list of covered ancillary services to reflect the payment status for the services under the OPPS and the reconciliation of packaged status. For example, if a covered ancillary service was separately paid under the ASC payment system in 2026 but will be packaged under the 2027 OPPS, CMS would also package the ancillary service under the ASC payment system for 2027 to maintain consistency with the OPPS. New CPT and HCPCS codes for covered ancillary services for 2027 can be found in section XIII.B of the proposed rule. All ASC covered ancillary services and their proposed payment indicators for 2027 are included in Addendum BB to this proposed rule.

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

1. Background

Section 4135(a) and (b) of the CAA, 2023 directs CMS to unpackage and provide separate payment for non-opioid treatments for pain relief furnished between January 1, 2025 and January 1, 2028. CMS describes the policies finalized in the 2025 OPPS ASC final rule,⁴³ 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

⁴³ See 42 CFR 416.174 and 42 CFR 419.43(k).

payment beginning January 1, 2025,⁴⁴ 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 replace, reduce, or avoid opioids, the medical device will not meet the evidence criterion to qualify for separate payment.

Non-Opioid Product Indications. CMS only approves separate payment for drug or biological products with an FDA-approved indication that closely aligns with the statutorily required indication language to reduce post-operative pain or produce post-surgical or regional analgesia. In the case of a medical device, the device must be used to deliver a therapy to reduce postoperative pain or produce post-surgical or regional analgesia to qualify for separate payment. Additionally, the device must have an application approved under section 515 of the Federal Food, Drug, and Cosmetic Act (FDCA), which has been cleared for market under section 510(k) of the FDCA, or be exempt from the requirements of section 510(k) of the FDCA pursuant to section 510(l) or (m) or 520(g) of the FDCA.⁴⁵

Amount of Payment. For a drug or biological that qualifies for separate payment, the statute sets payment with the methodology used under section 1847A (generally, ASP+6 percent) less the amount included in the OPPI or ASC payment for the product and capped at 18 percent of the OPPI 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 OPPI or ASC for the product and capped at 18 percent of the OPPI 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.

⁴⁴ See table 158 in the 2025 OPPI ASC final rule, beginning [89 FR 94358](#).

⁴⁵ 89 FR 94346 through 94347

CMS applies the 18 percent payment limitation per date of service billed rather than per HCPCS dosage unit. This is due to the fact that there are typically multiple HCPCS dosage units (also called billing units) of each drug or biological billed per claim. Thus, the total units of a drug billed on a date of service are more reflective of the cost of the drug in that encounter. CMS bases the 18 percent payment limitation on the volume weighted average of the payment rates of the top five primary procedures by volume into which a non-opioid treatment for pain relief would have its payment packaged, absent this policy.

For products with no claims data,⁴⁶ 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.

2. Final CY 2026 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023

CMS finalized continuing to use the policies it finalized in the 2025 OPPS ASC final rule without modification. The agency believes the zero-dollar offset policy is appropriate for all qualifying products. Last year, CMS also finalized a list of qualifying drugs, biologicals, and devices that meet the statutory criteria for separate payment under section 4135. CMS also finalized a modification to allow for more timely consideration of qualifying products by establishing a process to evaluate and approve additional non-opioid treatments for pain relief on a quarterly basis, rather than limiting consideration to annual rulemaking.

3. Proposed CY 2027 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023

For CY 2027, CMS proposes to continue the policies finalized in the CY 2026 OPPS/ASC final rule (90 FR 53448) without modification, aside from a technical modification to the payment limitation calculations. CMS continues to believe a zero-dollar offset is appropriate for all qualifying products regulated under the non-opioid policy as some of these products are new products or newly separately paid in the OPPS setting and their costs may not be fully reflected in the cost of procedures in which they may be used. A continued zero-dollar offset aligns with comment support for a zero-dollar offset as discussed in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53892).

Table 71 (summarized below) lists for 2026 the non-opioid alternatives proposed for separate payment as a non-opioid pain management drug or device under section 4135 criteria. CMS refers readers interested in submitting additional products for the agency's consideration to the guidance posted on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/non-opioid-treatments-pain-relief>.

TABLE 71: PROPOSED LIST OF QUALIFYING PRODUCTS FOR SEPARATE PAYMENT IN CY 2027 UNDER SECTION 4135 OF THE CAA, 2023

Brand Name	HCPCS Code	Long Descriptor
Exparel	J0666*	Injection, bupivacaine liposome, 1mg

⁴⁶ 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.

Brand Name	HCPCS Code	Long Descriptor
Omidria	J1097	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml
Dextenza	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg
Zynrelef	J0668 (previously C9088**)	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg
Ketorolac tromethamine Injection	J1885	Injection, ketorolac tromethamine, per 15 mg
Journavx	C9818	Suzetrigine, oral, 1 mg
Caldolor	J1741	Injection, ibuprofen, 100 mg
ON-Q Pump	C9804	Elastomeric infusion pump (e.g., ON-Q* Pump with Bolus), including catheter and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
SPRINT Peripheral Nerve Stimulator System	C9807	Nerve stimulator, percutaneous, peripheral (e.g., SPRINT Peripheral Nerve Stimulation System), including electrode and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
Cryo Nerve Block Therapy	C9808	Nerve cryoablation probe (e.g., cryoICE, cryoSPHERE, cryoSPHERE MAX, cryoICE cryoSPHERE, cryoICE Cryo2), including probe and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
ambIT Electronic Infusion Pump	C9806	Rotary peristaltic infusion pump (e.g., ambit Pump), including catheter and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
Iovera System	C9809	Cryoablation needle (e.g., iovera System), including needle/tip and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
IceMan	C9XX0	Water circulating motorized cold therapy device (e.g., IceMan) including all system components (e.g., pads, console, disposable parts), non-opioid medical device (must be a qualifying Medicare non-opioid medical device for postsurgical pain relief in accordance with section 4135 of the CAA, 2023)
Sapphire Infusion Pump	C9811	Electronic ambulatory infusion pump (e.g., Sapphire pump), including all pump components, including disposable components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
Ultrasound-visible nerve block needles (SonoPlex, SonoBlock, SonoTap)	C9812	Echogenic nerve block needles (e.g., SonoPlex, SonoBlock, SonoTap), non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
Perforated continuous infusion catheter set (InfiltraLong)	C9813	Perforated continuous infusion catheter set (e.g., InfiltraLong), including all 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)
Continuous anesthesia	C9814	Continuous anesthesia echogenic conduction catheter set (e.g., SonoLong, E-Cath), non-opioid medical device (must be a qualifying Medicare non-opioid

Brand Name	HCPCS Code	Long Descriptor
conduction catheter sets (SonoLong, E-Cath)		medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
CADD-Solis infusion pump	C9815	Linear peristaltic pain management infusion pump (<i>e.g.</i> , CADD-Solis ambulatory infusion pump), and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
ambIT Electronic Infusion Pump (Reusable)	C9816	Rotary peristaltic infusion pump (<i>e.g.</i> , reusable ambIT Pump) including all disposable system components, reusable non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
Game Ready System	C9817	Electronic cryo-pneumatic compression, pain management system (<i>e.g.</i> , Game Ready® GRPro 2.1 System), including control unit, anatomically correct wrap(s), and other system component(s), non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)

*Previously described by HCPCS code C9290.

**HCPCS Code C9088 was replaced by HCPCS code J0668 (Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg) effective October 1, 2025.

F. New Technology Intraocular Lenses (NTIOLs)

New Technology Intraocular Lenses (NTIOLs) are intraocular lenses that replace a patient's natural lens that has been removed in cataract surgery and that also meet the requirements listed in §416.195. CMS did not receive any requests for review to establish a new NTIOL class for 2027 by March 1, 2026, the due date published in the 2026 OPPI/ASC final rule with comment period (90 FR 53910). CMS does not propose to revise the current payment adjustment (\$50 per lens) for NTIOLs.

G. ASC Payment Rates and ASC Conversion Factor

CMS proposes to continue to update relative weights using the national OPPI 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 2025⁴⁷, CMS computes the ratio of:

- Estimated total payments using the 2026 relative payment rates, to
- Estimated total payments using the 2027 relative payment rates.

The 2027 total payments would also include spending and utilization related to ASC complexity adjustment codes or C codes. CMS estimates the change in ASC spending related to these codes for 2027 did not impact the ASC weight scalar. Regarding the application of the 18 percent payment limitation for separately payable non-opioid treatments for pain relief under section

⁴⁷ 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>.

4135, CMS estimates that the proposed 2027 payment limitations will not impact the ASC weight scalar.

The resulting ratio, 0.809,⁴⁸ is the proposed weight scaler for 2027. The scaler would apply to the ASC relative payment weights of covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes. The scaler would not apply to ASC payments for separately payable covered ancillary services that have a predetermined national payment amount and are not based on OPPS relative payment weights (e.g., drugs and biologicals that are separately paid and services that are contractor-priced or paid at reasonable cost in ASCs).

As the ASC payment system uses the OPPS conversion factor to determine payment for the device portions of device-intensive procedures, this alters the payment relativity between services under the OPPS because the entire portion of ASC payment rates for non-device-intensive procedures is based on the lower ASC conversion factor. Because of the proposed large increase in the device portions for device-intensive procedures in CY 2027 as a result of the proposed 340B drug payment policy discussed elsewhere in this proposed rule, **CMS solicits comment on whether the device portions of device-intensive procedures calculated using the OPPS conversion factor should continue to be excluded from the ASC weight scaler**, or alternatively, whether these device portions should be included in the expenditures subject to scaling through the ASC weight scaler.

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)⁴⁹ 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 2026 ASC wage indices, to
- ASC payments using the 2027 ASC wage indices.

The resulting ratio, 1.0016, is the proposed wage index budget neutrality adjustment to the conversion factor for 2027.

To update ASC rates, CMS would utilize the hospital market basket update of 3.2 percent minus the productivity adjustment of 0.8 percent. This yields an update of 2.4 percent for ASCs

⁴⁸ CMS has historically displayed this figure rounded to the nearest ten thousandth; however, it now believes this level of specificity is unnecessarily burdensome for an ASC payment system that is less than one-tenth the size of the OPPS.

⁴⁹ Consistent with CMS's proposed changes to other FY and CY 2027 fee-for-service payment systems, CMS here proposes to update the labor market definitions used to adjust ASC payments for geographic differences in wages using the most recent labor market definitions issued via OMB Bulletin No. 23-01 (86 FR 37770, July 21, 2023). Similarly, CMS proposes to limit reductions in the wage index values to 5 percent. All of these changes would be implemented in a budget-neutral manner.

meeting quality reporting requirements. CMS would continue its policy of reducing the update by 2.0 percentage points for ASCs not meeting the quality reporting requirements, yielding an update of 0.4 percent for such ASCs. The resulting proposed 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
2026 ASC conversion factor	\$56.322	
Wage adjustment for budget neutrality	x 1.0016	
Net MFP-adjusted update	<u>x 1.024</u>	<u>x 1.004</u>
2027 Proposed ASC conversion factor	\$57.766	\$56.638

H. Regulatory Impact

CMS provides the estimated aggregate payment changes for the six specialty groups that account for the most ASC utilization and spending, assuming the same mix of services from the 2025 claims data. (Table 89 of the proposed rule shown below.) The proposed update to ASC payment rates for 2027 would result in a 1 percent decrease in aggregate payment amounts for eye and ocular adnexa procedures, but a 6 percent increase in aggregate payments for musculoskeletal system procedures and for nervous system procedures.

Table 89: Estimated Impact of Proposed Rule on Surgical Specialty Groups		
Surgical Specialty Group	Estimated 2026 ASC Payments (in Millions)	Estimated CY 2027 Percent Change
Total	\$8,349	2%
Eye	\$2,120	-1%
Musculoskeletal	\$2,019	6%
Nervous system	\$1,580	6%
Gastrointestinal	\$1,059	-2%
Cardiovascular	\$635	5%
Genitourinary	\$365	1%

CMS provides estimated increases for 30 selected procedures in Table 90 in the proposed rule; the top 10 procedures are replicated below. CPT code 66984 (Cataract surgery with intraocular lens, 1 stage) is the largest aggregate payment procedure by far and is estimated to have a 2 percent decrease in payment. The second largest aggregate payment procedure, CPT code 27447 (total knee arthroplasty), is expected to see a 5 percent increase.

Excerpt from Table 90: Estimated Impact of the 2027 Update to the ASC Payment System on Aggregate Payments for the Top 10 Procedures			
CPT/ HCPS Code	Short Descriptor	Estimated 2026 ASC Payments (in Millions)	Estimate 2027 Percent Change
66984	Xcapsl ctrc rmvl w/o ecp	\$1,383	-2
27447	Total knee arthroplasty	\$529	5
63685	Ins/rplc spi npg/rcvr pocket	\$421	15
27130	Total hip arthroplasty	\$284	6

Excerpt from Table 90: Estimated Impact of the 2027 Update to the ASC Payment System on Aggregate Payments for the Top 10 Procedures			
CPT/ HCPS Code	Short Descriptor	Estimated 2026 ASC Payments (in Millions)	Estimate 2027 Percent Change
45385	Colonoscopy w/lesion removal	\$273	-2
45380	Colonoscopy and biopsy	\$253	-2
23472	Reconstruct shoulder joint	\$215	7
43239	Egd biopsy single/multiple	\$174	-2
63650	Implant neuroelectrodes	\$161	6
64590	Ins/rpl prph sac/gstr npg/r	\$131	8

Addenda tables available only on the website provide additional details, at <https://www.cms.gov/license/ama?file=/files/zip/2027-nprm-addendum-aa-bb-dd1-dd2-ee-and-ff.zip>. They include:

- AA: Proposed ASC Covered Surgical Procedures for 2027 (Including surgical procedures for which payment is packaged)
- BB: Proposed ASC Covered Ancillary Services Integral to Covered Surgical Procedures for 2027 (Including Ancillary Services for Which Payment is Packaged)
- DD1: Proposed ASC Payment Indicators for 2027
- DD2: Proposed ASC Comment Indicators for 2027
- EE: Proposed Surgical Procedures to be Excluded from Payment in ASCs for 2027
- FF: Proposed ASC Device Offset Percentages for 2027
- O: Long Descriptors for New Category I CPT Codes, Category III CPT Codes, C-codes, and G-Codes Effective January 1, 2027.

XIV. Measure Removal: Follow-Up for Normal Colonoscopy in Average Risk Patients

A. Background

Background on the Hospital Outpatient Quality Review Program (HOQRP) and ASC QRP is provided under sections XV and XVII, respectively.

B. Remove Measure: Follow-Up for Normal Colonoscopy in Average Risk Patients

The Colonoscopy Follow-Up Interval measure is included in both the HOQRP and ASC QRP. The measure assesses the percentage of patients aged 45 to 75 years who receive a screening colonoscopy without biopsy or polypectomy and had documented in their colonoscopy report a recommended follow-up interval of at least 10 years for a repeat colonoscopy. The measure was intended to increase provider and patient awareness of appropriate screening intervals by assessing whether the recommended follow-up interval was documented; it does not assess whether the follow-up screening was performed according to the recommended interval.

CMS proposes to remove the measure from both the HOQRP and ASC QRP beginning with the 2027 reporting period/2029 payment determination. The removal is proposed on the basis of

removal factor 6, which permits removal in the case of availability of a measure that is more strongly associated with a desired patient outcome for the particular topic.⁵⁰ The agency points to the Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure, which is already included in both reporting programs and assesses the incidence of hospital returns within seven days of a colonoscopy. CMS believes that the Facility 7-Day measure is a more patient-outcome focused measure of procedure-related adverse-events in comparison to the Colonoscopy Follow-Up Interval measure.

XV. Hospital Outpatient Quality Reporting Program (HOQRP)

A. Background

CMS provides references to the legislative and regulatory histories of the HOQRP.⁵¹ Section 1833(t)(17)(A) of the Act provides a 2.0 percentage point reduction in the annual Hospital Outpatient Department (HOPD) fee schedule increase factor (Annual Payment Update, APU) for each subsection (d) hospital that does not submit data as required for the HOQRP's measures. For 2027, CMS proposes to continue to implement the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements by applying a reporting ratio of 0.9805 to the OPPS payments and copayments for all applicable services. The proposed reporting ratio, when multiplied by the proposed full conversion factor of \$102.004, equals a proposed reduced conversion factor for hospitals that fail to meet the requirements of the HOQRP of \$100.015, which would apply for the 2027 payment determination.⁵²

In addition to the cross-program policy discussed in section XIV, CMS proposes changes to the validation of HOQRP data and to the HOQRP validation reconsiderations and appeals procedures. CMS also requests information on the potential inclusion in the HOQRP of the Advance Care Planning eCQM, described in greater detail below.

B. Program Measure Set

CMS is not proposing any changes to the HOQRP measure set other than the cross-program proposal to remove the Colonoscopy Follow-Up Interval measure discussed in section XIV.

The table below (based on the information provided in Table 72 in the rule) summarizes the previously finalized measure set for the 2028 to 2032 payment determinations.

⁵⁰ Measure removal factors are under 42 CFR 419.46(i)(3)(i) and 416.320(c)(2) for the HOQRP and ASC QRP, respectively.

⁵¹ 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>.

⁵² Note that these conversion factors are before application of the 340B adjustment. As discussed in section II.B, (i) for hospitals that submit quality data, the 340B recoupment adjustment of 0.9707 would result in a conversion factor of \$99.015, and (ii) for hospitals that do not submit quality data, the application of the 340B recoupment adjustment would result in a conversion factor of \$97.084.

Previously Finalized HOQRP Measure Set for 2028 to 2032 Payment Determinations

CBE	Measure	2028	2029	2030	2031	2032
Chart-Abstracted Measures						
None	Median Time from ED Arrival to ED Departure for Discharged ED Patients	X	X	Removed	Removed	Removed
None	Left Without Being Seen	X	X	Removed	Removed	Removed
0661	Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival	X	X	X	X	X
0658	Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients	X	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal
Claims-Based Measures						
None	Abdomen CT – Use of Contrast Material	X	X	X	X	X
2539	Facility 7-Day Risk Standardized Hospital Visit Rate After Outpatient Colonoscopy	X	X	X	X	X
3490	Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	X	X	X	X	X
2687	Risk-Standardized Hospital Visits 7 Days After Hospital Outpatient Surgery	X	X	X	X	X
None	Breast Cancer Screening Recall Rates	X	X	X	X	X
Survey-Based Measures						
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS-CAHPS)	X	X	X	X	X
None	Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary
Electronic Clinical Quality Measures (eQMs)						
None	ST-Segment Elevation Myocardial Infarction (STEMI)	X	X	X	X	X
3663e	Excessive Radiation	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary
4625e	Emergency Care Access & Timeliness (ECAT)		Voluntary	X	X	X
Patient-Reported Outcomes-Based Performance Measures (PRO-PMs)						
None	Risk-Standardized PRO-PM Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty in the HOPD Setting (THA/TKA PRO-PM)	Voluntary	Voluntary	Voluntary	X	X

CBE	Measure	2028	2029	2030	2031	2032
4210	Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery PRO-PM (Information Transfer PRO-PM)	Voluntary	X	X	X	X
X = Measure is mandatory for the specified payment determination year. Voluntary = Submission of the measure is optional; HOPDs that do not report the measure are not subject to a payment reduction.						

C. RFI: Advance Care Planning Electronic Clinical Quality Measure

1. Background and RFI

The agency discusses its policy finalized in the 2026 OPPS/ASC final rule to phase out the Inpatient-Only (IPO) list and the likely resulting shift of complex procedures to the HOPD setting. CMS believes this will provide opportunities for HOPD clinicians to build relationships with patients and that this in turn presents opportunities in which advance care planning could facilitate shared decision-making and ensure that care is aligned with patients' goals across settings.

CMS seeks feedback on the potential inclusion in the HOQRP of an Advance Care Planning eCQM and other quality measure concepts related to advance care planning. The agency specifically asks about several considerations, including: (i) the importance, relevance, appropriateness, and applicability of including such a measure concept in the HOQRP; (ii) tools that capture advance care planning processes and outcomes in hospital outpatient settings; (iii) any modifications to the Advance Care Planning eCQM to better tailor it for the HOQRP; (iv) other approaches, measure development ideas, or measure concepts to address advance care planning in the HOPD setting; and (v) timing and frequency of advance care planning in the HOPD setting.

2. Overview of Advance Care Planning eCQM

In the 2027 IPPS/LTCH PPS proposed rule, CMS proposed the Advance Care Planning eCQM for adoption in the Hospital Inpatient QRP, PPS-Exempt Cancer Hospital QRP, and Medicare Promoting Interoperability Program.⁵³ CMS believes that adoption of the eCQM across quality reporting programs could promote standardized advance care planning documentation to facilitate communication of patients' stated preference across their care continuum.

The Advance Care Planning eCQM⁵⁴ (as proposed in the 2027 IPPS/LTCH PPS proposed rule for the inpatient settings) calculates the proportion of adult patients with one or more inpatient hospitalizations during the measurement period who, by the time of hospital discharge for at least one encounter, have an advance care planning document or documentation of an advance

⁵³ 91 FR 19564 through 19568

⁵⁴ Details on the eCQM can be found at <https://www.p4qm.org/prmr-measures/muc2025-020>.

care planning discussion resulting in a documented decision in the patient's electronic health record (EHR). The measure is calculated as a proportion by dividing the number of patients who meet the numerator criteria by the number of eligible patients who meet the denominator criteria.

- *Numerator.* All adult patients with one or more inpatient encounters during the measurement period who have an advance care planning document or documentation of an advance care planning discussion resulting in a documented decision in the patient's EHR by the time of hospital discharge during at least one of the inpatient encounters.
- *Denominator.* All patients aged 18 years and older at the start of the measurement period who are discharged from an inpatient hospitalization during the measurement period.⁵⁵

D. Updates to the Validation of HOQRP Data

CMS is proposing several updates relating to validation of HOQRP data, including to:

- Incorporate the validation of eCQM data into the HOQRP's existing validation process;
- Change the validation selection pool from 500 to up to 400 hospitals;
- Clarify application of the targeting criteria to eCQMs;
- Update the number of cases for chart-abstracted and eCQM validation;
- Include eCQM validation in the timing and submission of medical record requests;
- Align the submission quarters for chart-abstracted and eCQM validation;
- Establish an eCQM validation scoring method based on data accuracy; and
- Update the educational review process for validation results.

1. Proposed eCQM Data Validation

For purposes of incorporating eCQMs into the HOQRP validation process, CMS proposes that validation begins for an eCQM after mandatory reporting of a full year of data is in effect for that eCQM. There are three eCQMs that have been finalized for inclusion in the measure set (excessive radiation, STEMI, and ECAT). The excessive radiation eCQM is voluntary so would not be eligible for validation under this proposal. Hospitals are required to submit all four quarters of data for the STEMI eCQM beginning with data from the 2027 reporting period; therefore, validation for the STEMI eCQM would begin with data from the 2027 reporting period. Validation for the ECAT eCQM would begin with data from the 2028 reporting period, since that is the first year for which four quarters of data for the measure is mandatory.

2. Proposed Changes to Selection Process for HOQRP Validation

a. Validation Selection Pool

Currently, a random sample of 450 hospitals is selected for validation and an additional 50 hospitals are selected based on specific targeting criteria. CMS has found that randomly selected hospitals generally have high accuracy rates for chart-abstracted measures. The agency believes the number of randomly selected hospitals could be reduced without affecting its ability to assess

⁵⁵ The measurement period is a 12-month period that would run from January 1 through December 31 of each applicable CY.

accuracy of the data and that the number of hospitals selected based on targeting criteria should be increased.

CMS proposes, beginning with hospital selections for validation affecting the 2030 payment determination, that up to 200 hospitals be randomly selected and up to 200 hospitals be selected using targeting criteria. Any hospital selected for validation would be required to submit for validation both chart-abstracted measure data and eCQM data (that is, for eCQMs eligible for validation under the proposal discussed above). The existing validation policy would apply to hospital selections for validation affecting 2029 payment determination, and hospitals so selected for that validation would submit only chart-abstracted data for validation since no eCQMs would yet be eligible for validation for that payment determination year.

b. Targeting Criteria

CMS proposes to apply the existing targeting criteria at §419.46(f)(3)(i) through (v) that currently applies to chart-abstracted measures to all measures eligible for validation in the HOQRP (i.e., also eCQMs).

3. Case Selection for Validation

Under current policy, CMS validates up to 48 randomly selected patient cases (12 cases per quarter) from the total number of cases that a hospital (selected for validation) successfully submitted to the CMS Clinical Data Warehouse via the HQR system.

CMS proposes to instead validate up to 32 randomly selected patient cases for each measure, starting with validation of 2027 data affecting the 2030 payment determination.⁵⁶ For each chart-abstracted clinical process of care measure, cases would be submitted quarterly (with up to 8 cases validated per quarter) and for each eCQM up to 32 cases would be submitted annually, allowing validation of up to 8 cases from each quarter.

4. Timing and Electronic File Submission for Medical Records Requests

CMS proposes to apply the same electronic file submissions policy to eCQM medical records requests as currently applies to the chart-abstracted measures.⁵⁷ A hospital, upon written request by CMS, would be required to submit, within 30 days of the written request, PDF copies of medical records using direct electronic file submission via a CMS-approved secure filing transmission process. CMS would continue to reimburse hospitals at \$3.00 per chart.

5. Submission Quarters

Currently, hospitals selected for validation are required to submit data from 2 years prior to the applicable payment determination year, consisting of 4 calendar quarters of chart-abstracted data.

⁵⁶ See section XV.D.5 for a discussion of the proposal to shift the payment impact of validation from 2 years after the reporting period to 3 years.

⁵⁷ Section 419.46(f)(1) includes policies on the use of electronic file submissions for chart-abstracted measure medical requests and the period for data validation.

CMS proposes that hospitals selected for eCQM validation for a payment determination year would be required to submit data from the year that is 3 years prior to the applicable payment determination since eCQM data are reported annually and not quarterly. Since CMS is proposing a combined validation process (for both chart-abstracted measures and eCQMs), the agency proposes to also shift to the 3-year cycle for chart-abstracted measures—meaning that the payment impact of validation would affect the payment determination occurring 3 years (rather than 2 years) after the reporting period.

To transition to this proposed policy, the validation results for 2027 chart-abstracted data would affect both 2029 and 2030 payment determination. This means there would be no change from the current policy for the 2029 payment determination, but for the 2030 payment determination, 2027 chart-abstracted data would again be used, plus the 2027 eCQM data would also be used for validation. CMS proposes that hospitals selected for validation based on 2027 data affecting the 2029 payment determination would not be selected again (randomly or through targeted selection) for validation of the same data affecting the 2030 payment determination.

Beginning with 2028 chart-abstracted and eCQM data, validation results would impact the payment determination 3 years after the reporting period.

6. Scoring Method

CMS proposes to determine the eCQM validation scores by using the same methodology the agency currently uses to score chart-abstracted measure validation. Accordingly, validation scoring would be based on the extent to which data abstracted for validation matches the data submitted to CMS, a minimum score of 75 percent accuracy would be required, and an upper bound of a 90 percent two-sided confidence interval would be used.⁵⁸

CMS also proposes, consistent with its existing policy for chart-abstracted data, that any missing medical records would be treated as mismatches beginning with validation of the 2027 eCQM data affecting the 2030 payment determination. Mismatches count against the agreement rate.

The same eCQM scoring method has been adopted for the Hospital Inpatient QRP.⁵⁹

Beginning with the validation of 2027 data for the 2030 payment determination, hospitals would receive two validation scores: one for chart-abstracted measure data and one for eCQM data. CMS proposes that if a hospital does not meet either validation requirement (e.g., does not attain at least a 75 percent validation score for each of chart -abstracted measure validation and for eCQM data validation), the hospital would not receive the full OPPS annual payment update (APU).

7. Educational Review Process

Under existing policy for chart-abstracted measures, if a hospital requests an educational review for any of the first three quarters of validation and the review yields incorrect CMS validation

⁵⁸ The current data validation scoring threshold for chart-abstracted measures is under §419.46(f)(2).

⁵⁹ 89 FR 69574-69577.

results, the corrected quarterly score is used to compute the final confidence interval.⁶⁰ Educational reviews for the final quarter of data are not completed soon enough to affect validation results and hospitals must use the reconsideration process. However, the proposal to extend the validation timeline from a 2-year cycle to a 3-year cycle would provide sufficient time to complete educational reviews for all four quarters.

Therefore, CMS proposes, beginning with the 2030 payment determination, to allow the results of educational reviews for all four quarters of chart-abstracted measure validation to be reflected in the final validation score before the calculation of the confidence interval.

CMS also proposes to extend the educational review process to eCQM validation beginning with validation affecting the 2030 payment determination. Hospitals have 30 calendar days from receipt of validation results to contact CMS' Validation Support Contractor requesting a written explanation of its performance. Hospitals would be able to request an educational review once annually for eCQM data since eCQM validation results would be received on an annual basis.

E. Validation Reconsiderations and Appeals Procedures

Under existing requirements at §419.46(g)(2)(vii), hospitals that submit reconsideration requests must submit a copy of all materials that the hospital submitted to comply with the requirements of the affected payment determination year. Beginning with validation affecting the 2024 payment determination, hospitals must submit only electronic files of medical records for HOQRP data validation. Given that electronic file-only requirement, CMS believes that the current reconsideration request requirement to resubmit medical documentation creates duplicative files and burden. A similar requirement to resubmit medical records as part of a request for reconsideration of a validation determination was removed from the Hospital Inpatient QRP beginning with 2023 discharges affecting FY 2026 payment determination.

Therefore, CMS proposes, beginning with data from the 2026 reporting period affecting the 2028 payment determination, to remove the requirement for hospitals to resubmit medical documentation as part of their request for reconsideration of validation.

F. Payment Reduction for Failing HOQRP Requirements

CMS proposes to continue its existing policies with respect to computing and applying the payment reduction for hospitals that fail to meet the HOQRP requirements for the 2027 update factor. The resulting reduction ratio for hospitals that fail to meet HOQRP requirements, called the "reporting ratio," for the 2027 payment determination would be 0.9805. CMS proposes to continue calculating the reporting ratio to four decimals. The reporting ratio is calculated by dividing the proposed reduced conversion factor of \$100.015 by the proposed full conversion factor of \$102.204. Continuing previous policies, the reporting ratio would be applied to all services calculated using the OPPS conversion factor and applied to all HCPCS codes to which CMS has assigned status indicators J1, J2, P, Q1, Q2, Q3, R, S, T, V, or U, excluding services paid under the New Technology APCs to which CMS has assigned status indicators S and T.

⁶⁰ Policies regarding the educational review process are under §419.46(f)(4).

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

XVI. Rural Emergency Hospital Quality Reporting Program (REH QRP)

Section 1861(kkk) of the Act establishes rural emergency hospitals (REHs) as a Medicare provider type that furnishes emergency department services and observation care. The REH must have a staffed emergency department 24 hours a day, 7 days a week and may elect to furnish other medical and health services on an outpatient basis. Payments specific to REHs began on January 1, 2023.

Section 1861(kkk)(7) of the Act establishes the REH QRP by requiring the Secretary to establish quality reporting requirements for REHs, require data submission at least quarterly, and publicly post performance data. There is no statutory incentive for submitting this data, nor statutory penalty for failing to submit the data. Program requirements are codified at 42 CFR 419.95.

CMS is not proposing any changes to the REH QRP. Below is a table showing the REH QRP measure set for 2026 through 2031 payment determinations (PDs), as previously finalized.

Previously Finalized REH QRP Measure Set by Data Collection Method and PD

CBE #	Measure Name	2026 PD	2027 PD	2028 PD	2029 PD	2030 PD	2031 PD
Chart-Abstracted Measures							
None	Median Time from ED Arrival to ED Departure 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 * REHs will have the option to report either the Median Time from ED Arrival to ED Departure for Discharged ED Patients measure OR the Emergency Care Access & Timeliness eCQM beginning with the 2027 reporting period/2029 PD.							

CMS estimates that for the 2027 reporting period there will be 48 REHs (an increase of 10 REHs from its estimate provided in the 2026 OPPS/ASC final rule) required to report under the REH QRP based on hospital conversions as of April 6, 2026.

XVII. Ambulatory Surgery Center Quality Reporting Program (ASC QRP)

A. Background

Under section 1833(i)(7) of the Act, an ambulatory surgical center (ASC) that does not submit for a year required data on quality measures specified by the Secretary receives a 2.0 percentage point reduction to the annual increase. Payment determinations are linked to a quality reporting period that occurs two years before the payment determination year (e.g., 2027 reporting is linked to 2029 payment). An exemption from program participation and payment reduction is given to an ASC that has fewer than 240 Medicare claims per year (the minimum case volume threshold).⁶¹ Many of the statutory provisions applied to the HOQRP are applied by statute to the ASC QRP. CMS provides references to the legislative and regulatory histories of the program.⁶²

CMS states that of 6,930 ASCs billing Medicare, 4,399 were required to participate in the ASC QRP for 2026 payment determinations. Of those not required, 650 ASCs chose to participate and met full requirements. Based on the 2026 payment determination data, CMS estimates that 5,149 ASCs will submit data for the program for the 2027 reporting period/2029 payment determination.⁶³

B. Program Measure Set

CMS is not proposing any changes to the ASC QRP measure set other than the cross-program proposal discussed in section XIV to remove the Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients measure beginning with the 2027 reporting period/2029 payment determination.

Table 75 in the rule lists the previously finalized measure set for the 2028 to 2032 PDs. The following table includes information from Table 75 and notes the proposed measure removal.

⁶¹ See §416.305(c). Also, under §416.305(b), ASCs may elect to withdraw from ASCQR program participation for a year but will be subject to the 2.0 percent payment reduction for that year.

⁶² 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>.

⁶³ CMS posts individual facility payment determination result lists on the website <https://qualitynet.cms.gov/asc/ascqr/apu#tab1>.

Previously Finalized ASC QRP Measure Set by Data Collection Method and PD

Measure Name	2028 PD	2029 PD	2030 PD	2031 PD	2032 PD
Chart-Abstracted Measures					
Patient Burn	X	X	X	X	X
Patient Fall	X	X	X	X	X
Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant	X	X	X	X	X
All-Cause Hospital Transfer/Admission	X	X	X	X	X
Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (CBE #0658)	X	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal
Normothermia Outcome	X	X	X	X	X
Unplanned Anterior Vitrectomy	X	X	X	X	X
Claims-Based Reporting					
Facility 7-Day Risk Standardized Hospital Visit Rate after Outpatient Colonoscopy (CBE #2539)	X	X	X	X	X
Hospital Visits After Orthopedic ASC Procedure (CBE #3470)	X	X	X	X	X
Hospitals Visits After Urology ASC Procedure CBE #3366)	X	X	X	X	X
Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at an ASC (CBE #3357)	X	X	X	X	X
Patient-Reported Outcomes-Based Performance Measures					
Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PROPM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO-PM)	Voluntary	Voluntary	Voluntary	X	X
Survey-Based Measures					
Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS-CAHPS) - 5 measures***	X	X	X	X	X
Cataracts Visual	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary
X= Measure is mandatory for the payment determination year. Voluntary= Submission of the measure is optional; ASCs that do not report on the measure are not subject to a payment reduction. *** Reporting on a set of OAS CAHPS measures: About Facilities and Staff; Communication About Procedure; Preparation for Discharge and Recovery; Overall Rating of Facility; and Recommendation of Facility.					

C. RFI on Stratification of the All-Cause Transfer/Admission Measure

The All-Cause Transfer/Admission measure is an outcome measure included in the ASC QRP that assesses the rate of ASC patients who require transfer to a hospital or admission to a hospital upon discharge from the ASC. The measure does not distinguish the phase of care (e.g., pre, during, or post procedure) in which the transfer occurs.

CMS is considering whether adding a phase of care stratification could improve the usefulness of the measure, provide insight into care processes between facilities, and support patient safety

monitoring. The agency seeks comment on clinically meaningful and feasible approaches for incorporating such a stratification for the measure, including on appropriate time anchors, their operational definitions, and corresponding timeframes that could be used to define each stratification category.

D. Form, Manner and Timing of Data Submission

CMS is not proposing any changes to its data submission and reporting requirement policies.⁶⁴

E. Payment Reduction for ASCs Failing ASC QRP

CMS proposes to continue applying its policies for determining the payment reduction for ASCs that fail to meet the ASCQR Program requirements. Statute requires that a 2.0 percentage point reduction to the ASC annual update be applied to ASCs that fail to meet the requirements. The reduction applies to services calculated using the ASC conversion factor with the payment indicators of A2, D2, G2, P2, R2, Z2, and the service portion of device-intensive procedures identified by J8. The reduction does not apply to services that are assigned other status indicators for which payments are not calculated using the ASC conversion factor, including separately payable drugs, biologicals, and radiopharmaceuticals; pass-through devices that are contractor-priced; brachytherapy sources that are paid based on OPPS payment rates; skin substitute supplies; software-as-a service codes; and others. All other applicable adjustments to the ASC national unadjusted payment rates apply (e.g., wage index adjustment, multiple procedure adjustment, interrupted procedure adjustment, and the adjustment for devices furnished with full or partial credit or without cost). When the update reduction is applied to a facility, beneficiary copayments are based on the reduced payment rate.

XVIII. Accrediting Organizations and Emergency Medical Treatment and Labor Act

A. Background

The Emergency Medical Treatment and Labor Act (EMTALA) applies to hospitals that participate in Medicare and operate emergency departments, including critical access hospitals (CAHs) and rural emergency hospitals (REHs). EMTALA requires that:

- When an individual comes to a hospital's emergency department and requests examination or treatment, the hospital must provide an appropriate medical screening examination to determine whether an emergency medical condition exists.
- If the hospital determines that the individual has an emergency medical condition, the hospital must provide either necessary stabilizing treatment within its capability or arrange for an appropriate transfer to another medical facility.
- Hospitals with specialized capabilities or facilities shall not refuse to accept appropriate transfers of individuals requiring such capabilities or facilities if the receiving hospital has the capacity to treat the individual.

⁶⁴ Data submission and reporting requirements are at §416.310.

The statute also authorizes the Office of Inspector General (OIG) to impose civil monetary penalties or exclude physicians from participation in Federal health care programs for EMTALA violations and permits CMS to terminate a hospital's Medicare provider agreement for non-compliance.

42 CFR §489.24 include detailed provisions governing the provision of medical screening examinations, stabilizing treatment, appropriate transfers, and receiving hospital responsibilities referred to below as the "core EMTALA requirements." 42 CFR §489.20(l), (m), (q) and (r) set forth requirements to post EMTALA signage, maintain a central log of individuals who present to the emergency department, retain transfer records for five years, and maintain an on-call physician list referred to below as the "EMTALA administrative requirements."

Enforcement of EMTALA has historically occurred through complaint investigations conducted by State Survey Agencies (SAs) under CMS direction. However, hospitals may also be accredited by an Accrediting Organization (AO) approved by CMS that meet or exceed applicable Medicare requirements. CMS' proposals will authorize AOs to take on some EMTALA responsibilities.

B. Proposals

CMS is making two proposals:

- An AO with CMS-approved accrediting programs for hospitals may assess compliance with the EMTALA administrative requirements as part of their initial accreditation and reaccreditation surveys.
- If an AO identifies EMTALA deficiencies at 42 CFR §489.24 during an accreditation or reaccreditation survey, the matter would be referred to CMS for further review and possible SA investigation.

If an AO identifies deficiencies with EMTALA administrative requirements, the AO will require the hospital or CAH to submit an acceptable Plan of Correction (PoC). If the PoC is accepted and the hospital has returned to compliance, then no further enforcement action would be taken. If the PoC is rejected, the AO would be required to contact the CMS location for further review.

The incorporation of EMTALA administrative requirements into the accreditation and reaccreditation survey process mean that AOs will assess whether hospitals are maintaining the documentation, recordkeeping, and operational safeguards that support transparency and accountability in emergency care. Because these obligations are record-based and procedural, CMS proposes to review AO survey processes as part its hospital accreditation program approval.

CMS would retain ultimate oversight responsibility and could take additional action as appropriate under its survey and enforcement authorities. This proposal would not authorize AOs to assess or enforce compliance with the core EMTALA requirements. CMS and OIG would

retain enforcement authority over those provisions.

Under section 1865(b) of the Act, the Secretary is prohibited from disclosing any accreditation survey conducted by a CMS-approved AO, unless it relates to an enforcement action or to a home health agency or hospice program survey. However, the statute does not prohibit the AO or a client hospital from disclosing its own survey findings.

XIX. Prior Authorization Botulinum Toxin Injection Codes

A. Background

In the 2020 OPDS final rule with comment period, CMS established a prior authorization process for certain hospital OPD services (84 FR 61142, 61446 through 61456) using its authority under section 1833(t)(2)(F) of the Act, which requires the Secretary to develop “a method for controlling unnecessary increases in the volume of covered OPD services. CMS added additional services to the prior authorization process in 2021 and 2023 (see 42 CFR §§419.80 through 419.89; the specific service categories are listed in 42 CFR §419.83).

B. Controlling Unnecessary Increases in the Volume of Covered OPD Services

1. Expansion of Service Category

In accordance with 42 CFR §419.83(b), **CMS proposes to expand prior authorization requirements to include additional Botulinum Toxin Injection services.** The eight additional Botulinum Toxin Injection codes would be incorporated into the existing list at proposed revised 42 CFR §419.83(a)(2) and would require prior authorization for services provided on or after July 1, 2027. The eight Botulinum Toxin Injection codes are listed in Table 76 of the proposed rule.

2. Basis for Expanding Service Category

In proposing the addition of these new services, CMS reviewed over 100 million OPD claims from 2017 through 2024. The agency determined that, on average, the number of OPD claims submitted for payment to the Medicare program decreased yearly by 1.1 percent. In contrast, over this same period, the volume of claims for the Botulinum Toxin Injection services listed in Table 76 increased by 42.8 percent. The codes CMS is proposing to add to the current prior authorization process represent approximately \$102 million in annual Medicare payments and constitute a subset of overall botulinum toxin utilization selected based on observed utilization volume, growth trends, and program integrity considerations.

CMS believes prior authorization for these additional codes will be an effective method for controlling unnecessary increases in the volume of these services and the agency expects that it will reduce the instances in which Medicare pays for services that are determined not to be medically necessary. **CMS requests comments on the addition of these new services, specifically on the potential for unintended clinical consequences that may result from this addition.**

XX. Provider-Based Requirements

A. Background

The provider-based rules (42 CFR §413.65) establish criteria that an entity must meet to be considered “provider-based” or a part of a provider. Among other requirements, off-campus provider-based facilities must be no more than 35 miles from the main provider or they must demonstrate that they serve the same patient population as the main provider. Outpatient provider-based departments are paid under either the OPPS or the “applicable system” under section 1833(t)(21) of the Act. The “applicable system” applies to off-campus provider-based departments that first began providing outpatient services after November 2, 2015 and is 40 percent of the OPPS amount.

B. Section 6225 of the Consolidated Appropriations Act (CAA), 2026

Section 6225 of the CAA, 2026 prohibits Medicare payments under either the OPPS or the applicable system beginning January 1, 2028, unless an off-campus outpatient department of a provider bills using a separate National Provider Identifier (NPI) and the main provider has submitted an attestation that the department meets the provisions at 42 CFR §413.65. An initial attestation is required during the 2-year period ending on the date such items and services are furnished. A subsequent attestation is required within a timeframe specified by the Secretary. The initial attestation can be submitted under the current 42 CFR §413.65 requirements until the Secretary establishes the new attestation process.

C. Modifications to Implement the Provisions of Section 6225 of the CAA, 2026

CMS is proposing to add a definition to 42 CFR §413.65(a)(2) describing an off-campus outpatient department of a provider as one that is not located on the campus of the main provider or within 250 yards of a remote location of a hospital. A remote location is a campus of the provider that is not the main campus and has inpatient facilities. The current regulations define a “campus” and a “remote location of a hospital” and imply an off-campus department is not within 250 yards of the inpatient buildings on a hospital’s campus. CMS’ proposal explicitly defines an “off-campus outpatient department” as being within 250 yards of the main buildings of the main hospital campus or the main buildings of a remote location.

For similar reasons, CMS proposes to explicitly exclude outpatient departments as off-campus departments if they are within 250 yards of the main buildings of a hospital’s main campus or remote location. CMS believes these changes will better clarify which facilities are affected by the new legislation and will better align the current provider based rules with statutory provisions regarding the distinction between on- and off-campus locations and services.

CMS proposes to require initial attestations between January 1, 2026 and December 31, 2027 for services furnished before January 1, 2028 and within two years of the date of service for services furnished on or after January 1, 2028. Subsequent attestation(s) would be submitted at an interval to be specified by CMS and not to exceed five years thereafter.

For a provider that has not received a provider-based determination, the submission of the initial

attestation will fulfill the CAA, 2026 attestation requirement to be paid under the OPPI or the applicable system. For a provider that has received a provider-based determination, CMS is considering having an authorized official attest using a letter with evidence of the prior provider-based determination and affirming continued compliance with the provider-based rules without having to separately attest to meeting all of the requirements of the provider-based rules.

CMS proposes to replace the current MAC-specific attestation templates with a standardized attestation form. Main providers would submit the attestation through a centralized electronic system. The rule indicates that a draft attestation form is located at the hyperlink provided at the beginning of this summary but it does not appear to have been posted yet. Until the standardized form and centralized electronic system are finalized, providers may continue to submit attestations using the current process.

Under the current attestation process, providers submit their attestations and supporting documentation to their MAC, which performs a preliminary review and forwards its recommendation to CMS for the initial determination. CMS proposes to modify this process so that the MACs conduct standardized review and validation activities in support of initial determination rather than requiring separate CMS review of each attestation recommendation. The MAC will provide written acknowledgment of receipt, review the attestation for completeness and consistency, and determine whether the facility or organization is provider-based.

For providers that submit attestations for more than one off-campus outpatient department, CMS is considering streamlined supporting documentation requirements and seeks input on how best to minimize burden while ensuring robust oversight. Further, CMS anticipates leveraging system capabilities to reduce duplicative documentation submissions by allowing supporting documentation applicable to multiple locations to be submitted a single time, where appropriate.

D. Documentation Requirements for Provider-Based Attestations

CMS proposes the following documentation requirements:

- **Attestation Form:** Providers must submit a completed attestation using the CMS standardized attestation form, signed and dated by an authorized official of the main provider as identified in the (Provider Enrollment, Chain, and Ownership System) PECOS. The attestation would be required to identify both the main provider and each off-campus outpatient department of the provider for which provider-based status is sought, including the applicable NPIs, provider numbers, addresses, and the date on which provider-based conditions were met or the date the department was acquired.
- **Location:** CMS anticipates the attestation system would have the ability to measure the distance requirement but also be supported with documentation from the provider.
- **Licensure:** Providers must be prepared to demonstrate that the off-campus outpatient department is operated under the same licensure as the main provider or document that the State does not require a separate license for the department.
- **Clinical Services Integration:** Providers must be prepared to demonstrate that the off-campus outpatient department professional staff hold privileges at the main provider; that

appropriate monitoring and oversight of the department by the main provider is in place; that inpatient and outpatient services of the department and the main provider are integrated; and that patients treated at the department who require further care have full access to all services of the main provider.

- **Financial Integration:** Providers must be prepared to demonstrate that the revenues and expenses of the off-campus outpatient department are integrated with those of the main provider and it does not maintain a separate general ledger or trial balance independent of the main provider.
- **Public Awareness:** Providers must be prepared to demonstrate that the off-campus outpatient department is clearly identified to the public as part of the main provider and that patients are aware they are receiving services from the main provider.
- **Obligations Specific to Off-Campus Outpatient Departments:** Off-campus provider-based departments must be prepared to demonstrate compliance with EMTALA, site-of-service billing requirements, and the requirement to provide written notice to Medicare beneficiaries of their potential financial liability prior to the delivery of services (likely a reference to the Medicare Outpatient Observation Notice or MOON).⁶⁵
- **Ownership, Control, Administration, and Supervision:** Providers must be prepared to demonstrate that the department operates under the ownership and control of the main provider including final approval over administrative decisions, personnel policies, and medical staff appointments as well as administrative functions of the department are integrated with those of the main provider.

E. CMS Verification and Oversight Activities

Section 6225 of the CAA, 2026 directs the Secretary to establish a process for determining compliance with its requirements and the provider-based rules. CMS proposes the following process:

- **Initial Review.** CMS and the MACs will conduct automated validation and screening of attestations to verify completeness, consistency with PECOS enrollment records, and the presence of required attestation elements. Attestations that pass automated validation would be processed for initial determination.
- **Targeted Review:** Additional documentation would be required for attestations that present indicators of incompleteness, inconsistency, or elevated compliance risk.
- **Extended Review:** CMS and its contractors, including program integrity contractors, would employ risk-based methodologies to select a subset of attestations for remote audits of provider records and documentation, site visits conducted by CMS or its contractors.

The criteria and methodologies CMS would use to select attestations for extended review would be established through operational guidance and would be designed to focus oversight resources on providers and departments that present the highest risk of non-compliance with the provider-based requirements. Failure to submit requested documentation within the timeframe specified

⁶⁵ The MOON is formal notification hospitals are required to give beneficiaries that they are receiving observation services as outpatients rather than being admitted as inpatients within 36 hours of the observation services being initiated.

by CMS may result in a determination of non-compliance and recovery of overpayments.

F. Information Collection Requirements

CMS believes its proposal to establish a standardized attestation form for provider-based determinations submitted through a centralized electronic system will reduce the time required to submit each attestation by 25 to 75 percent. As a result of the new mandatory attestation requirement, CMS expects there to be an increase in both the number of main providers submitting attestations and the number of attestations submitted by each main provider.

Under mandatory attestation requirements, CMS estimates that 1,832 main providers would take 5 hours per attestation, and, on average, each main provider would submit 9 attestations for provider based departments. Therefore, CMS has calculated the burden as 16,488 responses times 5 hours per response = 82,440 burden hours.

CMS the attestation will come from an executive officer of the hospital. Using the most recent Bureau of Labor and Statistics Occupational and Employment Data (May 2024) for the position of Top Executives (\$67.24 doubled to \$134.48 per hour for fringe benefits), CMS estimates total costs of \$11,086,531 (82,440 hours x \$134.48 per hour). This estimated increase is relative to \$327,150 from the current requirements.

XXI. Notice of Closure of Teaching Hospital

Section 5506 of the Affordable Care Act authorizes the Secretary to redistribute residency slots of a hospital that trained residents in an approved medical residency program after its closure. CMS is notifying the public of the closure of Louis A. Weiss Memorial Hospital located in Chicago, Illinois:

Available Resident Cap FTEs

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME Resident Cap	DGME Resident Cap
140082	Louis A. Weiss Memorial Hospital	Chicago, IL	16984	August 9, 2025	85.82	66.79

Application Process for Available Resident Slots

The application period for hospitals to apply for slots under section 5506 is 90 days following notification to the public of a hospital closure. Therefore, hospitals must apply to the CMS Central Office to be eligible to receive slots from this closed hospital by October 13, 2026.

CMS will only accept applications submitted via MEARIS™ ([MEARIS™ \(cms.gov\)](https://www.cms.gov/MEARIS)). 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.

XXII. Separate IPPS Payment: Personal Protective Equipment and Essential Medicines

In the 2026 “Ensuring Safety Through Domestic Security With Made in America Personal Protective Equipment (PPE) and Essential Medicine Procurement by Medicare Participating Hospitals” advance notice of proposed rulemaking ([91 FR 3851](#)),⁶⁶ CMS sought public comment on potential options that the agency could consider for Medicare participating hospitals to help foster a more resilient supply chain for American-made PPE and essential medicines to secure our nation's health and safety, and to reflect the additional resource costs incurred when procuring these domestically manufactured items.

In this proposed rule, CMS is seeking further public input on this issue after reviewing the comments on the ANPRM. Specifically, the agency is soliciting public comment on potential policy approaches for a payment adjustment, a methodology to calculate the price differential between domestic and non-domestic PPE and essential medicines, information sources of those price differentials, a definition of domestic essential medicine and PPE, and a process for verifying that a given essential medicine or PPE is “domestic.”

A. Overview

CMS believes that hospitals’ procurement preferences directly influence upstream intermediary and manufacturer behavior and can be leveraged to help foster a more resilient supply chain for domestically manufactured goods. CMS also believes that a voluntary payment adjustment that reflects the additional marginal costs that hospitals face in procuring these products may help to sustain their domestic production and availability and thereby help to safeguard personnel and beneficiary safety over the long term. Medicare currently has a voluntary payment policy under the IPPS and OPPTS for the additional resource costs that hospitals face in procuring domestic National Institute for Occupational Safety and Health (NIOSH)-approved surgical N95 filtering facepiece respirators (FFRs). CMS is considering⁶⁷ expanding the existing IPPS payment policy to include other forms of domestic PPE and certain essential medicines.

As part of this potential expansion, CMS seeks stakeholder input on:

1. Expanded Scope of PPE and Domestic Definition: Expanding current policy to include certain domestically produced face respirator, gloves, and gowns, defining “domestic” using the contract terms listed in the Make PPE In America Act, ([section 70953 of Pub. L. 117-58](#)), which identifies American-made PPE as domestically-made from domestic materials and components that are “grown, reprocessed, reused, or produced in the United States.”
2. Potentially Eligible Essential Medicines and Domestic Definition: Expanding current policy to include certain FDA-approved medicines which have existing U.S. finished dosage form (FDF) production and do not contain API from countries listed on the “foreign adversaries” list at 15 CFR 791.4,⁶⁸ and defining the drug as “domestic” if the

⁶⁶ Hereinafter in this section referred to as “the ANPRM.”

⁶⁷ CMS does not make specific proposals in this section of the proposed rule, but rather is seeking input on ideas the agency is considering for future rulemaking.

⁶⁸ <https://www.ecfr.gov/current/title-15/subtitle-B/chapter-VII/subchapter-E/part-791/subpart-A/section-791.4>.

country of origin is the U.S., where country of origin is defined through incorporation by reference as the country in which “substantial transformation” of the final dosage form occurs via 19 CFR 134.1(b).

3. Domestic and Non-domestic Cost Differential: Whether the methodology for determining the amount of the payment adjustment should be based on the use of standardized cost differentials for eligible domestic PPE and essential medicines, and the potential magnitude of such cost differentials.
4. Manufacturer Attestation of Domestic Origin: Whether under a potential policy a manufacturer should voluntarily be able to provide an attestation to HHS that its product meets the applicable domestic definition.
5. Potential Payment Adjustment Approaches: Different potential approaches under the IPPS to separately pay for the additional resource costs that hospitals face when purchasing eligible domestic PPE and essential medicines.
6. Annual Spending Threshold: Whether to establish an appropriate maximum annual amount of aggregate separate payment under this policy and to prospectively allocate shares of that amount to individual hospitals before the start of the fiscal year.

B. Prior Rulemaking

CMS recaps supply chain disruptions and shortages of certain PPE that occurred during the COVID-19 public health emergency (PHE) that began in the spring of 2020. CMS then reviews certain Medicare payment policy changes that were subsequently implemented to encourage hospitals to procure, and maintain buffer stocks of, certain domestically produced PPE (e.g., N95 respirators). The agency reviews its efforts during the 2025 OPPI/ASC rulemaking cycle to solicit input on potential expansions of the post-PHE policy, noting that stakeholders supported expanding the policy to more products beyond N95 respirators, and also supported increasing the financial incentives for hospitals to purchase domestically produced PPE.

C. Potential Eligible Domestic PPE Products and Cost Differentials

After consideration of the comments the agency received on the ANPRM, to further support a level of supply resilience that is critical to protect the health and safety of personnel and patients, CMS is now considering expanding the PPE products eligible for the separate IPPS payment adjustment to include all domestic NIOSH-approved FFRs that demonstrate compliance with the ASTM Respirator Fit Capability Standard, domestic medical gloves in compliance with FDA requirements and conforming to ASTM standards, and domestic gowns in compliance with FDA requirements and conforming to AAMI standards. CMS lists these items, and the price differentials under consideration, in Table 79 of this proposed rule, reproduced below.

TABLE 79: DOMESTIC PPE ITEMS BEING CONSIDERED WITH BASE COST DIFFERENTIALS AND QUALIFYING CRITERIA

Eligible PPE Item	Domestic Differential Per Single Item	Required Compliance
Filtering Facepiece Respirators	\$0.38	- NIOSH-approved - ASTM Respirator Fit Capability Standards

Eligible PPE Item	Domestic Differential Per Single Item	Required Compliance
Isolation gowns	\$0.82	- FDA Compliance - AAMI Standards
Nitrile exam gloves	\$0.05	- FDA Compliance - ASTM Standards

Interestingly, CMS notes that previously the agency had considered the Berry Amendment (87 FR 72039 through 40) as the best framework for determining whether or not a given PPE product should be considered domestically produced.⁶⁹ However, given that the inputs and constituent materials of some potentially eligible domestic PPE products (such as nitrile gloves) are not wholly defined by the Berry Amendment, CMS is considering defining domestic for purposes of this potential payment policy using the Make PPE In America Act domestic content requirements for Federal procurement contracts outlined in section 70953 of the Infrastructure Investment and Jobs Act.

D. Potential Eligible Domestic Essential Medicines and Cost Differentials

The report, *Essential Medicines Supply Chain and Manufacturing Resilience Assessment*, as developed by the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) with the Advanced Regenerative Manufacturing Institute’s (ARMI’s) Next Foundry for American Biotechnology, prioritized 86 essential medicines from the Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs, as developed under the Executive Order by the U.S. Food and Drug Administration (FDA).⁷⁰ For purposes of expanding Medicare’s current payment policy for domestically produced PPE, CMS is considering including certain FDA-approved medicines from the ARMI List which have existing U.S. FDF production, and do not contain API from countries listed on the “foreign adversaries” list at 15 CFR 791.4. CMS lists the medications it is considering for the PPE payment policy expansion in Table 80 of the proposed rule.

CMS also seeks comment regarding whether the methodology for determining the amount of the payment adjustment under this potential policy should be based on the use of standardized cost differentials for eligible categories of domestic essential medicines. For each eligible essential medicine, CMS solicits comment regarding whether it would be appropriate to use two separate possible base cost differentials, depending on whether both the FDF and API for the drug are manufactured domestically, or just the FDF is manufactured domestically. CMS provides

⁶⁹ The Berry Amendment is a statutory requirement familiar to manufacturers that restricts the Department of Defense (DoD) [*n.b.* – CMS uses the name Department of Defense] from using funds appropriated or otherwise available to DoD for procurement of food, clothing, fabrics, fibers, yarns, other made-up textiles, and hand or measuring tools that are not grown, reprocessed, reused, or produced in the U.S. Berry Amendment restrictions are implemented by the DoD Federal Acquisition Regulation Supplement (DFARS) 252.225-7002, and DoD cannot acquire specified “items, either as end products or components, unless the items have been grown, reprocessed, reused, or produced in the U.S.” With limited exceptions, the entire production process of an affected product, from the production of raw materials to the manufacture of all components to final assembly, must be performed in the U.S.

⁷⁰ <https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs>.

examples of the questions it is considering with respect to determining, and compensating for, cost differentials, in close detail, and lists the specific drugs and cost differentials it is currently considering in Table 81 of the proposed rule.

E. Public File of Potential Eligible Products

Under this potential policy, manufacturers of potentially eligible domestic PPE and essential medicines would voluntarily submit annual attestations to HHS that their products meet the agency's domestic definitions. The annual attestations from PPE manufacturers would have to demonstrate that the product was in compliance with the "Make PPE in America" standards for domestic procurement. Under this potential policy, HHS would compile the information provided by manufacturers and create an annual file of eligible domestic products and domestic cost differential estimates, including the NDC or UDI for the product, as applicable, manufacturer name, and part number. This public file would be intended to provide hospitals with a simple, reliable reference for identifying eligible domestic products and the estimated domestic cost differentials.

F. IPPS Payment Adjustments for Domestically Purchased PPE and Essential Medicines

CMS is considering using its authority under section 1886(d)(5)(I) of the Act to establish a voluntary separate IPPS payment adjustment for the IPPS share of the additional resource costs incurred by hospitals in procuring eligible domestic PPE and essential medicines. CMS is considering two approaches to making such payment adjustments: a claims-based approach (Approach 1) and a cost report-based approach (Approach 2).

Under Approach 1 the claims processing system would use the domestic cost differentials discussed above to automatically calculate and pay the separate IPPS payment adjustment based on the domestic NDCs and units of those NDCs for eligible domestic essential medicines furnished to an IPPS inpatient during an IPPS hospital stay that a hospital voluntarily bills on the IPPS claim for that IPPS stay. Under Approach 2, a hospital would voluntarily use that same information to calculate the payment across all of its IPPS stays during its cost reporting period and report that aggregated information on its cost report instead of billing individually on its IPPS claims. The payment is the same under either approach, but the hospital would not need to submit the NDCs on the claim under Approach 2. CMS is considering parallel approaches for PPE. For Approach 2, CMS discusses two different methods for allocating the costs of domestically produced PPE and essential medicines to Medicare hospital inpatients, and the agency provides detailed examples of how it is thinking of allocating costs under each of these alternatives.

CMS requests comments on a potential separate payment adjustment under the IPPS for the additional resource costs hospitals incur when procuring domestically manufactured items.

G. Maximum Annual Amount of Aggregate Payments

CMS asserts that regardless of any specific approach or option that may be proposed and

executed in the future, it may be prudent to establish an appropriate maximum annual amount of aggregate separate payments that would be available across all IPPS hospitals. If so, the agency could prospectively allocate shares of this aggregate amount to individual hospitals before the start of the fiscal year. If the actual separate payment to a hospital for the fiscal year exceeds its allocated maximum amount, the excess amount would be reconciled at cost report settlement, as the payment for that hospital's excess cost would be considered still bundled into the MS-DRG payment and not separately payable. CMS posits that one potential mechanism for allocating the amount to individual hospitals would be the Medicare inpatient days as reported on Worksheet S-3, Part I, column 6 (Title XVIII), or column 6.01 (if applicable), lines 1, 8 through 12, and subscripts as applicable.

H. Solicitation of Additional Options: Domestic PPE and Essential Medicines

In addition to the approaches described earlier, CMS asks for general input on additional options from the public. The agency states that comments that include detailed information on economic impacts, timing, potential statutory authorities, and a discussion of trade-offs with respect to such options are especially useful. CMS also requests comment on the operational feasibility and difference of the approach for PPE versus essential medicine of the different aspects of the potential policy. Lastly, CMS solicits comment and applicable data regarding current domestic production capacity, manufacturers' ability to expand output, expected expansion timelines, and barriers to scaling production.

XXIII. RFI: Standardization and Comparability of Hospital Price Transparency Data

A. Background

Since January 1, 2021, CMS has required each hospital operating in the United States to provide clear, accessible pricing information online about the items and services they offer in two ways: (1) as a comprehensive machine-readable file (MRF) and (2) via a consumer-friendly display. CMS describes the regulatory actions it has recently undertaken in response to Executive Order (E.O.) 14221, "Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information" (90 FR 11005) and reaffirms its commitment to "continue to promote universal access to clear and accurate healthcare prices" and "identify opportunities to further empower patients with meaningful price information" as directed by that E.O.

B. Machine Readable File (MRF) RFI

CMS believes that further enhancements to the format and content of the MRF will build on the progress already made to increase the utility and comparability of the data. Feedback received to date has emphasized the importance of standardization of data within the MRF to promote accuracy and completeness.

In particular, CMS notes specific challenges that users of MRFs encounter related to interpreting and parsing hospital contracting provisions that establish a negotiated rate, which are often presented in free text fields. CMS and interested parties have notes that common contracting

provisions include outlier provisions, stop-loss clauses, rate-tiering arrangements, and carve-out provisions. Some interested parties believe that requiring hospitals to report these clauses in a more standardized format would help MRF users better understand when a standard charge applies, and circumstances in which it may not apply.

Thus, CMS specifically seeks feedback on the following:

- Whether outlier, stop-loss, rate-tiering, and carve-out provisions are considered payer-specific negotiated charges at the item or service level (in which case they are already required to be encoded in the algorithm data element for each item or service), or whether they are more appropriately considered general contract provisions that apply broadly.
- If such contracting provisions are more appropriately considered general contracting provisions that apply broadly across items and services, what specific requirements for standardization of such complex contracting methodologies would facilitate hospital reporting of accurate and complete information.

Additionally, interested parties continue to express concerns related to variations in the names of payers and plans across hospitals' MRFs which makes it difficult for users to compare payer-plan combinations. Interested parties have provided a number of recommendations on how CMS should require more standardization including: publishing a standardized list of the top payer names, requiring a payer or plan unique identifier (for example, a tax identification number or employer identification number), and requiring additional clarifying information like product type and plan type.

CMS reiterates the importance of requiring more standardization in the MRF to increase the utility of the data and, thereby, increasing competition. As such, CMS seeks information from the public on how to strengthen the transparency and usability of the MRFs. Specifically, CMS welcomes public comment on the areas of consideration outlined below.

1. Increasing Transparency of Outlier Provisions and Additional Contract Terms

- What information is needed for users of the MRF to fully understand contract terms related to outlier payments, stop-loss, rate-tiering, carve-outs, and other adjustments that occur across hospital items and services?
- How are hospitals currently reporting contract terms for outlier payments, stop-loss, rate-tiering, carve outs or other adjustments in the MRFs? Are the current formats sufficient for conveying these and other important contract terms? If not, what changes to the current formats, such as separate data elements, would be advised to accommodate the disclosure of such contract terms in a standard manner?
- Do outlier and carve-out contract terms typically apply to individual services, a category of services, or across the entire contract? Should rate-tiering standard charge information be reflected in the payer-specific negotiated charge?
- What additional contracting or payment adjustments affect payer-specific negotiated charges at the item or service level, across items and services, or at the contract level, and should that information be encoded in the current data elements provided? If not, what

changes to the current formats would be advised to capture this information in a standard manner?

2. Standardization to Enhance Utility of the MRF

- Are there challenges in parsing and categorizing the free text fields when analyzing MRFs? If so, what parameters or requirements would facilitate parsing and categorizing free text fields?
- Are there categories of information or topics consistently included in free text fields that may be standardized through the addition of new data elements? If so, what topic areas should be considered?
- Are there additional contract methodologies that should be reflected as valid values in the MRF, outside the current valid values of fee schedule, capitation, per diem, case rate and other?
- Should CMS require more structured reporting of payer, plan, product, network, and employer (as applicable) information across hospital MRFs, and if so, which elements should be required? Are there existing identifiers for payers and plans, to which hospitals have access, that should be incorporated in the MRF?
- What additional information should CMS consider to enhance the utility and comparability of the MRF data?

CMS notes that the agency anticipates providing additional guidance to support clearer and more accurate reporting of this information and proposing additional requirements through future notice and comment rulemaking.

C. Consumer-Friendly Display

In the 2020 OPPS/ASC final rule (84 FR 65524), CMS established requirements for hospitals to display 300 items and services, 70 of which CMS specified, in a consumer-friendly display. CMS provided limited specifications related to data requirements for display of this information, allowing hospitals flexibility in the format which must be either in a shoppable services file or an online price estimator tool.

CMS summarizes feedback it received from a series of listening sessions with consumers, consumer advocacy organizations, hospitals, and price estimator tool developers in June and July 2025. Issues and concerns raised have included: (1) utility of online price estimator tools and CMS' policy (as provided at 45 CFR §180.60(a)(2)) to deem hospitals in compliance with the consumer-friendly display requirements if they offer a price estimator tool, (2) additional contextual information that may be important to the consumer to understand a "real price", (3) the specific currently required 70 CMS-specified shoppable services, and (4) mismatches in prices displayed in the hospitals' MRFs compared to consumer-friendly prices displayed for the same item or service.

CMS desires to strengthen the comparability of the data included in the consumer-friendly display to enhance consumers' ability to shop for care and obtain pricing information in advance of scheduled services. CMS therefore welcomes public comment on the following questions:

- Should the agency revisit the number and types of CMS-specified shoppable services? What are the advantages and disadvantages of increasing or decreasing the number of shoppable services? Are there specific shoppable services that CMS should include, exclude, or update on the list of 70 CMS-specified items and services?
- What would be the advantages and/or disadvantages of requiring hospitals to submit a shoppable services file? Alternatively, what would be the advantages and/or disadvantages of removing the deemed compliance for the price estimator tools? Does the current incongruity in how hospitals display shoppable services, with some posting a shoppable services file and others utilizing a price estimator tool, make it more difficult for consumers to compare prices for shoppable services across different hospitals? What positive or negative effects would consumers experience if the price estimator tool alone were no longer considered compliant?
- For hospitals that satisfy the consumer-friendly display requirements through a price estimator tool, what mechanisms could be used to make the underlying data available in a separate file?
- Are there circumstances in which the standard charges in a hospital's shoppable services file would not match the information for the same items and services listed in the hospital's MRF? Why would a hospital be able to provide a discounted cash price in its price estimator tool but not in its MRF?
- Which data elements are important for consumers to make comparisons between hospitals? Would a standard shoppable services file template make the information more comparable? How could a shoppable services file indicate the ancillary services that are included in or excluded from the price?
- How should hospitals present ancillary items, implants, and bundled services so consumers better understand total expected costs? What approaches most effectively distinguish included versus excluded services?
- What additional information should CMS consider to enhance the comparability of the consumer-friendly display data between hospitals?

Table 88: 2027 Proposed Rule Impact Table

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Number of Hospitals	APC Recalibration (all changes)	New Wage Index and Provider Adjustments	340B Adjustment	All Budget Neutral Changes with Market Basket Update	Payment Adjustment for Imaging w/o Contrast at Off Campus Providers	All 2027 Proposed Changes	Impact of Adjustment only for Providers Subject to 340B Remedy Offset
ALL PROVIDERS*	3,471	0.0	0.1	0.0	2.5	-0.4	1.9	-2.9
ALL HOSPITALS (excludes hospitals held harmless and CMHCs)	3,362	0.1	0.0	-0.1	2.4	-0.4	1.8	-2.9
URBAN HOSPITALS	2,693	0.1	0.0	-0.5	1.9	-0.4	1.3	-2.9
LARGE URBAN (>1M)	1,274	0.1	-0.2	-0.9	1.4	-0.4	1.0	-2.9
OTHER URBAN (<=1 M)	1,419	0.1	0.1	-0.3	2.3	-0.4	1.6	-2.9
RURAL HOSPITALS	669	-0.1	0.5	3.5	6.4	-0.1	5.9	-3.0
SOLE COMMUNITY	329	-0.2	0.7	5.7	8.8	0.0	8.3	-3.0
OTHER RURAL	340	-0.1	0.2	-0.1	2.5	-0.3	2.0	-3.0
BEDS (URBAN)								
0 - 99 BEDS	918	0.4	0.1	4.8	7.9	-0.2	7.5	-2.7
100 - 199 BEDS	741	0.3	0.1	3.0	6.0	-0.3	5.4	-2.9
200 - 299 BEDS	426	0.4	-0.2	2.0	4.6	-0.5	4.1	-2.9
300 - 499 BEDS	377	0.3	-0.1	0.3	2.9	-0.4	2.3	-2.9
500 + BEDS	231	-0.3	0.0	-5.2	-3.2	-0.5	-4.0	-2.9
BEDS (RURAL)								
0 - 49 BEDS	315	0.0	0.8	4.6	8.0	0.0	7.0	-2.9
50 - 100 BEDS	196	-0.1	0.3	3.9	6.6	0.0	6.2	-3.0
101 - 149 BEDS	89	-0.2	0.1	2.0	4.4	-0.2	4.3	-3.0
150 - 199 BEDS	39	-0.2	0.7	3.9	6.9	-0.2	6.2	-3.0
200 + BEDS	30	-0.3	0.8	2.7	5.6	-0.2	5.2	-3.0
REGION (URBAN)								
NEW ENGLAND	122	0.0	1.5	-0.7	3.1	-0.6	2.5	-3.0
MIDDLE ATLANTIC	290	0.0	-0.4	-1.2	0.7	-0.8	-0.1	-2.9
SOUTH ATLANTIC	445	0.2	0.0	-0.2	2.3	-0.4	2.0	-2.9

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Number of Hospitals	APC Recalibration (all changes)	New Wage Index and Provider Adjustments	340B Adjustment	All Budget Neutral Changes with Market Basket Update	Payment Adjustment for Imaging w/o Contrast at Off Campus Providers	All 2027 Proposed Changes	Impact of Adjustment only for Providers Subject to 340B Remedy Offset
EAST NORTH CENTRAL	410	0.0	-0.8	-0.9	0.6	-0.6	0.0	-3.0
EAST SOUTH CENTRAL	163	-0.1	0.3	-3.0	-0.4	-0.4	-0.7	-3.0
WEST NORTH CENTRAL	173	-0.1	0.9	-1.6	1.6	-0.2	0.4	-3.0
WEST SOUTH CENTRAL	442	0.4	-1.0	1.5	3.3	-0.4	3.1	-2.9
MOUNTAIN	222	0.2	-0.3	1.0	3.4	-0.2	2.6	-2.9
PACIFIC	376	0.2	0.5	-0.4	2.7	-0.2	2.0	-2.9
PUERTO RICO	50	0.5	-1.3	4.8	6.5	0.0	6.6	0.0
REGION (RURAL)								
NEW ENGLAND	20	-0.3	2.5	4.1	9.0	0.0	8.9	-3.0
MIDDLE ATLANTIC	46	-0.3	-0.6	1.3	2.8	-0.2	2.7	-3.0
SOUTH ATLANTIC	109	0.0	0.8	2.9	6.2	-0.4	6.0	-3.0
EAST NORTH CENTRAL	112	-0.1	-0.6	3.4	5.1	-0.2	5.0	(8)
EAST SOUTH CENTRAL	125	-0.1	0.3	1.0	3.6	-0.1	3.8	-3.0
WEST NORTH CENTRAL	73	-0.2	0.8	5.6	8.7	0.0	8.0	-3.0
WEST SOUTH CENTRAL	120	0.4	-0.8	5.0	7.0	-0.2	7.1	-3.0
MOUNTAIN	39	-0.2	1.2	5.6	9.1	0.0	7.5	-2.9
PACIFIC	24	-0.3	3.1	3.2	8.7	0.0	5.4	-3.0
PUERTO RICO	1	2.7	4.7	8.1	19.0	0.0	11.9	0.0
TEACHING STATUS								
NON-TEACHING	1,993	0.3	0.1	3.5	6.4	-0.3	6.0	-2.9
MINOR	905	0.3	0.1	1.1	3.9	-0.4	3.2	-3.0
MAJOR	464	-0.3	-0.1	-4.3	-2.4	-0.5	-3.1	-2.9
DSH PATIENT PERCENT								
0	10	-0.1	-1.3	8.1	9.1	-0.4	9.0	-2.5
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)

	Number of Hospitals	APC Recalibration (all changes)	New Wage Index and Provider Adjustments	340B Adjustment	All Budget Neutral Changes with Market Basket Update	Payment Adjustment for Imaging w/o Contrast at Off Campus Providers	All 2027 Proposed Changes	Impact of Adjustment only for Providers Subject to 340B Remedy Offset
> 0 - 0.10	232	0.5	-0.3	6.9	9.7	-0.3	9.3	-2.9
>= 0.10 - 0.16	266	0.5	0.2	6.6	10.0	-0.5	9.3	-2.8
>= 0.16 - 0.23	538	0.5	-0.2	6.4	9.3	-0.5	9.0	-2.9
>= 0.23 - 0.35	1,126	0.0	0.2	-0.7	1.9	-0.4	1.2	-2.9
>= GE 0.35	776	-0.3	-0.1	-5.8	-3.9	-0.3	-4.5	-2.9
DSH NOT AVAILABLE **	414	0.5	-0.2	6.8	9.8	-0.4	9.5	-2.8
URBAN TEACHING/ DSH								
TEACHING & DSH	1,204	0.0	0.0	-1.9	0.4	-0.5	-0.3	-2.9
NO TEACHING/DSH	1,086	0.4	0.0	3.3	6.2	-0.3	5.8	-2.9
NO TEACHING/NO DSH	10	-0.1	-1.3	8.1	9.1	-0.4	9.0	-2.5
DSH NOT AVAILABLE**	393	0.6	-0.2	6.8	9.8	-0.4	9.5	-2.8
TYPE OF OWNERSHIP								
VOLUNTARY	1,970	0.0	0.0	-0.5	2.0	-0.4	1.4	-2.9
PROPRIETARY	990	0.9	-0.4	7.4	10.6	-0.2	10.3	-2.9
GOVERNMENT	402	-0.3	0.2	-3.0	-0.8	-0.3	-1.3	-2.9
CMHCs	39	-0.5	-1.9	8.1	8.1	0.0	8.4	-0.2

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

Column (2) includes all CY 2027 OPPS policies and compares those to the CY 2026 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2027 hospital inpatient wage index. The rural SCH adjustment proposes to continue our current policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the cancer hospital adjustment is 0.9994 because the proposed CY 2027 target payment-to-cost ratio is higher than the CY 2026 PCR target.

Column (4) shows the impact of the proposed 340B drug payment adjustment and the corresponding increase in non-drug service payment.

Column (5) shows the impact of all budget neutrality adjustments and the addition of the 2.4 percent OPD rate update factor (proposed IPPS market basket

percentage increase of 3.2 percent reduced by proposed 0.8 percentage point for the productivity adjustment).

Column (6) shows the separate impact of the payment adjustment for imaging without contrast APC services furnished at excepted off campus providers.

Column (7) shows the combined impact of columns 5 and 6, plus additional adjustments to the conversion factor resulting from a change in the pass-through estimate and adding estimated outlier payments. Note that previous years included the frontier adjustment in this column, but we have included the frontier adjustment to Column 3 in this table.

The column for providers subject to the 340B Remedy Offset shows the separate impact of applying the proposed 3.0 percentage point reduction to the OPPS conversion factor update as part of the 340B Remedy Offset.

These 3,471 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.

We estimate that 3,217 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.