

RULE SUMMARY

AUGUST 2025

MEDICARE OUTPATIENT PROSPECTIVE PAYMENT SYSTEM PROPOSED RULE

Overview and Resources

On July 15, 2025, the Centers for Medicare & Medicaid Services (CMS) released its proposed calendar year (CY) 2026 payment <u>rule</u> for the Medicare Outpatient Prospective Payment System (OPPS). The proposed rule includes updates to the Medicare fee-for-service OPPS payment rates based on changes set forth by CMS and those previously adopted by Congress. In addition to the regular updates to wage indexes and market basket, the following policies are proposed in this rule:

- Updating Ambulatory Payment Classification (APC) Groups and Weights;
- Updating the 340B Final Remedy reduction to the OPPS conversion factor;
- Eliminating the Inpatient-Only (IPO) list;
- Updating current methodology for Overall Hospital Quality Star Rating;
- Updating requirements for the Hospital Outpatient Quality Reporting (OQR) Program;
- Updating requirements for the Rural Emergency Hospital Quality Reporting (REHQR) Program;
 and
- Updating payment rates and policies for Ambulatory Surgical Centers (ASCs).

A summary of the major hospital OPPS sections of the proposed rule is provided below. Program changes will be effective for discharges on or after January 1, 2026, unless otherwise noted. CMS estimates an increase of \$1.61 billion in OPPS payments for CY 2026 over CY 2025, prior to the application of the 340B remedy offset. For providers subject to the 340B remedy offset, CMS estimates a \$1.1 billion reduction in payments in CY 2026, resulting in a net increase of approximately \$0.51 billion for the year.

The proposed rule and other resources related to the OPPS are available on the CMS website.

Comments are due to CMS by September 15, 2025 and can be submitted electronically at http://www.regulations.gov by using the website's search feature for "CMS-1834-P".

Request for Information (RFI) - Deregulation

On Jan. 31, 2025, the Executive Order (EO) 14192 entitled "Unleashing Prosperity Through Deregulation" was issued, stating the Administration policy to significantly reduce the private expenditures required to comply with Federal regulations to secure America's economic prosperity and national security and the highest possible quality of life for each citizen. CMS requests input on approaches and opportunities to streamline regulations and reduce administrative burdens on providers, suppliers, beneficiaries, and other interested parties participating in the Medicare program. CMS has made available an RFI at https://www.cms.gov/medicare-regulatory-relief-rfi. All comments in response to this RFI should be submitted through the provided weblink.

OPPS Payment Rates

CMS typically uses the most up-to-date claims data and cost report data (cost report data that is one year behind claims data) to set OPPS rates for the upcoming year. CMS is proposing to use CY 2024 claims data and CY 2023 Healthcare Cost Report Information System (HCRIS) data for CY 2026 OPPS rate setting.

The table below shows the final CY 2025 conversion factor compared to the proposed CY 2026 conversion factor.

	Final CY 2025	Proposed CY 2026	Percent Change
OPPS Conversion Factor	\$89.169	\$91.747	+2.89%
OPPS Conversion Factor with 340B Remedy Offset	\$89.169	\$89.958	+0.88%

The following table provides details of the proposed annual updates to the CY 2026 update factor.

Proposed CY 2026 Update Factor Component	Change to OPPS Conversion Factor		
Market Basket Update	+3.2%		
Affordable Care Act (ACA)-Mandated MB Productivity Adjustment	-0.8 percentage points (PPTs)		
Wage Index Budget Neutrality (BN) Adjustment	+1.16%		
Wage Index 5% Stop Loss and Transitional Exception BN	-0.45%		
Pass-through Spending	-0.22%		
Cancer Hospital BN Adjustment	0.00%		
Outlier BN Adjustment	0.00%		
Overall Proposed Rate Update	+2.89%		
340B Remedy Offset	-1.95%		
Overall Proposed Rate Update with 340B Remedy Offset	+0.88%		

Payment Adjustments for Non-Drug Items and Services as a Result of the 340BB Payment Policy

The 340B Drug Pricing Program allows certain hospitals to purchase outpatient drugs at discounted prices. From CY 2018 to CY 2022, CMS expanded their policy to reduce payments for 340B-acquired drugs from Average Sales Price (ASP)+6% to ASP-22.5% to redistribute savings to increase payments for non-drug items and services under the OPPS. The Supreme Court ruled in *Am. Hosp. Ass'n v. Becerra* that the payment reductions for 340B drugs were unlawful because CMS had not conducted a survey of hospital acquisition costs. In turn CMS revised the payment policy to pay for 340B drugs at ASP+6% in a single-lump sum payment. To recoup the \$7.8 billion increase that was made for non-drug items and services from CY 2018 to CY 2022, CMS adopted an annual prospective payment reduction of 0.5 PPT to the OPPS conversion factor in the 340B Final Remedy Rule that was to start in CY 2026. Recoupment was estimated to take approximately 16 years, however CMS has since determined that a shorter timeframe would be more appropriate due to the potential that not all providers who were overpaid may remain by 2041.

Therefore, CMS is proposing to revise the annual reduction percentage for non-drug items and services from 0.5 PPT to 2.0 PPT (1.95%) effective for CY 2026 and estimated to end in CY 2031. This policy



excludes hospitals that enrolled in Medicare after January 1, 2018. Table 62 outlines the proposed 2.0 PPT conversion factor annual reduction from CY 2026 to CY 2031.

Payment Increase for Rural Sole Community Hospitals (SCHS) and Essential Access Community Hospitals (EACHS)

CMS is proposing to continue the 7.1% budget neutral payment increase for rural SCHs and EACHs. This payment add-on excludes separately payable drugs, biologicals, brachytherapy sources, devices paid under the pass-through payment policy, and items paid at charges reduced to costs. CMS would maintain this for future years until data supports a change to the adjustment.

Cancer Hospital Payment Adjustment and Budget Neutrality Effect

CMS provides payment increases to the 11 IPPS exempt cancer hospitals to address higher outpatient costs incurred by these hospitals. CMS does this by providing a budget neutral payment adjustment such that the cancer hospital's target payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for other non-cancer hospitals paid under the OPPS.

In the CY 2024 OPPS final rule, CMS adopted a policy to reduce the target PCR by 1.0 PPT each calendar year until the target PCR equals the PCR of non-cancer hospitals using the most recent data minus the 1.0 PPT as required by the 21st Century Cures Act. For CY 2025, CMS adopted a cancer hospital target PCR of 0.87. Since the target PCR based on OPPS payments to other hospitals furnishing services under the OPPS would be 0.87 after applying the 1.0 PPT reduction, and would equal the CY 2025 target PCR, CMS feels it is no longer necessary to continue the transition policy of gradually reducing the pre-COVID-19 PHE target PCR by 1.0 PPT. As such, CMS is proposing a target PCR of 0.87 for CY 2026. Table 7 outlines the estimated percentage increase in OPPS payments for each cancer hospital for CY 2026 due to the cancer hospital payment adjustment policy.

Outlier Payments

To maintain total outlier payments at 1% of total OPPS payments, CMS used CY 2024 claims to calculate a proposed CY 2026 outlier fixed-dollar threshold of \$6,450. This is a 19.4% decrease compared to the current threshold of \$8,000. Outlier payments would continue to be paid at 50% of the amount by which the hospital's cost exceeds 1.75 times the Ambulatory Payment Classification (APC) payment amount when both the 1.75 multiplier threshold and the fixed-dollar threshold are met.

Wage Index and Labor-Related Share

As in past years, CMS is proposing to continue to use federal fiscal year (FFY) 2026 inpatient PPS (IPPS) wage indexes, including all reclassifications, add-ons, and rural floors to be applied to the labor-related share of CY 2026 OPPS payments in a budget neutral manner.

CMS applies a 5% cap on any decrease in the hospital wage index, compared to the previous year's wage index. The cap is applied regardless of the reason for the decrease and implemented in a budget neutral manner nationally. This also means that if a hospital's prior CY wage index is calculated with the application of the 5% cap, the following year's wage index will not be less than 95% of the hospital's capped wage index in the prior year. Lastly, a new hospital will be paid the wage index for the area in which it is geographically located for its first full or partial year with no cap applied, because a new hospital will not have had a wage index in the prior year. CMS is proposing a budget neutrality factor of 0.9955 for the impact of the 5% cap on wage index decreases.

CMS is proposing a wage index and labor-related share budget neutrality factor of 1.0116 for CY 2026 to ensure that aggregate payments made under the OPPS are not greater or less than will otherwise be made if wage index adjustments had not changed.



The wage index is applied to the portion of the OPPS conversion factor that CMS considers to be labor-related. For CY 2026, CMS is proposing to continue to use a labor-related share of 60%.

Addressing Wage Index Disparities Between High and Low Wage Index Hospitals

In the FFY 2020 IPPS final rule, CMS made a variety of changes to reduce the disparity between high and low wage index hospitals where hospitals with a wage index value in the bottom quartile of the nation would have that wage index increased by a value equivalent to half of the difference between the hospital's post-rural floor, post-reclassification wage index and the 25th percentile wage index value across all hospitals. As adopted, this policy was to be in effect for a minimum of four years (through FFY 2024) in order to be properly reflected in the Medicare cost report for future years. In the FFY 2025 final rule, CMS adopted to continue this policy for at least three more years, beginning in FFY 2025, in order for sufficient wage data from after the end of the COVID–19 Public Health Emergency to become available.

This policy is subject to litigation (*Bridgeport Hospital, et al., v. Becerra*) in which the court found that the Secretary did not have the authority to adopt this low wage index policy and has ordered additional briefing on an appropriate remedy. On July 23, 2024, the U.S. Court of Appeals for the D.C. Circuit affirmed the lower court's ruling, holding that this policy for FFY 2020 was unlawful and that CMS had no statutory authority to issue it. As a result, the court ordered that the rule be vacated and that hospitals affected by the budget neutrality adjustment are entitled to back-payments, including interest.

At the time, CMS believed that their statutory authority in the OPPS setting differed enough from the IPPS setting. As such, in the CY 2025 OPPS final rule, CMS adopted to continue the policy that hospitals with a wage index value in the bottom quartile of the nation will have their OPPS wage index increased by a value equivalent to half of the difference between the hospital's pre-adjustment wage index and the 25th percentile wage index value across all hospitals. CMS acknowledged the differences between the OPPS and IPPS wage index values for FFY 2025 and noted their intentions to explore options to realign the wage index values in future rulemaking.

For CY 2026 and subsequent years CMS is proposing to realign the IPPS and OPPS wage index values and proposing to eliminate the low wage index hospital policy under the OPPS. CMS is proposing that the 5% cap that will apply to the CY 2026 OPPS wage index will be based off the IPPS wage index for FFY 2025 rather than the OPPS wage index for CY 2025. CMS notes that because the CY 2025 OPPS wage index was different than the FFY 2025 IPPS wage index, using the FFY 2026 IPPS wage index for CY 2026 OPPS wage index will result in decreases greater than 5% to some hospitals' wage indexes under the OPPS. Under CMS' proposal, the 5% cap on wage index decreases in the CY 2026 OPPS would apply in a similar manner to years prior to the CY 2025 OPPS, in which IPPS hospitals would receive the same wage index with the cap on wage index decreases as they would under the IPPS, and non-IPPS hospitals and Community Mental Health Centers (CMHCs) would receive a similar corresponding wage index with the cap on wage index decreases policy under the broader wage index adoption.

Additionally, in the FFY 2026 IPPS proposed rule CMS proposed to use a narrow transitional exception to the calculation of the FFY 2026 IPPS payments for low wage index hospitals significantly impacted by the discontinuation of the low wage index hospital policy. The temporary payment exception is meant "to mitigate short-term instability and payment fluctuations that can negatively impact hospitals consistent with principles of certainty and predictability under the prospective payment systems".

To address the same concerns under OPPS, CMS is proposing a transitional payment exception for CY 2026. The transitional payment exception policy would apply to hospitals that benefitted from the CY 2024 low wage index hospital policy. If the hospital's proposed CY 2026 wage index decreases by more than 9.75% from the hospital's CY 2024 wage index, the transitional payment exception would be set to



90.25% of the CY 2024 wage index. The transitional payment exception would be applied after the application of the 5% cap. CMS proposes to make this policy budget neutral under the OPPS.

In cases where the hospitals report the payer-specific negotiated share as a percentage or algorithm on the machine readable file (MRF), CMS is proposing that hospitals would instead use the proposed "median allowed amount" to calculate the negotiated charges to report on the Medicare cost report.

Updates To the APC Groups and Weights

As required by law, CMS must review and revise the APC relative payment weights annually. CMS must also revise the APC groups each year to account for drugs and medical devices that no longer qualify for pass-through status, new and deleted Healthcare Common Procedure Coding System/Current Procedural Terminology (HCPCS/CPT) codes, advances in technology, new services, and new cost data.

The proposed payment weights and rates for CY 2026 are available in Addenda A and B within Addendum P of the proposed rule is <u>here</u>.

For CY 2026, CMS is proposing to recalibrate payment weights for services furnished on or after January 1, 2026, and before January 1, 2027, using the CY 2024 claims data.

The table below, based on Addendum A, shows the update in the number of APCs per category from CY 2025 to CY 2026:

APC Category	Status Indicator	Final CY 2025	Proposed CY 2026
Pass-Through Drugs and Biologicals	G	107	97
Pass-Through Device Categories	Н	17	14
Non-opioid Medical Devices For Post-Surgical Pain Relief	H1	5	6
OPD Services Paid through a Comprehensive APC	J1	71	72
Observation Services	J2	1	1
Non-Pass-Through Drugs/Biologicals	K	490	482
Non-Opioid Drugs and Biologicals For Post-Surgical Pain Relief	K1	5	5
Partial Hospitalization	Р	8	8
Blood and Blood Products	R	41	41
Procedure or Service, No Multiple Reduction	S	80	64
Slom Substitute Products	S1	-	3
Procedure or Service, Multiple Reduction Applies	Т	29	29
Brachytherapy Sources	U	17	17
Clinic or Emergency Department Visit	V	11	11
New Technology	S/T	112	112
Total		994	962

Calculation of Cost-to-Charge Ratios (CCRs)

For CY 2026, CMS is proposing to continue to use the hospital-specific overall ancillary and departmental CCRs to convert charges to estimated costs. CMS is also proposing to not include cost report lines for



non-standard cost centers in OPPS rate setting when hospitals have reported this data on cost report lines that do not correspond to the cost center number.

Blood and Blood Products

For CY 2026, CMS is proposing to continue its policy to establish payment rates for blood and blood products using a blood-specific CCR methodology.

Brachytherapy Sources

For CY 2026, CMS is proposing to continue its policy to use the costs derived from the most recent set of claims data (CY 2024) to set payment rates for brachytherapy sources. With the exception of brachytherapy source C2645 and low volume brachytherapy APCs, CMS is proposing to base payment rates on the geometric mean unit costs (MUCs) for each source. For CY 2026 and future years, CMS is also proposing to "...pay for the stranded and non-stranded not otherwise specified (NOS) codes, HCPCS codes C2698 (Brachytherapy source, stranded, not otherwise specified, per source) and C2699 (Brachytherapy source, non-stranded, not otherwise specified, per source), at a rate equal to the lowest stranded or non-stranded prospective payment rate for such sources, respectively, on a per-source basis...."

Additionally, CY 2026 CMS is proposing to designate six brachytherapy APCs as low volume APCs.

Radioisotopes Derived From Non-Highly Enriched Uranium (NON-HEU) Sources

Historically, most of the supply of molybdenum (Mo-99) (used in the creation of Technetium-99m [Tc-99m], a commonly used diagnostic imaging radioisotope) used in the United States is sourced from reactors outside of the country using highly enriched uranium. In the CY 2025 OPPS final rule CMS adopted a new add-on payment of \$10 per dose for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99 to eliminate reliance on these foreign reactors.

CMS is proposing to clarify several criteria for classifying a TC-99m Radiopharmaceutical dose as domestically produced. Among the proposed include defining:

- Domestically produced Mo-99 to mean Mo-99 that was both irradiated and processed in the United States.
- "Irradiated," as the process of bombarding a uranium or molybdenum target with radiation in order to produce Mo-99, and to specify that irradiation is typically performed with a nuclear reactor or particle accelerator.
- "Processed" in this context to refer to the purification of Mo-99 from irradiated material.

Additionally, CMS is proposing to establish a new HCPCS C-code C917X (Tc-99m from domestically produced non-HEU Mo-99, [minimum 50%], full cost recovery add-on, per study dose), effective January 1, 2026. Hospitals will be able to report the new HCPCS C-code C917X once per dose, along with any diagnostic scans furnished using Tc-99m derived from domestically produced Mo-99. Hospitals can bill the add-on code if they can certify that at least 50% of the Mo-99 in the Tc-99m generator to produce the Tc-99m was domestically produced Mo-99.

CMS aims to limit administrative burden for hospitals while accounting for the per-dose cost of Tc-99m derived from domestically produced Mo-99 and seeks comments on this proposal.

Comprehensive APCS

A Comprehensive Ambulatory Payment Classification (C-APC) provides all-inclusive payments for certain procedures. A C-APC covers payment for all applicable Part B services that are related to the primary



procedure, including items currently paid under separate fee schedules. The C-APC encompasses diagnostic procedures, lab tests, and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; coded and un-coded services and supplies used during the service; outpatient department services delivered by therapists as part of the comprehensive service; durable medical equipment as well as the supplies to support that equipment; and any other components reported by HCPCS codes that are provided during the comprehensive service. The costs of blood and blood products are included in the C-APCs when they appear on the same claim as those services assigned to a C-APC. The C-APCs do not include payments for services that are not covered by Medicare Part B, nor those that are not payable under OPPS, such as: certain mammography and ambulance services; brachytherapy sources; pass-through drugs and devices; charges for self-administered drugs; certain preventive services; and procedures assigned to a New Technology APC either included on a claim with a "J1" or included on a claim with a "J2" indicator and packaged into payment for comprehensive observation services assigned to status indicator "J2".

For CY 2026, CMS is soliciting comments on potential refinements to the outlined C-APC complexity adjustment criteria.

For CY 2026 and subsequent years, CMS is proposing to exclude payment for cell and gene therapies from C-APC packaging listed in Table 1 into the payment for the primary C-APC service on the same claim when those cell and gene therapies are not functioning as integral, ancillary supportive, dependent, or adjunctive to the primary C-APC service. CMS is also proposing those products on this list with a pass-through status expiring in CY 2026 will be excluded from C-APC packaging after their pass-through status expires, which can be found in Table 57.

Each year CMS reviews and revises the services within each APC group and APC assignments under the OPPS. CMS is not proposing to convert any standard APCs to C-APCs. The proposed CY 2026 C-APCs can be found in Table 2.

Composite APCS

Composite APCs are another type of packaging to provide a single APC payment for groups of services that are typically performed together during a single outpatient encounter. Currently, there are six composite APCs:

- Mental Health Services (APC 8010)
- Multiple Imaging Services (APCs 8004, 8005, 8006, 8007, and 8008)

For CY 2026, CMS is proposing to continue its policy that when the aggregate payment for specified mental health services provided by a hospital to a single beneficiary on a single date of service exceeds the maximum per diem payment rate for partial hospitalization services, those services will continue to instead be paid through composite APC 8010. In addition, CMS is proposing that the payment rate for composite APC 8010 will continue to be set to that established for APC 5864 (four or more hospital-based partial hospitalization services per day) as it is the maximum partial hospitalization per diem payment rate for a hospital.

CMS is proposing to continue its current composite APC payment policies for multiple imaging services from the same family and on the same date for CY 2026. Table 3 lists the proposed HCPCS codes that would be subject to the multiple imaging procedure composite APC policy, their respective families, and each family's geometric mean cost.

Universal Low Volume APCS Payment Policy



For CY 2026, CMS is proposing to continue the universal low-volume APC payment methodology for services assigned to New Technology, clinical, and brachytherapy APCs with fewer than 100 single claims. This policy uses the highest of the geometric mean, arithmetic mean, or median based on up to four years of claims data to set the payment rate for the APC.

The proposed 11 low volume APCs for CY 2026 can be found in Table 39.

Payment For Medical Devices With Pass-Through Status

There are currently 17 device categories that are eligible for pass-through payment:

- C1826 Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system
- C1827 Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller
- C1747 Endoscope, single-use (i.e. disposable), urinary tract, imaging/illumination device (insertable)
- C1600 Catheter, transluminal intravascular lesion preparation device, bladed, sheathed (insertable)
- C1601 Endoscope, single-use (i.e. disposable), pulmonary, imaging/illumination device (insertable)
- C1602 Orthopedic/device/drug matrix/absorbable bone void filler, antimicrobial-eluting (implantable)
- C1603 Retrieval device, insertable, laser (used to retrieve intravascular inferior vena cava filter)
- C1604 Graft, transmural transvenous arterial bypass (implantable), with all delivery system components
- C1605 Pacemaker, leadless, dual chamber (right atrial and right ventricular implantable components), rate-responsive, including all necessary components for implantation
- C1606 Adapter, single-use (i.e. disposable), for attaching ultrasound system to upper gastrointestinal endoscope
- C8000 Support device, extravascular, for arteriovenous fistula (implantable)
- C1735 Catheter(s), intravascular for renal denervation, radiofrequency, including all single use system components
- C1736 Catheter(s), intravascular for renal denervation, ultrasound, including all single use system components
- C1737 Joint fusion and fixation device(s), sacroiliac and pelvis, including all system components (implantable)
- C1738 Powered, single-use (i.e. disposable) endoscopic ultrasound-guided biopsy device
- C1739 Tissue marker, probe detectable any method (implantable), with delivery system
- C9610 Catheter, transluminal drug delivery with or without angioplasty, coronary, non-laser (insertable)



CMS has received eight applications for device pass—through payment applications by the March 3, 2025, quarterly deadline, two were approved for pass-through payment:

- VasQ
- SCOUT MD™ Surgical Guidance System

Device-Intensive Procedures

CMS defines device-intensive APCs as those procedures which require the implantation of a device and are assigned an individual HCPCS code-level device offset of more than 30% of the procedures mean cost, regardless of APC assignment. In the CY 2025 final rule CMS modified their proposed device policy for new HCPCS codes for procedures that require the implantation/insertion of a single-use device meeting CMS' device-intensive requirements. If the procedures lack claims data CMS will apply a default device offset percentage that is the greater of 31% or the APC's devices offset percentage, when claims data is unavailable. CMS also updated its device edits policy so that procedures that cannot use the "CG" modifier will have their offset percentage calculated based on hospital claims that include a device code. Additionally, claims data from procedures with a status indictor "EI" during the rate setting year will be excluded and the process for applying device offset percentages will be refined to use claims data from predecessor codes' annually until successor code data is available. CMS is proposing to continue these policies for CY 2026.

The full list of proposed CY 2026 device-intensive procedures can be found in Addendum P of this proposed rule.

Device Edit Policy

In CY 2025 OPPS final rule CMS adopted device edit policy with modifications to apply the device edit policy permanently once a procedure is designated as a device-intensive procedure in a given year. Additionally, CMS also adopted a policy to reinstate the device edits policy for procedures that have been device-intensive since CMS began assigning device-intensive status at the HCPCS code level on or after January 1, 2017. CMS is not proposing any changes to the device edit policy for CY 2026.

Payment Adjustment For No Cost/Full Credit and Partial Credit Devices

For outpatient services that include certain medical devices, CMS reduces the APC payment if the hospital receives a credit from the manufacturer. The offset can be 100% of the device amount when a hospital attains the device at no cost or receives a full credit from the manufacturer; or 50% when a hospital receives partial credit of 50% or more. CMS determines the procedures to which this policy applies, using three criteria:

All procedures must involve implantable devices that will be reported if device-insertion procedures were performed;

- The required devices must be surgically inserted or must be implanted devices that remain in the patient's body after the conclusion of the procedure (even if temporarily); and
- The procedure must be device-intensive (devices exceeding 30% of the procedure's average cost).
- For CY 2026, CMS is not proposing any changes to the no cost/full credit and partial credit device policies.

Payment for Drugs, Biologicals and radiopharmaceuticals

CMS pays for drugs and biologicals that do not have pass-through status in one of two ways: either packaged into the APC for the associated service or assigned to their own APC and paid separately. The determination is based on the packaging threshold. CMS allows for a quarterly expiration of pass-through payment status of drugs and biologicals newly approved in order to grant a pass-through period as close to a full three years as possible, and to eliminate the variability of the pass-through payment eligibility period without exceeding the statutory three-year limit.

For CY 2026 and subsequent years CMS is proposing to use the same methodology finalized in CY 2025 to calculate the per day costs for diagnostic radiopharmaceuticals. Consistent with methodology and practices, CMS is also proposing to update the diagnostic radiopharmaceutical packaging threshold of \$630 to \$655 for CY 2026. In addition, CMS is also proposing to continue to pay radiopharmaceuticals with per day costs above the diagnostic radiopharmaceutical packaging threshold, based on their arithmetic MUC, derived from CY 2024 claims data.

Separately for CY 2026, CMS is proposing a packaging threshold of \$140. Drugs, biologicals, and radiopharmaceuticals (excluding diagnostic radiopharmaceuticals) that are above the \$140 threshold are paid separately, using individual APCs, and those below the threshold are packaged; the baseline payment rate for CY 2026 is the ASP+6%. Separately payable drugs and biological products that do not have pass-through status are to be paid wholesale acquisition cost (WAC)+3%, instead of WAC+6%.

For CY 2026, CMS is proposing to continue paying for blood clotting factors and therapeutic radiopharmaceuticals without pass-through payment status at ASP+6%. If ASP data are not available, payment instead will be made at WAC+3%; or 95% of average wholesale price (AWP) if WAC data are also not available.

For CY 2026 and subsequent years, for those HCPCS codes for drugs, biologicals and therapeutic radiopharmaceuticals that are impacted by the updated drug packaging threshold, CMS is proposing:

- HCPCS codes for drugs, biologicals, and radiopharmaceuticals that were paid separately in CY 2025 and that are finalized for separate payment in CY 2026, and that then have per day costs equal to or less than the CY 2026 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2026 final rule, would continue to receive separate payment in CY 2026.
- HCPCS codes for drugs, biologicals, and radiopharmaceuticals that were packaged in CY 2025 and that are finalized for separate payment in CY 2026, and that then have per day costs equal to or less than the CY 2026 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2026 final rule, would remain packaged in CY 2026.
- HCPCS codes for drugs, biologicals, and radiopharmaceuticals for which packaged payment was
 finalized in CY 2026 but that then have per-day costs greater than the CY 2026 final rule drug
 packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the
 updated ASPs and hospital claims data used for the CY 2026 final rule, would receive separate
 payment in CY 2026.

For CY 2026, CMS is proposing to continue to pay for non-pass-through diagnostic radiopharmaceuticals that are separately payable. CMS is proposing to continue to use MUC data for said radiopharmaceuticals that are finalized as separately payable due to their cost exceeding the per-day threshold.

Additionally, CMS is proposing to continue the policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis for HCPCS codes that describe the same drug or biological but different dosages. CMS is also proposing that this policy apply to diagnostic radiopharmaceuticals.

As there are often HCPCS codes for new drugs or biologicals that have received marketing approval, but for which there is no sales data available, the affected drugs and biologicals are assigned a non-payable indicator. For separately payable drugs and biologicals for which CMS does not provide a payment rate, CMS finalized in the CY 2025 OPPS final rule that Medicare Administrative Contractors (MACs) will calculate the payment based on provider invoices (net acquisition cost, less any rebates, chargebacks, or post-sale concessions). MACs will use the invoice to determine that the drug is not policy-packaged, and that the per-day cost is above the threshold packaging amount, as applicable. For CY 2026 CMS is proposing to clarify that CMS would determine whether the drug is not policy packaged, and the MAC would continue to determine whether the per-day cost is above the threshold packaging amount.

Lastly, CMS states that the pass-through status will expire by December 31, 2025 for 57 drugs and biologicals, listed in Table 57; by December 31, 2026 for 41 drugs and biologicals listed in Table 58; and will continue/establish pass-through status in CY 2026 for 41 drugs and biologicals shown in Table 59.

Packaged Items and Services

CMS is proposing to continue to conditionally package costs of selected newly identified ancillary services into payment for a primary service where CMS believes the packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary

For CY 2026, CMS is proposing to continue to unpackage, and pay separately at ASP+6%, the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting. CMS is unpackaging these drugs to address the decreased utilization of non-opioid pain management drugs and to encourage their use rather than prescription opioids. These drugs are only eligible if the drug or biological does not have transitional pass-through payment status and the drug must not already be separately payable in the OPPS or ASC payment system.

Table 82 lists the products that are proposed to have separate payment in the ASC setting under this policy for CY 2026.

Skin Substitutes

Since 2014, skin substitutes have been divided into a high-cost group and a low-cost group in terms of packaging under the OPPS. CMS assigns skin substitutes with a geometric MUC or a product's per day cost (PDC) that exceeds either the MUC threshold or the PDC threshold to the high-cost group.

Beginning January 1, 2026, CMS is proposing to separately pay for certain groups of skin substitute products as incident-to supplies under the PFS in the non-facility setting or the OPPS setting. This includes unpackaging the skin substitute products from the payment for administration of the skin substitute product separate from the skin substitute product itself. CMS is proposing to remove skin substitutes from the list of packaged items and services and specify that CMS would continue to package payment for products that aid wound healing that are not skin substitute products.

In addition, CMS is proposing to group skin substitutes that are not drugs or biologicals using three CMS payment categories based on FDA regulatory and proposing to create three new APCs:

- APC 6000 (PMA Skin Substitute Products)
- APC 6001 (510(k) Skin Substitute Products)



APC 6002 (361 HCT/P Skin Substitute Products)

CMS is proposing to establish an initial payment rate of \$125.38 for the three newly proposed APCs and would update the rates for skin substitute categories annually using the most recently available calendar quarter of ASP data. CMS is also proposing to create three new unlisted C-codes and assigning them to existing codes to prevent delays in Medicare payments for new FDA approved or cleared skin substitute products as follows:

- QXXX1 (Unlisted PMA skin substitute product) assigned to APC 6000 (PMA Skin Substitute Products);
- QXXX2 (Unlisted 510(k) skin substitute product) assigned to APC 6001 (510(k) Skin Substitute Products); and
- QXXX3 (Unlisted 361 HCT/P skin substitute product) assigned to APC 6002 (361 HCT/P Skin Substitute Products).

Lastly, CMS is proposing to create a new status indicator, "S1" to indicate that the skin substitute product is paid separately from other procedure codes under the OPPS. The proposed "S1" indicator would be assigned to all skin substitute products assigned to APCs 6000, 6001, 6002. Table 65 details the proposed status indicator, the descriptor, and payment status.

Payment For OFF-Campus Outpatient Departments

In order to control what CMS deemed an unnecessary increase in OPPS service volume for a basic clinic visit representing a large share of the services provided at off–campus provider-based departments (PBDs), CMS expanded the Medicare Physician Fee Schedule (MPFS) payment methodology in CY 2019 to excepted off–campus PBDs for HCPCS code G0463. As of CY 2024, this policy has the following additional exemptions:

- Excepted off-campus PBDs belonging to rural SCHs;
- Application of the CMHC per-diem rates for hospital partial hospitalization program (PHP) and intensive outpatient (IOP) services provided at an off-campus PBD, instead of the MPFS rate for that service; and
- Payment made for intensive cardiac rehabilitation (ICR) services.

For CY 2026, CMS is proposing to extend this policy for drug administration services furnished in excepted off-campus PBDs. In line with CMS' policy to exempt rural SCHs from the clinic visit policy, CMS is proposing to exempt rural SCHs from the site-specific PFS-equivalent payment for drug administration service when furnished at an off-campus PBD. Under this proposal, rural SCHs would continue to bill services in APC family 569X with the "PO" modifier for CY 2026 and payment rates for these services would continue to be the full OPPS payment without the PFS adjustment.

CMS is also soliciting comments on whether it would be appropriate to address unnecessary increase in volume of covered OPD services by expanding the method to control unnecessary increases in volume to on-campus clinic visits.

PHP and IOP Services

The PHP is an intensive outpatient psychiatric program that provides outpatient services in place of inpatient psychiatric care. PHP services may be provided in either a hospital outpatient setting or a freestanding CMHC. PHP providers are paid on a per-diem basis with payment rates calculated using CMHC-specific or hospital-specific data.



As required by the CAA of 2023, CMS adopted payment and program requirements for intensive outpatient program services beginning CY 2024. Intensive outpatient services are furnished under a distinct and organized outpatient program of psychiatric services for individuals who have an acute mental illness, called an IOP. IOP services are less intensive than PHP services and can be furnished by a hospital to its outpatients, a CMHC, a federally qualified health center, or a rural health clinic.

The table below compares the final CY 2025 and proposed CY 2026 PHP and IOP payment rates as found in Addendum A:

	Final Payment Rate 2025	Proposed Payment Rate 2026	% Change
APC 5851: Intensive Outpatient (3 services) for CMHCs	\$111.24	\$134.26	+20.69%
APC 5852: Intensive Outpatient (4+ services) for CMHCs	\$168.32	\$167.23	-0.65%
APC 5853: Partial Hospitalization (3 services) for CMHCs	\$111.24	\$134.26	+20.69%
APC 5854: Partial Hospitalization (4+ services) for CMHCs	\$168.32	\$167.23	-0.65%
APC 5861: Intensive Outpatient (3 services) for Hospital-based IOPs	\$269.19	\$335.67	+24.70%
APC 5862: Intensive Outpatient (4+ services) for Hospital-based IOPs	\$408.55	\$418.09	+2.34%
APC 5863: Partial Hospitalization (3 services) for Hospital-based PHPs	\$269.19	\$335.67	+24.70%
APC 5864: Partial Hospitalization (4+ services) for Hospital-based PHPs	\$408.55	\$418.09	+2.34%

For CY 2026, CMS is proposing to maintain the current payment methodology used for calculating hospital-based PHP and IOP payment rates using geometric per diem costs for PHP and IOP days with three services or four or more services. For CMHC PHP and IOP APCs, CMS is proposing to revise the methodology to calculate the CY 2026 geometric mean per diem costs based on 40% of the proposed hospital-based PHP costs for CY 2026 and subsequent years. Using the current methodology would result in inverted costs for CMHCs with higher geometric mean costs for 3-service than for 4-service. Table 67 lists the PHP and IOP APC geometric mean per diem costs based on the current methodology. CMS believes the proposed methodology would stabilize CMHC payment rates by setting them relative to hospital-based rates, while avoiding cost inversion in future years. Table 68 lists the PHP and IOP APC geometric mean per diem costs based on the proposed methodology.

CMS is proposing to continue to make outlier payments to CMHCs for 50% of the amount by which the cost for the PHP service exceeds 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year. As done in prior years, CMS is proposing to apply an 8% outlier payment cap to the CMHC's total per diem payments. CMS would also continue to include both PHP and IOP in the calculation of the CMHC outlier percentage.

Inpatient-Only (IPO) List

The IPO list specifies services/procedures that Medicare will only pay for when provided in an inpatient setting. For CY 2026 and subsequent years CMS is proposing to eliminate the IPO list through a three-year transition, beginning in CY 2026 and completing the elimination by January 1, 2029. For CY 2026, CMS identified and is proposing to remove 285 services from the IPO list which can be found in Table 69.



In addition, CMS is proposing to exempt procedures that have been removed from the IPO list from certain medical review activities to assess compliance with the two-midnight rule. The proposed exemption would continue for all services or procedures removed from the IPO list until the Secretary determines that the exemption is no longer appropriate for each specific service or procedure because it is more commonly performed in the outpatient setting.

CMS is soliciting comments on whether three years is an appropriate time frame for the transition, and whether other services are ideal candidates for removal from the IPO list in the near term. CMS is also seeking comments on whether CMS should restructure or create new APCs or C-APCs to allow for efficient OPPS payment for services that are removed from the IPO list.

Request For Information (RFI) – Adjusting Payment Under the OPPS For Services Predominately Performed in the Ambulatory Surgical Center or Physician Office Settings

CMS is seeking feedback for future rulemaking on the development of a more systematic process for identifying ambulatory services at high risk of shifting to the hospital setting based on financial incentives rather than medical necessity and adjusting payments accordingly.

Virtual Direct Supervision of Cardiac Rehabilitation (CR), Intensive Cardiac Rehabilitation (ICR), Pulmonary Rehabilitation (FR) Services, and Diagnostic Services Furnished to Hospital Outpatients

The Bipartisan Budget Act of 2018 required that services provided in a CR, ICR, or FR program can be provided under the supervision of a physician's assistant (PA), nurse practitioner (NP), or clinical nurse specialists (CNS) beginning January 1, 2024, rather than the current requirement that only physicians could supervise these services as part of the stated programs. In the CY 2024 Medicare PFS final rule, CMS adopted revisions to the regulations in order to match the new requirements.

In the April 6, 2020 "Policy and Regulatory Provisions in Response to the COVID-19 Public Health Emergency" interim final rule with comment period, CMS adopted that during a PHE, for the purposes of direct supervision, a physician can be present virtually through audio/video real-time communications technology for FR, CR, and ICR services when the use of technology reduces exposure risks for the patient or the provider. The CAA of 2023 extends this policy through the end of CY 2024. In order to maintain similar policies for OPPS as PFS, CMS adopted the inclusion of FR, CR, and ICR with supervision from an NP, PA, or CNS under this policy.

In the CY 2025 PFS proposed rule, CMS finalized an extension of the availability of virtual direct supervision of therapeutic and diagnostic services under the PFS. In the CY 2026 PFS proposed rule, CMS is proposing to revise the definition of direct supervision to make permanent the availability of virtual direct supervision of therapeutic and diagnostic services under the PFD, except for services that have a global surgery indicator of 010 or 090. To maintain alignment between the PFS and OPPS, CMS is also proposing a revision to make the availability of the direct supervision of CR, ICR, PR services and diagnostic services via audio-video real-time communications technology (excluding audio-only) permanent, except for diagnostic services that have a global surgery indicator of 010 or 090.

Payment For High-Cost Drugs Provided by Indian Health Service (HIS) and Tribal Facilities

For CY 2026, CMS is proposing that IHS and tribal hospitals would continue to receive separate payment for high-cost drugs furnished in hospital outpatient departments through an additional add-on payment using the authority under which the annual All-Inclusive Rate (AIR) is calculated. This add-on payment will be applicable to all Medicare Part B-covered high-cost drugs furnished in IHS/tribal hospital outpatient departments that would otherwise be paid for under OPPS, for whose per-day cost exceeds twice the lower 48 states' AIR in effect at the time of release of the CY 2026 OPPS final rule. This payment is in addition to the AIR and would have no impact on the calculation of the AIR.



Addendum Q includes a preliminary list of drugs qualifying for the proposed add-on payment and their respective payment rates for CY 2026.

Proposed Removals from the Hospital OQR, REHQR, and ASCQR Program Measure Sets

Beginning with the CY 2025 reporting period, CMS is proposing to remove the following measures from the Hospital OQR, REHQR, and ASCQR programs originally adopted in the CY 2025 OPPS final rule:

- Screening for Social Drivers of Health (SDOH);
- Screen Positive Rate for SDOH measures;

CMS is also proposing to remove the Hospital Commitment to Health Equity (HCHE) measure from the Hospital OQR and REHQR programs, and the Facility Commitment to Health Equity (FCHE) measure from the ASCQR program beginning with the CY 2025 reporting period.

For the Hospital OQR and ASCQR programs CMS is proposing to remove the COVID-19 Vaccination Coverage Among HCP measure beginning with the CY 2024 reporting period/CY 2026 payment determination.

Extraordinary Circumstances Exception (ECE) Policy

In the Hospital OQR, REHQR, and ASCQR programs CMS is proposing to update and codify the ECE policy to include extensions of time as a form of relief and to further clarify the policy, as well as to align the Hospital IQR program with the quality reporting programs. Specifically, these proposals note:

- CMS may grant an ECE with respect to reporting requirements in the event of an extraordinary circumstance—defined as an event beyond the control of a hospital, REH, or ASC (for example a natural or man-made disaster such as a hurricane, tornado, earthquake, terrorist attack, or bombing)—that affected the ability of the hospital, REH, or ASC to comply with one or more applicable reporting requirements with respect to a calendar year.
- A hospital, REH, or ASC, respectively, may request an ECE within 30 calendar days [down from the current 90 days] of the date that the extraordinary circumstance occurred.
- That CMS notify the requestor with a decision, in writing, via email. In the event that CMS grants
 an ECE to the hospital, REH, or ASC, the written decision will specify whether the hospital, REH,
 or ASC is exempted from one or more reporting requirements or whether CMS has granted the
 hospital, REH, or ASC an extension of time to comply with one or more reporting requirements.
- That CMS may grant an ECE to one or more hospitals, REHs, ASCs that have not requested an ECE, if CMS determines that: a systemic problem with CMS data collection system directly impacted the ability of the hospital, REH, or ASC to comply with a quality data reporting requirement; or that an extraordinary circumstance has affected an entire region or locale. As is the case under our current policy, any ECE granted will specify whether the affected hospitals, REHs, or ASCs are exempted from one or more reporting requirements or whether CMS has granted the hospital, REH, or ASC an extension of time to comply with one or more reporting requirements.

Updates to the OQR Program

The OQR program is mandated by law; hospitals that do not successfully participate are subject to a 2.0 PPT reduction to the OPPS market basket update for the applicable year.



CMS is proposing to adopt the Emergency Care Access & Timeliness electronic clinical quality measures (eCQM) beginning with voluntary reporting for the CY 2027 reporting period, and mandatory reporting beginning with the CY 2028 reporting period.

CMS is proposing to remove two measures beginning with the CY 2028 reporting period:

- Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients)
- · Left without Being Seen

Additionally, CMS is proposing to modify the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography in Adults (Hospital Level -Outpatient) measure from mandatory reporting to voluntary reporting in the CY 2027 reporting period. This modification would allow hospital outpatient departments additional time to integrate, test and gain experience with implementing the eCQM and allow CMS additional time to monitor implementation progress, data collection burden, and response rates.

Table 84 lists the previously finalized and newly proposed Hospital OQR program measure set for the CY 2026 to CY 2031 payment determinations.

For the Emergency Care Access & Timeliness eCQM, CMS is proposing to require hospitals to report all four calendar quarters of data for Emergency Care Access & Timeliness eCQM and proposing to require data submission by May 15 in the year prior to the affected payment determination.

Updates to the REHQR Program

The REHQR program is mandated by the CAA of 2021.

Beginning with the CY 2027 reporting period CMS is proposing to adopt the Emergency Care Access & Timeliness eCQM as an alternative to reporting the Median Time from ED Arrival to ED Departure for Discharged ED Patients measure. Under this proposal REHs must elect to report either the Emergency Care Access & Timeliness eCQM or the Median Time for Discharged ED Patients measure.

Table 85 lists the previously finalized and newly proposed REHQR program measure set for the CY 2026 to CY 2031 payment determinations.

Additionally, CMS is proposing to align eCQM data submission deadlines to align with the Hospital OQR to require eCQM data submission by May 15 of the following year for the applicable CY reporting period.

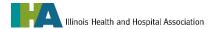
RFI – Measure Concepts Under Consideration for Future Years

CMS is seeking input on the Well-Being and Nutrition measures for consideration in future rulemaking for the Hospital OQR, REHQR, and ASCQR Programs.

Modification to the Overall Hospital Quality Star Rating

In the CY 2025 OPPS final rule CMS included an RFI discussing potential methodologic modifications to the Safety of Care measure group within the Overall Hospital Quality Star Rating. After considering public input, CMS is proposing to make the following two-stage modification to the Overall Hospital Quality Star Rating methodology:

 Stage 1: implement a 4-star cap for hospitals in the lowest-performing quartile of the Safety of Care measure group for the 2026 Overall Hospital Quality Star Rating



 Stage 2: implement a 1-star reduction, to a minimum 1-star rating for hospitals in the lowestperforming quartile of the Safety of Care measure group for the 2027 Overall Hospital Quality Star Rating and thereafter.

Under stage 1 the cap would be applied to hospitals that are initially assigned 5 stars in step 8 of the methodology but have a Safety of Care score in the lowest-performing quartile to 4 stars. Stage 2 would apply a blanket 1 star reduction to hospitals initially assigned a 2-,3-,4-, or 5-star rating in step 8 of the methodology, but have a Safety of Care score in the lowest performing quartile. With a minimum possible Overall Hospital Star Rating of one star, hospitals already receiving one star would not face further star reduction and would be exempt from this methodology update.

Hospital Price Transparency (HPT)

In alignment with EO 14221, "Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare", CMS is proposing modifications to the HPT regulations to enhance clarity and standardization in hospital pricing disclosures. Among the amendments include revisions to add definitions for the "10th percentile allowed amount", "median allowed amount", and "90th percentile allowed amount" to allow hospitals to more accurately reflect the distribution of actual amounts that a hospital has received for an item or service. In tandem, CMS is also proposing revisions to remove the requirement for hospitals to disclose the estimated allowed amount, and instead require hospitals, beginning CY 2026, to disclose the 10th percentile, median, and 90th percentile amounts, and count of allowed amount in MRFs when payer-specific negotiated charges are based on percentages or algorithms.

CMS is also proposing to require hospitals to use electronic data interchange 835 electronic remittance advice transaction data to calculate and encode these values and require that hospitals comply with specific instructions regarding the methodology, including lookback period, that should be used to calculate these amounts.

Beginning CY 2026, CMS is proposing to require hospitals to attest that in the MRF, that the hospital has included all applicable standard charge information in accordance with the requirements and information encoded is true, accurate, and complete as of the date in the file. Also, hospitals would have to attest in the MRF that the hospital has included all applicable payer-specific negotiated charges as dollars that can be expressed as a dollar amount, and for payer-specific negotiated charges that are not knowable in advance or cannot be expressed as a dollar amount, the hospital has provided in the MRF all necessary information available to the hospital for the public to be able to derive a dollar amount.

In addition, CMS is proposing that hospitals encode the name of the hospital chief executive officer, president, or senior official designated to oversee the encoding of true, accurate, and complete data in the MRF. To advance the comparability of HPT data with other healthcare data, CMS is proposing to require hospitals to encode their National Provider Identifiers in the MRFs. To encourage faster resolution and payment of civil monetary penalties (CMPs), CMS is proposing to reduce the amount of a CMP by 35% when a hospital agrees with CMS' determination of a hospital's noncompliance and waives its right to an administrative law judge hearing.

Market-Based Medicare Severity-Diagnosis Related Groups (MS-DRG) Relative Weights

CMS is proposing a new market-based methodology for estimating the MS-DRG relative weights, beginning in FY 2029. The proposed market-based methodology would be the same methodology that was adopted in the FFY 2021 IPPS final rule where relative weights are calculated using the median payer-specific negotiated charge for Medicare Advantage Organizations (MAOs) for each MS-DRG. CMS is



also proposing to require hospitals to report the median payer-specific negotiated charge with all of its MAOs, by MS-DRG on the Medicare cost report beginning in CY 2026.

Graduate Medical Education Accreditation

To align efforts with EO 14279, "Reforming Accreditation to Strengthen Higher Education" CMS is proposing that accreditors may not require as part of accreditation, or otherwise encourage institutions to put in place, diversity, equity, and inclusion programs that encourage unlawful discrimination on the basis of race or other violations of Federal Law. This proposal would be effective January 1, 2026.

Notice of Intent to Conduct Medicare OPPS Drugs Acquisition Cost Survey

As required by section 1833(t)(14)(A)(iii) of the Social Security Act, CMS will be conducting a survey of acquisition costs for each separately payable drug acquired by all hospitals paid under the OPPS, including specific covered outpatient drugs (SCODs), and drugs and biologicals CMS historically treats as SCODs. The survey will open from the end of CY 2025 to early CY 2026, and CMS intends to use survey results to inform policy making beginning with the CY 2027 OPPS proposed rule.

RFI – Software as a Service (SAAS)

CMS currently does not have a payment methodology specifically for SaaS and subsequently, CMS is seeking comments and information on alternative and consistent payment methods for SaaS services to consider for future rulemaking.

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