CMS Finalizes 2.6% OPPS/ASC Increase, Declines 340B Offset Acceleration, and Launches IPO Phase-Out

On November 21, 2025, the Centers for Medicare & Medicaid Services (CMS) issued the Calendar Year (CY) 2026 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Final Rule, which updates the Medicare OPPS and ASC payment system for calendar year (CY) 2026. See the press release here and the fact sheet here. A price transparency specific fact sheet is also available here.

Key policy updates include:

- A 2.6% payment rate increase for hospital outpatient departments and ASCs
- 340B Remedy: Implements the previously finalized 0.5% annual reduction to the OPPS conversion factor
- A national survey on drug acquisition costs to inform CY 2027 drug payment policy
- Transition to market-based MS-DRG weights using payer-negotiated charge data
- Community Mental Health Center payments stabilized with a 40% adjuster; maintains hospital-based rates for Partial Hospitalization Programs and Intensive Outpatient Programs
- Updated and streamlined quality reporting programs
- Phase-out of the Inpatient Only (IPO) list by 2029
- Expansion of the ASC Covered Procedures List with 560 new codes based on revised criteria
- Removal of skin substitutes from packaged status
- Continued use of New Technology APCs with protections for low-volume services
- Continued separate payment for qualifying non-opioid pain relief treatments
- Updated packaging thresholds: $140 for most drugs; $655 for diagnostic radiopharmaceuticals
- $10 add-on payment for Tc-99m made from at least 50% domestically produced Mo-99. (Tc-99m is a radioactive isotope used in nuclear medicine for diagnostic imaging)
- Continued pass-through payments for drugs, biologicals, and select devices
- Reviews device pass-through applications for 8 applications
- Expanded site-neutral payment to drug administration in off-campus PBDs using Physician Fee Schedule equivalent rates, with rural SCH exemption
- New hospital price transparency rules, including percentile-based allowed charges and named executive oversight
- Prohibits DEI elements from GME accreditation requirements
- Acknowledges stakeholder feedback to requests for information on site neutral ASC services and a consistent payment method for Software as a Service (SaaS)

This rule is scheduled to be published in the *Federal Register* on November 25, 2025.[1]

[1] This rule is unpublished as of November 21, 2025, and all page numbers contained within this document refer to page numbers specific to the unpublished PDF.

OUTPATIENT AND AMBULATORY SURGICAL CENTER PAYMENT UPDATE

FINALIZED WITH MODIFICATION- Page 116 (OPPS) and Page 1162 (ASC)

For CY 2026, CMS finalizes a 2.6% increase[2] in payment rates under the Hospital Outpatient Prospective Payment System (OPPS). This reflects a 3.3% hospital market basket increase reduced by a 0.7 percentage point productivity adjustment.[3] Hospitals that do not meet outpatient quality reporting requirements will continue to receive a 2.0% payment reduction.

CMS estimates that total payments to OPPS providers will be approximately $101 billion, an increase of about $8.0 billion compared to CY 2025. CMS also finalized several budget neutrality adjustments, including discontinuation of the OPPS low-wage index hospital policy, realignment with the FY 2026 IPPS wage index, application of the 5% cap on decreases, and a one-year transitional payment exception for CY 2026 to mitigate large reductions.

Under the Ambulatory Surgical Center (ASC) payment system, CMS finalizes the continued use of the hospital market basket for ASC updates through 2026. **ASCs that meet quality reporting requirements will receive a 2.6% payment increase, which considers a 3.3% market basket update reduced by a productivity adjustment of 0.7 percentage point.[4]** Therefore, total estimated ASC payments are estimated to be $9.2 billion in 2026—approximately $450 million more than in CY 2025. Budget neutrality adjustments applicable to ASC payments remain in place for wage index updates, outlier spending, and pass-through payment projections.

INCREASED OFFSET TO OPPS CONVERSION FACTOR TO ACCELERATE RECOVERY OF 340B REMEDY PAYMENTS

NOT FINALIZED- Pages 631-671

The Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022 Final Rule[5] finalized a 0.5 percent reduction to the OPPS conversion factor for non-drug items and services, excluding hospitals that enrolled in Medicare after January 1, 2018, beginning in CY 2026. (The conversion factor is part of the algorithm used by CMS to calculate OPPS payments). The rule followed the Supreme Court's decision in *American Hospital Association v. Becerra*[6] that addressed the previous CY 2018 OPPS/ASC Final Rule[7] which reduced payments for outpatient drugs purchased under the 340B Drug Pricing Program from ASP plus 6 percent to ASP minus 22.5 percent. To remedy the underpayments caused by that policy from 2018 through 2022, CMS finalized a one-time lump-sum payment to affected 340B hospitals. To ensure this remedy was budget neutral as required by

---

[2] Proposed: 2.4% payment update for OPPS
[3] Proposed: 3.2% market basket update and 0.8% productivity adjustment
[4] Proposed: 2.4% payment update, 3.2% market basket update, and 0.8% productivity adjustment for ASC
[5] 88 FR 77150
[6] 142 S. Ct. 1896 (2022)
[7] 82 FR 59369 through 59370

statute, CMS implemented the 0.5 percent annual reduction to the OPPS conversion factor to recoup these payments gradually, originally estimating full recovery by CY 2041.

After reconsidering the balance between restoring hospitals' financial positions and minimizing provider burden, CMS proposed increasing the annual reduction from 0.5 percent to 2 percent to accelerate repayment. However, in response to commenter feedback, **CMS is not finalizing this proposal at this time and will instead implement the previously finalized 0.5 percent reduction for CY 2026. The agency notes it anticipates proposing a larger reduction, such as 2 percent or another reduction greater than 0.5 percent, for CY 2027.**

DRUG ACQUISITION COST SURVEY

FINALIZED AS PROPOSED- Pages 777-814

Despite widespread opposition from commenters, **CMS confirms it will proceed with a mandatory Medicare OPPS Drugs Acquisition Cost Survey from January 1, 2026, through March 31, 2026, to collect data on hospital acquisition costs for each separately payable drug acquired by hospitals paid under the OPPS.** This survey is required by section 1833(t)(14)(D)(ii) of the Social Security Act and follows President Trump's Executive Order 14273, "Lowering Drug Prices by Once Again Putting Americans First,"[8] which directs HHS to publish a plan for conducting such a survey to better determine hospital acquisition costs for outpatient drugs.

The survey will include specified covered outpatient drugs (SCODs) as well as drugs and biologicals historically treated as SCODs. CMS will collect data on the total acquisition costs for each drug, net of all rebates and discounts, by National Drug Code (NDC) for the period July 1, 2024, through June 30, 2025. Hospitals will be required to report all applicable rebates and discounts in their acquisition costs, including those directly associated with individual NDCs as well as broader discounts linked to invoices, prompt pay arrangements, wholesaler agreements, or other purchase-based discounts.[9] CMS will use the survey findings to inform payment policy proposals in the CY 2027 OPPS/ASC Proposed Rule.

CMS acknowledges the burden this survey may place on hospitals and states that it has designed a streamlined survey instrument and submission process to minimize operational and financial strain. The agency also notes that it will provide user support, training, and technical assistance, including a simplified online portal, outreach and educational materials, and dedicated helpdesk resources, to facilitate accurate and efficient survey completion.

[8] https://www.federalregister.gov/d/2025-06837

[9] A draft survey template can be found at *https://www.cms.gov/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pra-listing/cms-10931*

MARKET-BASED MS-DRG RELATIVE WEIGHT METHODOLOGY BEGINNING FY 2029

FINALIZED AS PROPOSED- Pages 1491 and 1493

CMS finalizes a shift toward a market-based approach for calculating Medicare Severity Diagnosis Related Group (MS-DRG) relative weights under the Inpatient Prospective Payment System (IPPS). Beginning with cost reporting periods ending on or after January 1, 2026, hospitals will be required to report the median payer-specific negotiated charges for each MS-DRG with their Medicare Advantage Organizations (MAOs). This should match what is disclosed in their machine-readable files under existing price transparency rules, on their Medicare cost reports.

Starting in fiscal year (FY) 2029, CMS finalizes its proposal to update the methodology for calculating MS-DRG relative weights by incorporating this reported median payer-specific negotiated charge data, to replace the current cost-based approach. CMS is not finalizing a transition period for this change but may consider it in future rulemaking before FY 2029. With this change, CMS aims to reduce reliance on hospital chargemaster data and better reflect relative market-based pricing in Medicare inpatient payments.

COMMUNITY MENTAL HEALTH CENTER RATES AND HOSPITAL-BASED PAYMENT STRUCTURE FOR BEHAVIORAL HEALTH PROGRAMS

FINALIZED AS PROPOSED- Pages 839, 846, and 855

Partial Hospitalization Programs (PHPs) and Intensive Outpatient Programs (IOPs) provide structured psychiatric care as alternatives to inpatient hospitalization. PHPs offer intensive daily behavioral health services for individuals with acute mental illness, while IOPs deliver lower-intensity psychiatric care for at least nine hours per week across a broader range of settings, including hospital outpatient departments, community mental health centers (CMHCs), federally qualified health centers (FQHCs), rural health clinics (RHCs), and opioid treatment programs (OTPs).

Payment Methodology Updates

For CY 2026, CMS maintains its existing methodology for calculating per diem rates for hospital-based PHP and IOP services. These rates are based on geometric mean costs derived from hospital claims and cost reports and are tiered according to the number of services delivered per day, whether they are for PHP or IOP services, and the site where services are received.

However, CMS finalizes a change in how payment rates are determined for CMHCs. Current CMHC claims data are unstable and in some cases produce cost "inversions," where days with fewer services appear more costly than those with more services. To stabilize these rates, CMS will apply a 40% relativity adjuster to the hospital-based rates.

Final geometric mean costs are below.

Table 1: CY 2026 PHP And IOP APC Geometric Mean Per Diem Costs *(note that actual APC payment rates may be higher or lower than estimated geometric mean costs due to budget neutrality adjustments)*

CY 2026 APC	Final Rate
5851, Intensive Outpatient (3 services per day) for CMHCs	$128.73
5852, Intensive Outpatient (4 or more services per day) for CMHCs	$168.67
5853, Partial Hospitalization (3 services per day) for CMHCs	$128.73
5854, Partial Hospitalization (4 or more services per day) for CMHCs	$168.67
5861, Intensive Outpatient (3 services per day) for hospital-based IOPs	$321.83
5862, Intensive Outpatient (4 or more services per day) for hospital-based IOPs	$421.67
5863, Partial Hospitalization (3 services per day) for hospital-based PHPs	$321.83
5864, Partial Hospitalization (4 or more services per day) for hospital-based PHPs	$421.67

CMS continues to align service lists, billing codes, and program structure between PHP and IOP services. Both require at least one primary behavioral health service per day from a defined list to qualify for payment. PHP claims must include condition code 41, and IOP claims must include condition code 92. While services such as caregiver training and Principal Illness Navigation (PIN) may be provided, they do not count toward the daily service threshold for payment. CMS did not propose to add any new services to the CY 2026 list of PHP and IOP services.

QUALITY REPORTING PROGRAM CHANGES, INCLUDING CROSS-CUTTING REMOVALS OF COVID-19 AND HEALTH EQUITY MEASURES

FINALIZED WITH MODIFICATION- Pages 1174, 1182, 1189, and 1194

The Hospital Outpatient Quality Reporting (OQR) Program, Rural Emergency Hospital Quality Reporting Program (REHQR), Ambulatory Surgical Center Quality Reporting (ASCQR) Program are quality programs that require hospitals and ambulatory surgical centers (ASCs) to meet reporting requirements to maintain their annual payment updates.

In this final rule, CMS removes a total of five measures across three programs, including:

- The *COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP)*
- The *Hospital Commitment to Health Equity (HCHE)* measure in the OQR and REHQR, along with the ASCQR companion measure *Facility Commitment to Health Equity (FCHE)*
- Two Social Drivers of Health Measures *(Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers)*

The *COVID-19 Vaccination Coverage Among HCP* removal is effective beginning in the CY2024 reporting period, while all other measure removals take effect beginning in the CY2025 reporting period.

In addition to measure removals across the three programs, **CMS revises the Extraordinary Circumstances Exception (ECE) Policy to reduce the window where affected providers can submit a request for additional reporting flexibility due to events outside of their control from 90 to 60 days.**[10]

The agency also acknowledges comments received in response to its request for information on nutrition and well-being measures and will consider comments in future rulemaking.

HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM UPDATES

FINALIZED AS PROPOSED- Pages 1222, 1228-29, and 1238-1239

CMS finalizes the following changes to the Hospital OQR measures, in addition to the changes outlined above:

- Recognizing the documented impact of increased Emergency Department (ED) waiting times, CMS adopts a new measure, and removes two existing measures addressing the same dimension of care. CMS removes the *Median Time for Emergency Department (ED) Arrival to ED*

[10] Proposed: 30 days to 60 days

Departure for Discharged Patients (Median Time for Discharge ED Patients) and the *Left Without Being Seen Measure* beginning in CY2028 reporting period and adopts the *Emergency Care Access and Timelines* electronic clinical quality measure (eCQM). This new, more comprehensive measure utilizes electronic quality reporting rather than relying on manually abstracted chart data. Voluntary reporting begins in CY2027 with mandatory reporting in CY2028.

- Adopted in the CY2024 OPPS rule, CMS extends voluntary reporting for the *Modify Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Outpatient)* measure *(Excessive Radiation eCQM)* beginning in CY2027 reporting period. This change removes mandatory reporting set to begin in CY2027, in response to extensive stakeholder concerns about provider burden. However, CMS encourages hospitals to prepare for mandatory reporting at a future date and intends to propose mandatory reporting for this measure during next year's rule cycle.

CMS UPDATES THE RURAL EMERGENCY HOSPITAL QUALITY REPORTING PROGRAM

FINALIZED AS PROPOSED – Pages 1269, 1272, 1275, 1278 and 1280

CMS finalizes the following changes to the Rural Emergency Hospital Quality Reporting (REHQR) Program, in addition to the cross-program measures and policies outlined above:

- Adoption of the *Emergency Care Access & Timeliness* eCQM, an intermediate outcome measure, beginning with the CY 2027 reporting period/CY 2029 program determination. This optional measure is an alternative to reporting the *Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients* measure, although REHs are required to report either the *Emergency Care Access & Timeliness* eCQM or the *Median Time for Discharged ED Patients* measure to meet REHQR Program requirements.
- Containment of the technical specifications for eCQMs for the REHQR Program in the CMS Annual Update for the Hospital Quality Reporting Programs.
- Adoption of eCQM certification requirements if the REH chooses to submit the *Emergency Care Access & Timeliness* eCQM rather than the *Median Time for Discharged ED Patients* Measure.
- Adoption of the "case threshold exemption" beginning with the CY 2027 reporting period if an REH's EHR system meets certain eCQM-related criteria. For each quality measure where the minimum number of patients that meet the denominator criteria for the reporting period is not met, REHs can declare a "case threshold exemption."
- Adoption of a policy requiring eCQM data submission by May 15 of the following year for the applicable CY reporting period, beginning with the CY 2027 reporting period.
- Establishment of related eCQM data submission and reporting requirements, including REHs having the option of reporting these requirements for either the *Emergency Care Access & Timeliness* eCQM or the *Median Time for Discharged ED Patients* measure.

UPDATES TO THE AMBULATORY SURGICAL CENTER QUALITY REPORTING PROGRAM

NOT FINALIZED – Pages 1313 and 1320

In addition to the cross-program measures and policies outlined above, for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program, **CMS does not adopt the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (Information Transfer PRO–PM).** This measure would have assessed patient understanding of discharge information through a survey given to patients who had a procedure at an ASC. However, based on generally negative stakeholder feedback comments, highlighting concerns about survey fatigue and low response rates, CMS decided not to finalize its proposal to adopt the measure.

Additionally, CMS does not finalize its related proposal to require ASCs to use the Hospital Quality Reporting (HQR) system for data submission of PRO-PMs, including for the Information Transfer PRO-PM, which was also not finalized.

CMS ACKNOWLEDGES FEEDBACK ON MODIFICATIONS TO OVERALL HOSPITAL QUALITY STAR RATINGS TO INCREASE FOCUS ON THE SAFETY OF CARE MEASURE GROUP

FINALIZED AS PROPOSED – Page 1358

The Overall Hospital Quality Star Rating, which assigns hospitals a rating from one to five stars, summarizes publicly available quality measure results reported through CMS's hospital quality programs on Medicare.gov. These measures, displayed on the site's provider comparison tool, are grouped into five categories: Safety of Care, Mortality, Readmission, Patient Experience, and Timely and Effective Care.

Building on three options outlined in the CY2025 OPPS rule, stakeholder feedback, and further internal analysis, CMS finalizes two updates to the methodology to elevate the weight of the Safety of Care group. Currently, hospitals can receive an overall quality score by reporting only one Safety of Care measure and may still earn a five-star rating despite poor performance in this area. To address this, CMS will cap the overall star rating at four for hospitals in the lowest quartile of Safety of Care performance beginning in 2026 and apply a one-star reduction to these hospitals starting in 2027.

ELIMINATION OF THE INPATIENT ONLY LIST

FINALIZED AS PROPOSED- Page 888

The Inpatient Only (IPO) list was originally established to identify procedures that Medicare would cover only when performed in the inpatient hospital setting, due to their complexity, the patient's

health status, or the need for extended recovery time (typically at least 24 hours). Currently, the list includes approximately 1,731 services.

For CY 2026, CMS begins its three-year phase out the IPO list, with full elimination by January 1, 2029.[11]CMS believes the list is no longer necessary due to advancements in medical technology, surgical techniques, and recovery protocols that have significantly reduced the need for inpatient care. The phase-out begins on January 1, 2026, with the removal of 285 mostly musculoskeletal-related services.[12] CMS maintains that existing safeguards—such as physician judgment, accreditation standards, malpractice laws, hospital conditions of participation, and other regulatory measures—will continue to protect patient safety and ensure high-quality care in the absence of the IPO list.

EXPANSION OF THE ASC COVERED PROCEDURES LIST

FINALIZED AS PROPOSED – Page 1060

CMS finalizes the expansion of the Ambulatory Surgical Center (ASC) Covered Procedures List (CPL) by revising general standards and exclusion criteria. Specifically, CMS retains the requirement that covered surgical procedures must be separately payable under the OPPS but is relocating the remaining general standards under 42 CFR 416.166(b) to a new section focused on nonbinding physician considerations for site-of-service decisions. CMS also finalizes eliminating certain general exclusion criteria and moving them to this new section, stating that many ASCs can now safely perform procedures previously excluded. The remaining exclusion criteria would include procedures designated as inpatient-only, those that can only be reported with an unlisted CPT code, or those excluded under § 411.15. CMS notes that while there is a need to revisit the exclusion criterion related to inpatient procedures following the elimination of the IPO list, maintaining this criterion for CY 2026 will promote consistency between these two lists during the phaseout period of 3-years.

CMS believes these changes will increase the flexibility for physicians to exercise their clinical judgement and allow patients greater agency in determining which setting of care to undergo surgical procedures.

CMS Finalizes 560 Additions to the ASC CPL for CY 2026

FINALIZED WITH MODIFICATION- Page 1067

As a result of the finalized changes to the general standards and exclusion criteria, CMS finalizes the addition of 276 potential surgery or surgery-like codes[13] to the ASC CPL that are not on the CY 2025 IPO list and that the agency believes meet the revised criteria. Furthermore, CMS finalizes the addition of 271 codes[14] that are finalized for removal from the IPO list for CY 2026. Following

[11] The final rule states on page 888 "January 1, 2028" but this is likely a typo. AP to raise and confirm with CMS.
[12] A full list of procedures proposed for removal from the IPO List for CY 2026 is in Table 119, on page 888 of the unpublished final rule.
[13] For a full list of finalized additions, refer to Table 131 of the unpublished final rule.
[14] For a full list of finalized additions, refer to Table 132 of the unpublished final rule.

recommendations received in public comments, **CMS is also finalizing 13 additional codes to the ASC CPL for CY 2026.**[15]

Covered Ancillary Services

FINALIZED WITH MODIFICATION- Page 1093

Covered ancillary services eligible for separate ASC payments include brachytherapy sources, certain implantable items, contractor-priced items, specific drugs and biologicals, certain radiology services, and non-opioid pain management drugs that function as a supply during surgery. The ASC payment system is aligned with the OPPS to ensure consistency, which means that if a service becomes packaged under OPPS, it will also be packaged under the ASC payment system. **For CY 2026, CMS finalizes the updated list of covered ancillary services with new CPT and HCPCS codes, with additions as recommended by commenters.**[16]

CMS Finalizes Changes to the List of ASC Covered Items and Services for Skin Substitutes

FINALIZED AS PROPOSED- Page 1095

CMS finalizes the removal of skin substitutes from the list of packaged items and services at 42 CFR 419.2(b)(16) under the OPPS and under the ASC payment system at 42 CFR 416.164(a)(5). Similar to how ASCs are paid for brachytherapy sources integral to ASC covered procedures at rates adopted under the OPPS, CMS finalizes to pay for groups of skin substitute products at annual rates adopted under the OPPS effective January 1, 2026. Furthermore, these prospective rates wouldn't be affected by the ASC wage index adjustment. To separately pay for the use of certain groups of skin substitute products during a covered surgical procedure, CMS finalizes to include these products as covered ancillary items and services that are essential to a covered surgical procedure. For new skin substitute products proposed to be added to the list of ASC covered ancillary items and services, CMS finalizes the proposal that these products be given an ASC payment indicator of "S2."[17]

CMS PROPOSES CONTINUING EXISTING APPROACH TO NEW TECHNOLOGY APCS

FINALIZED AS PROPOSED- Page 198

CMS establishes New Technology ambulatory payment classifications (APCs) for new technology services not eligible for transitional pass-through payments. Each year CMS determines which new technology services, if any, should be placed in new technology APCs. CMS establishes these New Technology APCs based on costs. Services remain in these APCs for two to three years, while CMS collects the data necessary to assign them to clinically appropriate APC groups.

---

[15] For a full list of finalized additions, refer to Table 133 of the unpublished final rule.
[16] Refer to Table 123 of the unpublished final rule.
[17] S2 indicates a separately payable ancillary skin substitute supply when provided integral to a separately payable ASC covered surgical procedure.

CMS will continue its policy of exempting services assigned to New Technology APCs with fewer than 10 claims over the 4-year lookback period from APC reassignment based on the universal low volume policy.

Consistent with its current policy, for CY 2026, CMS will also retain services within New Technology APC groups until the agency obtains sufficient claims data to justify reassignment of the service to an appropriate clinical APC

The final payment rates for the CY 2026 New Technology APCs are included in Addendum D1 on the CMS website.

PRODUCT LIST: NON-OPIOID POLICY FOR PAIN RELIEF FOR 2026

FINALIZED WITH MODIFICATION- Page 1138

Section 4135 of the Consolidated Appropriations Act of 2023 (CAA, 2023)[18] provides for temporary separate payment for certain non-opioid pain relief treatments in the HOPD and ASC settings from January 1, 2025, through December 31, 2027

Non-Opioid Treatments

Relying upon the statutory definition of "non-opioid treatment for pain relief"[19] CMS finalizes five drugs and **13 devices**[20] as qualifying as non-opioid treatments for pain relief that will receive separate payments in the HOPD and ASC settings in CY 2026:

- **Drugs:** Exparel, Omidria, Dextenza, Zynrelef, Ketorolac tromethamine Injection
- **Devices:** ON-Q Pump, SPRINT Peripheral Nerve Stimulator System, Cryo Nerve Block Therapy, ambIT Electronic Infusion Pump, Iovera System, IceMan, Sapphire Infusion Pump, Ultrasound-visible nerve block needles (SonoPlex, SonoBlock, SonoTap), Perforated continuous infusion catheter set (InfiltraLong), Continuous anesthesia conduction catheter sets (Sonolong), CADD-Solis infusion pump, ambIT Electronic Infusion Pump (Reusable), Game Ready System

Proposed Payment Methodology and Payment Limitation

FINALIZED WITH MODIFICATION- Page 1109

For CY 2026, CMS maintains the payment methodology finalized for CY 2025 in the CY 2025 OPPS/ASC Final Rule, with a modification to allow more timely consideration of payment requests.[21] Payment for eligible non-opioid drugs and biological products will continue to be calculated using the amount determined under Section 1847A of the Act, with a zero-dollar offset, meaning no portion of

[18] *Access to Non-Opioid Treatments for Pain Relief* , Pub. L. 117-328
[19] Section 1833(t)(16)(G)(iv) of the Act
[20] Proposed: 6 devices
[21] 89 FR 94343 through 94361

the Medicare OPD fee schedule amount associated with the product will be subtracted. For eligible medical devices, payment will be based on the hospital's charges adjusted to cost, also minus a zero-dollar offset, allowing full separate payment.

Eligible non-opioid drugs, biologicals, and medical devices remain subject to a statutory payment limitation[22] that caps the payment amount at 18 percent of the OPD fee schedule amount for the service with which the non-opioid treatment is provided. This cap is based on the volume-weighted average of the payment rates of the top five primary procedures by volume where the non-opioid pain relief treatments would otherwise be packaged.[23]

CMS FINALIZES DRUG PACKAGING THRESHOLD OF $140 FOR NON-POLICY-PACKAGED DRUGS, BIOLOGICS, AND THERAPEUTIC RADIOPHARMACEUTICALS WITHOUT PASS-THROUGH PAYMENT STATUS

FINALIZED AS PROPOSED – Pages 605 and 614

For CY 2026, CMS finalizes its proposal to package drugs, biologicals, and therapeutic radiopharmaceuticals with a per day cost less than or equal to $140 and identify items with a per day cost greater than $140 as separately payable unless they are policy-packaged. CMS also finalizes its proposal to package diagnostic radiopharmaceuticals with a per day cost less than or equal to $655 and identify items with a per day cost exceeding $655 as separately payable.

CMS Finalizes Implementation Details for $10 Add-On Payment to Support Domestically Produced Tc-99m

FINALIZED AS PROPOSED – Page 776

CMS finalizes its proposal to codify a $10 add-on payment for each dose of Tc-99m derived from at least 50% domestically produced Mo-99, beginning January 1, 2026. This policy, finalized in the CY 2025 rule, aims to support domestic production and offset higher associated costs. A new HCPCS code (C9176) is finalized to streamline billing.

PASS-THROUGH PAYMENT POLICIES FOR DRUGS AND BIOLOGICALS

FINALIZED AS PROPOSED – Pages 582-600, 722

Under current law,[24] CMS provides temporary additional payments or "transitional pass-through payments" for certain drugs and biological agents. Under the statute, transitional pass-through payments can be made for at least 2 years but not more than 3 years. The total projected amount of

[22] Section 1833(t)(16)(G)(iii) of the Act
[23] See Table 83 on pages 606-607 for the proposed payment limitations for the qualifying products for CY 2026.
[24] Section 1833(t)(6) of the Social Security Act.

transitional pass-through payments for drugs, biologicals and devices for a given year is limited to a percentage below 2.0 percent of all payments estimated to be made under OPPS in the same year.[25]

CMS finalizes its proposal to continue existing pass-through payment policies for drugs, biologicals, and radiopharmaceuticals in CY 2026, applying a rate of ASP plus 6 percent. In addition, as skin substitutes with an approved Biologics License Application (BLA) would be considered under transitional drug pass-through payment status, CMS finalizes its proposal to amend its regulations to reflect that.

CMS will continue pass-through payment status for 61 drugs and biologicals through CY 2026, which were approved for pass-through payment status with effective dates beginning between April 1, 2024, and April 1, 2025.[26] CMS will end pass-through payment status for 28 drugs and biologicals, for which pass-through payment status expires by December 31, 2025.[27] CMS will also end pass-through payment status in CY 2026 for 52 drugs and biologicals, which were initially approved for pass-through payment status between April 1, 2023 and January 1, 2024.[28]

DEVICES UNDER CONSIDERATION FOR PASS-THROUGH STATUS AND QUARTERLY EXPIRATION OF DEVICE PASS-THROUGH PAYMENTS

FINALIZED AS PROPOSED- Page 439

The transitional device pass-through payment is designed to ensure beneficiary access to new and innovative medical devices by providing additional reimbursement while CMS collects the cost data needed to incorporate these devices into the procedure APC rates. Currently, 17 device categories qualify for pass-through payment.[29]

New Device Pass-Through Applications for CY 2026

FINALIZED AS PROPOSED- Page 442

CMS received eight complete device pass-through applications by the March 3, 2025, deadline, all of which are addressed in this proposed rule. Two devices—VasQ (preliminarily approved under the alternate pathway effective July 1, 2024) and the SCOUT MD Surgical Guidance System (preliminarily approved effective September 1, 2024)—were approved through the quarterly review process and will be incorporated into the next OPPS annual rulemaking cycle. One application was withdrawn. CMS received public comments on whether the submitted devices meet the criteria for pass-through payment.[30]

---

[25] Section 1833(t)(6)(E) of the Act

[26] See Table 106 on pages 596-600 of the of the unpublished rule for a list of these drugs and biologicals.

[27] See Table 104 on pages 582-583 of the unpublished rule for a list of these drugs and biologicals.

[28] See Table 105 on pages 587-590 of the unpublished rule for a list of these drugs and biologicals.

[29] A list of the current device categories is in Table 99, on page 440 of the unpublished final rule.

[30] Devices under consideration and summary of comments received are on pages 446-549

Device-Intensive Procedures

FINALIZED AS PROPOSED- Page 571

CMS previously established that device-intensive procedures must involve the implantation of a device and meet three key criteria: (1) the procedure includes an implantable device typically reported when device insertion is performed; (2) the device is surgically inserted or implanted and remains in the patient's body post-procedure; and (3) the device offset amount exceeds 40% of the procedure's mean cost. After the comments received, CMS is finalizing its' continued use of HCPCS code device-intensive determination and three key criteria to designate device-intensive procedures. CMS is also finalizing using CY 2024 claims information for determining device offset percentages and assigning device-intensive status.

SITE NEUTRAL PAYMENT POLICY FOR DRUG ADMINISTRATION SERVICES

FINALIZED AS PROPOSED- Page 960

In the CY 2019 OPPS/ASC final rule, CMS established a "method to control" the growth in the volume of outpatient department services delivered in off-campus provider-based departments (PBDs). The intent was to ensure that Medicare and beneficiaries do not pay more for services simply because they are furnished in a hospital setting rather than in a physician's office. CMS achieved this by aligning the payment rate for clinic visits (HCPCS code G0463) provided in off-campus PBDs with the site-specific Medicare Physician Fee Schedule (PFS) rate.

CMS finalized the expansion of this site-neutral payment policy to include drug administration services provided in off-campus PBDs. Specifically, CMS will apply the site-specific PFS-equivalent payment rate for any HCPCS codes assigned to the drug administration Ambulatory Payment Classifications (APCs 5691–5694). This update was informed by CMS analyses showing increases in both the volume and total spending associated with these services. CMS aims to implement volume controls for drug administration in off-campus PBDs to promote more efficient use of resources, aligning with Section 11 of President Trump's Executive Order 14273, "*Lowering Drug Prices by Once Again Putting Americans First.*"

In response to comments, CMS finalized the proposal to exempt rural Sole Community Hospitals (SCHs) from this expanded site-neutral policy, consistent with prior exemptions finalized in the CY 2023 OPPS/ASC final rule. The agency sought public comment on whether this exemption remains appropriate and invited feedback on the broader application of the "method to control" policy. CMS acknowledged these comments and will consider them for future rulemaking.

UPDATES TO REQUIREMENTS FOR HOSPITALS TO MAKE A PUBLIC LIST OF THEIR STANDARD CHARGES

FINALIZED WITH MODIFICATIONS- Pages 1392, 1400-1413, 1442-1454

Following up on the Executive Order "*Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information,*" CMS finalized with modifications several updates to the hospital price transparency regulations aimed at enhancing clarity and

empowering beneficiaries. These efforts build on prior rulemaking, including the CY 2020, CY 2022, and CY 2024 OPPS/ASC final rules. CMS amended the hospital price transparency regulations to further clarify and standardize how hospitals post their standard charges.

CMS released a separate fact sheet regarding these policies and states that they will be providing additional technical guidance and examples regarding how to encode the new data elements they are finalizing in this rule.[31] **The hospital price transparency policies are effective as of January 1, 2026, but CMS delayed enforcement until April 1, 2026.**

CMS finalized the proposal to replace the current requirement that hospitals disclose estimated allowed amounts in the machine-readable file (MRF) with a requirement to report the 10th, median, and 90th percentile of allowed amounts with modification: When payer-specific negotiated rates are determined using percentage-based methods or algorithms, hospitals will be required to list the 10th percentile, median, and 90th percentile allowed amounts, along with the total number of allowed amounts, in their machine-readable files.

CMS is finalizing a proposal that requires hospitals to use data from electronic remittance advice (ERA) transactions—specifically, the EDI 835 format—to calculate these percentiles. In response to comments, CMS is finalizing the allowance of an alternative equivalent source of remittance data that includes the same information as EDI 835 ERA transaction data. CMS extends the lookback period in the final rule to allow for no less than 12 months and no longer than 15 months for calculating the 10th, median, and 90th percentile allowed amounts prior to MRF publication and provides detailed instructions to support compliance. If the payer-specific negotiated charge is based on a percentage or algorithm, CMS is also finalizing that the **hospital must calculate and encode the total number of allowed amount remittances from the transaction data or an alternative source.**[32]

In addition, CMS finalized that hospitals be required to include the name and National Provider Identifier(s) (NPIs) of the chief executive officer, president, or other senior official designated to oversee the hospital's price transparency data within the MRF.

To encourage faster resolution of enforcement actions, CMS finalized with clarifying language modifications a 35% reduction in the civil monetary penalty (CMP) for hospitals that acknowledge a violation and waive their right to an administrative law judge (ALJ) hearing. Hospitals would still have the option to request a hearing, but would forgo that right in exchange for the reduced penalty if they accept CMS's finding of noncompliance.

[31] See fact sheet here.
[32] CMS is accepting comments on the modifications to this finalized policy.

CMS AMENDS GRADUATE MEDICAL EDUCATION ACCREDITATION REQUIREMENTS

FINALIZED WITH MODIFICATION – Page 1503

Pursuant to Executive Order 14279, "Reforming Accreditation to Strengthen Higher Education,"[33] CMS finalizes, **with clarification to more explicitly specify the types of practices that will be prohibited**, that graduate medical education (GME) accreditors may not require institutions to include diversity, equity, and inclusion programs that may encourage unlawful discrimination on the basis of race or additional violations of Federal law.

CMS also notes that in alignment with the Administrations goals, the agency is considering, for future rulemaking, how to best encourage the incorporation of nutrition education requirements into accreditation standards for GME programs.

REQUESTS FOR INFORMATION

Site Neutral Payment for ASC Services

In the proposed rule, CMS requested public input to help develop a process for identifying ambulatory services that may be shifting to the hospital setting due to financial incentives rather than clinical need. This request for information was intended to address the growth of volume in outpatient department services due to the higher payments made in hospital outpatient departments as compared to ASCs. CMS specifically sought feedback on identifying services with unnecessary volume increases; aligning payment rates with the most common care setting; determining appropriate data sources and timeframes; accounting for geographic availability of care settings; addressing differences in packaging and bundling across payment systems; considering exemptions for emergent or trauma-related care and certain hospital types; deciding whether to apply policies broadly or selectively; exploring non-payment-rate strategies like prior authorization; and understanding the potential effects on beneficiaries. **CMS thanks stakeholders for their comments and may use them to inform future rulemaking.**

Payment Methods for "Software as a Service" Under OPPs

There have been rapid developments in the use of software-based technologies as software as a service (SaaS) which have new functionalities, including artificial intelligence, to support clinical decision-making in the outpatient and physician office settings. Initially, CMS considered SaaS procedures supportive or ancillary services and provided payment which was packaged into the payment for the underlying clinical service. More recently, CMS has paid separately for SaaS procedures under the OPPS through New Technology APCs. However, CMS does not currently have a consistent payment methodology specifically for SaaS. **CMS will consider comment input as it develops proposals for future rulemaking.**

***

This Applied Policy® Summary was prepared by Meghan Basler with support from the Applied Policy team of health policy experts. If you have any questions or need more information, please contact her at mbasler@appliedpolicy.com or at (908) 752-9875.