CMS Proposes Payment Increase, Site-Neutral Drug Administration Policy, and Full Phase-Out of IPO List by 2029

On July 15th, the Centers for Medicare & Medicaid Services (CMS) issued the Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems proposed rule, which proposes updates to the Medicare OPPS and ASC payment system for calendar year (CY) 2026. See the press release here and the fact sheet here.

Key proposals include:

- A 2.4% payment rate increase for hospital outpatient departments and ASCs;
- Faster repayment of 340B remedy via a 2% annual reduction to the OPPS conversion factor.
- A national survey on drug acquisition costs to inform CY 2027 payment policy.
- Transition to market-based MS-DRG weights using payer-negotiated charge data by FY 2029.
- Stabilized Community Mental Health Center payments with a 40% adjuster; hospital-based rates maintained for Partial Hospitalization Programs and Intensive Outpatient Programs.
- Removal of select quality measures and addition of new Emergency Department (ED) access and patient experience measures.
- Phase-out of the Inpatient Only (IPO) list by 2029, starting with 285 procedures in 2026, significantly expanding the types of service Medicare will pay for in an outpatient setting.
- Expansion of the ASC Covered Procedures List with 547 new codes based on revised criteria.
- 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.
- Eight new device pass-through applications under review; broader definition of device-intensive procedures.
- Expanded site-neutral payment to drug administration in off-campus PBDs, with rural SCH exemption.
- RFI on outpatient service migration from ASCs to hospital settings.
- New hospital price transparency rules, including percentile-based allowed charges and named executive oversight.
- GME accreditation changes limiting required DEI elements.
- Solicits stakeholder feedback on site neutral ASC services, a consistent payment method for Software as a Service (SaaS), and a standalone RFI on reducing Medicare administrative burden.

This proposed rule is scheduled to be published in the *Federal Register* on July 17, 2025, and comments are due by September 15, 2025.

CMS PROPOSES 2.4 PERCENT INCREASE IN OUTPATIENT AND ASC PAYMENT RATES

Page 86-120 (OPPS conversion factor); Page 617-623 (ASC conversion factor)

For calendar year 2026, CMS proposes a 2.4% increase in payment rates under both the Hospital Outpatient Prospective Payment System (OPPS) and the Ambulatory Surgical Center (ASC) payment system. This update reflects a projected 3.2% hospital market basket increase, reduced by a 0.8 percentage point productivity adjustment.

Under the proposal, total OPPS payments (including patient cost-sharing and adjustments for enrollment, utilization, and case mix) are expected to reach $100 billion, a rise of $8.1 billion from 2025. Hospitals that do not meet outpatient quality reporting requirements would continue to receive a 2.0% payment reduction. Additionally, hospitals affected by the proposed 340B remedy offset would see an additional 2.0% reduction in payments for applicable services.

For ASCs, CMS proposes to extend the use of the hospital market basket update through 2026, continuing the policy in place since 2019. ASCs meeting quality reporting requirements would also see a 2.4% increase in payment rates, with total payments estimated at $9.2 billion—up $480 million from 2025.

CMS also includes several budget neutrality adjustments to account for wage index updates and associated caps, rural and cancer hospital payment policies, and projected outlier and pass-through payment levels.

In a statement, the American Hospital Association's senior vice president for public policy analysis and development, Ashley Thompson, expressed disappointment with the inadequate payment levels, particularly for hospitals in rural and underserved communities facing significant financial strain. The Association of American Medical Colleges (AAMC) echoed these concerns, warning that several provisions in the proposed CY 2026 OPPS rule—particularly site-neutral payment cuts to off-campus hospital outpatient departments and the accelerated 340B clawback—would severely undermine academic health systems and teaching hospitals.

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

Pages 352-367

The Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022 Final Rule[1] 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*[2] that addressed the

[1] 88 FR 77150
[2] 142 S. Ct. 1896 (2022)

previous CY 2018 OPPS/ASC Final Rule[3] which reduced payments for outpatient drugs purchased under the 340B 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 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 now proposes increasing this annual reduction from 0.5 percent to 2 percent to accelerate repayment. This higher reduction rate would apply only to hospitals enrolled before January 1, 2018, and continue until $7.8 billion is recovered, which CMS projects will occur in CY 2031.

AGENCY ANNOUNCES INTENT TO CONDUCT DRUG ACQUISITION COST SURVEY FROM LATE 2025-EARLY 2026

Pages 414-417

The agency announces its intent to conduct a Medicare OPPS Drugs Acquisition Cost Survey from late CY 2025 through early CY 2026 to gather data on hospital acquisition costs for each separately payable drug acquired by all hospitals paid under the OPPS. This includes specified covered outpatient drugs (SCODs) as well as drugs and biologicals historically treated as SCODs. 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,"[4] which directs HHS to publish a plan for conducting such a survey to better determine hospital acquisition costs for outpatient drugs.

CMS plans to collect data on total acquisition costs for each drug, net of all rebates and discounts, reported by National Drug Code (NDC) for the 12-month period from July 1, 2024, through June 30, 2025. Hospitals will be asked to include all applicable rebates and discounts in their reported acquisition costs, including those tied directly to individual NDCs as well as broader discounts linked to invoices, prompt pay arrangements, wholesaler agreements, or other purchase-based discounts.

CMS intends to use the survey findings to inform payment policy proposals in the CY 2027 OPPS/ASC Proposed Rule. The agency expects timely responses from all hospitals paid under the OPPS and is considering making survey participation mandatory. CMS is seeking public input on how to address hospitals that do not respond, including potentially relying on data from similar hospitals, alternative pricing sources, or assuming lower acquisition costs and packaging drug payments accordingly.

340B Health has expressed concern about both the proposed acceleration of repayment cuts and the use of the acquisition cost survey to inform new 340B payment reductions beginning in 2027. The organization warns that if CMS uses the survey to reduce drug reimbursement rates, hospitals could

[3] 82 FR 59369 through 59370

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

effectively lose the financial benefit of 340B pricing for Medicare patients. This, they note, would be a significant financial setback for hospitals that serve low-income and rural populations.[5]

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

Pages 758-780

CMS proposes 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). If finalized, beginning with cost reporting periods ending on or after January 1, 2026, hospitals would 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 proposes 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. With this change, CMS aims to reduce reliance on hospital chargemaster data and better reflect relative market-based pricing in Medicare inpatient payments.

CMS PROPOSES STABILIZED CMHC RATES AND MAINTAINS HOSPITAL-BASED PAYMENT STRUCTURE FOR BEHAVIORAL HEALTH PROGRAMS

Pages 425-449

CMS outlines proposed updates to payment policies for Partial Hospitalization Programs (PHPs) and Intensive Outpatient Programs (IOPs), which 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).

Proposed Payment Methodology Updates

For CY 2026, CMS proposes to maintain 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. The proposed rates are $340.90 for days with three services and $424.60 for days with four or more services.

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[5] https://www.340bhealth.org/newsroom/340b-health-responds-to-cms-proposals-to-accelerate-pay-reductions-to-340b-hospitals-and-pursue-new-cuts/

However, CMS proposes 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—due largely to limited and unrepresentative billing data. To stabilize these rates, CMS proposes applying a 40% relativity adjuster to the hospital-based rates, yielding proposed CMHC per diem rates of $136.36 (three services) and $169.84 (four or more services). This approach reflects the typically lower overhead and wage structures of CMHCs while avoiding flawed reliance on early IOP claims data.

CMS proposes to continue 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 emphasizes its intent to monitor utilization trends and service delivery patterns as claims data stabilize. The agency invites comments on the proposed application of the 40% relativity adjuster and invites input on any alternative approaches that may ensure accurate, reliable payments for community mental health services without introducing instability or overpayment risk.

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

Cross-Cutting Changes in Quality Reporting Programs

Pages 623-633

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.

CMS proposes to remove a total of five measures across three programs. Citing provider burden and the end of the COVID-19 Public Health Emergency (PHE), CMS seeks to remove:

- The *COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP)*
- Two Social Drivers of Health Measures *(Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers)*
- 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)*

If finalized, the *COVID-19 Vaccination Coverage Among HCP* removal would be effective beginning in the CY2024 reporting period, while all other measure removals would take effect beginning in the CY2025 reporting period. CMS invites comments on these proposals.

In addition to measure removals across the three programs, CMS proposes to revise the Extraordinary Circumstances Exception (ECE) Policy. Proposed changes would reduce the window where affected providers could submit a request for additional reporting flexibility due to events outside of their control from 90 to 30 days, though would clarify provider notification requirements and allow CMS additional flexibility to grant ECEs.

Finally, CMS also includes a similar request for information as seen in other recent rules, as the agency looks to develop well-being and nutrition measures for potential inclusion in future rulemaking. This broad request includes feedback on tools or measures that assess overall health and happiness (including mental health) for the well-being concept, along with nutrition assessments or guidelines (including associated physical activity and sleep) for the nutrition concept.

Proposed Changes to Hospital OQR Program Quality Measures and Program

Pages 633-659

CMS proposes the following changes to the Hospital OQR measures, in addition to the changes outlined above and requests feedback:

- Recognizing the documented impact of increased Emergency Department (ED) waiting times, CMS proposes to adopt a new measure, and contingent on its adoption, remove two existing measures addressing the same dimension of care. If finalized, these proposals would remove the *Median Time for Emergency Department (ED) Arrival to ED Departure for Discharged Patients (Median Time for Discharge ED Patients)* and the *Left Without Being Seen Measure* beginning in CY2028 reporting period contingent on adoption of the *Emergency Care Access and Timelines* electronic clinical quality measure (eCQM). This new more comprehensive measure would also utilize electronic quality reporting rather than relying on manually abstracted chart data and begin voluntary reporting in CY2027/mandatory reporting in CY2028.
- Adopted in the CY2024 OPPS rule, CMS proposes to extend 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)* indefinitely beginning in CY2027 reporting period. This proposed change would remove mandatory reporting set to begin in CY2027, with CMS stating this change would be responsive to extensive stakeholder concerns about provider burden that already delayed mandatory reporting from CY2025 to CY2027.

Proposed Updates to the Ambulatory Surgical Center Quality Reporting Program

Pages 18, 682-701

In addition to the cross-program measures and policies outlined above, for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program, CMS proposes the adoption of 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 assesses patient understanding of discharge information through a survey given to patients who had a procedure at an ASC. This survey evaluates patient reported understanding of information received across various domains including medication, daily activities, and applicability to patient needs. This

would begin with voluntary reporting beginning in the CY 2027 reporting period with mandatory reporting beginning with the CY 2029 reporting period.

Additionally, CMS proposes that ASCs be required to use the Hospital Quality Reporting (HQR) system for data submission of PRO-PMs, including for the proposed *Information Transfer PRO-PM*. CMS proposes that ASCs would be required to submit their *Information Transfer PRO-PM* data by May 15 of the year prior to the applicable payment determination year in the HQR system. CMS further proposes to require ASCs to make this survey available to all patients meeting the measure's specifications and to report all completed surveys received, unless a facility has a large patient population. To lessen the burden associated with this required reporting, facilities with a large patient population would be allowed to randomly sample their patient population, as long as this yields at least 200 completed surveys in a reporting period.

CMS seeks comment on all aspects of these proposals.

CMS Proposes Updates to the Rural Emergency Hospital Quality Reporting Program

Pages 17, 659-682

CMS proposals include 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 would be an optional measure that is an alternative to reporting the *Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients* measure, although REHs would be required to report either the *Emergency Care Access & Timeliness* eCQM or the *Median Time for Discharged ED Patients* measure to meet REHQR Program requirements.
- Establishment of related eCQM data submission and reporting requirements that would include REHs being provided with an option of reporting these requirements for either the *Emergency Care Access & Timeliness* eCQM or the *Median Time for Discharged ED Patients* measure.
- 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.

CMS seeks comment on these proposals.

CMS Seeks Feedback on Modifications to Overall Hospital Quality Star Ratings to Increase Focus on the Safety of Care Measure Group

Pages 701-711

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 proposes 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 proposes capping the overall star rating at four for hospitals in the lowest quartile of Safety of Care performance beginning in 2026, and applying a one-star reduction to these hospitals starting in 2027.

CMS invites comment on all quality program proposals.

CMS PROPOSES TO ELIMINATE THE INPATIENT ONLY LIST

Page 452-464

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 proposes to phase out the IPO list entirely over the next three years, with full elimination by January 1, 2029. 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 would begin on January 1, 2026, with the removal of 285 musculoskeletal-related services.[6] 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.

CMS seeks comments on whether three years is the appropriate period of time to eliminate these codes and if there are certain services that could be removed early in the process. Additionally, CMS requests feedback on whether the removal of these services requires restructuring to allow for

[6] A full list of procedures proposed for removal from the IPO List for CY 2026 is in Table 69, on page 465 of the unpublished proposed rule.

efficient OPPS payments. Finally, CMS seeks comments on other alternatives to the complete removal of the IPO list, as they acknowledge that some may not agree with the proposed approach.

CMS PROPOSES TO EXPAND ASC COVERED PROCEDURES LIST

Pages 16, 562-593

CMS proposes to expand the Ambulatory Surgical Center (ASC) Covered Procedures List (CPL) by revising general standards and exclusion criteria. Specifically, CMS would retain the requirement that covered surgical procedures must be separately payable under the OPPS but would relocate 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 proposes to eliminate certain general exclusion criteria and move 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, with the proposed phase-out of the Inpatient Only (IPO) list beginning in CY 2026, the exclusion criterion related to inpatient procedures will need to be revisited.

CMS believes these proposals will increase the flexibility for physicians to exercise their clinical judgement and would allow for more patients to be safely diverted to ASCs for treatment, thus allowing hospitals to focus on more acute patients. Furthermore, CMS believes this expansion of the ASC CPL will build upon changes the agency has made to further site neutrality between the ASC and HOPD settings of care.

CMS Proposes 547 Additions to the ASC CPL for CY 2026

As a result of the proposed changes to the general standards and exclusion criteria, CMS proposes to add approximately 276 potential surgery or surgery-like codes[7] to the ASC CPL that are not on the CY 2025 IPO list that the agency believes would meet these proposed revised criteria. Furthermore, CMS proposes to add 271 codes[8] that are proposed for removal from the IPO list for CY 2026.

The Ambulatory Surgery Center Association (ASCA) noted their support for the proposed expansion in surgical procedures that may be performed in ASCs, as it will allow a greater number of Medicare beneficiaries to receive care in this setting and lower costs for both the Medicare program and beneficiaries.

Covered Ancillary Services

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

[7] For a full list of proposed additions, refer to Table 80 of the unpublished proposed rule.
[8] For a full list of proposed additions, refer to Table 81 of the unpublished proposed rule.

packaged under OPPS, it will also be packaged under the ASC payment system. For CY 2026, CMS proposes to update the list of covered ancillary services with new CPT and HCPCS codes.[9]

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

CMS proposes to remove skin substitutes from the list of packages 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 proposes 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 proposes 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 proposes that these products be given an ASC payment indicator of "S2."[10]

CMS PROPOSES CONTINUING EXISTING APPROACH TO NEW TECHNOLOGY APCS

Pages 148-206

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.

CMS proposes to 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. CMS plans to continue this policy in future years, until, or unless, an alternative policy is finalized. This is informed by CMS concern regarding how services with so few claims over the 4-year lookback period would be especially vulnerable to large changes in payment rates year-to-year.

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

Currently, there are 52 New Technology APC levels, ranging from the lowest cost band assigned to APC 1491 (New Technology—Level 1A ($0– $10)) to the highest cost band assigned to APC 1908 (New Technology—Level 52 ($145,001–$160,000)) in increments ranging from $10 to $14,999. Cost bands identify the APCs to which new technology procedures and services with estimated service costs that

[9] Refer to Table 73 of the unpublished proposed rule.
[10] S2 indicates a separately payable ancillary skin substitute supply when provided integral to a separately payable ASC covered surgical procedure.

fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. The proposed payment rates for these New Technology APCs 1491 to 1599 and 1901 through 1908 are included in Addendum A to this rule.

CMS OUTLINES PRODUCTS PROPOSED FOR INCLUSION IN NON-OPIOID POLICY FOR PAIN RELIEF FOR 2026

Pages 593-608

Section 4135 of the Consolidated Appropriations Act of 2023 (CAA, 2023)[11] 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. In this proposed rule, CMS outlines the implementation of this statute for 2026.

Proposed Non-Opioid Treatments

Relying upon the statutory definition of "non-opioid treatment for pain relief"[12] CMS proposes that the following five drugs and six devices qualify as non-opioid treatments for pain relief and qualify for separate payments in the HOPD and ASC settings in CY 2026:[13]

- **Drugs:** Exparel (J0666), Omidria (J1097), Dextenza (J1096), Zynrelef (C9088), Ketorolac tromethamine Injection (J1885)
- **Devices:** ON-Q Pump (C9804), SPRINT Peripheral Nerve Stimulator System (C9807), Cryo Nerve Block Therapy (C9808), ambIT Electronic Infusion Pump (C9806), Iovera System (C9809), IceMan (C9XX0)

CMS invites public comment on whether additional drugs, biologics, or devices should be included. Final decisions on eligibility will be addressed in the CY 2026 OPPS/ASC Final Rule, which is expected to be published in early November 2025.

Proposed Payment Methodology and Payment Limitation

For CY 2026, CMS proposes maintaining the payment methodology finalized for CY 2025 in the CY 2025 OPPS/ASC Final Rule.[14] If finalized, the 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 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.

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[11] *Access to Non-Opioid Treatments for Pain Relief* , Pub. L. 117-328
[12] Section 1833(t)(16)(G)(iv) of the Act
[13] See Table 82 on pages 604-605 of the unpublished rule for a list of these products.
[14] 89 FR 94343 through 94361

If finalized, eligible non-opioid drugs, biologicals, and medical devices will remain subject to a statutory payment limitation[15] 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 will be 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.[16]

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

Pages 329-351

For CY 2026, CMS proposes 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 proposes to package diagnostic radiopharmaceuticals with a per day cost less than or equal to $655 and identify items with a per day cost greater than $655 as separately payable.

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

Page 407

CMS proposes 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 (C917X) is proposed to streamline billing, and CMS is seeking comment on its implementation.

CMS PROPOSES CONTINUING EXISTING PASS-THROUGH PAYMENT POLICIES FOR DRUGS AND BIOLOGICALS

Pages 313-329 and 417-424

Under current law,[17] 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 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.[18]

CMS proposes 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

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

with an approved Biologics License Application (BLA) would be considered under transitional drug pass-through payment status, CMS proposes amending its regulations to reflect that.

CMS estimates that total spend for drugs and biological pass-through payment will be $15.2 million. The projected total amount of pass-through spending for the device categories and the drugs and biologicals would be $587.0 million or 0.59 percent of total projected OPPS payments for CY 2026.

CMS proposes to continue pass-through payment status for 41 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.[19] CMS will end pass-through payment status for 28 drugs and biologicals, for which pass-through payment status expires by December 31, 2025.[20] CMS proposes to 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.[21]

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

Page 221

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.[22]

New Device Pass-Through Applications for CY 2026

Page 224

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 invites public comment on whether the submitted devices meet the criteria for pass-through payment.[23]

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[19] See Table 59 on page 327-329 of the of the unpublished rule for a list of these drugs and biologicals.
[20] See Table 57 on pages 317-318 of the unpublished rule for a list of these drugs and biologicals.
[21] See Table 58 on pages 321-324 of the unpublished rule for a list of these drugs and biologicals.
[22] A list of the current device categories is in Table 46, on page 223 of the unpublished proposed rule.
[23] Devices under consideration are described on pages 229-283

Device-Intensive Procedures

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. In response to stakeholder feedback, CMS now proposes to broaden the definition to include certain procedures that do not meet all these criteria—specifically, those involving high-cost, surgically inserted or implanted devices that are not considered capital equipment, even if the device does not remain in the patient's body.

CMS PROPOSES A SITE NEUTRAL PAYMENT POLICY FOR DRUG ADMINISTRATION SERVICES

Pages 478-503

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.

In this proposed rule, CMS proposes to expand this site-neutral payment policy to include drug administration services provided in off-campus PBDs. Specifically, CMS would apply the site-specific PFS-equivalent payment rate for any HCPCS codes assigned to the drug administration Ambulatory Payment Classifications (APCs 5691–5694). This proposal is 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.*" CMS estimates that this proposal would generate total savings of $280 million—$210 million for Medicare and $70 million for Medicare beneficiaries through reduced coinsurance.

CMS proposes 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 seeks public comment on whether this exemption remains appropriate and invites feedback on broader application of the "method to control" policy—specifically, whether applying a PFS-equivalent rate to additional services provided in off-campus PBDs would be an effective strategy to curb unnecessary volume growth.

The American Hospital Association (AHA) and the American Society of Health-System Pharmacists (ASHP) have already expressed concerns regarding the site-neutral expansion as the policies fail to account for additional requirements PBDs face.

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

Pages 712-758

Following up on the Executive Order "*Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information,"* CMS proposes 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. In this proposed rule, CMS aims to amend the hospital price transparency regulations to further clarify and standardize how hospitals post their standard charges.

Beginning January 1, 2026, CMS proposes 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. This change responds to feedback from hospitals and MRF users citing confusion over previous requirements. CMS acknowledges that, in some cases, payer-specific negotiated charges are based on a percentage of a fee schedule not accessible to the hospital. In such situations, hospitals would be required to include as much detail as possible, including an estimated dollar amount, which would later be replaced by the median charge. CMS believes this additional context will help MRF users better interpret pricing information.

Hospitals would be required to use data from electronic remittance advice (ERA) transactions—specifically the EDI 835 format—to calculate these percentiles. CMS outlines a 12-month lookback period for calculating the 10th, median, and 90th percentile allowed amounts prior to MRF publication and provides detailed instructions to support compliance.

CMS also considered an alternative approach under which hospitals would publish a range of allowed amounts instead of specific percentiles. The agency seeks comment on this option, including input on appropriate range parameters or criteria.

In addition, CMS proposes 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 proposes 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.

The Healthcare Financial Management Association (HFMA) has expressed concern with these proposals as the changes appear to be burdensome and overly complex.

CMS seeks comment on these proposals.

CMS PROPOSES TO AMEND GRADUATE MEDICAL EDUCATION ACCREDITATION REQUIREMENTS

Pages 23, 780-784

Pursuant to Executive Order 14279, "Reforming Accreditation to Strengthen Higher Education,"[24] CMS proposes 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. This proposal, if finalized, would be effective January 1, 2026.

CMS also notes that the Secretary may identify other organizations that meet or surpass Medicare's requirements as accreditors to increase competition in the accreditation space and to improve the quality of accreditation.

CMS SEEKS FEEDBACK ON SEVERAL REQUESTS FOR INFORMATION

Site Neutral Payment for ASC Services

Pages 503-506

CMS requests 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 is 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. In this proposed rule, CMS expands the site-neutral policy to drug administration services but also poses 11 question topics for stakeholders regarding a potential shift of some services from ASCs to the hospital setting. More specifically, CMS seeks 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.

Payment Methods for "Software as a Service" Under OPPs

Pages 213-216

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 and is seeking input from the public on alternative and consistent payment methods for SaaS under the OPPS to consider for future rulemaking. CMS notes that there is a similar comment solicitation on a payment policy for SaaS under the CY 2026 Physician Fee Schedule.

Reducing Medicare Regulatory Burden

Page 6

CMS invites public feedback on ways to simplify Medicare regulations and ease administrative burdens for program participants. Stakeholders can share their suggestions through a dedicated Request for Information (RFI), accessible at https://www.cms.gov/medicare-regulatory-relief-rfi.

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