CMS Finalizes Hospital Outpatient and Ambulatory Surgical Center Update for CY 2025, with New Conditions of Participation for Hospital Obstetrical Services

On November 1, 2024, the Centers for Medicare & Medicaid Services (CMS) issued the Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems final rule, which finalizes updates to the Medicare OPPS and ASC payment system for calendar year (CY) 2025. See the press release here and the fact sheet here.

CMS finalizes policies to:

- apply a payment update of 2.9 percent for CY 2025,
- update payment rates for Partial Hospitalization Programs and Intensive Outpatient Programs,
- address the maternal health crisis through new obstetrical services specific conditions of participation,
- update the hospital, ASC, and Rural Emergency Hospital quality reporting programs,
- continue pass-through payment for certain drugs, biologicals, and devices,
- implement payment for non-opioid pain management drugs and devices,
- exclude qualifying cell and gene therapies from Comprehensive Ambulatory Payment Classification (C-APC) packaging,
- pay separately for diagnostic radiopharmaceuticals that meet a cost threshold,
- change prior authorization timeframes for outpatient services that require prior authorization,
- add 21 surgical procedures to the ASC Covered Procedures List,
- add exceptions to the Medicaid clinic services "four walls" requirement,
- clarify payment for telehealth outpatient therapy services, and
- provide an add-on payment for high-cost drugs provided by Indian Health Service and tribal facilities.

CMS does not finalize a proposed change to payment policy for coverage with evidence development clinical trials.

This final rule is scheduled to be published in the *Federal Register* on November 27, 2024.

CMS FINALIZES 2.9 PERCENT INCREASE IN OUTPATIENT AND ASC PAYMENT RATES

CMS finalizes an increase of 2.9 percent (2.6 percent proposed) for OPPS payment rates in CY 2025, based on a market basket update of 3.4 percent (3.0 percent proposed) reduced by a productivity adjustment of 0.5 percentage points (0.4 percentage points proposed).[1] CMS estimates this will result in a total of approximately $87.2 billion in payments ($88.2 billion proposed) to OPPS providers ($2.2 billion more than CY 2024). For CY 2025, CMS finalizes an OPPS conversion factor of $89.169 ($89.379 proposed) for hospitals that meet quality reporting requirements.

CMS finalizes an increase of 2.9 percent (2.6 percent proposed) for ASC payment rates in CY 2025, consistent with CMS' policy for CYs 2019 through 2024 to update the ASC payment system using the hospital market basket update.[2] CMS estimates this will result in a total of approximately $7.4 billion in payments to ASC suppliers ($308 million more than CY 2024). For CY 2025, CMS finalizes an ASC conversion factor of $54.895 ($54.675 proposed) for ASCs that meet quality reporting requirements.

For CY 2025, CMS finalizes its proposal to use the most current cost report and claims data available (CY 2023) to calculate CY 2025 OPPS and ASC payment rates.

In addition, CMS finalizes its proposal to:

- continue the cancer hospital payment adjustment for CY 2025,
- keep outlier estimated payments at 1.0 percent of total OPPS payments for CY 2025,[3] and
- continue the OPPS labor-related share as 60 percent of the national OPPS payment.

CMS FINALIZES UPDATED RATES FOR PARTIAL HOSPITALIZATION PROGRAM AND INTENSIVE OUTPATIENT PROGRAMS

The Partial Hospital Program (PHP) is an intensive, structured outpatient program provided as an alternative to psychiatric hospitalization and consists of a specified group of mental health services paid on a per diem basis for a minimum of 20 hours of PHP services per week. CMS finalizes the proposal to maintain the current methodology for calculating rates for these services, based on cost per day OPPS data including PHP and non-PHP days to capture data from hospital claims that are not identified as PHP but include service codes and intensity required for a PHP day.

---

[1] Hospitals that fail to meet hospital outpatient quality reporting requirements will have a 2.0 percentage point reduction to their update factor.

[2] ASCs that fail to meet ASC quality reporting requirements will have a 2.0 percentage point reduction to their update factor.

[3] CMS finalizes an outlier fixed-dollar threshold of $8,000.

In CY 2024, CMS established payment for Intensive Outpatient Programs (IOP) in various care settings with the goal of addressing gaps in behavioral health coverage, promoting access to necessary care, and improving treatment outcomes for beneficiaries. IOPs are distinct programs providing psychiatry services for individuals with acute mental illness or substance use disorder. This group of behavioral health services are paid on a per diem basis for a minimum of 9 hours of IOP services per week, and can be furnished in hospital outpatient departments, Community Mental Health Centers (CMHCs), Federally Qualified Health Centers (FQHCs), and Rural Health Clinics (RHCs), and Opioid Treatment Programs (OTPs) for the treatment of opioid use disorder.

Based on CY 2023 claims data, for CY 2025, CMS finalizes the proposal to update payment rates for IOP services provided in hospital outpatient departments and CMHCs. The proposal to use the same rate structure established in CY 2024, provides two APCs for each provider type: the first is for days with three services per day and the second for days with four or more services per day. CMS finalizes the proposal to calculate rates for both of these APCs based on CY 2023 claims data.

CMS AIMS TO ADDRESS MATERNAL HEALTH

The U.S. faces both a high national maternal mortality rate and disparities within this mortality rate. In 2022, there were 22 maternal deaths per 100,000 live births, with this rate being two to four times higher for Native Hawaiian and Pacific Islander women, Black women, and American Indian/Alaska Native (AI/AN) women compared to that for non-Hispanic White women. This rate is also 60 percent higher for women in rural areas than those in urban settings.

To address this issue, CMS finalizes several conditions of participation (CoPs) for obstetrical (OB) services in hospitals and critical access hospitals (CAH). In addition, CMS finalizes the proposal to revise the Quality Assessment and Performance Improvement (QAPI) Program for hospitals and CAHs that offer OB services and require staff trainings for these facilities to improve maternal care.

CMS has pushed back the implementation timelines in response to concerns about hospitals' and CAHs' ability to comply with the new requirements within 60 days after publication of the final rule. Hospitals and CAHs will now have between 6 months and 2 years to comply with the various requirements. A timeline of the requirement effective dates can be found at page 1482 of the unpublished final rule.

At this time, in response to commenter concerns, CMS is not expanding these requirements to rural emergency hospitals (REHs).

CMS Finalizes New Obstetrical Services Specific Conditions of Participation

The final CoPs specific to OB services will not reference any specific organizations' guidelines, rather require that all standards set to satisfy the CoPs by impacted hospitals be based on evidence from nationally recognized sources. The conditions will:

- Require that OB services be well-organized and meet nationally recognized standards of practice for physical and behavioral health,
- Require that OB services be integrated with other departments at the facility and be organized in a way appropriate to the services offered by the facility,
- Require that an individual with the necessary education and training (either a registered nurse, certified nurse midwife, nurse practitioner, physician assistant, or a doctor of medicine or osteopathy) supervise OB patient care units,
- Require that the facility keep a roster of all OB practitioners detailing the privileges afforded to each practitioner, and that these privileges match the practitioners' competencies,
- Require OB services to be consistent with the facility's resources and needs,
- Require that labor and delivery room suites have a call-in-system, cardiac monitor, and fetal doppler or monitor kept at the hospital and readily available for use, and
- Require protocols for patient health and safety events such as obstetrical emergencies, complications, and immediate post-delivery care.

CMS received numerous comments regarding the fact that failure to comply with these new CoPs could result in loss of certification, potentially hindering access to care. CMS reiterates that the first step, if a surveyor finds a deficiency in a hospitals CoP, is not to immediately terminate the hospital from the Medicare program, rather to develop a Plan of Correction (PoC) for the hospital, and that the Agency will then provide technical assistance and release further guidance to help hospitals remain compliant with the new CoPs.

The effective date for these CoPS will be January 1, 2026, which is 1 year following the effective date of the final rule.

CMS Finalizes Revisions to Quality Assurance & Performance Improvement (QAPI) Program

Existing CoPs require hospitals to operate a QAPI program in which they collect data to evaluate the quality of care at their facility and conduct quality improvement activities. While the hospital does not need to transmit QAPI data to CMS, they do need to maintain the program. Given the health disparities in maternal mortality rates, CMS believes the data driven improvements that a well-run QAPI program facilitates are well suited to addressing the maternal health crisis. Accordingly, CMS finalizes the proposal that hospitals and CAHs offering OB services will need to use the QAPI program to analyze and improve outcomes and disparities for OB patients. This analysis will need to be broken out by diverse subpopulations. Facilities will also be required to conduct at least one performance improvement project addressing maternal health disparities annually, to involve OB leadership in the QAPI, and, if applicable, to incorporate any Maternal Mortality Review Committee (MMRC) data and recommendations into their QAPI. The effective date for these revisions will be January 1, 2027.

CMS Finalizes New Staff Trainings for OB Services

CMS finalizes that hospitals and CAHs offering OB services would be required to develop staff trainings to improve maternal care. The facility will need to document the staff required to complete the trainings and when this training was completed, and to be able to demonstrate that the staff are knowledgeable and competent in how to improve delivery and maternal care. Findings from the QAPI programs will also need to be incorporated into the trainings. To reduce the administrative burden posed by this provision, CMS reduced the frequency of the trainings from annual to biannual and delayed the effective date of this requirement to January 1, 2027.

CMS Finalizes New Standard Within Emergency Services CoP

To improve care for all patients, including pregnant, birthing, and postpartum women receiving emergency services, CMS finalizes a new standard, "Emergency Services Readiness," within the Emergency Services CoPs. This standard will require facilities to have protocols and provisions consistent with nationally recognized and evidence-based guidelines to meet the emergency needs of patients, and to train staff these protocols and provisions annually. Hospitals provisions will be required to include the following[4]:

1. "drugs, blood and blood products, and biologicals commonly used in life-saving procedures;
2. equipment and supplies commonly used in life-saving procedures; and
3. a call-in-system for each patient in each emergency services treatment area."

Hospitals will be given flexibility in identifying the provisions that would meet the needs of their patient population. These new standards will be effective 6 months after the effective date of the final rule.

CMS FINALIZES QUALITY REPORTING PROGRAM CHANGES, INCLUDING THE ADOPTION OF HEALTH EQUITY MEASURES

The Hospital Outpatient Quality Reporting (OQR) Program and 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 establishes cross-program measures to enhance health equity through quality reporting in the OQR, Rural Emergency Hospital (REHQR), and ASCQR Programs. This commitment aligns with CMS's broader health equity framework, focusing on inclusive, equitable care across various demographics, socioeconomic statuses, and geographic locations.

Key Health Equity Measures Adopted

In this rule, CMS finalizes the Hospital Commitment to Health Equity (HCHE) for the OQR and REHQR programs, while the Facility Commitment to Health Equity (FCHE) measure is

[4] While CMS did not propose this requirement for CAHs, they already have similar supply standards in an existing CoP.

implemented in the ASCQR program. Both measures evaluate healthcare facilities on their leadership commitment to advancing health equity, with domains that include:

- **Equity as a Strategic Priority** – Facilities must identify priority populations and dedicate resources to health equity.
- **Data Collection** – Accurate collection of demographic and social data for equity insights.
- **Data Analysis** – Stratification of performance data to reveal health equity gaps.
- **Quality Improvement** – Participation in initiatives that aim to reduce health disparities.
- **Leadership Engagement** – Senior leadership reviews on health equity strategy and performance indicators.

Facilities must submit annual attestations on their performance across these domains, with public reporting planned to encourage transparency and accountability. Although the HCHE and FCHE measures are not tied to direct financial penalties, compliance is required to maintain program eligibility without payment reductions.

In finalizing these measures, CMS considered extensive public input, adjusting reporting requirements and finalizing provisions for gradual implementation. Stakeholder feedback will continue to guide future health equity measure development and refinement, ensuring adaptability across healthcare settings.

Additionally, CMS finalizes the adoption of the Screening for SDOH measure and the Screen Positive Rate for SDOH measures as proposed in the Hospital OQR, REHQR and ASCQR programs beginning with voluntary reporting for CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period.

Changes to Hospital OQR Program Quality Measures and Program

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

- 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, with voluntary reporting beginning with CY 2025 and mandatory reporting beginning with CY 2026, impacting the CY 2028 payment determination. The goal of this measure is to provide insight into the communication of recovery information and improve patient understanding of this information.
- Removal of the MRI Lumbar Spine for Low Back Pain measure beginning with the CY 2025 reporting period, impacting the CY 2027 payment determination, as recent studies have shown that performance on this measure did not improve patient outcomes.

- Removal of the Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measure beginning with the CY 2025 reporting period, impacting the CY 2027 payment determination, due to a lack of meaningful data.

CMS also finalizes the proposal to modify the Hospital OQR Program's immediate measure removal policy to an immediate suspension policy, which is used when continued use of a measure raises patient safety concerns. If an immediate suspension occurs, CMS will address the suspension and propose to retain, modify, or remove the measure in the next reasonable rulemaking opportunity. This change aligns measure suspension policies across the REHQRP, Hospital OQRP, and ASCQRP, and is intended to increase transparency and provide opportunity for public input before a measure is potentially removed.

Additionally, CMS finalizes the proposal to require that Electronic Health Record (EHR) technology be certified to all available electronic clinical quality measures (eCQMs), to ensure hospitals can accurately capture and report the data needed for these measures.

CMS also finalizes the proposal to include the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients measure – Psychiatric/Mental Health Patients strata publicly on Care Compare. While this data is already available on data.medicare.gov, CMS believes that displaying this information on Care Compare will be useful to patients when choosing care locations, as well as for researchers and hospital staff aiming to address health disparities and improve timely access to care.

CMS TO CONTINUE EXISTING PASS-THROUGH PAYMENT POLICIES FOR DRUGS, BIOLOGICALS, AND DEVICES

Under current law,[5] 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.[6]

CMS finalizes the proposal to continue existing pass-through payment policies for drugs, biologicals, and radiopharmaceuticals in CY 2025 applying a rate of ASP plus 6 percent. CMS estimates that total spend for drugs and biologicals will be $10.2 million. In addition, CMS estimates that total spend for devices that are currently eligible for pass-through and will be through CY 2025 will be $ 318.1 million. The projected total amount of pass-through spending would be 0.37 percent of total projected OPPS payments for CY 2025.

[5] Section 1833(t)(6) of the Social Security Act.
[6] Section 1833(t)(6)(E) of the Act

CMS finalizes the proposal to continue pass-through payment status for 80 drugs and biologicals through CY 2025.[7] CMS finalizes the proposal to end pass-through payment status for 28 drugs and biologicals, which were initially approved for this special status between April 1, 2022, and January 1, 2023, in CY 2025.[8]

Transitional device pass-through payment allows beneficiaries to access innovative devices by allowing payment for these devices while necessary cost data is being collected to incorporate the devices into a procedure rate. There are currently 13 device categories eligible for pass-through payments.[9] For CY 2025, 14 applications for device pass-through payment were submitted. Of these, 10 applications were for devices that received Breakthrough Device designation from the FDA. Three of these applications were approved during the quarterly review process, these being the DETOUR™ System, the AVEIR™ DR Dual Chamber Leadless Pacemaker System, and the EndoSound Vision System™.

CMS FINALIZES ELIGIBLE PRODUCTS AND PAYMENT AMOUNTS FOR NON-OPIOID PAIN MANAGEMENT PAYMENT POLICY

Section 4135 (Access to Non-Opioid Treatments for Pain Relief) of the Consolidated Appropriations Act of 2023 (CAA, 2023)[10] provides for temporary separate payments for certain non-opioid treatments for pain relief in the HOPD and ASC settings from January 1, 2025, through December 31, 2027. In this final rule, CMS outlines the implementation of this statute.

Non-Opioid Treatments

Relying upon the statutory definition of non-opioid treatment for pain relief outlined in section 1833(t)(16)(G)(iv) of the Act, CMS finalizes that the following six drugs will qualify as non-opioid treatments for pain relief and will receive separate payments in HOPD and ASC settings starting in CY 2025. Five devices will qualify.[11]

- Exparel (HCPCS Code J9066 (previously HCPCS code C9290), Injection, bupivacaine liposome, 1 mg),
- Omidria (HCPCS code J1097, Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml),
- Dextenza (HCPCS code J1096, Dexamethasone, lacrimal ophthalmic insert, 0.1 mg),
- Xaracoll (HCPCS code C9089, Bupivacaine, collagen-matrix implant, 1 mg),
- Zynrelef (HCPCS code C9088, Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg), and

[7] See Table 132 on page 747 of the of the unpublished rule for a list of these drugs and biologicals.
[8] See Table 131 on page 742 of the unpublished rule for a list of these drugs and biologicals.
[9] See Table 112 on page 486 of the unpublished rule for list of devices with pass-through status expiring in 2024-2027
[10] Pub. L. 117-328
[11] See Table 157 on pages 1072-1073 and Table 158 on page 1073-1074 of the unpublished rule for a list of these products and their payment amounts.

- Ketorolac tromethamine injection (J1885, Injection, ketorolac tromethamine, per 15 mg).

Payment Amount and Payment Limitation

CMS finalizes a payment methodology under Section 1833(t)(16)(G)(ii) of the Act for non-opioid treatments for pain relief, similar to transitional pass-through provisions in Sections 1833(t)(6)(D)(i) and (ii). For drugs or biological products, the payment will be calculated by subtracting the portion of the Medicare OPD fee schedule associated with the product, with a finalized zero-dollar offset for CY 2025. For medical devices, the payment will be based on the hospital's adjusted charges minus the relevant portion of the fee schedule, also finalized to be zero dollars for CY 2025. This final initial zero-dollar offset is meant to account for the newness of these products and ensure access to opioid alternatives is not hindered by Medicare payment policies.

Consistent with statute,[12] CMS also finalizes a payment cap at 18 percent of the OPD fee schedule amount for the service with which the non-opioid treatment is provided, determined by the top five volume-based OPPS procedures associated with each non-opioid product. CMS also clarifies the description of the payment limitation in the regulatory text to state that the volume weighted average for the payment limitations will be based on the most frequent five OPD primary procedures into which a non-opioid treatment for. In this final rule, CMS has updated the payment limitations based on the most recently available data and has excluded any procedures with which the payment for the non-opioid product was not packaged. This payment limitation will apply to the total separate payment amount billed per date of service, rather than per HCPCS dosage unit, to ensure it accurately reflects total costs. Additionally, CMS finalizes new status indicators (K1 for drugs and biologicals, H1 for devices) under the OPPS for these non-opioid products.

CMS FINALIZES SEPARATE PAYMENT FOR CERTAIN CELL AND GENE THERAPIES, EXCLUDING THEM FROM C-APC BUNDLING IN 2025 AND BEYOND

For CY 2025 and beyond, CMS will exclude certain cell and gene therapies from Comprehensive APC (C-APC) packaging, recognizing these treatments as primary, independent therapies rather than adjunctive to any C-APC primary service. CMS will provide separate payment for cell and gene therapies like CAR-T cell treatments and gene therapy for spinal muscular atrophy, ensuring these are not bundled with unrelated procedures.

Specifically, CMS finalizes its proposal to exclude the following qualifying therapies: Yescarta (Q2041), Kymriah (Q2042), Provenge (Q2043), Tecartus (Q2053), Breyanzi (Q2054), Abecma (Q2055), Carvytki (Q2056), Luxturna (J3398), Zolgensma (J3399), CASGEVY (J3392).[13]

Public comments supported the exclusion policy, noting that bundling these high-cost therapies could limit access and misrepresent their function as standalone treatments. Many

[12] Section 1833(t)(16)(G)(iii) of the Act

[13] See Table 4 on page 81 of the unpublished final rule.

urged CMS to make this policy permanent and suggested extending it to other high-cost primary therapy drugs. In response, CMS decided to exclude these therapies from C-APC packaging indefinitely but chose not to expand the exclusion to other drug categories at this time, citing the need for further evaluation. CMS also declined to create a new C-APC specifically for cell and gene therapies, as stakeholders emphasized the unique costs and administration requirements of these treatments, which make a bundled payment approach unsuitable.

CMS FINALIZES THE PROPOSAL TO PAY SEPARATELY FOR DIAGNOSTIC RADIOPHARMACEUTICALS THAT MEET COST THRESHOLD

Under the OPPS, CMS has implemented packaging policies for various types of drugs, biologicals, and radiopharmaceuticals, regardless of their cost. These packaged products are referred to as "policy-packaged" items. Diagnostic radiopharmaceuticals, including contrast agents and stress agents, fall under this category and are packaged based on their use in diagnostic tests or procedures.

To address concerns regarding access for safety net hospitals and underserved communities, CMS finalizes the proposal to pay separately for diagnostic radiopharmaceuticals with per day costs above $630 and will remove their costs from the payment amounts for the nuclear APCs.[14] CMS believes that this policy maintains beneficiary access without disincentivizing the use of clinically appropriate, high-cost, low-utilization agents.

Although CMS has the authority[15] to use Average Sales Price (ASP) methodology to determine the payment amount, CMS finds ASP data unusable for these purposes due to insufficient reporting by manufacturers. Instead, CMS finalizes using mean unit cost (MUC) based on hospital claims data as a reasonable alternative, consistent with current practice for therapeutic radiopharmaceuticals. CMS sought feedback on the use of ASP for payment determinations in future years; in response to comments, CMS encouraged manufacturers to engage with CMS on reporting of ASP for radiopharmaceuticals, given the complexities associated with reporting data for these products.

CMS FINALIZES CHANGES TO PRIOR AUTHORIZATION TIMEFRAMES

For CY 2020, CMS established a nationwide prior authorization process and requirements for certain OPD services. Providers must submit to the Medicare Administrative Contractor (MAC) a prior authorization request for services included on the list of OPD services that require prior authorization. These services currently include blepharoplasty, rhinoplasty, botulinum toxin

[14] See Table 8 on pages 133-134 of the unpublished rule for a list of these products and their final status indicators.
[15] Section 1847A of the Act

injections, panniculectomy, vein ablation, cervical fusion with disc removal, implanted spinal neurostimulators, and facet joint interventions.

In the CMS Interoperability and Prior Authorization final rule, CMS finalized for Medicare Advantage and other plans that response times of 7 calendar days for standard prior authorization requests. Even though Medicare was not subject to this rule, CMS finalizes the proposal to align the timeframe for prior authorization requests for FFS hospital outpatient services to 7-calendar days, instead of 10-business days, for standard reviews.

CMS FINALIZES 21 ADDITIONS TO ASC COVERED PROCEDURES LIST

The 2025 update to the Ambulatory Surgical Center Covered Procedures List (ASC CPL) adds 21 new procedures, including 19 dental and 2 regenerative therapy codes, selected based on safety standards and clinical data.[16] Medicare requires ASC-covered procedures to not pose a significant risk, avoiding major blood loss or invasive procedures that typically need inpatient monitoring. CMS excluded procedures, like leadless pacemakers, from ASC eligibility, and reviewed suggestions for additions like anesthesia and musculoskeletal codes, rejecting those requiring substantial postoperative monitoring or that failed to meet ASC safety criteria.

The added dental services, typically prohibited for Medicare coverage, are included due to their necessity in supporting broader medical treatments, such as those related to head, neck cancers, or surgeries like organ transplants. Finalized codes for the ASC CPL include specific dental procedures for tooth and lesion removal, osseous adjustments, and complicated drainage, as well as autologous cell therapies for rotator cuff injuries. CMS also encourages future nominations for procedures that meet ASC safety and efficacy standards, reflecting an ongoing approach to expand access responsibly.

CMS DOES NOT EXTEND SINGLE BLENDED PAYMENT POLICY USED FOR IDE STUDIES TO CED CLINICAL TRIALS

In the CY 2023 OPPS/ASC final rule, CMS finalized a policy to make a single blended payment for devices and services in Category B Investigational Device Exemption (IDE) studies to preserve the scientific validity of these studies. This policy involves creating or revising HCPCS codes to describe Category B IDE studies, including both treatment and control arms, along with routine care items and services. The single blended payment rate considers the frequency of device use compared to the control group, averaging the payment for the device with zero payment for the control in a 1:1 ratio. CMS has clarified that this policy only applies to IDE studies with a control arm. Studies without a control arm would be paid using standard Medicare payment methodologies.

[16] For a full list of finalized additions, refer to Table 154 of the unpublished proposed rule.

In its proposed rule for CY 2025, CMS proposed extending this blended payment method to drugs and devices studied under the Coverage with Evidence Development (CED) designation. This would involve averaging payments for investigational and control arms to preserve trial integrity. Payment rates would follow a hierarchy (ASP, WAC, AWP) based on available pricing data. However, the proposal raised concerns, with some stakeholders fearing reduced payments might hinder provider participation in trials, particularly in underserved communities. CMS acknowledged ethical concerns about requiring coinsurance for placebo participants in CED trials, especially for FDA-approved treatments.

Following public feedback, CMS chose not to finalize the CED payment proposal for CY 2025, citing the need for further analysis of the policy's broader implications, including the ethical and financial impacts on study enrollment and access. CMS will continue to refine its payment methodology for future rulemaking. The regulation at § 419.47 was revised to clarify that the blended payment applies only to IDE trials with control arms and where payment adjustments are essential to maintain study validity.

CMS FINALIZES EXCEPTIONS TO THE MEDICAID CLINIC SERVICES "FOUR WALLS" REQUIREMENT

CMS has historically interpreted section 1905(a)(9) of the Act to limit Medicaid clinic services to those provided within the clinic, except for services provided to individuals who are unhoused. The agency believes that, while they do not have the statutory authority to eliminate the "four walls" requirement entirely, they do have the authority to extend exceptions for other groups that face similar healthcare access issues as the unhoused[17]. In this final rule, CMS adds three new exceptions to the "four walls" requirement:

First, CMS finalizes an exception for IHS and Tribal clinics, allowing them to provide services outside the clinic walls. This change is mandatory for all states that opt to cover Medicaid clinic services.

Second, CMS finalizes creating an optional exception for clinics primarily organized to treat outpatients with behavioral health disorders, including mental health and substance use disorders. These clinics will be allowed to provide services outside the clinic walls, including non-behavioral health services. This exception is optional for states.

Third, CMS finalizes an optional exception for clinics located in rural areas (excluding Rural Health Clinics), allowing them to offer services outside the clinic walls. This change aims to improve access to healthcare services for residents in rural areas who often lack access due to distance and transportation challenges. States can choose to adopt this exception to better serve their rural populations.

[17] These being: High Rates of Behavioral Health Diagnoses or Difficulty Accessing Behavioral Health Services, Issues Accessing Services Due to Lack of Transportation, Historical Mistrust of the Health Care System, and High Rates of Poor Health Outcomes and Mortality

These exceptions are designed to remove barriers to accessing care for vulnerable populations, ensuring they receive necessary services regardless of their ability to visit a clinic in person.

CMS Responds to Comments on Approach to Establishing "Rural" Definition

For clinics located in rural areas related to the above "four wall" requirement exceptions, CMS sought comment on the definition of rural the agency should allow States to use when crafting their exception.

Specifically, CMS sought comment on the following approaches to defining rural:

1. **Federal Definitions:** Adopt a commonly used federal definition from the Census Bureau, Office of Management and Budget (OMB), or the Federal Office of Rural Health Policy (FORHP).
2. **State Adoption of Federal Definitions:** Allow states to adopt a federal definition of rural used for programmatic purposes. States would specify the chosen federal definition in their state plan and justify how it best captures the rural population meeting the four criteria in the finalized rule.
3. **State-Specific Definitions:** Permit states to use a rural definition from a state agency involved in rural health policy. States would detail this definition in their state plan and explain its alignment with the criteria.
4. **No Definition:** Not define rural in the final rule, giving states the flexibility to choose any reasonable definition linked to the four criteria. States would publish their definition on a public website, allowing for flexibility but risking overly broad or narrow definitions.

The "overwhelming majority" of commentors supported either not defining rural in the final rule, which would allow states the most flexibility, or allowing states to choose either a state or federal definition of rural. CMS ultimately decided to go with the latter option, and, when writing their state plan amendments (SPAs) for this exception, states must include a definition of rural that is either used by a Federal governmental agency or by a state agency to set rural health policy.

CMS CLARIFIES PAYMENT FOR TELEHEALTH OUTPATIENT THERAPY SERVICES, DSMT AND MNT

During the COVID-19 public health emergency, outpatient therapy services, Diabetes Self-Management Training (DSMT), Medical Nutrition Therapy (MNT), and mental health services could all be furnished remotely to beneficiaries in their homes. CMS also expanded the range of practitioners that could serve as distant site practitioners for Medicare telehealth services and waived originating site requirements for Medicare telehealth services. CMS issued a separate waiver under Hospitals Without Walls to allow hospitals to bill for these services furnished by hospital staff remotely. In the CY 2025 OPPS proposed rule, CMS clarified that it will continue to align its payment policies for these services under the OPPS with policies under

the PFS and that that outpatient therapy services, DSMT and MNT, would be available via telehealth regardless of the institutional setting so long as the providers who administer them continued to be considered valid distant site practitioners under Medicare telehealth services. As the flexibility for the provider types who administer outpatient therapy, DSMT, and MNT services be considered valid distant site practitioners, which was granted by the Consolidated Appropriations Act of 2023 (CAA, 2023), will expire at the end of 2024, CMS will no longer pay for these services when furnished via telehealth beginning gin CY 2025.

CMS FINALIZES ADD-ON PAYMENT FOR HIGH-COST DRUGS PROVIDED BY IHS AND TRIBAL FACILITIES

The CY 2000 OPPS final rule, which first implemented PPS for hospital outpatient services, exempts outpatient services provided by hospitals of the IHS. CMS paid for these services under separately established rates. IHS and tribal facilities have since been reimbursed under the All-Inclusive Rate (AIR), with separate rates for Alaska and the lower 48 states due to varying costs of living. These facilities have expanded their services over time, often providing essential higher-cost drugs and services. However, the AIR sometimes fails to cover the full cost of these drugs, threatening these facilities' ability to offer such treatments.

CMS finalizes the proposal to implement an add-on payment for high-cost drugs, defined as drugs covered under Medicare Part B with per-day costs that exceed two times the lower 48 states' AIR. This payment, in addition to the AIR, will be the average sales price (ASP) for the drug with no additional payment. If ASP pricing is not available, the add-on payment will be the Wholesale Acquisition Cost (WAC), and if that is unavailable, CMS finalizes the proposal to pay 89.6 percent of the Average Wholesale Price (AWP). The final policy is in response to agency concern over equity and beneficiary access and aims to help these facilities afford to provide expensive medications without compromising their financial stability. This add-on payment will be effective January 1, 2025, permanently, with quarterly updates to the drug list.

CMS Responds to Comment on IHS and Tribally Operated Clinics' Payment

The Tribal Technical Advisory Group (TTAG), which advises HHS on issues impacting American Indian and Alaskan Native (AI/AN) populations, includes representatives from IHS, national Indian health organizations, and urban Indian health organizations. In June 2020, the TTAG requested that CMS expand eligibility for payment at the IHS Medicare outpatient per visit rate/AIR to all IHS and tribally operated outpatient facilities. According to the TTAG, outpatient clinics are paid at different rates depending on whether they are a provider-based facility, a grandfathered or non-grandfathered tribal FQHC, or none of the above.

To address disparities in payment rates among different provider types, CMS sought comments on the types and number of facilities eligible for the Medicare outpatient IHS AIR, whether these facilities would enroll as FQHCs or be categorized differently, and their operational costs relative to existing payment methodologies. CMS also requested feedback regarding why payment at the IHS AIR might be more suitable than rates under the FQHC PPS or other Medicare payment systems. The agency will use stakeholder input to inform future

policy decisions. Commenters broadly supported the TTAG's request, noting that it would provide financial stability and improve care for tribal communities.

***

This Applied Policy® Summary was prepared by Emma Hammer with support from the Applied Policy team of health policy experts. If you have any questions or need more information, please contact her at ehammer@appliedpolicy.com or at (202) 558-5272.