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CMS FINALIZES PAYMENT CUTS FOR PHYSICIANS IN 2025, UPDATES SEVERAL PAYMENT POLICIES [CMS-1807-F]

On November 1, 2024 the Centers for Medicare & Medicaid Services (CMS) issued the final calendar year (CY) 2025 Physician Fee Schedule (PFS), which finalizes policies for physician payment and other outpatient services covered under Medicare Part B. CMS released a rule overview fact sheet and official press release. CMS finalizes the following proposals:

- Decrease the conversion factor for CY 2025 by 2.83 percent from the conversion factor for 2024,
- Extend some telehealth flexibilities and add services to the Medicare Telehealth List,
- Permanently adopt virtual supervision and teaching physician policies for telehealth services,
- Expand coverage for colorectal cancer screening,
- Relax direct supervision requirements for certain provider types and services,
- Expand ability to bill the G2211 add-on code,
- Establish new HCPCS codes to describe Advanced Primary Care Management Services,
- Update the Shared Savings Program and the Quality Payment Program,
- Update policies for advancing behavioral health services,
- Update Medicare inflation rebate guidance with new policies,
- Expand coverage of hepatitis B vaccines
- Establish fee schedule for drugs covered as additional preventative services,
- Clarify payment for radiopharmaceuticals in the physician office setting,
- Clarify policies on manufacturer refunds for discarded drugs,
- Expand coverage of dental services linked to certain covered treatments,
- Update the data reporting timeline for the Clinical Laboratory Fee Schedule, and
- Update the portable X-ray transportation rates.

This final rule is scheduled to be published in the *Federal Register* on December 9, 2024.

CMS DECREASES CONVERSION FACTOR, LOWERS PAYMENT RATES FOR PHYSICIANS

CMS finalizes payment reduction for physicians for CY 2025. Physicians and other health professionals are paid under Medicare Part B for services that include office visits, surgical procedures, and other diagnostic and therapeutic efforts. To determine payment, Medicare uses a physician fee schedule that is based on the resources typically used to furnish the service. The appropriate number of relative value units (RVUs) are assigned to each service for physician work, practice expense (PE), and malpractice.

CMS multiplies these RVUs by a "conversion factor" to determine the Medicare payment amounts for each physician service. For 2025, CMS finalizes decreasing the conversion factor by 2.83 percent, which reflects the 2024 conversion factor of $33.29 multiplied by an RVU budget neutrality adjustment of 0.02 percent, 0.0 percent statutory update adjustment factor[1], and removal of the temporary 2.93 percent payment increase provided by the Consolidated Appropriations Act (CAA), 2024.

Specifically, CMS finalizes a conversion factor of $32.3465, which is a decrease of $0.94 from the 2024 conversion factor of $33.2875. This means that each physician service will be paid less in 2025 than in 2024, except for services for which CMS finalizes an increase to the RVUs or otherwise specifically finalizes payment increases.

TABLE 1. Physician Fee Schedule Conversion Factor (CF) Comparison[2]

2024 Final CF	2024 Adjusted CF	2025 Final CF
33.2875	32.3400	32.3465

CMS FINALIZES CHANGES TO TELEHEALTH POLICIES

Additions to the Medicare Telehealth Services List

CMS finalizes several of its proposals to add services to the Medicare Telehealth Services List. Many of these services were initially added on a temporary basis during the COVID-19 Public Health Emergency (PHE) and later retained provisionally. Medicare requires that the telehealth service be analogous to an in-person service, therefore, certain services, such as continuous glucose monitoring interpretation, were not proposed for addition to the Medicare Telehealth Services list. Table 2 reflects CMS's final determinations on requests received for additions to the Medicare Telehealth Services list.

[1] Section 1848(d)(19) of the Social Security Act
[2] See Table 108 on page 2324 of the unpublished rule.

Table 2. CMS Categorization of Services That Will be Added to the Medicare Telehealth List

Proposed Permanent Additions	Services Proposed to Remain Provisional	Services Proposed Not to Be Added
Preexposure Prophylaxis (PrEP) for HIV • HCPCS code G0011 • HCPCS code G0013	**Cardiovascular and Pulmonary Rehabilitation Services** • CPT codes 93797, 93798, 94625, 94626 **Health and Well-Being Coaching** • CPT codes 0591T-0593T **Psychological and Developmental Testing** • CPT codes 96112, 96113, 96130, 96136, 96137 **Therapy, Audiology, and Speech-Language Pathology Services** • Various CPT codes **Radiation Treatment Management** • CPT code 77427 **Caregiver Training Services** • CPT codes 97550, 97551, 97552, 96202, 96203 • HCPCS codes GCTD1-3, GCTB1-2	**Continuous Glucose Monitoring** • CPT code 95251 **General Behavioral Health Integration** • CPT code 99484 **Principal Care Management** • CPT codes 99424-99427 **Posterior Tibial Nerve Stimulation for Voiding Dysfunction** • CPT code 64566

Extended Telehealth Flexibilities, Including Frequency Limitation Suspensions and Audio-Only Communication Options

CMS finalizes several updates for CY 2025 concerning frequency limitations on Medicare telehealth subsequent care services in inpatient and nursing facility settings, as well as critical care consultations. Historically, there were restrictions on how often these services could be provided via telehealth, such as one subsequent hospital care service every three days and one subsequent nursing facility visit every fourteen days. These limitations were temporarily lifted during the COVID-19 PHE to ensure patients had access to necessary care. The suspension of these limitations continued through CY 2024, and CMS now finalizes the decision to extend this suspension through CY 2025. The aim is to gather more data to understand evolving practice patterns and to determine if permanent changes are needed. CMS found that lifting these limitations did not significantly increase service utilization and believes that extending the suspension will not pose a safety risk.

Additionally, CMS finalizes a measure to include audio-only communication technology in the definition of an "interactive telecommunications system" for any telehealth service provided to a beneficiary in their home if the patient cannot use or does not consent to video technology.

This policy acknowledges varying broadband access and patient preferences, ensuring telehealth services remain accessible.

Lastly, CMS will continue to allow distant site practitioners to use their currently enrolled practice location instead of their home address when providing telehealth services from home through CY 2025. This flexibility aims to protect the safety and privacy of healthcare professionals while reducing administrative burdens.

CMS Finalizes Extension and Permanent Adoption of Virtual Supervision and Teaching Physician Policies for Telehealth Services

CMS finalizes several proposals regarding non-face-to-face services involving communications technology.

First, CMS finalizes the proposal to extend the definition of "direct supervision" to include virtual presence through audio-video communications technology until December 31, 2025. This allows supervising physicians or practitioners to be considered "immediately available" through real-time audio-visual technology for certain services, including diagnostic tests, incident-to services, pulmonary rehabilitation, cardiac rehabilitation, and hospital outpatient services. This extension is due to the lack of evidence that virtual supervision compromises patient safety and aims to avoid abrupt changes that could disrupt access to services.

Additionally, CMS finalizes the proposal to permanently adopt this definition for a subset of lower-risk services that do not typically require the presence of the supervising practitioner. These include services furnished incident to a physician or other practitioner's service when provided by auxiliary personnel and office visits for the evaluation and management of established patients that may not require the presence of a physician.

CMS also finalizes the proposal to continue allowing teaching physicians to have a virtual presence for billing purposes when services involving residents are furnished virtually. This policy would be extended through December 31, 2025, for all teaching settings where services are provided via telehealth.

Telehealth Originating Site Facility Fee Payment Amount Update

The Medicare telehealth originating site facility fee for CY 2025 is $31.04 for HCPCS code Q3014.

CMS FINALIZES PROPOSAL TO EXPAND COVERAGE FOR COLORECTAL CANCER SCREENING

CMS finalizes the proposal to update and expand colorectal cancer (CRC) screening coverage by removing barium enema procedures, adding coverage for computed tomography colonography (CTC), and including follow-on screening colonoscopies after positive results from blood-based biomarker tests, in addition to stool-based tests. CRC screening frequency

limitations will not apply to the follow-on screening colonoscopy. CMS states that these changes aim to enhance early detection and treatment, address health disparities, and align with modern clinical guidelines, supporting the Administration's goals to improve cancer outcomes and advance health equity.

CHANGES TO OUTPATIENT THERAPY SERVICES

General Supervision of Therapy Assistants in Private Practices

Prior to the CY 2024 PFS final rule, CMS required physical therapists and occupational therapists in private practices (PTPPs and OTPPs, respectively) to provide direct supervision of their therapy assistants. While this rule finalized provisions allowing for the lower general supervision of therapy assistants by PTPPs and OTPPs for remote therapeutic monitoring (RTM) services to align with CMS' RTM general supervision policy, direct supervision of therapy assistants is still required for all other therapy services in the private practice setting.

General supervision requires the physician to provide overall direction and control but does not require the physician to be present during the performance of a procedure. In contrast, direct supervision requires the physician to be immediately available to assist throughout the performance of the procedure.

CMS now finalizes its proposal to allow for general supervision of physical therapy assistants and occupational therapy assistants by OTPPs and PTPPs for outpatient occupational and physical therapy services. This would align with the supervision levels required in institutional settings, as well as with most state-established supervision levels.[3] The direct supervision requirement would still be in place for OTs and PTs who are not enrolled in Medicare.

CMS Finalizes Changes to Signed Plan of Care Requirements for Therapy Services

Therapy services may only be covered by Medicare if a physician certifies the plan of care for the patient. Stakeholders have raised concerns that, in some cases, patients have written orders from their physician to receive therapy, but when therapists attempt to contact the physician to receive a signature on the care plan itself, they do not respond, making it impossible for the therapist to be paid for their services. PTs, OTs, and speech language pathologists can technically begin to provide care prior to the plan of care being signed, but they risk not being paid for these services if the physician never signs the plan, incentivizing them to delay care and wait for the signature.

In response to these concerns, CMS finalizes its proposal to permit the physician/non-physician practitioner (NPP) written order or referral for therapy services to substitute for the signature on the initial certification of the therapist-established treatment plan. CMS notes that this approach would allow therapists to provide therapy services without any delay and at the same

[3] 44 States allow general supervision of PTAs and 49 States that allow general supervision of OTAs.

financial risk that he/she would have after receiving a signed POC from the physician/NPP without an order

CMS Finalizes KX Modifier Threshold of $2,410

Using the final CY 2025 Medicare Economic Index (MEI) of 3.5 percent, CMS finalizes its proposed KX modifier threshold of $2,410 for physical and speech-language pathology combined services, and $2,410 for occupational therapy.

CMS FINALIZES ITS PROPOSAL TO EXPAND ABILITY TO BILL G2211

In the CY 2024 PFS final rule, CMS finalized the change in status for HCPCS code G2211, or the other outpatient (O/O) evaluation and management (E/M) visit complexity add-on code, to make it separately payable by assigning an "active" status indicator. This add-on code is billed in addition to the standard codes for office and other outpatient (O/O) E/M visits, and provides extra payment meant to capture the effort required by clinicians to build a longitudinal relationship with patients. Payment of G2211 was not allowed when reported with the payment modifier -25, which indicates an independently billable E/M service provided by the same practitioner on the same day as a procedure or other service. Many practitioners have expressed to CMS that this prevents the add-on code from being billed for an E/M visit taking place on the same day as a preventive immunization, annual wellness visit (AWV), or other Medicare preventive service. In response to these concerns, CMS finalizes proposal to allow payment of G2211 when the O/O E/M base code is reported on the same day as any Part B preventative service, including an annual wellness visit, vaccine administration, and Initial Preventive Physical Examination (IPPE), furnished in the office or outpatient setting, beginning CY 2025.

CMS ESTABLISHES NEW HCPCS G-CODES TO DESCRIBE APCM SERVICES

CMS establishes specific coding and payment policy for three new HCPCS G-codes that will describe advanced primary care management (APCM) services. CMS states that the new codes incorporate lessons learned from the CMS Innovation Center's testing of APCMs and aim to streamline billing and documentation requirements while promoting access to a range of advanced primary care services.

In order to reduce administrative burden, the finalized HCPCS codes do not include time-based thresholds but rather are stratified based on an individual's number of chronic conditions:

- **G0556**: Advanced primary care management services for a patient with one chronic condition [expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline], or fewer, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and

serves as the continuing focal point for all needed health care services, per calendar month.

- **G0557**: Advanced primary care management services for a patient with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month.

- **G0558:** Advanced primary care management services for a patient that is a Qualified Medicare Beneficiary with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month.

Physicians and NPPs using an advanced primary care model of care delivery could bill for APCM services beginning January 1, 2025, when they are solely responsible for the patient's primary care services. Through this approach, CMS would pay for larger units of service with the intention of supporting patient-provider relationships.

CMS FINALIZES CHANGES TO THE MEDICARE SHARED SAVINGS PROGRAM

CMS builds on changes made in CY 2023 and CY 2024 PFS final rules to the Medicare Shared Savings Program (MSSP) with the goal of furthering value-based care. Changes from the previously finalized rules are expected to increase the number of beneficiaries assigned to ACOs by up to four million over the next several years and are key to CMS's goal of having 100 percent of fee-for-service (FFS) Medicare beneficiaries in an accountable care relationship by 2030. A Fact Sheet specifically addressing the Medicare Shared Savings Program policies included in this year's final rule can be found here.

A New "Prepaid Shared Savings" Option for Certain ACOs

CMS finalizes its proposal to implement a "prepaid shared savings" option for eligible ACOs that have historically earned shared savings. ACOs participating in Levels C-E of the BASIC track or the ENHANCED track with consistent prior success in earning shared savings would be eligible. Prepaid shared savings would be paid on a quarterly basis and are intended to allow ACOs to make investments in infrastructure and services that would improve care coordination

and quality for beneficiaries and address health disparities. CMS has outlined spending requirements and options for the prepaid sharing savings:

- A minimum of 50 percent of prepaid shared savings would need to be spent on direct beneficiary services not otherwise payable in FFS Medicare that have a reasonable expectation of maintaining health or overall function of the beneficiary, including meals, transportation, dental, vision, hearing, or Part B cost-sharing reductions.
- Up to 50 percent of the prepaid sharing savings can be spent on staffing and health infrastructure.

ACOs would repay their prepaid shared savings through earned shared savings and would be required to repay any outstanding balance if they are unable to repay their balance through earned savings. CMS will monitor prepaid savings to decrease overpayments. The option will be available beginning January 1, 2026.

Health Equity Benchmark Adjustment to Incentivize ACOs to Serve Beneficiaries from Underserved Communities

CMS finalizes its proposal to implement a Health Equity Benchmark Adjustment (HEBA), with the goal of increasing the number of beneficiaries from underserved communities served by ACOs. Starting with agreement periods beginning on January 1, 2025, CMS will adjust an ACO's historical benchmark using a HEBA. The HEBA is based on the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D low-income subsidy (LIS) or dually eligible for Medicare and Medicaid. As this would be the third method CMS uses to upwardly adjust an ACO's historical benchmark, in addition to the positive regional adjustment or prior savings adjustment, CMS would use the highest of the three values.

New Alternative Payment Model (APM) Performance Pathway (APP) Plus Measure Set to Promote Quality Measure Alignments, Aims to Spur Electronic Clinical Quality Measure (eCQM) Use

CMS finalizes, with modification, its proposal to create an APP Plus quality measure set under the APP that aligns with the Adult Universal Foundation quality measures, which would better align with quality measures reported across other CMS programs. Under this **measure**, MSSP ACOs would be required to report the APP Plus quality measure set beginning with the 2025 performance year, and the APP quality measure set would no longer be available.

The measure set consists of six measures in the current APP quality measure set and five new measures from the Adult Universal Foundation set that would be incrementally incorporated, over the later of either performance years 2025 through 2028 or the performance year that is one year after eCQM specifications become available for Quality IDs 493 (Adult Immunization

Status) and 487 (Screening for Social Drivers of Health), to eventually include all eleven measures.[4]

Furthermore, CMS finalizes its proposal to establish a Complex Organization Adjustment beginning in the CY 2025 performance period/2027 Merit-Based Incentive Payment System (MIPS) payment year to account for challenges faced by virtual groups and APM Entities when reporting eCQMs. A virtual group and APM entity would receive one measure achievement point for each eCQM submitted that meets data completeness and case minimum requirements, with caps on the total points.

CMS Finalizes Proposal to Mitigate the Impact of Significant Anomalous, and Highly Suspect (SAHS) Billing Activity on Shared Savings Program Financial Calculations in CY 2024 and Beyond

CMS finalizes its proposal to exclude payment amounts from expenditure and revenue calculations for the relevant calendar year for which the SAHS billing is identified, in addition to the historical benchmarks used to reconcile the ACO for the performance year corresponding to the calendar year when SAHS billing activity occurred and outlines its methodology for doing so in this finalized rule.

These finalized policies are intended to complement proposals issued in the June 28, 2024, proposed rule, "Medicare Program: Mitigating the Impact of Significant, Anomalous, and Highly Suspect Billing Activity on Medicare Shared Savings Program Financial Calculations in Calendar Year 2023" (CMS-1799-P)."[5] which seeks to address SAHS billing activity associated with certain intermittent catheter supplies in CY 2023. While CMS believes similar SAHS billing occurrences would be rare, the agency asserts that having a permanent policy in place will allow CMS to make more timely adjustments and strengthen program integrity.

Policies Related to Reopening Payment Determinations

CMS states that the MSSP's current financial methodology limits CMS's ability to address the impact of improper payments on program calculations. As such, CMS establishes a methodology to account for the impact of improper payments in recalculating expenditures and payment amounts used upon reopening a payment determination.

CMS also finalizes a process by which an ACO could request its initial determination of shared savings or shared losses be reopened and finalizes revisions to MSSP regulations to make

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[4] See Tables 39, 40, 41, and 42 for a list of the measures included in performance years 2025, 2026 and 2027, and 2028 or the Performance Year that is one year after the eCQM Specifications become available for Quality IDs: 487 and 493, respectively.

[5] See the Federal Register for the rule: https://www.federalregister.gov/documents/2024/07/03/2024-14601/medicare-program-mitigating-the-impact-of-significant-anomalous-and-highly-suspect-billing-activity

CMS's discretion clear. CMS anticipates providing information on the reopening request process for ACOs through sub-regulatory guidance.

CMS FINALIZES UPDATES TO THE QUALITY PAYMENT PROGRAM

In the annual PFS rulemaking, CMS includes its proposals for the MIPS, a Quality Payment Program (QPP). MIPS includes three reporting options: Traditional MIPS, MIPS Value Pathways, and Alternative Payment Model (APM) Performance Pathways (APP). MIPS includes four performance categories: quality, cost, improvement activities, and promoting interoperability.

Quality Measurement Proposals

CMS finalizes several updates to measure/activity inventories and scoring methodologies impacting different MIPS reporting pathways, including but not limited to:

- 195 total quality measures for the 2025 performance period,
- Adding six new episode-based cost measures: Chronic Kidney Disease, End-Stage Renal Disease, Kidney Transplant Management, Prostate Cancer, and Rheumatoid Arthritis,
- Revising two episode-based cost measures, Cataract Removal with Intraocular Lens Implantation and Inpatient Percutaneous Coronary Intervention, to reflect reevaluated versions,
- Revising the cost measure scoring methodology to more appropriately assess clinician cost of care in relation to national averages,
- A minimum criteria for a qualifying data submission in the quality, improvement activities, and Promoting Interoperability performance categories, which would represent the minimum needed to be eligible for scoring.

The CMS Quality Payment Program Resource Library 2025 Quality Payment Program Final Rule Fact Sheet and Policy Comparison Table, available here, includes a complete list of the finalized quality payment program proposals.

MVP Proposals

In 2020 rulemaking, CMS finalized the creation of the MIPS Value Pathways (MVPs), a reporting option for MIPS that the agency believes will provide a more cohesive participation experience by aligning activities from the four MIPS performance categories around a certain specialty, medical condition, or patient population.

CMS finalizes the proposal to add six new MVPs while proposing revisions to the fifteen previously finalized MVPs. The CMS Quality Payment Program Resource Library 2025 MVPs Guide, available here, includes a complete list of the measures included in the proposed MVPs and changes to the modified MVPS.

CMS has previously announced its intent to complete the transition to MVPs and sunsettting traditional MIPS and has identified the 2029 performance period as the potential timeline for finalizing this transition. CMS sought feedback on challenges related to this timeline, and noted that traditional MIPS would not be sunset in this performance period.

POLICIES FOR ADVANCING ACCESS TO BEHAVIORAL HEALTH SERVICES

In line with CMS's Behavioral Health Strategy, CMS finalizes several policies to enhance access to behavioral health services.

Safety Planning Interventions

With over 49,000 suicides in 2022, a notable increase among older adults, and concerns about intentional overdose, particularly in young people, older adults, and black women,[6] CMS highlights the importance of safety planning interventions. These interventions involve creating personalized coping strategies and support networks with a clinician to help prevent suicide. As such, CMS finalizes a new add-on G-code (HCPCS code GSPI1) that would be billed as a standalone service.

Post-Discharge Telephonic Follow-up Contacts Intervention (FCI)

CMS finalizes a new monthly billing code (HCPCS code GFCI1) for post-discharge telephonic follow-up contacts for patients discharged from the ED after a crisis encounter. According to CMS, research indicates that patients seen in the emergency department (ED) for deliberate self-harm, intentional overdose, or suicidal ideation face significantly increased risks of suicide and other mortality within the year following their visit. To address this, the Follow-up Contact Intervention (FCI) involves 10–20-minute post-discharge phone calls between providers and patients to update Safety Plans, offer psychosocial support, and ensure follow-up care, effectively reducing suicidal behaviors. Despite proven effectiveness, a national survey revealed that less than half of hospitals conduct these follow-up contacts, with few meeting the essential FCI goals.[7]

Coverage for Digital Mental Health Treatment (DMHT) Devices

To further support access to psychotherapy, CMS finalizes Medicare payment for digital mental health treatment (DMHT) devices used with professional behavioral health services in ongoing treatment plans. DMHT refers to software devices cleared by the Food & Drug Administration (FDA) that are intended to treat mental health conditions by delivering effective therapeutic interventions alongside ongoing behavioral health care.

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[6] https://www.nih.gov/news-events/news-releases/suicides-drug-overdose-increased-among-young-people-elderly-people-black-women-despite-overall-downward-tren

[7] https://www.sciencedirect.com/science/article/pii/S1553725024000679?via%3Dihub

As such, CMS finalizes three new HCPCS codes for DMHT devices: G0552 for the supply of the device and initial education, and G0553 and G0554 for monthly treatment management services. These codes require ongoing use of the DMHT device and monitoring by the practitioner or their clinical staff.

Interprofessional Consultation by Authorized Behavioral Health Practitioners

In the CY 2019 PFS final rule,[8] the agency established billing[9] for interprofessional consultations via phone, internet, or electronic health records, enabling diagnosis and management without face-to-face contact. Initially limited to practitioners who can independently bill Medicare for E/M visits, CMS now finalizes expanding billing eligibility to include clinical psychologists, social workers, marriage and family therapists, and mental health counselors. CMS also finalizes new G codes (GIPC1-6) for these practitioners to bill interprofessional consultations.

EXISTING MEDICARE INFLATION REBATE GUIDANCE TO BE CODIFIED WITH NEW POLICIES

Under the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169), drug companies must pay inflation rebates if they raise their prices for certain Part B and Part D drugs faster than the rate of inflation.

In this rule, CMS is codifying policies established in the revised guidance for the Medicare Part B Drug Inflation Rebate Program and Medicare Part D Drug Inflation Rebate Program. Policies to be codified include the requirement for manufacturers to pay rebates for certain single source drugs and biological products with prices that increase faster than the rate of inflation; criteria for the identification of Part B rebatable drugs; computation of the beneficiary coinsurance adjustment for Part B rebatable drugs; determination of the rebate amount for Part B rebatable drugs; reduction of the rebate amount for Part B rebatable drugs in shortage and when there is a severe supply chain disruption; provision of reports to each manufacturer of a Part B rebatable drug; and establishment of enforcement provisions via civil money penalties.

Additionally, CMS is finalizing new policies for program including:

- Removal of units of drugs subject to discarded drug refunds from the Part B rebate amounts,
- Establishment of a process for reconciliation of a Part B or Part D rebate amount including the circumstances that may trigger such a reconciliation, and
- Establishment of procedures for imposing civil money penalties on manufacturers that do not pay Part B or Part D inflation rebate amounts within a specified period.

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[8] 83 FR 59489

[9] CPT codes 99451, 99452, 99446, 99447, 99448, 99449

CMS indicated that it will explore establishing a Medicare Part D claims data repository to comply with the statutory obligation for removal of 340B units from Part D drug inflation rebate calculations, starting January 1, 2026. Detailed policies and requirements related to any such repository may be explored and considered in future rulemaking, starting January 1, 2026.

CMS FINALIZES PROPOSAL TO EXPAND COVERAGE OF HEPATITIS B VACCINES

Hepatitis B vaccines are currently covered under the Medicare Part B benefit per section 1861(s)(10)(B) of the Act. In this rule, CMS finalizes its proposal to expand coverage of hepatitis B vaccinations by covering individuals who have not previously received a completed hepatitis B vaccination series or whose vaccination history is unknown. An assessment of an individual's vaccination status could now be made without the clinical expertise of a physician, and a doctor's order would no longer be necessary for the administration of a hepatitis B vaccine under Part B, which would facilitate roster billing by mass immunizers for hepatitis B vaccine administration. CMS indicates the change reflects the agency's view that current Medicare coverage of hepatitis B vaccination is outdated in light of recent information about the risks of contracting hepatitis B. CMS also finalizes its proposal that payment for hepatitis B vaccines and their administration be made at 100% of reasonable cost in Rural Health Clinics (RHC) and Federally Qualified Health Centers (FQHC), separate from payment under the FQHC PPS or the RHC All-Inclusive Rate (AIR) methodology, in order to improve payment for all Part B vaccines in those settings.

CMS FINALIZES PROPOSAL TO ESTABLISH FEE SCHEDULE FOR DRUGS COVERED AS ADDITIONAL PREVENTATIVE SERVICES

In addition to expanding Hepatitis B vaccine coverage, per section 1833(a)(1)(W)(ii) of the Act, CMS finalizes its proposal for a new fee schedule for Drugs Covered as Additional Preventive Services (DCAPS drugs). While currently CMS has not yet covered or paid for any drugs under the benefit category of additional preventive services, CMS noted that on September 30, 2024 it released a national coverage determination (NCD) for Pre-Exposure Prophylaxis (PrEP) to Prevent Human Immunodeficiency Virus (HIV), which established coverage of HIV PrEP drugs under Part B as additional preventive services. PrEP for HIV drugs will be paid under this new DCAPS fee schedule effective January 1, 2025.[10]

CMS will set payment limits for DCAPS drugs under Part B, which will be updated and published on the CMS website quarterly using the below methodology:

[10] https://www.cms.gov/medicare/coverage/prep

(1) If ASP data is available for the DCAPS drug, the payment limit would be determined based on the methodology under section 1847A(b) of the Act (usually 106 percent of ASP);
(2) If ASP data is not available, the payment limit would be calculated using National Average Drug Acquisition Cost (NADAC) prices for the drug;
(3) If ASP data and NADAC prices are not available, the payment limit would be calculated using the FSS prices for the drug; and
(4) If ASP data, NADAC prices, and FSS prices are not available, payment limit would be the invoice price determined by the Medicare Administrative Contractor (MAC).

CMS FINALIZES CHANGES TO CALCULATING PAYMENT LIMITS WHEN NEGATIVE OR ZERO AVERAGE SALES PRICE DATA IS REPORTED

In response to a 2022 U.S. Department of Health and Human Services Office of Inspector General (OIG) report noting issues with potential inaccuracies in manufacturer reporting of Average Sales Price (ASP) and the need for additional guidance on manufacturer ASP reporting and CMS payment calculations, CMS reviewed its current guidance and proposed changes to its approach for drug payment calculation when manufacturer reported ASP negative or zero.

Specifically, CMS finalizes that negative and zero ASP data be considered "not available" under section 1847A(c)(5)(B) of the Act and that positive ASP data be considered available. In addition, CMS's finalized policies for the payment limit when ASP data is not available based on factors about the drug or biological, such as whether the drug is single source or multiple source; whether some, but not all National Drug Codes (NDCs) for a billing and payment code have a negative or zero ASP data, or all NDCs for a billing and payment code have a negative or zero ASP data; and whether relevant applications for all NDCs for a billing and payment code have a marketing status of discontinued.

CHANGES TO INCREASE ACCESS TO IMMUNOSUPPRESSIVE DRUGS

Currently, compounded formulations of immunosuppressive drugs are not included in the immunosuppressive therapy benefit because these formulations are not approved by the FDA. CMS noted concerns that such formulations are frequently used in the treatment of transplant recipients who cannot swallow oral capsules or tablets due to age or oral-motor dysfunction.

In response, CMS finalizes its revisions to regulations to include certain compounded formulations of FDA-approved drugs that have approved immunosuppressive indications in the immunosuppressive drug benefit, or for use in conjunction with immunosuppressive drugs, or that have been determined by a MAC to be reasonable and necessary to prevent or treat rejection of a transplanted organ or tissue. CMS is limiting the included compounded

formulations to those products with oral and enteral routes of administration (for example, oral suspensions or solutions).

Additionally, to align with current standards of practice and reduce barriers to medication adherence, CMS finalizes changes to allow payment of a supplying fee for a prescription of a supply of up to 90 days and to allow payment for refills of prescriptions for these immunosuppressive drugs.

CMS CLARIFIES MEDICARE CONTRACTOR-BASED PAYMENT FOR RADIOPHARMCEUTICALS IN THE PHYSICIAN OFFICE SETTING

Currently, per statute and the Medicare Claims Processing Manual (MCPM) Chapter 17, section 20.1.3, MACs determine payment limits for radiopharmaceuticals in the physician office based on the methodology in place as of November 2003, before the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Currently, payment can vary by MAC and can be based on 95 percent of Average Wholesale Price (AWP), invoices, or other reasonable payment methods/data made available when the product is contractor priced.

In response to feedback from MACs and other interested parties that there is confusion about the methodologies available to MACs for pricing of radiopharmaceuticals in the physician office setting, CMS clarifies that any methodology that was in place to set pricing of radiopharmaceuticals in the physician office setting prior to November 2003 can be used by any MAC, whether or not that specific MAC used the methodology prior to November 2003, including the use of invoice pricing.

CMS FINALIZES CLARIFICATIONS TO CURRENT POLICIES REQUIRING MANUFACTURER REFUNDS FOR DISCARDED SINGLE-DOSE OR SINGLE-USE DRUGS

Under current law,[11] drug manufacturers must provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The refund amount is equal to the amount of discarded drug that exceeds an applicable percentage, which is generally required to be at least 10 percent, of total charges for the drug in a given calendar quarter. This refund applies to refundable single-dose container or single-use package drugs beginning January 1, 2023.

In this rule, CMS finalizes the following policy changes:

[11] Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117-9).

- Clarification of exclusions of drugs for which payment has been made under Part B for fewer than 18 months from the definition of refundable single-dose container or single-use package drug to allow for an alternate approach for determining the beginning of the 18-month exclusion period based on date on which the drug is first paid under Part B (as opposed to date of first sale) if the date the drug was first marketed (as reported to CMS) does not adequately approximate the first date of payment under Part B due to an applicable NCD (CMS cited Alzheimer's disease Leqembi® (lecanemab-irmb) as an example),
- Clarification on identifying single-dose containers by including "single-patient-use container" as a package type term and adding three types of products that may be considered refundable single-dose container or single-use package drugs.
- Requiring the JW modifier if a billing supplier is not administering a drug, but there are discarded amounts discarded during the preparation process before supplying the drug to the patient, and
- Continuation of exclusion of skin substitutes from application of the refund.

For CY 2025, CMS also reviewed an application for increased applicable percentage for determining the refund from the manufacturer of Leukine® (sargramostim) but noted that the agency is not finalizing an increase in the applicable percentage for the drug at this time.

CMS FINALIZES NEW CLINICAL SCENARIOS FOR MEDICARE REIMBURSEMENT OF DENTAL SERVICES LINKED TO COVERED TREATMENTS

In the CY 2023 PFS final rule,[12] CMS established that Medicare payment under Parts A and B could be made for dental services in the inpatient or outpatient setting under certain circumstances, such as when linked to the clinical success of a covered medical service. In the CY 2025 proposed rule, CMS responded to stakeholder feedback by proposing new clinical scenarios for Medicare reimbursement of dental services linked to covered treatments. These clinical scenarios include: (1) dental or oral examination in the inpatient or outpatient setting prior to Medicare-covered dialysis services for beneficiaries with end-stage renal disease (ESRD); and (2) medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to or concurrent with Medicare-covered dialysis services. CMS finalizes that it will include these clinical scenarios under covered dental services.

CMS finalizes its proposal to require the KX modifier on claims for dental services considered integral to covered medical services to improve claims processing and ensure program integrity. However, CMS delays the implementation of the KX modifier until July 1, 2024 in

[12] 87 FR 69663 through 69688

response to stakeholder comments. Additionally, CMS finalizes its proposal to mandate the inclusion of a diagnosis code on the 837D dental claims format, aligning with existing requirements for physician service. Implementation of the inclusion of a diagnosis code has also been delayed to July 1, 2025, to allow for comprehensive testing, reporting, and educational materials for healthcare providers, vendors, and payors.

Lastly, stakeholders have previously advocated for Medicare payment of dental services for individuals diagnosed with diabetes, arguing that dental treatments can significantly improve diabetes management and outcomes. However, in the CY 2025 proposed rule, CMS stated that current evidence does not sufficiently link dental services to specific covered medical services for diabetes treatment under Medicare rules. CMS sought input on whether certain dental services are clinically connected to covered medical treatments for diabetes and whether dental services, such as prophylaxis, are considered standard in managing the condition. CMS noted they remain committed to understanding the link between dental and medical services associated with diabetes and will take comments into consideration in future rulemaking.

REVISIONS TO CLINICAL LABORATORY FEE SCHEDULE DATA REPORTING AND PAYMENT REDUCTION PHASE-IN

CMS finalizes revisions to the data reporting period and the phase-in of payment reductions for the Clinical Laboratory Fee Schedule (CLFS). Prior to January 1, 2018, Medicare paid for clinical diagnostic laboratory tests (CDLTs) based on various criteria, with most tests being paid at the national limitation amount (NLA). The Protecting Access to Medicare Act of 2014 (PAMA) introduced changes, shifting payments to be based on private payor rates and requiring periodic data reporting.

In accordance with section 502 of the Furthering Continuing Appropriations and Other Extensions Act, 2024 (FCAOEA, 2024), the next data reporting period for CDLTs that are not Advanced Diagnostic Laboratory Tests (ADLTs) is proposed for January 1, 2025, through March 31, 2025, based on data collected from January 1, 2019, through June 30, 2019. The reporting cycle will resume every three years after this period. Payment reductions will be phased in through CY 2027, extending the previous schedule. Per Section 221 of Continuing Appropriations and Extensions Act (CAEA), 2025, for CY 2025, there will be no reduction in payment rates compared to CY 2024, and a maximum reduction of 15 percent per year will apply for CYs 2026 through 2028.

CMS SUGGESTS MACS UPDATE PORTABLE X-RAY TRANSPORATION RATES

CMS acknowledges longstanding concerns from portable X-Ray (PXR) suppliers that payment rates for transportation for PXR services are insufficient. Although CMS continues to leave these rates to the discretion of the MACs, CMS finalizes its proposal to revise Chapter 13, 90.3 of the Medicare Claims Processing Manual, to provide guidance to MACs to update the rate for transportation of PXR equipment and apply the appropriate inflation factor for the update.

CMS states that the MACs should consider using the ambulance inflation factor (AIF), which is used to adjust ambulance service rates, to price PXR services.

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