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CMS Finalizes Payment Increase for Physicians, New Ambulatory Specialty Model for Heart Failure and Low Back Pain, and Changes to Several Payment Policies

On October 31, 2025, the Centers for Medicare & Medicaid Services (CMS) issued its final calendar year (CY) 2026 Physician Fee Schedule (PFS), which finalizes policies for physician payment and other outpatient services covered under Medicare Part B. CMS also released a rule overview fact sheet and a press release. **Key policy updates include:**

- Separate conversion factors (CF) for qualifying vs. non-qualifying alternative payment model (APM) participants, with increased payment rates for both groups,
- A 2.5 percent efficiency adjustment to work relative value units (RVU) for most non-time-based services and reallocate indirect practice expense (PE) RVUs by site of service,
- Streamlining of the Medicare Telehealth List review by removing steps and adding services,
- New remote therapeutic monitoring (RTM) and remote physiological monitoring (RPM) codes,
- Expanded billing for the Complex Patient E/M add-on code G2211,
- New HCPCS codes for Advanced Primary Care Management (APCM) services,
- Policies to improve care for chronic illnesses and behavioral health,
- Changes to the payment system for skin substitutes,
- Clarifications on price concessions, bona fide service fees (BFSF), and units sold at maximum fair price (MFP) for Average Sales Price (ASP) reporting,
- A mandatory Ambulatory Specialty Model (ASM) for chronic care quality and cost accountability,
- Updates to the Medicare Part B and Part D Inflation Rebate Programs,
- Updates to the Shared Savings Program (SSP) and the Quality Payment Program (QPP), and
- Alignment of the Medicare Diabetes Prevention Program (MDPP) with Centers for Disease Control and Prevention (CDC) standards.

This final rule is scheduled to be published in the *Federal Register* on November 5, 2025.

SEPARATE CONVERSION FACTORS FOR QUALIFYING VS. NON-QUALIFYING APM PARTICIPANTS, INCREASED PAYMENT RATES

FINALIZED WITH MODIFICATION – Page 1,735 of Unpublished Rule

CMS finalizes its proposal to codify a statutory increase to Medicare Part B payments to physicians and other health professionals for 2026. These payments cover services such as office visits, surgeries, and diagnostic or therapeutic procedures. Medicare determines payment rates through the PFS, which assigns RVUs to each service based on physician work, PE, and malpractice costs. These RVUs are then multiplied by a CF to calculate final payment amounts.

For 2026, there will be two separate CFs, as required by statute:[1] one CF for qualifying APM participants (QPs) and one for non-qualifying APM (non-QP) participants. Both CFs are derived from the single 2025 CF, adjusted separately based on rates specified by statute. CMS finalizes a **CF of $33.5675 (3.77 percent increase) for QPs**, and **$33.4009 (3.26 percent increase) for non-QPs**.[2] Both reflect the 2025 CF multiplied by a **0.49 percent positive budget neutrality adjustment**[3,4], a **statutory update of 0.75 percent for QPs (0.25 percent for non-QPs)**[5], and an additional **one-time 2.50 percent increase for 2026**, also required by law.[6]

This is the first year CMS will implement separate CFs based on QP status. The policy results in a higher CF for QPs due to a larger update. Payment rates in 2026 will therefore vary depending on a provider's QP status.

Table 1. Physician Fee Schedule CF Comparison[7]

2025 CF	2026 Proposed CF	
	Qualifying APM Participant	Non-Qualifying APM Participant
$32.3465	$33.5675	$33.4009

Update to Efficiency Adjustment

FINALIZED AS PROPOSED – Page 208 of Unpublished Rule

CMS finalizes a new "efficiency adjustment" that reduces work RVUs and associated intraservice physician time by 2.5 percent for most non-time-based services. This adjustment reflects anticipated productivity gains from improvements in clinician experience, workflows, and technology. Time-based services are excluded. Specialties that rely more heavily on time-based codes could see small RVU increases, while procedural or diagnostic specialties may see slight reductions.

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[1] Section 1848(d)(1)(A) of the Social Security Act
[2] **Proposed CF:** $33.5875 (3.83 percent increase) for QPs, and $33.4209 (3.62 percent increase) for non-QPs
[3] Section 1848(c)(2)(B)(ii)(II) of the Social Security Act
[4] **Proposed Budget Neutrality Adjustment:** 0.55 percent
[5] Section 1848(d)(19) of the Social Security Act
[6] Section 71202 of the One Big Beautiful Bill Act – OBBB, H.R. 1
[7] See Table DB-3 and Table D-B4 on pages 1,753-1,754 of the unpublished rule.

Site of Service Payment Differential

FINALIZED AS PROPOSED – Page 81 of Unpublished Rule

The agency finalizes its proposal to adjust the methodology for allocating indirect PE RVUs based on the site of service. Specifically, for services valued in the facility setting, the portion of indirect PE RVUs tied to work RVUs will be reduced to half the amount used for non-facility services. This change will increase PE RVUs for specialties that primarily deliver care in non-facility settings (e.g., offices) and decrease PE RVUs for those working mostly in facility settings (e.g., hospitals). This change is budget neutral and does not affect the overall CF, as it only redistributes PE RVUs between settings.

CHANGES TO TELEHEALTH POLICIES

CMS finalizes several changes to simplify telehealth policies by streamlining the approval process, expanding covered services, and making certain pandemic-era flexibilities permanent.

Changes to the Medicare Telehealth Services List Review Process

FINALIZED AS PROPOSED – Page 142 of Unpublished Rule

The agency finalizes its proposal to streamline the Medicare Telehealth Services List review process by simplifying the current five-step evaluation. In response to stakeholders' concerns that the existing process is unclear and requires clinical evidence that is often difficult to provide, CMS is eliminating Steps 4 and 5, which involved comparing the service being considered to existing services that have already been permanently approved and assessing whether the telehealth version provides the same clinical benefit as in-person care. CMS believes these steps are unnecessary, as patients and providers can determine the appropriateness of telehealth delivery.

CMS will maintain Steps 1 through 3, which include confirming that the service is separately payable under the PFS, meets the statutory requirements under Section 1834(m) of the Social Security Act, including provider eligibility, geographic and site limitations, and technology standards, and assessing whether the service can be effectively delivered via interactive telecommunications without compromising quality or clinical benefit.[8]

Additionally, CMS finalizes the elimination of the "permanent" and "provisional" service designations and treating all services on the list as permanent, while retaining the ability to remove services if needed.

Additions to the Medicare Telehealth Services List

FINALIZED AS PROPOSED – Page 154 of Unpublished Rule

CMS finalizes several additions 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. Table 2 reflects CMS's finalized determinations on requests received for additions

[8] An interactive telecommunications system is defined under § 410.78(a)(3).

to the Medicare Telehealth Services List. CMS is also finalizing its proposal to make all services on the list permanent.

Table 2. Categorization of Services Requested to be Added to the Medicare Telehealth List

Proposed Additions	Services Proposed Not to Be Added
Multiple-Family Group Psychotherapy • CPT code 90849 **Group Behavioral Counseling for Obesity** • HCPCS code G0473 **Infectious Disease Add-On** • HCPCS code G0545 **Auditory Osseointegrated Sound Processor** • CPT code 92622, 92623	**Dialysis** • CPT codes 90935, 90937, 90945, 90947 **Home INR Monitoring** • HCPCS code G0248 **Telemedicine E/M** • CPT codes 98000-98015

Extended Telehealth Flexibilities, Including Frequency Limitation Suspensions and Direct Supervision Requirements

FINALIZED AS PROPOSED – Page 162 of Unpublished Rule

CMS finalizes several updates for frequency limitations on Medicare telehealth subsequent care services in inpatient and nursing facility settings, as well as critical care consultations. Historically, there were limitations on the frequency of these services when delivered via telehealth. For example, subsequent hospital care was limited to once every three days, and follow-up visits in nursing facilities were allowed only once every fourteen days. These restrictions were temporarily waived during the COVID-19 Public Health Emergency (PHE) to ensure continued access to care, and the suspension remained in effect through CY 2024 and 2025. CMS is making this change permanent by removing the frequency limitations for subsequent inpatient visits, subsequent nursing facility visits, and critical care consultations.

CMS also finalizes that for services requiring direct physician supervision, the physician or practitioner does not need to be physically present. Instead, real-time audio/video communication is permitted, as long as the physician or practitioner is "immediately available." CMS will also allow Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) to use audio/video communications to meet direct supervision requirements for their applicable services and supplies.

NOT FINALIZED – Page 170 of Unpublished Rule

CMS is not finalizing its proposal to revert to the pre-COVID policy, where teaching physicians must have physical presence when residents are performing services in order to qualify for Medicare payments. Instead, **the agency will permanently allow teaching physicians to have a virtual presence** through audio/video real-time communications in all residency training locations, **only in clinical instances when the service was furnished virtually.**

Telehealth Originating Site Facility Fee Payment Amount Update

FINALIZED AS PROPOSED – Page 171 of Unpublished Rule

Under statute, CMS must annually update the telehealth originating site facility fee based on the percentage increase in the Medicare Economic Index (MEI). Based on a 2.7 percent MEI increase, the Medicare telehealth originating site facility fee for CY 2026 is $31.85 for HCPCS code Q3014.

REMOTE PATIENT MONITORING

FINALIZED AS PROPOSED – Pages 341 and 355 of Unpublished Rule

CMS finalizes several new RTM and RPM codes for CY 2026. These codes are intended to support providers in tracking patients' adherence to therapy plans and digital therapeutic interventions (RTM), as well as monitoring relevant physiological parameters, such as blood pressure (RPM). These new codes reduce the minimum data collection requirement for reimbursement from 16 days to two days and introduce shorter-duration treatment management codes that allow billing for 10 minutes of care coordination per month, provided there is at least one clinical staff interaction with the patient during that period.

RTM codes will be classified as New Technology through 2030, with coverage to be reassessed after three years of utilization data becomes available. In contrast, RPM codes do not receive the New Technology designation and are instead scheduled for resurvey after one year of use, with revaluation planned for the January 2028 American Medical Association (AMA)/Specialty Society Relative Value Sales (RVS) Update Committee (RUC) meeting.

G2211 TO BE BILLED WITH HOME OR RESIDENCE E/M VISITS

FINALIZED AS PROPOSED – Page 417 of Unpublished Rule

In the CY 2024 PFS Final Rule, CMS finalized the change in status for the office and outpatient (O/O) E/M visit complexity add-on code, HCPCS code G2211, to make it separately payable by assigning an "active" status indicator. This code is billed in addition to the standard codes for 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 for home or residence visits under the original finalized policy, but stakeholders have recommended that CMS either create a distinct complexity add-on payment code for home-based E/M visits or expand the use of G2211 to include E/M visits in settings such as nursing facilities, assisted living facilities, and beneficiaries' homes.

CMS recognizes that home or residence visits often require a long-term plan, at least monthly visits, and consistent follow-up, in which there is more cost associated with building trust and a long-term relationship. Therefore, CMS is finalizing its proposal to allow HCPCS code G2211 to be billed as an add-on code with the home or residence E/M visits codes. This change would increase reimbursement for clinicians providing ongoing, relationship-based care in home or residence settings.

ENHANCED CARE MANAGEMENT UPDATES

FINALIZED AS PROPOSED – Page 429 of Unpublished Rule

CMS finalizes its proposal to create optional add-on codes for APCM services that would facilitate offering complementary behavioral health integration (BHI) services. CMS is removing the time-based requirements of the existing BHI and Psychiatric Collaborative Care Model (CoCM) services as CMS believes that this would reduce administrative burden. These optional add-on codes are considered a "designated care management service" and thus could be provided by auxiliary personnel when under the supervision of the billing practitioner.

CMS also finalizes its proposal to establish three new HCPCS G-codes to be billed as add-on services when the APCM base code is reported by the same practitioner in the same month. These finalized codes are G0568, G0569, G0570 and are add-on codes based on existing CPT codes 99492, 99493, and 99484, respectively. CMS is finalizing a direct crosswalk to the current work RVU values for CPT codes 99492 for G0568, 99493 for G0569, and 99484 for G0570. CMS is also finalizing a direct crosswalk to the current direct PE units for CPT codes 99492, 99493, and 99484 to HCPCS codes G0568, G0569, G0570 respectively.

Additionally, CMS will adopt the APCM add-on codes to support billing for BHI and CoCM services when RHCs and FQHCs deliver advanced primary care. Further, services that are considered care management services will be designated as care coordination services eligible for separate payment in RHCs and FQHCs.

IMPROVING CARE FOR CHRONIC ILLNESS AND BEHAVIORAL HEALTH NEEDS

Updates to Payment for DMHT

FINALIZED AS PROPOSED – Page 444 of Unpublished Rule

Effective January 1, 2025, CMS finalized three HCPCS G-codes for DMHT devices to be billed by physicians and practitioners authorized to furnish services for the diagnosis and treatment of mental illness: G0552, G0553, and G0554.[9] In this rule, CMS finalizes its proposal to expand the payment policies for these codes to include devices classified as digital therapy devices for ADHD under §882.5803 of section 510(k) of the FD&C Act or granted De Novo authorization by the FDA.

In the proposed rule, CMS sought feedback on establishing coding and payment policies for the following categories:

- Computerized behavioral therapy devices for treating symptoms of gastrointestinal conditions;
- Digital therapy devices to reduce sleep disturbance for psychiatric conditions; and
- Computerized behavioral therapy device for the treatment of fibromyalgia symptoms.

[9] See pages 436-437 of the published proposed rule for code descriptors.

CMS also sought input on establishing coding and payment for the broader category of digital tools to maintain or encourage a healthy lifestyle, including clinical use cases and justification for their use. Finally, CMS invited feedback on a specific request to create a new G-code to report administration of an FDA authorized eye-tracking technology to aid in diagnosing autism spectrum disorder (ASD) in pediatric patients.

CMS expressed appreciation for feedback submitted by commenters regarding expanding coding and payment policies and will take the comments into consideration for future rulemaking.

Community Health Integration and Principal Illness Navigation for Behavioral Health

FINALIZED AS PROPOSED – Page 459 of Unpublished Rule

CMS clarifies that Clinical Social Workers (CSWs), Marriage and Family Therapists (MFTs), and Mental Health Counselors (MHCs) meet the requirements to perform Community Health Integration (CHI) and Principal Illness Navigation (PIN) services if under supervision of a billing practitioner. CMS also finalizes its proposal to allow CPT code 90791 (*Psychiatric diagnostic evaluation*) or Health Behavior Assessment and Intervention (HBAI) services to serve as initiating visits for CHI services.

Additionally, based on comments received in response to the CY 2024 PFS Proposed Rule, CMS finalizes its proposal to change the long descriptor of G0019 to better fit the purpose of CHI services. Specifically, CMS finalizes its proposal to replace the term "social determinants of health (SDOH)" with the term "upstream driver(s)."

NOT FINALIZED – Page 464 of Unpublished Rule

CMS proposed to remove G0136 (*Administration of a standardized, evidence-based social determinants of health risk assessment tool, 5 to 15 minutes*) from the Medicare Telehealth Services List as it is already described in other existing codes. However, **based on comments received, CMS will retain G0136 with a revised descriptor to read "Administration of a standardized, evidence-based assessment of physical activity and nutrition, 5-15 minutes, not more often than every 6 months" and all current billing rules and clarifies that, in addition to an outpatient E/M visit (excluding a level 1 visit by clinical staff), G0136 may also be reported alongside CPT code 90791 (psychiatric diagnostic evaluation) or HBAI service codes.**

CHANGES TO PAYMENT SYSTEM FOR SKIN SUBSTITUTES

FINALIZED WITH MODIFICATION – Pages 538-539 of Unpublished Rule

In its proposed rule, CMS stated that existing payment policies for skin substitutes are unsustainable due to dramatic price increases for these products and proposed paying for certain skin substitutes as incident-to supplies when they are used during a procedure paid under the physician office (non-

facility) setting or under the outpatient department setting. Incident-to supplies are those furnished as an integral part of the physician's professional services during diagnosis or treatment.[10]

CMS finalizes its proposal to group skin substitutes based on their FDA regulatory category[11] **and to use a single payment rate for all skin substitutes at $127.28/cm²**, which is updated from the proposed rule based on recent data.[12] Skin substitutes licensed under section 351 of the Public Service Act would be excluded and continue to be paid as a biological product.

CMS currently considers skin substitutes to be biologicals under Medicare Part B and establishes a unique billing code and payment for each product. Skin substitutes are paid similar to biological drugs under 1847A of the Act, therefore requiring the manufacturers to submit ASP data to CMS every quarter. However, since skin substitutes are not like typical biologicals and do not have National Drug Codes (NDCs), it has been difficult for CMS to operationalize calculating payment for these products.

NEW GUIDANCE ON PRICE CONCESSIONS AND BONA FIDE SERVICE FEES FOR AVERAGE SALES PRICE AND CLARIFICATION ON INCLUSION OF UNITS SOLD AT MAXIMUM FAIR PRICE

FINALIZED WITH MODIFICATION – Pages 626-627, 629 of Unpublished Rule

CMS calculates the payment limits for drugs payable under Medicare Part B on a quarterly basis using the manufacturer's ASP, as defined in § 414.902 and using the methodology in section 1847A of the Act. Manufacturers must report ASP data to CMS and, per section 1847A(c)(3) of the Act and § 414.804(a)(2), are required to deduct price concessions such as volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (excluding rebates under the Medicaid Drug Rebate Program and the Medicare Prescription Drug Inflation Rebate Program). However, BFSFs are not considered price concessions and, therefore, are not deducted when calculating the manufacturer's ASP.

Bundled Arrangements and Bona Fide Service Fees

In response to a December 2022 report by the Office of Inspector General (OIG) titled, "Manufacturers May Need Additional Guidance to Ensure Consistent Calculations of Average Sales Prices,"[13] which called for more guidance on ASP reporting and calculations, CMS finalizes changes relating to bundled arrangements and BFSFs. Changes include:

- **Bundled Arrangements:** Add regulatory text defining "bundled arrangement" with the removal of the phrases of "purchasing patterns" and "prior purchases" and new paragraphs to

[10] 42 CFR 410.26
[11] See "Skin Substitute Products by FDA Regulatory Category" file on the CMS website
[12] **Proposed Payment Rate:** $125.38/cm2
[13] Manufacturers May Need Additional Guidance to Ensure Consistent Calculations of Average Sales Price, Office of Inspector General, U.S. Department of Health and Human Services. December 2022. https://oig.hhs.gov/documents/evaluation/3215/OEI-BL-21-00330-Complete%20Report.pdf

provide guidance to manufacturers regarding allocating pricing under bundled arrangements, and

- **Revised Evidence Requirements for BFSF:** Starting January 1, 2026, require manufacturers submit reasonable assumptions including documentation of the FMV methodology for current, new, and renewed contracts and certification letters from the recipient of a BFSF for prospective contracts that the fee is not passed on in whole or in part to a client or customer of the recipient of the fee. CMS indicates following publication of the final rule it will provide a template of the reasonable assumptions letter for manufacturers to document FMV analyses.

CMS is **NOT** moving forward with the following:

- **Adoption of Medicaid Definition of Bundled Sales:** CMS solicited feedback on adopting the Medicaid definition of bundled sale that states that value-based purchasing arrangements may qualify as a bundled sale.
- **Regulatory Clarification on Fees Presumed to be Price Concessions**: Proposed new regulatory text to specify when certain fees are considered price concessions,
- **Revised BFSF Definition:** Proposed revised BFSF definition language regarding FMV methodology standards, FMV reassessments, and independent third-party valuator requirement (NOTE: CMS indicates intention to address this in rulemaking next year), and
- **Examples of Price Concessions**: Proposed non-exhaustive list of fees that CMS would either not consider BFSFs or may not be in line with FMV.

Units Sold at Maximum Fair Price

Under the Medicare Drug Price Negotiation Program, CMS negotiates a MFP for certain high-expenditure, single-source drugs payable under Medicare Part B and covered under Part D (i.e., selected drugs). In this rule, CMS finalizes its clarification that, because the statute does not explicitly exclude these sales, units of selected drugs sold at the MFP must be included in the calculation of a manufacturer's ASP, effective January 1, 2026.

INCLUDING TISSUE PROCUREMENT COSTS IN PAYMENT AND ASP FOR AUTOLOGOUS CELL AND GENE THERAPIES

FINALIZED AS PROPOSED – Page 640 of Unpublished Rule

Consistent with current payment policies for Chimeric Antigen Receptor (CAR) T-cell therapies, CMS finalizes its proposal to not pay separately for individual steps involved in manufacturing autologous cell-based immunotherapies or gene therapies, such as raw material collection or related labor. CMS considers these manufacturing steps to be included in the payment for the drug or biological itself, as reflected in the billing and payment code for the product.

NOT FINALIZED – Page 640 of Unpublished Rule

CMS is not finalizing its proposal that preparatory procedures for tissue procurement be required to be included in ASP beginning January 1, 2026. Per feedback received, CMS indicates that it believes that

payments for such preparatory procedures may be treated as BFSFs when the four-part test is satisfied and, therefore, may be excluded from ASP.

AMBULATORY SPECIALTY MODEL WILL HOLD INDIVIDUAL CLINICIANS ACCOUNTABLE FOR CHRONIC CARE QUALITY AND COSTS

CMS FINALIZES WITH MODIFICATION – Page 680 of Unpublished Rule

In this rule, CMS finalizes the Ambulatory Specialty Model (ASM), a mandatory APM meant to improve care for Medicare beneficiaries with heart failure and low back pain while reducing spending. The model will begin on January 1, 2027, and span seven years: five performance years (2027-2031) followed by two years for data submission and payment adjustments, ending in 2033.

ASM aims to enhance care quality and coordination through a targeted and accountable payment approach. It builds on the MIPS Value Pathways (MVP) framework but introduces key changes. Rather than selecting their own measures, participating clinicians will report on a fixed set of condition- and specialty-specific measures. Performance will be assessed against peers managing the same condition, allowing for more relevant comparisons.

Clinicians will be evaluated across four categories: quality, cost, improvement activities, and Promoting Interoperability. **Quality and cost will be the primary determinants of the final score, while the improvement activities and Promoting Interoperability categories can modify scores through negative adjustments for non-reporting or poor performance.** The model also includes patient-reported outcome measures. Based on performance, clinicians will receive positive or negative adjustments to their Medicare Part B payments, applied two years after the performance year, as under MIPS. MIPS-eligible clinicians participating in ASM will be exempt from MIPS reporting requirements for any ASM performance year. **CMS clarifies that ASM will apply a broader range of positive and negative payment adjustments than MIPS, retain a portion of funds to ensure net Medicare savings, and align adjustment timing with MIPS (two years after the performance year).**

To address stakeholder concerns about burden and fairness, CMS finalized several refinements and guardrails. These include:

- **Scoring protections for clinicians who do not meet minimum case thresholds for required measures,**
- **Automatic positive scoring adjustments for small practices, solo practitioners, and clinicians serving medically or socially complex populations (with the ability to qualify for both adjustments concurrently),**
- **Advance notification of participation and educational resources in 2026 to support readiness, and**
- **Monitoring and evaluation to identify and mitigate unintended consequences, such as access barriers or consolidation pressures.**

CMS also clarified that ASM does not require telehealth use but offers a telehealth waiver and that interoperability requirements will be proportionally weighted to minimize burden, particularly for small and rural practices.

CMS finalizes individual clinician-level participation rather than group-level participation to promote competition, transparency, and fairness for smaller practices. It also allows better identification of variation and low-value care, such as unnecessary surgeries or imaging. The model also encourages closer coordination with primary care and supports preventive care and chronic condition management.

Participation is mandatory for eligible clinicians in selected geographic areas. To be included, clinicians must:

- Bill under the Medicare PFS,
- Have a targeted specialty designation (e.g., cardiology for heart failure; orthopedic surgery, pain management, or rehabilitation for low back pain),
- Meet a minimum volume threshold of at least 20 attributed episodes based on MIPS episode-based cost measures, and
- Practice in a selected geographic area, based on stratified random sampling of Core-Based Statistical Areas (CBSAs) and metropolitan divisions.

Geographic areas will be selected to ensure variation in spending, volume, and market type. CMS will exclude areas such as U.S. territories and CBSAs with too few eligible clinicians. Assignment will be based on the clinician's service ZIP code.

By focusing on heart failure and low back pain (two high-cost, high-volume conditions), CMS aims to test whether a condition-specific, peer-comparison model can reduce fragmented or duplicative care.

MEDICARE INFLATION REBATE PROGRAM

FINALIZED AS PROPOSED – Pages 1155, 1156, 1157, 1163, 1164, 1169, 1184-1185, 1192, 1203 of Unpublished Rule

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 finalizing several new policies for the Medicare Part B Drug Inflation Rebate Program and Medicare Part D Drug Inflation Rebate Program.

For Medicare Part B, finalized policies:

- Clarify that Drugs Covered as Additional Preventive Services (DCAPS) will be treated as Part B rebatable drugs, with rebates calculated in alignment with the methodology described in §§ 427.300 through 427.402 and rebate reports issued in line with §§ 427.500 through 427.505,
- Establish how CMS would identify the payment amount benchmark quarter if the necessary data are not available,

- Outline how CMS would calculate the payment amount in the benchmark quarter if no published payment limit exists, and
- Define the methodology for calculating the payment amount in the payment amount benchmark quarter if there is no published payment limit and neither positive ASP nor positive Wholesale Acquisition Cost (WAC) data are available in the ASP Data Collection System.

For Medicare Part D, finalized policies:

- Clarify the payment amount benchmark period for certain subsequently approved drugs,
- Clarify the calculation of the benchmark period manufacturer price or annual manufacturer price (AnMP) when monthly units are available but Average Manufacturer Price (AMP) is unavailable for a given quarter,
- Adopt a claims-based methodology, for claims with dates of service on or after January 1, 2026, and with respect to an applicable period, to exclude units of a Part D rebatable drug for which a manufacturer provided a discount under the 340B Program, and
- Establishing a 340B repository to receive voluntary submissions of certain data elements from 340B covered entities with dates of service on or after January 1, 2026.

MAJOR OVERHAUL OF ACO PARTICIPATION AND QUALITY RULES IN SHARED SAVINGS PROGRAM

In its proposed rule, CMS outlined a series of reforms to the Medicare MSSP, aiming to strengthen accountability, streamline program operations, improve quality measurement, and accelerate the transition to value-based care. These changes are set to begin with agreement periods starting January 1, 2027.

CMS estimates that the combined impact of the final changes, outlined below, would result in a net reduction in Medicare spending of $20 million over ten years.

Five-Year Limit on One-Sided Risk for ACOs, Mandated Transition to Two-Sided Risk in Second Agreement Period

FINALIZED AS PROPOSED – Page 1,259 of Unpublished Rule

CMS finalizes its proposal to limit ACOs inexperienced with performance-based risk to a single five-year agreement period in the one-sided (shared savings only) BASIC track (Levels A–D). Currently, these ACOs may remain in one-sided risk for up to seven performance years across two agreement periods. Under the policy, they will be required to transition to two-sided risk (BASIC Level E or ENHANCED) at the start of any second agreement period.

In their first agreement period, inexperienced ACOs would retain the option to start at any level of the BASIC track, including Level E, or the ENHANCED track, unless they have fewer than 5,000 assigned beneficiaries in either of their first two benchmark years, in which case they would be prohibited from entering the ENHANCED track. These smaller ACOs could still participate in the BASIC track, but CMS cites concerns over population instability and financial risk as justification for this restriction.

CMS indicates that this policy shift aligns with its broader strategy to accelerate movement toward value-based care and improve accountability for cost and quality outcomes. The agency sees two-sided risk models as stronger incentives for care transformation and cites growing interest in higher-risk tracks. For example, in PY 2025, 71 percent of SSP ACOs participate in two-sided risk arrangements, up from 18 percent in 2018.

For ACOs, this shift may increase financial risk and operational demands but aligns with CMS's goal to accelerate value-based care adoption and improve Medicare program savings.

Mid-Year Change of Ownership Updates for ACO Participants and SNF Affiliates

FINALIZED AS PROPOSED – Page 1,277 of Unpublished Rule

To prevent disruptions in care coordination and ACO operations, CMS finalizes its proposal to allow ACOs to update their certified participant list and SNF affiliate list during a performance year if a participant or SNF affiliate experiences a Change of Ownership (CHOW) resulting in a new Medicare-enrolled Tax Identification Number (TIN) with no prior billing history. Currently, ACOs can only update these lists during the annual change request cycle, even if the change affects eligibility or operational continuity.

Effective January 1, 2026, ACOs will be required to notify CMS within 30 days of a qualifying CHOW and submit supporting documentation (e.g., legal agreements, IRS notices). Such documentation will demonstrate the CHOW and validate the absence of claims history for the new TIN. CMS will then review and may approve the update outside the normal cycle.

CMS also outlines when this policy applies for ACO participants and SNF affiliates.

Tightened Beneficiary Threshold Requirements

FINALIZED AS PROPOSED – Page 1,293, 1,304, and 1,310 of Unpublished Rule

CMS finalizes its proposal to codify and clarify that ACOs must have at least 5,000 assigned beneficiaries in Benchmark Year 3 (BY3) to enter a new agreement period starting on or after January 1, 2027. While ACOs could fall below 5,000 in Benchmark Years 1 or 2 (BY1 or BY2) and still qualify for participation, they will be restricted to the BASIC track and barred from the ENHANCED track due to concerns over expenditure variability in smaller populations.

To mitigate financial risk to ACOs and the Medicare Trust Funds, CMS also finalizes its proposal to use a more conservative methodology to calculate shared savings and losses for ACOs with fewer than 5,000 assigned beneficiaries in any benchmark year. Rather than using BY3 to determine benchmark-based performance payment and loss recoupment limits, CMS will apply the lesser of two values: the standard calculation based on performance year person years or an alternative benchmark derived from the year with the fewest assigned beneficiaries. This will apply during financial reconciliation for any year of an agreement period starting in 2027 or later where the ACO fell below 5,000 assigned beneficiaries in any benchmark year.

Such ACOs will also be ineligible for the enhanced shared savings policy under § 425.605(h), which allows certain low-revenue ACOs to share in savings without meeting the minimum savings rate

(MSR). CMS argues that this is necessary to prevent payments based on random variation in expenditures, rather than true performance, and to maintain statistical reliability in program results.

Updates to Primary Care Service Codes for ACO Assignment

FINALIZED AS PROPOSED – Page 1,318 of Unpublished Rule

CMS finalizes as proposed its revisions to the definition of primary care services used for beneficiary assignments in the SSP beginning in performance year 2026, to align with updates to the PFS. Specifically, CMS is adding three new HCPCS codes (GPCM1, GPCM2, and GPCM3) related to Enhanced Care Model Management Services, designed to support the integration of BHI and CoCM services with APCM. These new codes are intended to reduce documentation and time-based burdens, thereby encouraging greater adoption of BHI and CoCM in primary care.

NOT FINALIZED – Page 436 of Unpublished Rule

CMS does not finalize its proposal to remove HCPCS code G0136 for Social Determinants of Health (SDOH) risk assessments. Instead, CMS will retain the code and revise the descriptor to reflect the code's updated purpose: "Administration of a standardized, evidence-based assessment of physical activity and nutrition, 5-15 minutes, not more often than every 6 months."

Eliminate Health Equity Adjustment and Streamline ACO Quality Scoring

FINALIZED WITH MODIFICATION – Pages 1,370 and 1,375 of Unpublished Rule

CMS finalizes its proposal with modification to eliminate the health equity adjustment for SSP ACOs starting in performance year 2026 (rather than 2025 retroactively as proposed), citing overlap with other incentives like the electronic clinical quality measure (eCQM)/MIPS clinical quality measure (CQM) reporting bonus and the Complex Organization Adjustment, which sufficiently support underserved populations. CMS also conducted additional analysis of performance year 2024 results that were released after the CY 2026 PFS Proposed Rule.

To streamline scoring, CMS will revise terminology (e.g., replacing "health equity adjustment" with "population and income adjustment").

Enforcement Actions for ACOs Failing Both Quality Standards Beginning in 2026

FINALIZED AS PROPOSED – Page 1,425 of Unpublished Rule

CMS finalizes its proposal that starting in 2026, ACOs that fail to meet both the quality performance standard and the alternative quality performance standard may face pre-termination actions (e.g., warnings, corrective action plans, special monitoring). CMS also finalizes its proposal to update the renewal application review process to consider past failure to meet either quality standard, giving the agency additional discretion in evaluating applications from ACOs with past performance concerns in line with its goal of upholding high participation standards in MSSP.

QUALITY PAYMENT PROGRAM

FINALIZED WITH MODIFICATION – Pages 1,431-1,657 of Unpublished Rule

In the annual PFS rulemaking, CMS includes its proposals for the QPP's two tracks: MIPS and Advanced APM participation. MIPS includes three reporting options: Traditional MIPS, MIPS Value Pathways (MVP), and APM Performance Pathways (APP), each with four performance categories: quality, cost, improvement activities (IA), and promoting interoperability (PI).

MIPS Performance Measurement Proposals

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

- 190 total quality measures for the 2026 performance period,
- Setting of the performance threshold through the CY2028 performance period at 75 points to provide program stability,
- Implementation of five new MIPS quality measures, including three high priority measures,
- Removal of 10 MIPS quality measures,
- Substantive changes to 30 MIPS quality measures,
- Updates to the APP Plus measures set to align with the MIPS quality measure inventory,
- Modifications to the MIPS cost measure inventory,
- Updates to the operational list of care episode and patient condition groups and codes to align with changes in service and diagnosis codes used to define these groups,
- Adoption of a two-year informational-only feedback period for new cost measures, during which they will not affect MIPS cost performance category scores, final scores, or payment adjustments until the third year after introduction,
- Revision of two population-based cost measures, including Total Per Capita Cost (TPCC),
- Modification of the definition of "high priority measure" to remove references to health equity,
- Addition of the "Advancing Health and Wellness" IA subcategory, removal of the "Achieving Health Equity" IA subcategory, and addition of three new IAs, and
- Changes to two PI measures and addition of a new optional bonus measure: Public Health Reporting Using Trusted Exchange Framework and Common Agreement ™ (TEFCA ™).

MVP Proposals

CMS previously finalized the creation of the MVP, a reporting option for MIPS intended to 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 six new MVPs for the CY 2026 performance period, including Diagnostic Radiology, Interventional Radiology, Neuropsychology, Pathology, Podiatry, and Vascular Surgery. Additionally, CMS finalizes:

- Modification to all 21 existing MVPs,
- Requiring groups to attest to their specialty composition (i.e., whether they are single-specialty or multispecialty small practices) during the MVP registration process, rather than CMS making this determination,
- Allowing multispecialty small practices to report an MVP as a group, without being required to form subgroups starting in the CY 2026 performance period, and

- Giving Qualified Clinical Data Registries (QCDRs) and Qualified Registries one year after a new MVP is finalized before they are required to fully support that MVP.

Advanced APM Changes

Following up on the CY 2025 Proposed Rule, CMS finalizes a broader approach to QP determinations. CMS will now perform both an individual- and APM entity-level QP calculation. **CMS also finalizes its proposal, with modifications, to expand the definition of "attribution-eligible beneficiary" to perform QP determinations through both E/M services and Covered Professional Services.** Lastly, CMS finalizes removal of the existing limit of 50 clinicians for a Medical Home Model participant.

CHANGES TO THE MEDICARE DIABETES PREVENTION PROGRAM TO INCREASE PROGRAM UPTAKE

FINALIZED WITH MODIFICATION – Pages 1117, 1120, 1121, 1130, 1132, 1133, 1135, 1137, 1140, and 1145 of Unpublished Rule

CMS finalizes changes to the MDPP, an evidence-based behavioral intervention aimed at preventing or delaying type 2 diabetes in Medicare beneficiaries with prediabetes. The updates are intended to increase uptake, as less than one percent of eligible beneficiaries participate in the program, and to better align with the CDC Diabetes Prevention Recognition Program (DPRP) standards. CMS finalizes its proposal to add definitions for terms including "live coach interaction," "online delivery period," and "online session," and modify the definition of "online." To address barriers related to physical weight collection requirements, CMS is amending MDPP program language, including allowing for weight documentation in the patient's medical record within five days of the MDPP session rather than on the same date of the session.[14]

In the proposed rule, CMS proposed extending flexibilities allowed during the PHE through 2029 and testing an asynchronous delivery modality that aligns with the CMS Innovation Center strategy to Make America Healthy Again by promoting evidence-based prevention. This modality would permit MDPP suppliers to offer program services online through 2029, eliminate the requirement to maintain in-person delivery capability during that period, and establish a new HCPCS G-code (G9871) with an associated $18 payment for asynchronous delivery. **CMS finalizes these proposals with two amendments: (1) updating the language to explicitly allow online delivery for make-up sessions, and (2) incorporating G9871 into the billing guidance for identifying MDPP make-up sessions.**

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

[14] **Proposed Policy:** Allowed for weight documentation in the patient's medical record within two days of the MDPP session.