THORN RUN PARTNERS
GOVERNMENT RELATIONS

Memorandum *November 4, 2024*

CMS Finalizes Revisions to Physician Fee Schedule, Medicare Part B for CY 2025

Executive Summary

On November 1, the Centers for Medicare & Medicaid Services (CMS) finalized its calendar year **(CY) 2025 updates to the Medicare Physician Fee Schedule (PFS)** (fact sheet; press release; fact sheet on Shared Savings proposals). This annual rulemaking revises payment policies under the Medicare PFS and makes other policy changes to payments under Medicare Part B, **to be applied to services furnished beginning January 1, 2025.**

- **Context & Next Steps.** Since 1992, CMS has used the PFS to update reimbursement for physician and supplier services within the Medicare program annually, and payments are based on the relative resources typically used to furnish the service. The final rule is expected to be published in the *Federal Register* on December 9, 2024

This major rule finalizes **the CY 2025 PFS conversion factor** to $32.35, a decrease of $0.94 or 2.8 percent decrease from the CY 2024 PFS conversion factor of $33.29. Additionally, the final rule extends certain **telehealth flexibilities** adopted during the public health emergency (PHE). Notably, this final rule codifies changes to the **Medicare Prescription Drug Inflation Rebate Program** for Part B and D drugs. CMS is also finalizing provisions to establish new payments to account for the complexity of primary care, improve **behavioral health services**, and increase access to caregiver training services, among other things. Additionally, the agency is finalizing several notable policy changes related to payment for services provided by **rural health clinics** (RHC) and **Federally Qualified Health Centers** (FQHC), including a proposal to rebase the FQHC market basket.

Key policies finalized under the rule include:

Conversion Factor — The finalized CY 2025 conversion factor is $32.35, a decrease of $0.94 from the CY 2024 PFS conversion factor of $33.29. CMS calculated this figure by applying a 0.05 percent positive budget neutrality update and removing the temporary 2.93 percent payment increase for CY 2024, as required by statute.

Telehealth

- *Telehealth Services List* — Following public comments, CMS is not finalizing the addition of the home-international normalized ratio (INR) to the Medicare Telehealth Service List. However, CMS is finalizing maintenance additions to the Service list, including:
    - Health and well-being coaching on a provisional basis;

- Therapy, audiology, speech-language pathology on a provisional basis;
- General behavioral health integration and principal care management on a permanent basis;
- Caregiver training services with training codes CPT codes 97550, 97551, 97552, 96202, 96203 and Healthcare Common Procedure Coding System (HCPCS) codes G0541-G0543 (GCTD1-3) and G0539-G0540 (GCTB1-2) on a provisional basis; and
- Preexposure Prophylaxis (PrEP) of Human Immunodeficiency Virus (HIV) HCPCS codes G0011 and G0013 on a permanent basis.

The agency states interest in incorporating additional input from interested parties for future rulemaking.

- *Audio-Only Services* — The Consolidated Appropriations Act (CAA), 2023, extended the range of telehealth services permitted to be furnished through audio-only technology and other COVID-19 era telehealth flexibilities through December 31, 2024. Given the successive extensions of audio-only telehealth flexibilities, CMS is finalizing, as proposed, to allow interactive telecommunications systems to include two-way, real-time audio-only communication technology for any telehealth service furnished to a beneficiary in their home.

- *Direct Supervision* — In the CY 2024 PFS final rule, CMS extended the definition of the term "direct supervision" to permanently allow practitioner supervisions through real-time audio and video interactive telecommunications through December 31, 2024. While CMS acknowledges the benefit of this flexibility, the agency is exercising caution and prioritizing patient safety by further extending this flexibility on a temporary basis through December 31, 2025. However, the agency is electing to permanently extend this definition for a certain subset of services that are furnished incident to a physician's service when they are provided in their entirety by auxiliary personnel working under the direct supervision of the physician. Notably, this definition will continue to exclude audio-only communications for all services furnished under direct supervision.

- *Telehealth Expansion* — Within the final rule, several COVID-19 PHE telehealth flexibilities are to be extended through the end of 2025. Among these extensions, the agency continues to suspend the frequency of limitations for subsequent inpatient visits, nursing facility visits, and critical care consultations. Following public comment, the agency is finalizing, as proposed, to allow distant site practitioners to continue using their practice location rather than their home address when providing telehealth services from their home. Further, teaching physicians are permitted to have a virtual presence for services furnished involving residents in all teaching settings. CMS plans to use feedback from a request for information (RFI) on expanding teaching physician services under the primary care exception to inform future rulemaking.

OUD — In CY 2020, the Substance Use-Disorder Prevention that Promotes Opioid Recover and Treatment (SUPPORT) for Patients and Community Act established a new Medicare Part B benefit

for opioid use disorder (OUD) treatment services furnished by opioid treatment programs (OTPs). Since then, CMS has refined and expanded the services covered under the Medicare OTP benefit, including several modifications for CY 2025 outlined in this final rule. CMS also highlights the rule's clarification that all claims submitted to Medicare under the OTP benefit must include an OUD diagnosis, sharing its intent to issue additional guidance on attaching diagnostic codes to claims.

- *Telecommunication Technology Flexibilities* — The agency is codifying several telecommunication technology flexibilities for these services, provided that their use is permitted under applicable Substance Abuse and Mental Health Services Administration (SAMHSA) and Drug Enforcement Administration (DEA) requirements. Specifically, CMS is finalizing its proposals to: (1) make permanent the current flexibility that allows periodic assessments to be furnished through audio-only telecommunications when video is not available; and (2) allow the OTP intake add-on code to be furnished through audio-visual telecommunications for initiation of treatment with methadone.

- *Payment for SDOH Risk Assessments* — Following recent SAMHSA regulatory reforms for OUD treatment finalized at 42 CFR part 8, CMS is establishing payment for social determinants of health (SDOH) risk assessments as part of OUD intake activities. The agency specifies that this payment is for assessments determined by OTPs to be medically reasonable and necessary for OUD treatment or diagnosis.

  CMS initially proposed to revise the descriptor for the HCPCS intake add-on code, G2076, and update the adjustment to its bundled payment to include the value of the non- facility rate for SDOH risk assessments, G0136. Under the final rule, CMS is finalizing these proposed changes with modifications based on stakeholder feedback. Based on feedback regarding the need for multiple SDOH risk assessments to address unmet needs impacting OUD treatment outcomes, CMS is finalizing an update to the payment for SDOH risk assessments during periodic assessments, G2077, to include the value of G0136, consistent with the finalized payment update for intake activities, G2076. Additionally, CMS is finalizing the proposed descriptor for G2076 with revisions to reflect this change and to include all appropriately licensed professionals conducting OTP assessments, addressing comments that the initially proposed descriptor did fully align with current OTP regulatory requirements.

- *Payment for Coordinated Care and Referrals to Community-Based Organizations* — In the proposed rule, CMS issued an RFI on activities that OTPs perform to coordinate care and refer patients to community-based organizations (CBOs). While these activities support addressing unmet needs, facilitating harm reduction, and providing recovery support services, they currently lack specific coding. In response to comments advocating for additional payment for these services under the Medicare OTP benefit, CMS is establishing new codes and payments under this final rule: (1) G0534 for coordinated care and/or referral services; (2) G0535 for patient navigational services; and (3) G0536 for peer recovery support services.

- *Payment for New FDA-Approved Medications* — For CY 2025, CMS is establishing payment for new opioid agonist and antagonist medications approved by the Food and Drug Administration (FDA). Specifically, CMS is finalizing a new add-on code, G0532, and payment for nalmefene hydrochloride nasal spray, which is indicated for the emergency treatment of known or suspected opioid overdoses. CMS is finalizing monthly payments for a new injectable buprenorphine product, Brixadi, through the existing code for monthly injectable buprenorphine, G2069. While the agency originally proposed using this code for weekly payments as well, the final rule establishes a new weekly payment code, G0533. In response to stakeholder feedback, CMS will use a volume-weighted average sale price (ASP) methodology to calculate the drug component of the monthly payment, which CMS anticipates will provide a more accurate reflection of market utilization and costs.

Behavioral Health — CMS is finalizing several changes that promote access to behavioral health services and are aligned with CMS' Behavioral Health Strategy, including:

- Establishing separate coding and payment under the PFS for safety planning interventions by creating a standalone code, G0560 — revised from an initially proposed add-on code — for use when these interventions are performed by the billing practitioner;
- Creating a monthly billing code, G0544, to describe specific protocols involved in furnishing post-discharge follow-up contacts following a beneficiary's discharge following a crisis encounter;
- Establishing payments to billing practitioners for digital mental health treatment (DMHT) devices furnished to professional behavioral health services used in conjunction with ongoing behavioral health treatment and in accordance with their FDA-classified use by creating three new HCPCS codes; and
- Creating six new G-codes that will provide payment for interprofessional consultations performed through communications technology by practitioners in specialties whose covered services are limited by statute, including clinical psychologists, clinical social workers, marriage and family therapists, and mental health counselors.

Electronic Prescribing of Controlled Substances (EPCS) — In the CY 2022 PFS final rule, CMS established a policy that on January 1, 2025, the agency would begin pursuing compliance actions against prescribers based on Part D controlled substance prescriptions written for beneficiaries in long-term care (LTC) facilities. Though the agency initially opposed stakeholder feedback suggesting extension of the compliance threshold until after the new National Council for Prescription Drug Programs (NCPDP) SCRIPT standard version 2023011 was adopted, CMS clarified in the CY 2024 PFS final rule that it would automatically adopt electronic prescribing standards for the CMS EPCS Program as they are updated. As such, CMS is finalizing its proposal that the date after which prescriptions for covered Part D drugs for eligible individuals in LTC facilities would be included in the CMS EPCS Program compliance threshold is extended to January 1, 2028. CMS is also finalizing that compliance actions against noncompliant LTC prescribers will commence on January 1, 2028, as well. CMS notes that this extension will align CMS' EPCS Program compliance calculations with the date that the new NCPDP SCRIPT standard version 2023011 will be the required standard for prescribing and dispensing Part D drugs to eligible beneficiaries.

Part B Drugs and Biologics

- *Requirements for Manufacturers of Certain Single-dose Container of Single-use Package Drugs* — A provision within the Infrastructure Investment and Jobs Act required manufacturers to provide CMS with a refund for certain discarded amounts of a refundable single-dose container or single-use package drug. To implement this provision, CMS has finalized several policies in recent rulemaking that it is clarifying in this final rule. First, CMS finalized that the 18-month period for a drug to be excluded from the definition of "refundable drug" begins on the first day of the calendar quarter following the first date of sale reported to CMS. In the CY 2025 proposed rule, CMS proposed to clarify that it will continue to define the 18-month period as the first date of sale reported to CMS, unless the reported date of first sale does not approximate the first date of payment under Part B due to applicable National Coverage Determination (NCD) — in which case CMS proposed that the date the drug is paid under Part B would be used to determine the beginning of the 18-month exclusion period. CMS is finalizing this clarification as proposed, with a modification to use "date the drug was first marketed" instead of "date of first sale" to ensure consistent terminology within the regulatory text.

  The agency is also finalizing its proposal, without change, to clarify the definition of refundable single-dose container or single-use package drugs to include "single-patient-use container" as a package type and including the following products under the definition: (1) products furnished from a single-use package based on FDA-approved labeling; (2) injectable drugs with a labeled volume of two mL or less and lack both package type terms and explicit discard statements; and (3) drugs contained in ampules that have no discard statement. Additionally, the agency is finalizing its proposed clarification regarding the use of the JW and JZ modifiers. Specifically, CMS is finalizing that the JW modifier be required if there are amounts discarded during the preparation process before supplying a drug to a patient — even if a billing supplier is not administering a drug. Conversely, the JW modifier is required if no drug amounts are discarded during preparation, as finalized under this final rule.

- *Payment Calculations for Negative or Zero ASP* — Following a report from the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) that manufacturers require additional guidance when reporting negative average sales price (ASP) data, CMS proposed clarifications in how it handles payment for drugs separately payable under Part B when the reported manufacturer's ASP data is negative or zero. Specifically, CMS proposed to clarify that positive ASP data are considered "available" and that negative or zero ASP data are considered "not available" when calculating payment limits. The agency is finalizing this policy as proposed.

  CMS proposed several policies for determining payment limits when ASP data is not available, which vary based on: (1) whether the drug or biologic is single- or multiple-source; (2) whether some or all of the National Drug Codes (NDCs) have a negative or zero ASP; and

(3) whether relevant applications for all NDCs have a "discontinued" marketing status. CMS is largely finalizing these payment limit calculation methodologies as proposed.

In instances where negative or zero ASP data is reported for all NDCs for a biosimilar and positive ASP data is available for another biosimilar with the same reference product, CMS proposed setting the payment limit as equal to the sum of: (1) the volume-weighted average of the positive ASP data from all other biosimilars with the same reference product; and (2) the reference product plus six or eight percent of the amount determined under 1847A(b)(4) of the Act for the reference product for the given quarter. In response to stakeholder feedback, the agency is finalizing a modified calculation of the payment limit to include the volume-weighted average of *the biosimilar's own, most recently available, positive manufacturer's ASP data*, rather than ASP data of other biosimilars with the same reference product.

- *Radiopharmaceuticals* — Under current statute, Medicare Administrative Contractors (MAC) determine payment limits for radiopharmaceuticals furnished outside of hospital outpatient departments. To eliminate confusion on the methodologies available to MACs, CMS is finalizing its proposal to clarify that MACs must determine payment limits for radiopharmaceuticals using any methodology in place on, or prior to, November 2003.

- *Compounded Immunosuppressive Drugs* — CMS is finalizing its proposals modifying several current regulations to improve access to FDA-approved compounded formulations of immunosuppressive drugs by: (1) including orally and enterally administered compounded formulations; (2) allowing payment of a supply fee for a prescription supply of up to 90 days; and (3) allowing payment for refills of compounded immunosuppressive drugs.

- *Blood Clotting Factors* — Recently, the FDA approved gene therapies for the treatment of hemophilia. To avoid the possibility of double payments for administering gene therapies for the treatment hemophilia, the agency is finalizing its proposal to update current regulations and clarify that: (1) blood clotting factors must be self-administered; and (2) the furnishing fee is only available to entities that furnish blood clotting factors.

Dental Services

- *Expansion of list of covered services* — In the CY 2023 final rule, CMS finalized its proposal to provide payment for dental services under Medicare Parts A and B, beginning in CY 2024, that are determined to be "inextricably linked" to the clinical success of an otherwise covered medical service. Additionally, CMS finalized its proposal to pay for dental exams and necessary treatments provided prior to the treatment for head and neck cancers. Under the CY 2025 final rule, CMS is finalizing its proposal to amend existing regulations and expand upon the list of services that are considered to be "inextricably linked to the clinical success of an otherwise covered medical service." Accordingly, the rule permits Medicare payments for: (1) dental examination in an 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 infection prior to dialysis services for beneficiaries with ESRD.

Under the proposed rule, CMS also noted it received several requests to cover dental services for Medicare beneficiaries with diabetes, autoimmune diseases, sickle cell disease, and hemophilia. Based on the research currently available, the agency reiterates in the final rule it is not providing Medicare coverage for dental services for these populations at this time. However, the agency will continue engaging with stakeholders to understand the relationship between dental services and services for these conditions, as well as the specific medical services used in the treatment for these conditions in which dental services may be inextricably linked. In the proposed rule, CMS also sought stakeholder feedback on furnishing oral devices used to treat obstructive sleep apnea, including CPAP devices. In the final rule, the agency indicates it will address the comments received in future rulemaking.

- *Billing and claims processing*—In response to comments received in the CY 2024 final rule requesting more guidance on how providers submitting claims for dental services can demonstrate that the dental and medical services are inextricably linked, CMS proposed, and is subsequently finalizing with a slight delay in implementation, to require the use of the KX modifier on both the 837D and 837P claim format for claims submissions, beginning July 1, 2025. In addition to requiring the use of the KX modifier, CMS is finalizing requirements for the use of a diagnosis code on claims submitted for a provider's services for dental services inextricably linked to covered medical services on both the 837D and 837P formats beginning July 1, 2025.

Payment for Preventative Services

- *Hepatitis B vaccine administration* — In an effort to improve access and utilization of the hepatitis B vaccine, CMS is finalizing several proposed policies including:
    - Removing the current policy that the administration of a hepatitis B vaccine be preceded by a doctor's order;
    - Expanding coverage of the vaccine to include individuals who have not previously received a completed hepatitis B vaccination and those for whom the previous vaccination history is unknown; and
    - Aligning payment for hepatitis B vaccinations in RHCs and FQHCs with the payment for pneumococcal, influenza, and COVID-19 vaccines at 100 percent of reasonable costs for the vaccine and its administration.

- *Drugs covered as additional preventative services* — Additionally, the agency is finalizing its proposal to cover certain drugs or biologicals under the "additional preventative services" benefit category pursuant to sections 1861(ddd(3) and 1833(a)(12(W)(A) of the Social Security Act (SSA). Notably, coverage for PreP for HIV Infection Prevention may be included under this benefit category. Regarding payment for drugs covered under the additional preventative services benefit, CMS is establishing a fee schedule that uses the existing Part B ASP methodology under section 1847A of the SSA when ASP data is available. The agency is

also applying payment limits for administering and supplying drugs covered as additional preventative services similar to those currently set forth under the ASP methodology for Part B drugs, if ASP data is available. Finally, the rulemaking applies payment limits for the supply and administration of drugs covered as additional preventative services. Specifically, CMS is establishing a payment limit of $24 to a pharmacy for the first prescription that the pharmacy supplies to a beneficiary in a 30-day period, and a payment limit of $16 to a pharmacy for all subsequent prescriptions. For drugs under this benefit category administered by a physician or a non-physician practitioner, the payment limit for administration will be paid in alignment with the administration fee for other drugs under Part B provided as incident to physician services. Notably, no cost sharing will apply for the administration or supplying of drugs covered as additional preventative services.

RHCs and FQHCs

- *General Care Management Services* — Under the proposed rule, CMS reevaluated its payment policy for care management services and proposed several changes related to their reporting. Specifically, the agency proposed, and is subsequently finalizing, policies requiring RHCs and FQHCs to bill the individual codes that make up the general care management HCPCS code G0511 in CY 2025, making the general code no longer payable when billed. CMS is also finalizing its proposal to allow RHCs and FQHCs to bill add-on codes for additional time spent to offset any decrease in payment. Additionally, CMS is finalizing its proposed coding and policies regarding Advanced Primary Care Management services for RHC and FQHC payment, described and defined by three new HCPCS G-codes (GPCM1, GPCM2, and GPCM3). CMS also previously issued an RFI on the payment policy for care coordination services and how to improve transparency and predictability of HCPCS codes, and the agency notes that it may use the comments received in potential future rulemaking.

- *Telecommunication Services* — The agency is finalizing its proposal to maintain the current telecommunication flexibility in RHCs and FQHCs through CY 2025 to support access to care and preserve workforce capacity. This includes allowing: (1) direct supervision through audio and video telecommunications through December 31, 2025; and (2) payment using code G2025 for non-behavioral health visits furnished through telecommunication technology through December 31, 2025. CMS is also proposing to continue delaying the in-person visit requirement for mental health services furnished at-home through communication technology by RHCs and FQHCs until January 1, 2026.

- *Intensive Outpatient Program (IOP) Services* — CMS is finalizing a payment rate for four or more services per day in an RHC or FQHC setting to ensure parity for IOP services across various settings while still monitoring access. This payment rate will be aligned with the associated rate for hospital outpatient departments and updated annually.

- *Productivity Standards* — Given the restructured payment limits for RHCs established in the CAA, 2021, CMS believes that the current productivity standards for RHCs are outdated and

redundant. As such, the agency is finalizing its proposal to remove the productivity standards for RHCs.

- *FQHC Market Basket* — For CY 2025, CMS is finalizing its proposal to rebase and revise the 2017-based FQHC market basket to reflect a 2022 base year while continuing to apply a productivity adjustment to the proposed market basket increase — which is consistent with the agency's historical frequency of rebasing the market basket every four years to reflect more recent data. The final CY 2025 productivity-adjusted 2022-based FQHC market basket update is 3.4 percent, adjusted from the proposed 3.5 percent, and reflects a 4.0 percent market basket increase reduced by a 0.6 percentage point productivity adjustment.

- *Conditions of Certification and Conditions for Coverage (CfCs)* — CMS is finalizing several changes to the RHC and FQHC "Provision of Services" CfCs to better clarify and align program requirements, provide flexibility, decrease provider burden, and improve access. Specifically, the agency is: (1) explicitly requiring RHCs and FQHCs to provide primary care services, rather than enforcing the standard of "primarily engaged" in furnishing primary care services for RHCs; and (2) removing hemoglobin and hematocrit (H&H) from the listed laboratory services that RHCs must directly perform.

E/M Visits — In the CY 2024 PFS, CMS finalized its policy to introduce a separate add-on payment for HCPCS code G2211 to more accurately account for the resource costs linked to an office or outpatient (O/O) evaluation and management (E/M) visit in primary care for the ongoing care of complex patients. Notably, CMS finalized its proposal in the CY 2024 PFS final rule that the add-on payment code is not payable when the O/O E/M visit is reported with CPT modifier -25, which denotes a separately identifiable visit by the same physician or other qualified health care professional on the same day as a procedure or other service. Based on feedback from stakeholders that some preventative services, including annual wellness visits or preventative vaccines, are provided on the same day as a separately identifiable O/O E/M visit and that some providers may avoid providing the preventative service on the same day as a result of this policy, the agency is finalizing its proposal to allow payment of the O/O E/M visit complexity add-on code G2211 when the code is reported by the same practitioner on the same day as: (1) an annual wellness visit; (2) vaccine administration; or (3) any Medicare Part B preventative service furnished in the office or outpatient setting.

Caregiver Training Services — CMS is finalizing the proposal to establish new payment and coding for caregiver training for direct care and support. CMS notes that the finalized codes focus on specific clinical skills aimed at the caregiver providing hands-on treatment, reducing complications, and monitoring the patient. Importantly, the agency highlights that the caregiver training services must be consistent with the beneficiary's treatment plan and designed to effectuate the intended patient outcome. For CY 2025, CMS is finalizing actions to add three new HCPCS codes—GCTD1, GCTD2, and GCTD3— to be cross-walked with existing CPT codes 97550, 97551, and 97552 respectively. In addition to establishing new payment and coding for caregiver training for direct care and supports, the CY 2025 PFS rule is also finalizing the establishment of a new coding and payment for caregiver

behavior management and modification training to be provided to the caregiver of an individual patient. CMS is additionally finalizing the proposal to allow services to be accessed through telehealth. Finally, in the CY 2024 PFS rule, CMS finalized a requirement that the provider must obtain the beneficiary's consent for the caregiver to receive the caregiver training services. In the CY 2025 PFS rule, the agency is finalizing that such consent may be provided verbally by the beneficiary.

Advanced Primary Care Management (APCM) — In an effort to improve primary care, CMS is finalizing its proposal to establish payment for a new set of APCM services through three new HCPCS codes — G0556, G0557, and G0558 — that encompass a broader range of services and simplify billing for clinicians using an APCM beginning January 1, 2025. Collectively, as detailed in the code descriptors, the three new codes would provide payment for a broad range of APCM services that are: (1) provided by clinical staff and directed by a physician or other qualified health professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services; (2) for a patient with multiple chronic conditions expected to last at least 12 months provided by clinical staff and directed by a physician or other qualified health professional who is responsible for all primary care; and (3) for a patient that is a Qualified Medicare Beneficiary with multiple chronic conditions provided by clinical staff and directed by a physician or other qualified health professional who is responsible for all primary care. Notably, CMS issued an RFI in the proposed rule on additional payment policies that should be considered for APCSs, and the agency indicates it intends to use the comments received to inform future rulemaking.

Medicare Shared Savings Program — To further advance value-based care and allow for timely improvements to program policies and operations, CMS is finalizing a series of proposed changes to the Shared Savings Program. Among these changes, the agency will require that ACOs report the proposed APM Performance Pathway (APP) Plus quality measure set in order to improve quality measure reporting. Additionally, the agency is finalizing its proposal to establish a new "prepaid shared savings" option to allow eligible ACOs to receive advances of earned shared savings that may be used to make investments aiding beneficiaries. CMS is finalizing several proposed changes, with slight modifications, to the program's financial methodology by removing barriers for ACOs serving underserved communities. These finalized changes include: (1) ensuring benchmarking methodology includes sufficient incentive for ACOs serving underserved communities; (2) specifying calculation methodology to account for the impact of improper payments in recalculating expenditures; (3) establishing a methodology for excluding payment amounts for certain HCPCS and CPT codes; and (4) clarifying the methodology for capping an ACO's risk score.

CMS is also finalizing several changes to improve the Shared Savings Program eligibility requirements and application procedures, including sunsetting population requirements for terminating participation agreements and updating provisions of application procedures and beneficiary notification requirements.

Medicare Prescription Drug Inflation Rebate Program — Under the final rule, CMS is codifying the policies established in the revised guidance for the Medicare Prescription Drug Inflation Rebate Program (Part B guidance; Part D guidance). The final rule codifies the definitions of several terms

based on the meaning provided in the statute or established in the revised guidance. CMS is also finalizing several new policies for both the Part B and Part D Drug Inflation Rebate Programs, including:

- CMS will compare the payment amount in quarterly pricing files to the inflation-adjusted amount to determine eligibility for coinsurance adjustments for Part B drugs;
- For Part B and Part D rebatable drugs, CMS defines payment amount benchmark quarters based on approval and marketing dates; and
- CMS excludes 340B units and single-dose container drugs from rebate calculations and set processes for rebate reconciliation and penalties for unpaid rebates.

CMS will apply a rebate reduction for the affected drugs if a significant supply chain disruption affects drug availability. This reduction will take effect for the quarter in which the disruption began, or, if the request was submitted less than 60 days before the quarter ends, it will apply to the following quarter. Additionally, the rebate reduction will continue for three more quarters. This reduction will be applied regardless of whether the drug qualifies as a "Part B rebatable drug" in those quarters or if any rebate is owed. In all cases, CMS will enforce a 75 percent reduction in the total rebate amount.

Following public comment, CMS noted interest within creating a Medicare Part D claims data repository to meet the requirement to exclude 340B drug units from Part D drug inflation rebate calculations, beginning January 1, 2026. CMS intends to continue specific policy and guideline development for the repository and the exclusion of 340B units for future rulemaking.

Other Policies

- *Diabetes Prevention Program* — The CMS Medicare Diabetes Prevention Program Expanded Model (MDPP) — established in the CYs 2017 and 2018 PFS rules — is a behavioral intervention designed to prevent or delay the onset of type 2 diabetes for beneficiaries diagnosed with prediabetes. To align with policies included in the CY 2024 PFS final rule, CMS is finalizing several definitional changes including modifying the definition of "online" to add "combination with an online component" to confirm that only MDPP "in-person," "distance learning," and "in-person with a distance learning component" delivery modalities, and not chat bots and AI forums, can be utilized.

- *Supervision for Certain Services* — CMS is finalizing amendments to its existing regulations to permit general supervision of physical therapist assistants and occupational therapy assistants by PTs and OTs in private practice. Under the final rule, PTs and OTs in private practice would be required to only provide general supervision to their therapy assistants as opposed to direct supervision. The agency notes that this policy reflects the supervision level currently specified in 44 state physical therapy practice laws an all but on state occupational therapy practice act.

- *Clinical Lab Fee Schedule* — With respect to clinical diagnostic laboratory tests, CMS is finalizing conforming regulatory changes to certain data and payment requirements in accordance with section 502 of the Further Continuing Appropriations and Other Extensions

Act, 2024 (FCAOEA, 2024). Specifically, the rule specifies that, for the data reporting period of January 1, 2026, through March 31, 2026, the period for data collection is January 1, 2019, through June 30, 2019. Data reporting, under this revised definition, would begin January 1, 2017, and would be required in three-year increments beginning in January 2026. The rule also establishes payment reduction parameters for clinical diagnostic laboratory tests to indicate that payments for CY 2026 through CY 2028 may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

- *Colorectal Cancer Screening* — In the final rule, CMS is updating and expanding Medicare coverage for colorectal cancer (CRC) screening tests under Part B by: (1) removing coverage for the barium enema procedure; (2) adding coverage for the computed tomography colonography (CTC) procedure; and (3) expanding the approach of complete CRC screenings to include a Medicare covered blood-based biomarker CRC screening test alongside the Medicare covered non-invasive stool-based CRC screening test. If either screening test returns a positive result, a follow-on colonoscopy would be covered with no beneficiary cost-sharing.

- *Global Surgery Payment Accuracy* — Beginning in CY 2025, CMS is finalizing its proposal to broaden the applicability of the transfer of care modifiers for the 90-day global packages. Specifically, the final rule requires the use of an appropriate transfer of care modifier (modifier -54) for all 90-day global surgical packages when a practitioner plans to furnish only the surgical portion of a global package. Notably, CMS is not finalizing changes regarding the use of modifier -55 and modifier -56 for CY 2025. Additionally, the rule establishes a new add-on code, GPO559, to be billed for post-operative follow-up care during the global period of a global package. This new add-on code would help capture additional resources associated with practitioners who were not involved in furnishing the surgical procedure.

- *Ambulance Fee Schedule* — The rule finalizes several changes to the ambulance fee schedule. Specifically, CMS is modifying the definition of advanced life support level two (ALS2) to include the administration of low titer O+ whole blood transfusion and O- whole blood transfusion therapy, packed red blood cells, plasma, or a combination of packed red blood cells and plasma to the current list of ALS2 level transport procedures. The agency indicates this policy would improve survival rates for patients in hemorrhagic shock compared to traditional therapies.

- *Misvalued Services* — CMS indicated in the proposed rule that it intends to continue to examine potentially misvalued Current Procedural Terminology (CPT) codes over the coming years, as required by statute. For CY 2025, CMS reviewed the following public nominations of potentially misvalued codes:
    - *CPT codes 22210, 22212, 22214, 22216:* CMS agrees with the nominator and is finalizing its determination that this code family as potentially misvalued.

- *CPT code 27279:* CMS is finalizing its decision not to consider this code potentially misvalued.

- *CPT code 95800:* While CMS is finalizing its proposal to not consider this code as potentially misvalued, the agency indicates it will consider additional information as to whether disposable or reusable equipment is more common.

- *CPT code 10021, 10004, 10005, 10006:* CMS highlights that these codes have been recently reviewed numerous times and as such, is finalizing its proposal that the code family is not misvalued.