Small Entity Compliance Guide

Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program; Final Rule (CMS-1832-F)

[CMS-1832-F], [RIN 0938-AV50]

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The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104-121, as amended by Pub. L. 110-28, May 25, 2007) contains requirements for issuance of "small entity compliance guides." Guides are to explain what actions affected entities must take to comply with agency rules. Such guides must be prepared when agencies issue final rules for which agencies are required to prepare a Final Regulatory Flexibility Analysis under the Regulatory Flexibility Act.

This final rule is estimated to have a significant economic impact on a substantial number of small entities. The complete text of this final rule can be found on the CMS website at https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices/cms-1832-f.

Summary

This major final rule addresses: changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; codification of establishment of new policies for: the Medicare Prescription Drug Inflation Rebate Program under the Inflation Reduction Act of 2022; the Ambulatory Specialty Model; updates to the Medicare Diabetes Prevention Program expanded model; updates to drugs and biological products paid under Part B; updates to the Medicare Shared Savings Program requirements; updates to the Quality Payment Program; updates to policies for Rural Health Clinics and Federally Qualified Health Centers; update to the Ambulance Fee Schedule regulations; codification of the Inflation Reduction Act and Consolidated Appropriations Act, 2023 provisions; updates to the Medicare Promoting Interoperability Program.

We have prepared this guide to address the following provisions of the final rule.

Physician Fee Schedule (PFS)

***Geographic Practice Cost Indices (GPCI)*:** Section 1848(e)(1)(A) of the Social Security Act (the Act) requires CMS to develop three separate GPCIs to measure resource cost differences among localities compared to the national average for work, practice expense (PE), and malpractice (MP). The statute requires that the physician work GPCI reflect

only one-quarter of the relative cost differences compared to the national average. The statute requires updated GPCIs at least every 3 years and the phase-in of the updated adjustment over 2 years, therefore, the CY 2026 GPCIs are a 50/50 blend of the previous year's GPCI value and the updated GPCI value for each locality.

***Potentially Misvalued Services*:** The statute requires the Secretary to periodically identify, review, and make appropriate adjustments to the relative values for potentially misvalued services. In partial fulfilment of this requirement, CMS maintains a long-established process that takes public nominations and conducts an internal review to identify services that may be potentially misvalued and discusses those requests through PFS annual rulemaking.

For purposes of the Regulatory Flexibility Act (RFA), physicians, nonphysician practitioners (NPPs), and suppliers including independent diagnostic testing facilities (IDTFs) are considered small businesses if they generate revenues of $10 million or less, according to the Small Business Administration size schedule. We estimate that approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon the SBA (Small Business Administration) standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in section VI. of the final rule (Regulatory Impact Analysis), as well as elsewhere in the final rule are intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities. See Table D-B7 (CY 2026 PFS Estimated Impact on Total Allowed Charges by Specialty) of the final rule, which shows the payment impact on PFS services of the policies contained in this final rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues will be different from those shown in Table D-B7.

Quality Payment Program (QPP): For QPP, we estimate 441,334 clinicians will become Qualifying APM Participants (QPs) in the 2026 Performance Period.

We estimate that approximately 607,419 clinicians will be MIPS eligible clinicians for the 2026 MIPS (Merit-based Incentive Payment System) performance period. We estimate that approximately 11.92 percent of MIPS eligible clinicians will receive a negative payment adjustment and 84.04 percent will receive a positive adjustment in the 2026 MIPS Performance Period/ 2028 MIPS payment ($463 million redistributed) to MIPS eligible clinicians, as required by the statute to ensure budget neutrality.

Section 101(a) of the Medicare Access and CHIP Reauthorization Act of 2015 repealed the previous statutory update formula (known as the Sustainable Growth Rate) and specified the PFS update for CY 2015 and beyond. The PFS update for CY 2024 is 0.0 percent, which is due to the removal of the temporary 2.93 percent increase that applied from March 9, 2024 through December 31, 2024, as specified by the Consolidated Appropriations Act, 2024.

After applying the required budget neutrality adjustment, the conversion factor for January 1, 2026 through December 31, 2026 is $33.57 for qualifying alternative payment model participants (QPs) and $33.40 for non-QP clinicians.

Please refer to section VI. of the final rule for the full regulatory impact analysis.

This rule imposes no direct Federal compliance requirements with significant economic impacts on small entities. To assist physicians, NPPs, and suppliers including IDTFs in understanding and adapting to changes in Medicare billing and payment procedures, we have developed webpages that include additional material on the PFS at https://www.cms.gov/medicare/payment/fee-schedules/physician.

Ambulance Fee Schedule (AFS): Extensions of the Temporary Add-on Payments for Ground Ambulance Transports

Under the AFS, Part B covers a medically necessary ground and air ambulance transport to the nearest appropriate facility that can treat the patient's condition, and any other methods of transportation are contraindicated. The fee schedule payment for ambulance services includes a base payment for the level of service and a separate payment for mileage and applicable adjustment factors. The AFS also incorporates two permanent add-on payments and three temporary add-on payments to the base and mileage rate. The AFS is updated annually by an ambulance inflation factor and updates to the non-facility practice expense of the geographic practice cost index of the Medicare PFS.

The three temporary add-on payments, predominantly related to rural areas, were set to expire on April 1, 2025. Section 2203 of the Full-Year Continuing Appropriations and Extensions Act, 2025 (Pub. L. 119-4, March 15, 2025) extended the temporary add-on payments through September 30, 2025. Under section 1834 (l)(12)(A) of the Act, the temporary add-on payment includes a 22.6 percent increase in the base rate for ground ambulance transports that originate in an area designated as "super rural." Under section 1834(l)(13)(A) of the Act, there are two add-on payments that include a 3 percent increase in the base and mileage rate for ground ambulance services that originate in rural areas, and a 2 percent increase in the base and mileage rate for ground ambulance services that originate in urban areas. CMS revised § 414.610(c)(1)(ii) and (c)(5)(ii) to conform the regulations to this statutory requirement.

Ambulatory Specialty Model (ASM)

We finalized ASM as a 5-year mandatory alternative payment model for relevant specialists treating heart failure and low back pain. ASM creates incentives for specialists to improve upstream chronic condition management, strengthen integration with primary care, and leverage technology to empower patients to improve the quality of care, patient experience, and reduce Medicare spending. To create these incentives, ASM will adjust Medicare Part B payments for covered professional services based on performance relative to other specialists treating the same condition using a focused measure set for each chronic condition. The model will be tested for 5 performance

years, beginning on January 1, 2027 and ending December 31, 2031, with payment adjustments applied 2 calendar years after the performance year (January 1, 2029 through December 31, 2033).

For purposes of the RFA, ASM participants, who are all physicians, are considered small business if they generate revenues of $10 million or less, according to the Small Business Administration size schedule. Approximately 95 percent of ASM participants are considered to be small entities. This assumption aligns with the Physician Fee Schedule assumptions for the RFA because all ASM participants must submit claims under the Physician Fee Schedule. There will be about 6,600 ASM participants for the 2027 performance year (January 1, 2027 through December 31, 2027).

This rule imposes no direct Federal compliance requirements with significant economic impacts on small entities. In order to assist ASM participants in understanding the requirements of the Innovation Center model, we have developed the ASM website: https://www.cms.gov/priorities/innovation/innovation-models/asm.

Medicare Prescription Drug Inflation Rebate Program

Sections 11101 and 11102 of the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117-169, enacted August 16, 2022) established requirements under which drug manufacturers must pay inflation rebates if they raise their prices for certain drugs payable under Part B and/or covered under Part D faster than the rate of inflation. As required by the Inflation Reduction Act, CMS must remove 340B units from the calculation of Part D rebates beginning January 1, 2026.

To implement this requirement, in this final rule, CMS adopted its proposal to establish a claims-based methodology to remove 340B units from the Part D drug inflation rebate calculations by evaluating whether a Prescription Drug Event (or PDE) record is potentially 340B-eligible based on-- (1) the affiliation of the National Provider Identifier (NPI) of the prescriber associated with that PDE record with a registered 340B covered entity; and (2) the designation of the dispensing pharmacy associated with that PDE as a 340B contract pharmacy. In the final rule, we finalized refining the methodology to improve the capture of 340B units associated with certain providers and covered entity "in-house" pharmacies. Additionally, in the final rule, CMS stated that it will use the described methodology unless and until a different method to remove 340B units is proposed and finalized.

Additionally, we adopted our proposal to establish a 340B repository to receive voluntary submissions from 340B covered entities of certain data elements from Part D 340B claims. We will assess such data for use in identifying units of Part D rebatable drugs for which a manufacturer provides a discount under the 340B Program in a future applicable period. We will not use data reported to the repository to remove 340B units until and unless we propose to do so.

For purposes of the RFA, drug manufacturers and 340B covered entities (hereinafter "covered entities"), are considered small business if they generate revenues of $6.5 million or less, according to the Small Business Administration size schedule. We estimate that very few drug manufacturers are considered to be small entities, based upon SBA standards. While we are unable to estimate the number of covered entities that would qualify as small entities, we anticipate that some will meet the classification, based upon SBA standards. There are approximately 500 drug manufacturers that could potentially owe drug inflation rebates under the PFS and approximately 13,000 covered entities that could respond to the 340B Repository Data Elements Reporting Form. Because some of the affected entities may be defined as small entities, the analysis and discussion provided in section VII. of the final rule (Regulatory Impact Analysis), as well as elsewhere in the final rule are intended to comply with the RFA requirements regarding significant impact on substantial number of small entities.

This rule imposes no direct Federal compliance requirements with significant economic impacts on small entities. In order to assist drug manufacturers in understanding and adapting to changes in Medicare billing and payment procedures, we have developed a Web page for the Prescription Drug Inflation Rebate Program at https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-inflation-rebate-program.

Medicare Shared Savings Program

The major changes to the Shared Savings Program include: modifying the requirements for determining an ACO's eligibility for Shared Savings Program participation options, applicable for agreement periods beginning on or after January 1, 2027. Under the finalized approach, an ACO identified as inexperienced with performance-based risk Medicare ACO initiatives (defined in 42 CFR 425.20) may participate in the Shared Savings Program under a one-sided model for up to 5 performance years under the ACO's first agreement period in the BASIC track's glide path (if eligible), instead of a maximum of 7 performance years spanning two agreement periods in the BASIC track's glide path, as previously allowed. We will also require ACOs inexperienced with performance-based risk Medicare ACO initiatives to progress more rapidly to higher levels of risk and potential reward under a two-sided model by their second agreement period, by allowing for participation under Level E of the BASIC track, that has a moderate level of risk and reward, or the ENHANCED track, which is the highest level of risk and reward under the program. BASIC track Level E and the ENHANCED track each qualify as an Advanced Alternative Payment Model (APM) under the Quality Payment Program.

In addition, we finalized the removal of the health equity adjustment with an effective date of performance year 2026. We also finalized the terminology changes for performance years 2023 to 2025, such as changing "health equity adjustment bonus points" to "population and income adjustment bonus points."

For purposes of the RFA, **physicians**, are considered small business if they generate revenues of $6.5 million or less, according to the Small Business Administration size schedule, and non-profit organizations including hospitals are considered small businesses. Approximately **95** percent of **physicians** are considered to be small entities. There are over 600,000 physician and non-physician participants in the Shared Savings Program.

Although the Shared Savings Program is a voluntary program and payments for individual items and services will continue to be made on a FFS basis, we acknowledge that the program can affect many small entities and have developed our rules and regulations accordingly in order to minimize costs and administrative burden on such entities as well as to maximize their opportunity to participate. (For example: Networks of individual practices of ACO professionals are eligible to form an ACO; and the option of a variable Minimum Savings Rate (MSR), that varies by the size of the ACO's population and is calculated based on confidence intervals so that smaller ACOs have relatively lower MSRs).

Small entities are both allowed and encouraged to participate in the Shared Savings Program, provided the ACO has a minimum of 5,000 assigned beneficiaries, thereby potentially realizing the economic benefits of receiving shared savings resulting from the utilization of enhanced and efficient systems of care and care coordination. Therefore, a solo, small physician practice or other small entity may realize economic benefits as a function of participating in this program and the utilization of enhanced clinical systems integration, which otherwise may not have been possible. We believe the policies included in this final rule may further encourage participation by a subset of small entities by easing the minimum baseline assignment criteria to only apply the 5,000 minimum to the third base year rather than all 3 base years. However, in total, the Shared Savings Program provisions in the final rule were not estimated to have a material impact on overall program participation or spending.

Strategies for Reducing Chronic Illness:

Integrating Behavioral Health into Advanced Primary Care Management (APCM): In the CY 2025 PFS final rule, we finalized separate coding and payment for APCM services, which are care management services that do not require practitioners to count minutes of care provided per month. We also adopted these services in Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) settings.

In CY 2017, CMS began making separate payments for Behavioral Health Integration (BHI) services, including the Psychiatric Collaborative Care Model as well as General BHI. The services are based on a model of behavioral health integration that enhances usual primary care by adding two key services to the primary care team: care management support for patients receiving behavioral health treatment, and regular psychiatric inter-specialty consultation. For CY 2026, we finalized add-on codes for APCM that allow BHI services to be billed with the APCM codes.

For purposes of the RFA, physicians, nonphysician practitioners (NPPs), and suppliers including independent diagnostic testing facilities (IDTFs) , are considered small business if they generate revenues of $6.5 million or less, according to the Small Business Administration size schedule. We estimate that approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in section VI. of the final rule (Regulatory Impact Analysis), as well as elsewhere in the final rule are intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities. (See Table D-B7 (CY 2026 PFS Estimated Impact on Total Allowed Charges by Specialty) of the final rule, which shows the payment impact on PFS services of the policies contained in this final rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues will be different from those shown in Table D-B7.)

Updates to Digital Mental Health Treatment (DMHT): In the CY 2025 PFS final rule CMS finalized the definition of DMHT device as devices cleared under section 510(k) of the Federal Food, Drug, and Cosmetic (FD&C) Act or granted De Novo authorization by FDA, and classified under 21 CFR 882.5801 furnished incident to professional behavioral health services used as an adjunct to clinician supervised ongoing behavioral health care treatment under a behavioral health treatment plan of care. Healthcare Common Procedure Coding System (HCPCS) code G0552, which describes "*Supply of digital mental health treatment device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan*" continues to be assigned contractor-pricing. HCPCS code G0553 and G0554 continue being assigned national pricing. CMS stated those policies were a starting point of Medicare payment for DMHT devices and anticipated that establishing payment for DMHT devices would be an iterative process. Beginning in CY 2026 to further support access to behavioral health services, CMS is expanding payment policies for HCPCS codes G0552, G0553, and G0554 to also make Medicare payment for DMHT devices cleared under section 510(k) of the FD&C Act or granted de no novo authorization by the FDA and classified under 21 CFR 882.5803 Digital therapy device for Attention Deficit Hyperactivity Disorder (ADHD).

Home or Residence E/M Visit Inherent Complexity Add-on Technical Update: In the CY 2024 PFS final rule, CMS began making separate payment of HCPCS code G2211 as an add-on code with the office/outpatient evaluation and management (E/M) visits code family (CPT codes 99202-99205, 99211-99215). CMS stated that the most important information used to determine whether or not the add-on code for inherent complexity could be billed is the relationship between the practitioner and the patient. If the practitioner is the focal point for all needed services, such as a primary care practitioner, the G2211 add-on could be billed. Or, if the practitioner is part of ongoing care for a single, serious, and complex condition, then the add-on code could be billed. For CY 2026, CMS finalized payment of HCPCS code G2211 as an add-on code with the home

or residence E/M services code family (CPT codes 99341, 99342, 99344, 99345, 99347, 99348, 99349, 99350). The add-on code aims in part to make payment for previously unaccounted resources inherent in the complexity of all longitudinal primary care visits.

Medicare Diabetes Prevention Program (MDPP): The MDPP expanded model is an evidence-based, non-pharmacological behavioral intervention that aims to prevent or delay the onset of type 2 diabetes for eligible Medicare beneficiaries diagnosed with prediabetes. Historically, uptake of MDPP has been low, with less than one percent of eligible beneficiaries participating in the program. While an estimated 9.3 million FFS beneficiaries are potentially eligible for the program (that is, have a pre-diabetes diagnosis but not a diabetes diagnosis in claims), fewer than 11,000 beneficiaries have participated in MDPP during the first 6 years of the program.

For CY 2026, we finalized several policy changes to: (1) update weight collection requirements to allow beneficiaries to self-report weight for all MDPP sessions from home or a reasonable location outside of an in-person delivery site; (2) update weight collection requirements to allow for the submission of weight collected as part of a medical record, dated within 5 days of a scheduled MDPP session; (3) extend the flexibilities allowed during the Public Health Emergency (PHE) through December 31, 2029, including the option for MDPP suppliers to deliver the program through synchronous distance learning sessions; (4) test the additional coverage of asynchronous, online delivery of MDPP through December 31, 2029; and (5) clarify that MDPP suppliers are not required to maintain in-person delivery capability during the online delivery period. These finalized changes aim to increase program participation by allowing more beneficiaries to access coaching and training in dietary change, physical activity, and behavior change strategies to delay or prevent Type 2 diabetes.

***Telehealth*:** For telehealth, from CY 2003 to CY 2021, we used two categories of criteria: the first to assess whether the requested service was similar to other services on the list, and the second to assess whether there was clinical benefit to the service being available as telehealth. During the COVID-19 PHE, we added a third category of criteria to address the emergency changes we made to increase access during the pandemic. For CY 2024, we further refined the process to include five steps and redefine the categories as provisional or permanent in the interests of simplifying the process, but our subsequent experience has indicated that these changes only increased the complexity.

For CY 2026, we finalized simplifying our telehealth list review process by removing the distinction between temporary and permanent services and focusing our review on whether the service can be furnished using an interactive telecommunications system. Instead of designating a code as “provisional” or “permanent", we finalized that requested codes are simply on or off the list permanently.

Strategies for Improving Global Surgery Payment Accuracy: The rule also finalizes a provision to broaden the downward payment adjustment for 90-day global surgical packages in any case when a practitioner (or group practice) does not expect to furnish the post-operative care portion of the complete payment package, even when there is no

formal, documented transfer of care.

Outpatient Therapy Services and KX Modifier Threshold Amounts: We also revised the basic rule for speech-language pathology services at § 410.62(a) to reference the correct condition of payment that was inadvertently not updated at the time we finalized the special provisions related to the services furnished by speech-language pathologists in private practice at § 410.62(c) for 2009.

We also finalized the CY 2026 KX modifier threshold amount of $2,480 for physical therapy and speech-language pathology services combined and $2,480 for occupational therapy services based on the most recent estimate of the CY 2026 update of the 2017-based MEI of 2.7 percent.