Small Entity Compliance Guide

Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program Final Rule (CMS 1784-F)

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42 CFR Parts 405, 410, 411, 414, 415, 418, 422, 423, 424, 425, 455, 489, 491, 495, 498, and 600

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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 were required to prepare a Final Regulatory Flexibility Analysis under the Regulatory Flexibility Act (RFA).

The complete text of this final rule can be found on the CMS website at https://www.cms.gov/medicare/medicare-fee-service-payment/physicianfeesched/pfs-federal-regulation-notices/cms-1784-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; payment for dental services inextricably linked to specific covered medical services; Medicare Shared Savings Program requirements; updates to the Quality Payment Program; Medicare coverage of opioid use disorder services furnished by opioid treatment programs; updates to certain Medicare and Medicaid provider and supplier enrollment policies, electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA-PD plan under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act); updates to the Ambulance Fee Schedule regulations and the Medicare Ground Ambulance Data Collection System; codification of the Inflation Reduction Act and Consolidated Appropriations Act, 2023 provisions; expansion of the diabetes screening and diabetes definitions; pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation expansion of supervising practitioners; appropriate use criteria for advanced diagnostic imaging; early release of Medicare Advantage risk adjustment data; a social determinants of health risk assessment in the annual wellness visit and Basic Health Program.

Background

The statute requires us to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. Per the statute, RVUs must be established for three categories of resources (work, practice expense (PE); and malpractice expense) and we must establish by regulation each year's payment amounts for all physicians' services paid under the PFS, incorporating geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas.

Provisions of the Final Rule

Advancing Access to Behavioral Health

For CY 2024, we are:

- Implementing section 4121 of the CAA, 2023, which provides Part B coverage and payment for marriage and family therapists (MFTs) and mental health counselors (MHCs) when services are billed by these professionals. Consistent with statute, we will allow MFTs and MHCs to enroll in and bill Medicare for services starting January 1, 2024. We are also making corresponding changes to Behavioral Health Integration HCPCS codes to allow MFTs and MHCs to provide integrated behavioral health care as part of primary care settings.
- Including Addiction Counselors or Alcohol and Drug Counselors who meet all of the applicable requirements to enroll in Medicare as MHCs.
- Implementing section 4123 of the CAA, 2023, which requires the Secretary to establish new HCPCS codes for psychotherapy for crisis services that are furnished in an applicable site of service (any place of service at which the non-facility rate for these services applies, other than the office setting) furnished on or after January 1, 2024.
- Establishing national Medicare policy to allow t Health Behavior Assessment and Intervention (HBAI) services to be billed by clinical social workers, MFTs, and MHCs, in addition to clinical psychologists. Allowing a wider range of practitioner types to furnish these services will allow for better integration of physical and behavioral health care.
- Increasing the valuation for timed behavioral health services to apply an adjustment to the work relative value units (RVUs) for psychotherapy codes (including psychotherapy billed with an E/M visit) and HBAI services payable under the PFS, to be implemented over a four year transition. This will begin to correct for historic distortions that have devalued time-based behavioral health services to more accurately value them in the future.

Payment for Caregiver Training Services (CTS)

For CY 2024, we will make payment for a new family of CTS that describe how practitioners train and involve caregivers in the medically reasonable and necessary treatment of patients with certain disease (e.g., dementia). We will pay for these services when furnished by a physician or non-physician practitioner (nurse practitioner, clinical nurse specialist, certified nurse-midwife, physician assistant, or clinical psychologist), or therapist (physical therapist, occupational therapist, or speech language pathologist) under an individualized treatment plan or therapy plan of care. This is consistent with the recent Executive Order (E.O.) on Increasing Access to High Quality Care and Supporting Caregivers, and will help promote necessary care for persons with Medicare by better training the caregivers.

Services Addressing Health-Related Social Needs (Community Health Integration services, SDOH Assessment, and Principal Illness Navigation Services)

To reduce health disparities, for CY 2024 we are finalizing coding and payment changes to better account for resources involved in furnishing patient-centered care involving a multidisciplinary team of clinical and auxiliary personnel. Specifically, we are finalizing new coding to pay separately for principal illness navigation services and for community health integration services to account for resources and capture when clinicians involve community health workers, care navigators, and peer support specialists, facilitating access to community-based social services to address unmet SDOH needs that affect the diagnosis and treatment of their medical problems.

In addition to better recognizing costs associated with patient-centered care, these services contribute to equity, inclusion, and access to care for the Medicare population and improve outcomes for patient (particularly in RHCs, FQHCs, and underserved and low-income populations, where there is a disparity in access to quality care). We are also finalizing coding and payment revisions to recognize when practitioners incur additional time and resources assessing and addressing SDOH that are impacting their ability to treat the patient, including in conjunction with an E/M visit and as an additional element in the AWV. These payments and services are aligned with the HHS Social Determinants of Health Action Plan and also help implement the White House Cancer Moonshot goal of having patient navigation services for every American with cancer.

Telehealth

In this final rule, we:

- Continue to allow those services that were available temporarily for the duration of the COVID-19 PHE until December 31, 2024, in alignment with the extension of many flexibilities enacted in the CAA, 2023.
- Update modifiers and place of service codes to improve tracking of how and where Medicare telehealth services are furnished.
- Update the Medicare Telehealth Services list to reflect new services requested by interested parties that we reviewed and approved as part of the annual PFS rulemaking process; Simplify the categorization of telehealth services on the list; and Make technical updates to the list in alignment with active CPT coding.

As finalized, these provisions align many telehealth-related flexibilities with those associated with the CAA, 2023, including more accurately recognizing the resource costs associated with telehealth services furnished when the patient is at home.

Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Medical Services

In consideration of issues raised by interested parties, we:

- Codify the previously finalized payment policy for dental services that are inextricably linked to, and substantially related to, the clinical success of head and neck cancer treatments.
- Finalize payment for other dental services that are inextricably linked to, and substantially related to, the clinical success of certain covered medical services, specifically chemotherapy

services, CAR-T Cell therapy, and the use of high-dose bone modifying agents (antiresorptive therapy), each when used to treat cancer.

Evaluation & Management (E/M) Services

For CY 2021, we established Medicare payment for HCPCS add-on code G2211 describing visit complexity inherent to office/outpatient E/M (O/O E/M) visits associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services. These services are part of ongoing care related to a patient's single, serious condition or a complex condition to better recognize the resource costs associated with primary care and other longitudinal care of complex patients. However, Congress suspended the add-on code (or any successor or substantially similar code) until January 1, 2024. For CY 2024, we are implementing separate payment for G2211. We refined our utilization estimates in consideration of interested party concerns about initial uptake for code G2211. These refinements collectively reduce the redistributive impact to the CY 2024 conversion factor by about a third of the previously estimated impact.

Medicare Shared Savings Program

The changes to Medicare Shared Savings Program (Shared Savings Program) policies support our goals for growth, equity, and alignment with a particular focus on growing accountable care in underserved communities, and with medically complex and high-cost beneficiaries. We are continuing to move Accountable Care Organizations (ACOs) toward digital quality measurement and addressing challenges in the transition to all payer/patient quality measures by establishing the Medicare Clinical Quality Measures (CQMs) for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs) as a new collection type for Shared Savings Program ACOs under the Alternative Payment Model (APM) Performance Pathway (APP) for performance year 2024 and subsequent performance years. We are also aligning the Shared Savings Program Certified Electronic Health Record Technology (CEHRT) requirement with the Merit-based Incentive Payment System (MIPS) by sunsetting the Shared Savings Program CEHRT threshold requirements beginning performance year 2025 and adding a new requirement that, for performance years beginning on or after January 1, 2025, unless otherwise excluded, an ACO participant, ACO provider/supplier, and ACO professional that is a MIPS eligible clinician, Qualifying APM Participant (QP), or Partial QP, regardless of track, will be required to report the MIPS Promoting Interoperability performance category measures and requirements to MIPS and earn a performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM Entity level.

PFS Conversion Factor

We implement both the PFS update and budget neutrality to account for changes in values for individual services through a combination of changes to both the PFS conversion factor and RVUs. Under current law, the CY 2024 Conversion Factor (CF) will reflect a –1.25 percent reduction to reflect the expiration of the single year update for CY 2023. The remaining changes to CY 2024 PFS rates are budget neutral, as required by the statute, so the overall increases in RVUs, largely attributed to the reactivation of the O/O E/M inherent complexity add-on code, will require an additional projected –2.20 percent reduction in the CF. Overall, the CY 2024 CF is projected to be $32.74, a decrease of $1.15 (-3.35 percent) from CY 2023 ($33.89) though the overall reduction in PFS payment rates will be -1.25 percent as specified under current statute.

TABLE 1: Physician Fee Schedule (PFS) Payment Rate Updates

PFS Conversion Factor	Percentage	Actual Adjustment	Conversion Factor
Conversion Factor in effect in CY 2023			33.8872
Expiration of CY 2023 Consolidated Appropriations Act Provision			33.0607
Positive Adjustment Due to Statutory single-year 1.25 Increase for CY 2024 (CAA, 2023)	1.25 %	1.0125	
CY 2024 RVU Budget Neutrality Adjustment	-2.18 %	0.9778	
CY 2024 Conversion Factor			**32.7442**

TABLE 2: Historical Updates and PFS Conversion Factors[1]

	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
Update Factor (percent)	0	0	0	0	0	0
Conversion Factor	36.0391	36.0896	34.8931[2]	34.6062[3]	33.8872[4]	32.7442[5]

[1]The Social Security Act requires that increases or decreases in relative value units (RVUs) may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. We implement the PFS update to maintain this budget neutral requirement through changes to both the conversion factor and RVUs.

[2] The CAA, 2021 provided a 3.75 percent increase in Medicare Physician Fee Schedule (MPFS) payments for CY 2021 which is due to expire for CY 2022.

[3] The CAA, 2022 provided a 3.00 percent increase in MPFS payments for CY 2022 which is due to expire for CY 2023.

[4] The CAA, 2022 provided a 2.50 percent increase in MPFS payments for CY 2023 which is due to expire for CY 2024.

[5] The CAA, 2022 provided a 1.25 percent increase in MPFS payments for CY 2024 which is due to expire for CY 2025.

Quality Payment Program (QPP)

Updates to the MIPS Program: We included a request for information on how we can create opportunities for continuous improvement for clinicians in the Quality Payment Program (QPP) and emphasized the value of participation in accountable care relationships within APMs. In addition, we are expanding our MIPS Value Pathway (MVP) inventory through modifications to existing MVPs and the addition of five new MVPs which include: Focusing on Women's Health; Prevention and Treatment of Infectious Disease Including Hepatitis C and Human Immunodeficiency Virus (HIV); Quality Care in Mental Health and Substance Use Disorders; Quality Care for Ear, Nose, and Throat; and Rehabilitative Support for Musculoskeletal Care. In addition, for the Quality performance category, we finalized: the data completeness criteria threshold to be 75 percent for the 2026 performance period; requiring groups, virtual groups, subgroups, and APM Entities to contract with a CAHPS for MIPS survey vendor to administer the Spanish survey translation to Spanish-preferring patients using the procedures detailed in the CAHPS for MIPS Quality Assurance Guidelines and recommend that the CAHPS for MIPS Survey is administered in the other available translations to the extent feasible; We are also expanding the definition of collection type (the way in which data is collected for a measure) to include Medicare CQMs; We are adding, removing, and modifying the availability of quality measures within MIPS quality measure inventory; In support of the E.O. on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, we are finalizing one new health equity related quality measure titled "Connection to Community Service Provider," which assesses patients who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation problems, utility help needs, or interpersonal safety and had contact with a Community Service Provider, for at least one of their HRSNs within 60 days after screening. With regards to MIPS final scoring and payment adjustments, for the CY 2024 performance period, we are finalizing to establish the performance threshold at 75 points (a continuation from CY 2023) in

an effort to respond to commenter concerns of the time need to recover from the PHE and face staffing and bed shortages.

CEHRT Definition for APM: We are amending the CEHRT criteria as it applies to Advanced APMs to clarify that Advanced APMs need not enforce a requirement that all participants report on all of the requirements under meaningful use, but rather that they need only meet the definition of CEHRT.

A SDOH Risk Assessment in the AWV

We are finalizing our proposal for a new SDOH Risk Assessment as an optional, separately payable (with no beneficiary cost sharing) additional element within the AWV. This includes the administration of a standardized, evidence-based SDOH risk assessment tool, and shall be furnished in a manner that all communication be appropriate for the patient's educational, developmental, and health literacy level, and be culturally and linguistically appropriate. The SDOH Risk Assessment will identify health-related social needs and inform the medical care the patient is receiving during the AWV visit, including taking a medical and social history, applying health risk assessments, and prevention services education and planning.

BHP

We are finalizing our proposal to allow a state to suspend, rather than terminate, its BHP. This will allow a state to retain the money in its BHP trust fund, with guardrails, rather than returning it to HHS as required under current regulations. States that suspend their BHP must submit a suspension application demonstrating compliance with several requirements, including:

1. The benefits BHP-eligible individuals will receive during the suspension are at least equal to the benefits provided under the certified BHP Blueprint in effect on the effective date of suspension;

2. The median actuarial value of the coverage provided to the BHP-eligible individuals during the suspension is no less than the median actuarial value of the coverage under the certified BHP Blueprint in effect on the effective date of suspension;

3. The premiums imposed on BHP-eligible individuals during the suspension are no higher than the premiums charged under the certified BHP Blueprint in effect on the effective date of suspension, except that premiums imposed during the suspension may be adjusted for inflation, as measured by the Consumer Price Index; and

4. The eligibility criteria for coverage during the suspension is not more restrictive than the criteria described in § 600.305.

We are also finalizing our proposals to establish a process for submission and review of BHP Blueprint revisions; require that BHP enrollees have an opportunity to appeal a delay, denial, reduction, suspension, or termination of health services; and require that notices be available to individuals with limited English proficiency.

Provider Enrollment

We are finalizing several provisions regarding Medicare provider enrollment. The most prominent of these are:

- Creation of a new provider "stay of enrollment" status, which will ease the burden on providers and suppliers while strengthening program integrity.
- Requiring all Medicare provider and supplier types to report additions, deletions, or changes in their practice locations within 30 days.
- Establishing several new and revised Medicare denial and revocation authorities. (However, based on commenters' concerns regarding the possible negative impact on equity, we are not finalizing our proposal to deny or revoke enrollment based on a misdemeanor conviction that CMS deems detrimental to Medicare's best interests.)

Small Entities Affected

For purposes of the 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 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 118 (CY 2024 PFS Estimated Impact on Total Allowed Charges by Specialty) of the final rule, which show 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 118.)

For the Quality Payment Program, we estimate that between 316,767 and 407, 272 clinicians will become Qualifying APM Participants (QPs) in the 2024 P Performance Period. We estimate that approximately 810,000 clinicians will be MIPS eligible clinicians for the 2022 MIPS performance period.

We estimate that approximately 686,650 clinicians will be MIPS eligible clinicians for the 2024 MIPS performance period. We estimate that approximately 21.63 percent of MIPS eligible clinicians will receive a negative payment adjustment and 78.37 percent will receive a positive adjustment in the 2024 MIPS Performance Period/ 2026 MIPS payment ($491 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 3.4 percent, which is due to the removal of a 2.5 percent increase that applied for 2023 and the application of a 1.25 percent increase for 2023 as specified by the Consolidated Appropriations Act, 2023.

After applying the required budget neutrality adjustment, the conversion factor for January 1, 2024 through December 31, 2024 will be $32.74."

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. In order 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 http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html and https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

FOR FURTHER INFORMATION CONTACT:

MedicarePhysicianFeeSchedule@cms.hhs.gov, for any issues not identified below. Please indicate the specific issue in the subject line of the email.

MedicarePhysicianFeeSchedule@cms.hhs.gov, for the following issues: practice expense, work RVUs, conversion factor, and PFS specialty-specific impacts; the comment solicitation on strategies for updates to practice expense data collection and methodology, caregiver training services, community health integration services, social determinants of health risk assessment, and principal illness navigation services; potentially misvalued services under the PFS, direct supervision using two-way audio/video communication technology, telehealth, and other services involving communications technology; teaching physician services, advancing access to behavioral health services, PFS payment for evaluation and management services, geographic practice cost indices (GPCIs), payment for skin substitutes, supervision of outpatient therapy services, KX modifier thresholds, diabetes self-management training (DSMT) services, and DSMT telehealth services, and dental services inextricably linked to specific covered services.

Laura Ashbaugh, (410) 786-1113, and Erick Carrera, (410) 786-8949, Zehra Hussain, (214) 767-4463, or MedicarePhysicianFeeSchedule@cms.hhs.gov, for issues related to dental services inextricably linked to specific covered medical services.

Laura Kennedy, (410) 786-3377, Adam Brooks, (202) 205-0671, and Rachel Radzyner, (410) 786-8215, for issues related to Drugs and Biological Products Paid Under Medicare Part B

MedicarePhysicianFeeSchedule@cms.hhs.gov, for issues related to complex drug administration.

Laura Ashbaugh, (410) 786-1113, and Ariana Pitcher, (667) 290- 8840, or CLFS_Inquiries@cms.hhs.gov for issues related to Clinical Laboratory Fee Schedule.

Lisa Parker, (410) 786-4949, or FQHC-PPS@cms.hhs.gov, for issues related to FQHC payments.

Michele Franklin, (410) 786-9226, or RHC@cms.hhs.gov, for issues related to RHC payments.

Kianna Banks (410) 786-3498 and Cara Meyer (667) 290-9856, for issues related to RHCs and FQHCs definitions of staff and Conditions for Certification or Coverage.

Sarah Fulton, (410) 786-2749, for issues related to pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation expansion of supervising practitioners.

Lindsey Baldwin, (410) 786-1694, Ariana Pitcher, (667) 290- 8840, or OTP_Medicare@cms.hhs.gov, for issues related to Medicare coverage of opioid use disorder treatment services furnished by opioid treatment programs.

Sabrina Ahmed, (410) 786-7499, or SharedSavingsProgram@cms.hhs.gov, for issues related to the Shared Savings Program Quality performance standard and quality reporting requirements.

Janae James, (410) 786-0801, or Elizabeth November, (410) 786-4518, or SharedSavingsProgram@cms.hhs.gov, for issues related to Shared Savings Program beneficiary assignment and benchmarking methodology.

Lucy Bertocci, (410) 786-3776, or SharedSavingsProgram@cms.hhs.gov, for issues related to Shared Savings Program advance investment payments, and eligibility requirements.

Rachel Radzyner, (410) 786-8215, and Michelle Cruse, (443) 478-6390, for issues related to preventive vaccine administration services.

Mollie Howerton (410) 786-5395, for issues related to Medicare Diabetes Prevention Program.

Sarah Fulton (410) 786-2749, for issues related to appropriate use criteria for advanced diagnostic imaging.

Frank Whelan, (410) 786-1302, for issues related to Medicare and Medicaid provider and supplier enrollment regulation updates.

Daniel Feller (410) 786-6913 for issues related to expanding diabetes screening and definitions.

Daniel Feller (410) 786-6913 for issues related to a social determinants of health risk assessment in the annual wellness visit.

Mei Zhang, (410) 786-7837, and Kimberly Go, (410) 786-4560, for issues related to requirement for electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA-PD plan (section 2003 of the SUPPORT Act).

Amy Gruber, (410) 786-1542, or AmbulanceDataCollection@cms.hhs.gov, for issues related to the Ambulance Fee Schedule (AFS) and the Medicare Ground Ambulance Data Collection System.

Mary Rossi-Coajou (410) 786-6051, for issues related to hospice Conditions of Participation.

Cameron Ingram (410) 409-8023 for issues related to Histopathology, Cytology, and Clinical Cytogenetics Regulations under CLIA of 1988.

Meg Barry (410)786-1536, for issues related to the Basic Health Program (BHP) provisions.

Renee O'Neill, (410) 786-8821, or Sophia Sugumar, (410) 786-1648, for inquiries related to Merit-based Incentive Payment System (MIPS) track of the Quality Payment Program.

Richard Jensen, (410) 786-6126, for inquiries related to Alternative Payment Models (APMs).