Calendar Year (CY) 2025 Medicare Physician Fee Schedule Proposed Rule

On July 10, 2024, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that announces and solicits public comments on proposed policy changes for Medicare payments under the Physician Fee Schedule (PFS), and other Medicare Part B issues, effective on or after January 1, 2025.

The calendar year (CY) 2025 PFS proposed rule is one of several proposed rules that reflect a broader Administration-wide strategy to create a more equitable health care system that results in better accessibility, quality, affordability, empowerment, and innovation for all Medicare beneficiaries.

Background on the Physician Fee Schedule

Since 1992, Medicare payment has been made under the PFS for the services of physicians and other billing professionals. Physicians' services paid under the PFS are furnished in a variety of settings, including physician offices, hospitals, ambulatory surgical centers (ASCs), skilled nursing facilities and other post-acute care settings, hospices, outpatient dialysis facilities, clinical laboratories, and beneficiaries' homes. Payment is also made to several types of suppliers for technical services, most often in settings for which no institutional payment is made.

For most services furnished in a physician's office, Medicare makes payment to physicians and other professionals at a single rate based on the full range of resources involved in furnishing the service. In contrast, PFS rates paid to physicians and other billing practitioners in facility settings, such as a hospital outpatient department (HOPD) or an ASC, reflect only the portion of the resources typically incurred by the practitioner while furnishing the service.

For many diagnostic tests and a limited number of other services under the PFS, separate payment may be made for the professional and technical components of services. The technical component is frequently billed by suppliers, like independent diagnostic testing facilities and radiation treatment centers, while the professional component is billed by the physician or practitioner.

Payments are based on the relative resources typically used to furnish the service. Relative value units (RVUs) are applied to each service for work, practice expense, and malpractice expense. These RVUs become payment rates through the application of a conversion factor. Geographic adjusters (geographic practice cost indices) are also applied to the total RVUs to account for variation in costs by geographic area. Payment rates are calculated to include an overall payment update specified by statute.

Caregiver Training Services (CTS)

For CY 2025, we are proposing to establish new coding and payment for caregiver training for direct care services and supports. The topics of trainings could include, but would not be limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, infection control, special diet preparation, and medication administration. We are also proposing to establish new coding and payment for caregiver behavior management and modification training that could be furnished to the caregiver(s) of an individual patient. We are also proposing to allow the proposed CTS to be furnished via telehealth.

Services Addressing Health-Related Social Needs (Community Health Integration Services, Social Determinants of Health Risk Assessment, and Principal Illness Navigation Services)

For CY 2025, we are issuing a broad RFI on the newly implemented Community Health Integration (CHI) services, Principal Illness Navigation (PIN) services, and Social Determinants of Health (SDOH) Risk Assessment to engage interested parties on additional policy refinements for CMS to consider in future rulemaking. We request information on other factors for us to consider, such as other types of auxiliary personnel (including clinical social workers) and other certification and/or training requirements that are not adequately captured in current coding and payment for these services and how to improve utilization in rural areas. We are also seeking comment about how these codes are being furnished in conjunction with community-based organizations.

Telehealth Services under the PFS

For CY 2025, we are proposing to add several services to the Medicare Telehealth Services List on a provisional basis, including demonstration prior to initiation of home International Normalized Ratio (INR) monitoring and caregiver training services. We are proposing to continue the suspension of frequency limitations for subsequent inpatient visits, subsequent nursing facility visits, and critical care consultations for CY 2025.

We are proposing that beginning January 1, 2025, an interactive telecommunications system may include two-way, real-time audio-only communication technology for any telehealth service furnished to a beneficiary in their home if the distant site physician or practitioner is technically capable of using an interactive telecommunications system but the patient is not capable of, or does not consent to, the use of video technology.

We are proposing that, through CY 2025, we will continue to permit the distant site practitioner to use their currently enrolled practice location instead of their home address when providing telehealth services from their home.

We are proposing, for a certain subset of services that are required to be furnished under the direct supervision of a physician or other supervising practitioner, to permanently adopt a definition of direct supervision that allows the physician or supervising practitioner to provide such supervision through real-time audio and visual interactive telecommunications. We are specifically proposing that the physician or supervising practitioner may provide such virtual direct supervision for services furnished incident to a physician's service when they are provided by auxiliary personnel employed by the physician and working under his or her direct supervision and for which the underlying HCPCS code has been assigned a PC/TC indicator of office or other outpatient visit for the evaluation and management of an established patient who may not require the presence of a physician or other qualified health care professional. For all other services furnished under the direct supervision of the supervising physician or other practitioner, we are proposing to continue to define "immediate availability" to include real-time audio and visual interactive telecommunications technology only through December 31, 2025.

We are proposing to continue our current policy to allow teaching physicians to have a virtual presence for purposes of billing for services furnished involving residents in all teaching settings, but only in clinical instances when the service is furnished virtually (for example, a three-way telehealth visit, with the patient, resident, and teaching physician all parties in

separate locations) through December 31, 2025. This virtual presence will continue to meet the requirement that the teaching physician be present for the key portion of the service. We are also requesting information to help us consider whether and how best to expand the array of services included under the primary care exception in future rulemaking.

Cardiovascular Risk Assessment and Management

The CMS Innovation Center tested the Million Hearts® Model, which coupled payments for cardiovascular risk assessment with cardiovascular care management, and was found to reduce the rate of death by lowering heart attacks and strokes amongst Medicare fee-for-service beneficiaries. In order to incorporate these lessons learned and increase access to these lifesaving interventions, beginning with CY 2025, we are proposing coding and payment for an Atherosclerotic Cardiovascular Disease (ASCVD) risk assessment service and risk management services. The ASCVD risk assessment would be performed in conjunction with an E/M visit when a practitioner identifies a patient at risk for CVD who does not have a diagnosis of CVD. The standardized, evidence-based risk assessment tool used would include demographic data (e.g., age, sex), modifiable risk factors for CVD (e.g., blood pressure & cholesterol control, smoking status/history, alcohol and other drug use, physical activity and nutrition, obesity), possible risk enhancers (e.g., pre-eclampsia), and laboratory data (lipid panel), and the output must include a 10-year estimate of the patient's ASCVD risk. We are also proposing coding and payment for ASCVD risk management services that include service elements related to the ABCS of CVD risk reduction (aspirin, blood pressure management, cholesterol management, smoking cessation), for beneficiaries at medium or high risk (>15% in the next 10 years) for CVD.

Behavioral Health Services

In this rule, CMS is proposing several additional actions to help support access to behavioral health, in line with the CMS Behavioral Health Strategy.

Several studies have demonstrated that safety planning, when properly performed, can help prevent suicide. For CY 2025, we are proposing to establish separate coding and payment under the PFS describing safety planning interventions for patients in crisis, including those with suicidal ideation or at risk of suicide or overdose. Specifically, we are proposing to create an add-on G-code that would be billed along with an E/M visit or psychotherapy service when safety planning interventions are personally performed by the billing practitioner in a variety of settings. Additionally, we are proposing to create a monthly billing code to that requires specific protocols in furnishing post-discharge follow-up contacts that are performed in conjunction with a discharge from the emergency department for a crisis encounter, as a bundled service describing four calls in a month.

To further support access to psychotherapy, we are also proposing Medicare payment for digital mental health treatment devices furnished incident to or integral to professional behavioral health services used in conjunction with ongoing behavioral health care treatment under a behavioral health treatment plan of care. We are proposing to create three new HCPCS codes and we would monitor how digital mental health treatment devices are used as part of overall behavioral health care. We are also proposing to create six G codes to be billed by practitioners in specialties whose covered services are limited by statute to services for the diagnosis and treatment of mental illness (including Clinical Psychologists, Clinical Social Workers, Marriage and Family Therapists, and Mental Health Counselors) to mirror current interprofessional

consultation CPT codes used by practitioners who are eligible to bill E/M visits. If finalized, this would allow for better integration of behavioral health specialty treatment into primary care and other settings.

Lastly, we are seeking comment on whether coding and payment for Intensive Outpatient Program (IOP) services under the PFS would be appropriate services in additional settings (such as Certified Community Behavioral Health Clinics (CCBHCs)), as well as seeking comment on facilities that offer crisis stabilization services and non-emergent, urgent care.

Opioid Treatment Programs (OTPs)

CMS is proposing several telecommunication technology flexibilities for opioid use disorder (OUD) treatment services furnished by OTPs, as long as the use of these technologies are permitted under the applicable SAMHSA and DEA requirements at the time the services are furnished and all other applicable requirements are met. First, CMS is proposing to make permanent the current flexibility for furnishing periodic assessments via audio-only telecommunications beginning January 1, 2025 so long as all other applicable requirements are met. Second, CMS is proposing to allow the OTP intake add-on code to be furnished via two-way audio-video communications technology when billed for the initiation of treatment with methadone (using HCPCS code G2076) if the OTP determines that an adequate evaluation of the patient can be accomplished via an audio-visual telehealth platform. We believe these telecommunication flexibilities would meaningfully promote access to care for populations that often face barriers to entering and participating in OUD treatment and allow OTPs and their patients to mutually decide the best modality for receiving care.

CMS is also proposing payment increases in response to recent regulatory reforms for OUD treatment finalized by SAMHSA at 42 CFR part 8. Specifically, CMS is proposing to update payment for intake activities furnished by OTPs to include payment for social determinants of health risk assessments to adequately reflect additional effort for OTPs to identify a patient's unmet health-related social needs or the need and interest for harm reduction interventions and recovery support services that are critical to the treatment of an OUD. We believe this proposed update would help OTPs address key issues during initial assessments that may increase the risk of a patient leaving OUD treatment prematurely or that pose barriers to treatment engagement. CMS is also requesting information to understand how OTPs currently coordinate care and make referrals to community-based organizations that address unmet health-related social needs, provide harm reduction services, and/or offer recovery support services.

CMS is also proposing to establish payment for new opioid agonist and antagonist medications approved by the FDA. First, CMS is proposing a new add-on code for a nalmefene hydrochloride nasal spray product (Opvee®) indicated for the emergency treatment of known or suspected opioid overdose. Second, CMS is proposing payment for a new injectable buprenorphine product (Brixadi®) via a new weekly bundled payment code for the weekly formulation of Brixadi®, and by including payment for the monthly formulation of Brixadi® into the existing code for monthly injectable buprenorphine.

Lastly, CMS is clarifying a billing requirement that OTPs must append an OUD diagnosis code on claims for OUD treatment services, consistent with Medicare coverage and payment provisions under the Social Security Act.

Dental and Oral Health Services

We are proposing to amend our regulations at § 411.15(i)(3) to add to the list of clinical scenarios under which FFS Medicare payment may be made for dental services inextricably linked to covered services to include: (1) dental or oral examination in the inpatient or outpatient setting prior to Medicare-covered dialysis services for beneficiaries with end-stage renal disease; and (2) medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, Medicare-covered dialysis services for beneficiaries with end-stage renal disease. Interested parties have suggested that we should focus on this patient population and have submitted clinical evidence describing the links between dental and oral health and dialysis for beneficiaries with end-stage renal disease through our established public submissions process.

CMS is also soliciting comment on the potential connection between dental services and covered services used in the treatment of diabetes and covered services for individuals with autoimmune diseases receiving immunosuppressive therapies, as well as requesting any additional evidence regarding covered services for sickle cell disease and hemophilia. We describe evidence submitted by the public regarding the possible linkage between dental services and services for these conditions, request comment on defining the patient population subset for which dental services may lead to improved outcomes, and the specific medical services used in the treatment of these conditions to which dental services may be linked.

CMS is also proposing two policies related to billing of dental services inextricably linked to covered services. We are proposing to require the submission of the KX modifier on claims for dental services that clinicians believe to be inextricably linked to covered medical services beginning in CY 2025. We believe that the required usage of the KX modifier would support claims processing and program integrity efforts.

CMS is also proposing to require the submission of a diagnosis code on the 837D dental claims format beginning January 1, 2025. Both the statute and our regulations require the submission of a diagnosis code on claims for physician services. However, this requirement has not been specifically addressed in the context of the 837D dental claims format. Therefore, we are proposing that a diagnosis code would be required on claims for dental services inextricably linked to covered medical services submitted via the 837D dental claims format. We are considering using enforcement discretion for the required diagnosis code on the 837D form for a limited time in order to support clinicians and billing entities as they work to change their workflows to include dental claims form for the submission of claims for dental services inextricably linked to covered services.

CMS is also including a request for information regarding services associated with furnishing oral appliances used for the treatment of obstructive sleep apnea. We are seeking comment on whether oral sleep apnea appliances can be rented and used by successive patients and therefore should be classified as durable medical equipment, or if they should potentially be considered as supplies incident to a physician service, when furnished by dentists. We are also requesting information regarding the information needed to describe the furnishing of this appliance and related services under the Medicare Physician Fee Schedule.

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

Care Coordination Services in RHCs and FQHCs

We are proposing several changes related to reporting care coordination services in RHCs and FQHCs to better align payment to RHCs and FQHCs for these services with other entities furnishing this kind of care. Specifically, we are proposing that starting in 2025, RHCs and FQHCs would report the individual CPT and HCPCS codes that describe care coordination services instead of the single HCPCS code G0511.We are also proposing to permit billing of the add-on codes associated with these services. This will improve payment accuracy for RHCs and FQHCs when furnishing these services and will allow beneficiaries to better understand which services (generally not furnished face-to-face) they are receiving. For 2025, we are also proposing to adopt the coding and policies regarding Advanced Primary Care Management services for RHC and FQHC payment. Under these proposals, payment to RHCs and FQHCs would be made at the national non-facility PFS amounts when the individual code is on an RHC or FQHC claim, either alone or with other payable services and the payment rates. We would pay for these services in addition to the RHC AIR or FQHC PPS. Payment rates would be updated annually based on the PFS amounts for these codes.

We are also seeking comment on the payment policy for care coordination services to gather feedback on how we can improve the transparency and predictability regarding which HCPCS codes are eligible for this policy.

Telecommunication Services in RHCs and FQHCs

We are proposing to continue to allow direct supervision via interactive audio and video telecommunications and to extend the definition of “immediate availability” as including real-time audio and visual interactive telecommunications (excluding audio-only) through December 31, 2025.

We are proposing to allow payment, on a temporary basis, for non-behavioral health visits furnished via telecommunication technology. Under the proposal, RHCs and FQHCs would continue to bill for RHC and FQHC services furnished using telecommunication technology services by reporting HCPCS code G2025 on the claim, including services furnished using audio-only communications technology through December 31, 2025.

We are proposing to continue to delay the in-person visit requirement for mental health services furnished via communication technology by RHCs and FQHCs to beneficiaries in their homes until January 1, 2026.

Intensive Outpatient Program Services (IOP) in RHCs and FQHCs

We are proposing to provide a different payment rate when four or more services per day in the RHC and FQHC setting compared to the current payment amount based on only three services. Although we previously stated we would evaluate these services further before establishing differential payment, we believe that we should provide parity for IOP services across the various settings while continuing to monitor access to these services. We are also proposing to align with the four or more services per day payment rate for hospital outpatient departments, which will be updated annually.

Payment for Preventive Vaccine Costs in RHCs and FQHCs

We are proposing to allow RHCs and FQHCs to bill and be paid for Part B preventive vaccines and their administration at the time of service. We propose that payments for these claims will be made according to Part B preventive vaccine payment rates in other settings, to be annually reconciled with the facilities' actual vaccine costs on their cost reports. Due to the operational systems changes needed to facilitate payment through claims, we propose that RHCs and FQHCs begin billing for preventive vaccines and their administration at the time of service, for dates of service beginning on or after July 1, 2025. The intent of this proposal is to improve the timeliness of payment for critical preventive vaccine administration in RHCs and FQHCs.

Clarification for Dental Services Furnished in RHCs and FQHCs

In this proposed rule, we discuss alignment between the policies for dental services furnished in the physician office that are inextricably linked to certain covered services and when these services are furnished in RHCs and FQHCs. We are clarifying that in those scenarios, we would consider those services to be RHC and FQHCs services and paid under the RHC All-Inclusive Rate (AIR) methodology and FQHC PPS, respectively. We also would align with any operational requirements, including the submission of the KX modifier.

Rural Health Clinics and Federally Qualified Health Centers Conditions for Coverage

CMS is proposing changes to the RHC Conditions for Certification and the FQHC Conditions for Coverage to increase flexibility and, decrease burden for these providers and improve access to services for patients.

First, we are proposing to explicitly require that RHCs and FQHCs provide primary care services rather than being "primarily engaged" in furnishing these services as indicated in the sub-regulatory guidance. This proposal more closely aligns with the intent of the statute while also preserving access to primary care services in communities served by RHCs and FQHCs, particularly in rural areas. This proposal would not prevent RHCs or FQHCs from providing or continuing to provide specialty services; rather, it would clarify that RHCs and FQHCs must provide primary care services.

Second, CMS is proposing to remove hemoglobin and hematocrit (H&H) from the listed laboratory services that RHCs must perform directly. Typically, H&H levels are not ordered as standalone tests but as a part of a larger test panel completed at an offsite laboratory. As a result, RHCs report the test ordered infrequently, if at all. By removing this requirement, CMS aims to decrease the burden associated with purchasing and maintaining the laboratory equipment needed to process these tests. Alleviating this burden will allow RHCs to focus their resources on more frequently ordered tests and services, thereby improving overall efficiency and patient care. CMS is also proposing to update the regulations text for laboratory tests in RHCs to reflect modern lab techniques.

Medicare Part B Payment for Preventive Services

For CY 2025, we are addressing two items related to coverage and payment of the hepatitis B vaccine and its administration under Part B. Hepatitis B is a vaccine-preventable, communicable disease of the liver. In this proposed rule, we propose to expand coverage of hepatitis B vaccinations by covering individuals who have not previously received a completed hepatitis B vaccination series or whose vaccination history is unknown. This proposal will help protect

Medicare beneficiaries from acquiring hepatitis B infection and contribute to eliminating viral hepatitis as a viral health threat in the United States.

If the proposed coverage expansion of hepatitis B vaccines under Part B is finalized, we clarify that a physician's order would no longer be required for the administration of a hepatitis B vaccine in Part B, which would facilitate roster billing by mass immunizers for hepatitis B vaccine administration. We also propose that payment for hepatitis B vaccines and their administration be made at 100% of reasonable cost in RHCs and FQHCs, separate from payment under the FQHC PPS or the RHC All-Inclusive Rate (AIR) methodology, in order to streamline payment for all Part B vaccines in those settings.

We are also proposing a fee schedule for Drugs Covered as Additional Preventive Services (DCAPS drugs), per section 1833(a)(1)(W)(ii) of the Act. CMS has not yet covered or paid for any drugs under the benefit category of additional preventive services. On July 12, 2023, CMS released a Proposed NCD for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention, which proposes to cover HIV PrEP drugs under Part B as additional preventive services.

We propose to determine a payment limit for DCAPS drugs according to the ASP methodology set forth in section 1847A of the Act when ASP data is available, and we propose alternative payment mechanisms for calculating payment limits for DCAPS drugs if ASP data is not available. We also propose payment limits for the supplying and administration of DCAPS drugs that are similar to those fees for drugs paid in accordance with the ASP methodology set forth in section 1847A of the Act. Finally, we propose to use this same fee schedule for DCAPS drugs and any administration and supplying fee when those services are provided in RHCs and FQHCs. In RHCs and FQHCs, DCAPS drugs and any administration and supplying fee would be paid at 100% of the Medicare payment amount and would be paid on a claim-by-claim basis.

Expand Colorectal Cancer Screening

We are proposing to update and expand coverage of colorectal cancer (CRC) screening. We are proposing to remove coverage of barium enema as a method of screening. This service is rarely used in Medicare and is no longer recommended as an evidence-based screening method. We are also proposing to expand coverage for CRC screening to include Computed Tomography (CT) Colonography. And finally, we are proposing to expand our approach to a "Complete CRC Screening" finalized in the CY 2023 PFS by adding that either a positive Medicare-covered blood-based biomarker test or non-invasive stool-based test is part of the CRC screening continuum and the follow-on colonoscopy would not incur beneficiary cost-sharing. Our proposal will promote access and remove barriers for much needed cancer prevention and early detection within rural communities and communities of color that are especially impacted by the incidence of CRC.

Medicare Prescription Drug Inflation Rebate Program

The Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169, enacted August 16, 2022) established new requirements under which drug companies must pay inflation rebates if they raise their prices for certain Part B and Part D drugs faster than the rate of inflation. In this proposed rule, CMS is proposing to codify policies established in the revised guidance for the Medicare Part B Drug Inflation Rebate Program and Medicare Part D Drug Inflation Rebate

Program[1] (collectively referred to as the “Medicare Prescription Drug Inflation Rebate Program”). Additionally, CMS is proposing policies that include, but are not limited to, the following:

- Establishing the method and potential data sources to remove 340B units from the total number of units used to calculate the total rebate amount for a Part D rebatable drug.
- Establishing the method and process for reconciliation of a rebate amount for Part B and Part D rebatable drugs, including the circumstances that may trigger such a reconciliation.
- Clarifying rebate calculations for Part B and Part D rebatable drugs in specific circumstances, including exclusion of Part B units of single-dose container or single-use package drugs subject to discarded drug refunds.