Fact Sheets Nov 01, 2024

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

Medicare Parts A & B

On November 1, 2024, the Centers for Medicare & Medicaid Services (CMS) issued a rule finalizing changes for Medicare payments under the PFS and other Medicare Part B policies, effective on or after January 1, 2025.

The CY 2025 PFS final rule is one of several final 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 an office setting, Medicare makes payments to physicians and other practitioners 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, such as 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.

CY 2025 PFS Rate Setting and Conversion Factor

By factors specified in law, average payment rates under the PFS will be reduced by 2.93% in CY 2025, compared to the average

amount these services were paid for most of CY 2024. The change to the PFS conversion factor incorporates the 0% overall update required by statute, the expiration of the temporary 2.93% increase in payment for CY 2024 required by statute, and a relatively small estimated 0.02% adjustment necessary to account for changes in work relative value units (RVUs) for some services. This amounts to an estimated CY 2025 PFS conversion factor of $32.35, a decrease of $0.94 (or 2.83%) from the current CY 2024 conversion factor of $33.29.

Caregiver Training Services (CTS)

For CY 2025, we are finalizing our proposal to establish new coding and payment for caregiver training for direct care services and supports. The topics of trainings can include, but would not be limited to, techniques to prevent decubitus ulcer formation, wound care, and infection control. We are also finalizing our proposal to establish new coding and payment for caregiver behavior management and modification training that can be furnished to the caregiver(s) of an individual patient. We are also finalizing a policy to allow these 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)

In the CY 2025 PFS proposed rule, we issued a broad request for information (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 requested information on other factors for us to consider, such as other types of auxiliary personnel (including clinical social workers) and other certification and training requirements that are not adequately captured in current coding and payment for these services, and how to improve utilization in rural areas. We also

sought comment about how these codes are being furnished in conjunction with community-based organizations. We received many detailed comments in response to this RFI, which we summarize in the final rule and may consider for future rulemaking.

Office/Outpatient (O/O) Evaluation and Management (E/M) Visits

For CY 2025, we are finalizing our proposal to allow payment of the O/O E/M visit complexity add-on code, Healthcare Common Procedure Coding System (HCPCS) code G2211, when the O/O E/M base code — Current Procedural Terminology (CPT) codes 99202-99205, 99211-99215 — is reported by the same practitioner on the same day as an annual wellness visit (AWV), vaccine administration, or any Medicare Part B preventive service, including the Initial Preventive Physical Examination (IPPE), furnished in the office or outpatient setting.

Telehealth Services under the PFS

Absent Congressional action, beginning January 1, 2025, the statutory limitations that were in place for Medicare telehealth services prior to the COVID-19 PHE will retake effect for most telehealth services. These include geographic and location restrictions on where the services are provided, and limitations on the scope of practitioners who can provide Medicare telehealth services. However, the final rule reflects CMS' goal to preserve some important, but limited, flexibilities in our authority, and expand the scope of and access to telehealth services where appropriate.

For CY 2025, we are finalizing our proposal to add several services to the Medicare Telehealth Services List, including caregiver training services on a provisional basis and PrEP counseling and safety planning interventions on a permanent basis. We are finalizing to continue the suspension of frequency limitations for subsequent inpatient visits, subsequent nursing facility visits, and

critical care consultations for CY 2025.

We are finalizing that beginning January 1, 2025, an interactive telecommunications system may include two-way, real-time, audio-only communication technology for any Medicare 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 finalizing that, through CY 2025, we will continue to permit distant site practitioners to use their currently enrolled practice locations instead of their home addresses when providing telehealth services from their home.

We are finalizing, 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 supervising physician or practitioner to provide such supervision via a virtual presence through real-time audio and visual interactive telecommunications. We are specifically finalizing to make permanent that the supervising physician or practitioner may provide such virtual direct supervision (1) for services furnished incident to a physician or other practitioner's professional service, when provided by auxiliary personnel employed by the billing physician or supervising practitioner and working under his or her direct supervision, and for which the underlying HCPCS code has been assigned a PC/TC indicator of "5" and services described by CPT code 99211, and (2) for office or other outpatient visits 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 incident that require the direct supervision of the physician or other supervising practitioner, we are finalizing to continue to permit direct supervision be provided through real-time audio and visual interactive telecommunications technology only through

December 31, 2025.

We are finalizing a policy to continue 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 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.

Advanced Primary Care Management Services (APCM)

A strong foundational primary care system is fundamental to improving health outcomes, lowering mortality, and reducing health disparities, which is why the Department of Health and Human Services has been taking action to strengthen primary care, including establishing coding and payment for advanced primary care management services in the CY 2025 PFS final rule.

For CY 2025, we are finalizing our proposal to establish coding and payment under the PFS for a new set of APCM services described by three new HCPCS G-codes (G0556, G0557, G0558). The finalized APCM services incorporate elements of several existing care management and communication technology-based services into a bundle of services that reflects the essential elements of the delivery of advanced primary care, including Principal Care Management, Transitional Care Management, and Chronic Care Management. However, unlike existing care management codes, there are no time-based thresholds included in the service elements, which is intended to reduce the administrative burden associated with current coding and billing. Instead, the new APCM codes are stratified into three levels based on an individual's number of chronic conditions and status as a Qualified Medicare Beneficiary, reflecting the patient's medical and social complexity.

Level 1 (G0556) is for persons with one chronic condition; Level 2 (G0557) is for persons with two or more chronic conditions; and Level 3 (G0558) is for persons with two or more chronic conditions and status as a Qualified Medicare Beneficiary.

This new finalized coding and payment makes use of lessons learned from the CMS Innovation Center's testing of a series of advanced primary care models, such as Comprehensive Primary Care Plus (CPC+) and Primary Care First (PCF), to inform the service elements and practice-level capabilities of APCM services. The code requirements that we are finalizing include consent, initiating visit, 24/7 access and continuity of care, comprehensive care management, patient-centered comprehensive care plan, management of care transitions, care coordination, enhanced communication, population-level management, and performance measurement. In addition, we are finalizing that for MIPS eligible clinicians, the performance management service element can be satisfied by reporting the Value in Primary Care MIPS Value Pathway (MVP), as it was developed to include quality measures that reflect clinical actions that are indicative of high-quality primary care. Reporting for the MVP would begin in 2026 based on the 2025 performance year.

CMS received many comments recommending increased valuation of the codes, and CMS may revisit the valuation for all of these services in future rulemaking. After consideration of the comments, CMS is finalizing an increase in the valuation for the Level 1 code (HCPCS code G0556). Beginning January 1, 2025, physicians and non-physician practitioners (NPPs) who use an advanced primary care model of care delivery as described by the service elements of the APCM codes could bill for APCM services when they are the continuing focal point for all needed health care services and responsible for all the patient's primary care services. This new finalized coding and payment better recognizes and describes advanced primary care services, encourages primary care practice transformation, helps ensure that patients have

access to high quality primary care services, and simplifies billing and documentation requirements, as compared to existing care management and communication technology-based services codes. The finalized codes also represent a step towards paying for primary care services with hybrid payments (a mix of encounter and population-based payments) to support longitudinal relationships between primary care providers and beneficiaries, by paying for care in larger units of service, and also help drive accountable care. A practitioner who is participating in a Shared Savings Program ACO, a Realizing Equity, Access, and Community Health ACO (REACH ACO), a Primary Care First practice, or a Making Care Primary practice may satisfy requirements for these codes by virtue of meeting requirements under the Shared Savings Program or Innovation Center model.

We sought comment from interested parties through an Advanced Primary Care Hybrid Payment RFI on whether and how we should consider additional payment policies that recognize the delivery of advanced primary care services, and we will take these comments into consideration for 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 among 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 finalizing coding and payment for an Atherosclerotic Cardiovascular Disease (ASCVD) risk assessment service and risk management services. The ASCVD risk assessment will 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 includes 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 finalizing 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 intermediate, medium, or high risk in the next 10 years for CVD.

Behavioral Health Services

In this rule, CMS is finalizing 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 finalizing 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 finalizing payment for a G-code that may be billed in 20-minute increments when safety planning interventions are personally performed by the billing practitioner in a variety of settings. Additionally, we are finalizing payment for a monthly billing code 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, CMS worked with the U.S. Food & Drug Administration (FDA) and is also finalizing Medicare payment for digital mental health treatment devices, cleared under section 510(k) of the Federal Food, Drug and Cosmetic Act or granted de no novo authorization by FDA and classified under 21 CFR 882.580 furnished incident to professional

behavioral health services, used in conjunction with ongoing behavioral health care treatment under a behavioral health treatment plan of care. CMS is finalizing three new HCPCS codes to describe these services and will monitor how digital mental health treatment devices are used as part of overall behavioral health care. We are also finalizing 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), that mirror current interprofessional consultation CPT codes used by practitioners who are eligible to bill E/M visits.

Lastly, we summarize comments received from the comment solicitation on coding and payment for Intensive Outpatient Program (IOP) services under the PFS, as well as Certified Community Behavioral Health Clinics (CCBHCs) and facilities that offer crisis stabilization services and non-emergent, urgent care. We will take these comments into consideration for future rulemaking.

Opioid Treatment Programs (OTPs)

CMS is finalizing several telecommunication technology flexibilities for opioid use disorder (OUD) treatment services furnished by OTPs, so long as all requirements are met, and the use of these technologies are permitted under the applicable Substance Abuse and Mental Health Services (SAMHSA) and the Drug Enforcement Administration (DEA) requirements at the time the services are furnished. First, CMS is making 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 allowing 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 will 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 agree on the best modality for receiving care.

CMS is also finalizing payment increases in response to recent regulatory reforms for OUD treatment finalized by SAMHSA at 42 CFR part 8. Specifically, CMS is updating payment for SDOH risk assessments as part of intake activities within OUD treatment services furnished by OTPs, if medically reasonable and necessary to adequately reflect additional effort for OTPs, to identify a patient's unmet health-related social needs (HRSNs) or the need and interest for harm reduction interventions and recovery support services that are critical to the treatment of an OUD. After consideration of public comments, CMS is also updating payment for periodic assessments to include payment for SDOH risk assessments to reflect additional reassessments that OTPs may conduct throughout treatment, to monitor potential changes in a patient's HRSNs or support services. We believe these updates will help OTPs address key issues, during initial and periodic assessments, that may increase the risk of a patient leaving OUD treatment prematurely or that pose barriers to treatment engagement.

In the proposed rule, CMS requested information to understand how OTPs currently coordinate care and make referrals to community-based organizations that address unmet HRSNs, provide harm reduction services, and/or offer recovery support services. After receiving detailed, supportive comments of these integral activities in OTP settings, CMS is finalizing new add-on codes to account for coordinated care and referral services, patient navigational services, and peer recovery support services. Establishing payment for these services can support OTPs in coordinating with community-based organizations to address various patient needs across the continuum of care, and directly

provide or refer patients to navigational and/or peer recovery support services to assist patients in navigating multiple care settings and meeting MOUD treatment and recovery goals.

CMS is finalizing payment for new opioid agonist and antagonist medications approved by the FDA. First, CMS is finalizing a new add-on code for nalmefene hydrochloride nasal spray, indicated for the emergency treatment of known or suspected opioid overdose. CMS is also finalizing payment for a new injectable buprenorphine product via (1) a new weekly bundled payment code for the weekly formulation of the new injectable buprenorphine product, and (2) including payment for the monthly formulation of the new injectable buprenorphine product 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.

Hospital Inpatient or Observation (I/O) Evaluation and Management (E/M) Add-On for Infectious Diseases

For CY 2025, we are finalizing a new HCPCS add-on code to describe the intensity and complexity inherent to hospital inpatient or observation care, associated with a confirmed or suspected infectious disease, performed by a practitioner with specialized training in infectious diseases. The new HCPCS add-on code describes service elements, including disease transmission risk assessment and mitigation, public health investigation, analysis, and testing, and complex antimicrobial therapy counseling and treatment.

Strategies for Improving Global Surgery Payment Accuracy

For CY 2025, we are finalizing a policy to broaden the applicability of the transfer of care modifier 54, for all 90-day global surgical packages (global packages), in any case when a practitioner

expects to furnish only the surgical procedure portion of the global package, including but not limited to when there is a formal, documented transfer of care as under current policy or an informal, non-documented but expected, transfer of care.

This finalized policy will improve payment accuracy for these 90-day global package services and is expected to inform CMS about how global package services are typically furnished. For CY 2025, we are also finalizing a new add-on code, HCPCS code G0559, for post-operative care services furnished by a practitioner other than the one who performed the surgical procedure (or another practitioner in the same group practice). This add-on code will more appropriately reflect the time and resources involved in these post-operative follow-up visits by practitioners who were not involved in furnishing the surgical procedure.

Supervision Policy for Physical Therapists (PTs) and Occupational Therapists (OTs) in Private Practice

For CY 2025, we are finalizing a regulatory change to allow for general supervision of physical therapist assistants (PTAs) and occupational therapy assistants (OTAs) by PTs in private practice (PTPPs) and OTs in private practice (OTPPs) for all applicable physical and occupational therapy services. This finalized change will give PTPPs and OTPPs more flexibility in meeting the needs of beneficiaries and safeguard patient access to medically necessary therapy services, including those experiencing challenges accessing these services in rural and underserved areas, and it will align with general supervision of PTAs and OTAs by PTs and OTs who work in institutional providers.

Certification of Therapy Plans of Treatment with a Physician or NPP Order

For CY 2025, CMS is finalizing amendments to the certification regulations to lessen the administrative burden for therapists (PTs, OTs, and speech-language pathologists (SLPs)) and

physician/NPPs. These changes will provide an exception to the physician/NPP signature requirement on the therapist-established treatment plan for purposes of the initial certification, in cases where a written order or referral from the patient's physician/NPP is on file and the therapist has documented evidence that the treatment plan was transmitted to the physician/NPP within 30 days of the initial evaluation. CMS also solicited comment, as suggested by interested parties, as to the need for a regulation to address the amount of time during which the physician/NPP who signed the written order for therapy services could make changes to the therapist-established treatment plan by contacting the therapist directly, but CMS did not adopt such a timeline restriction. Instead, CMS clarified that, for the cases meeting the exception to the signature requirement policy, payment should be made available for any therapy services furnished prior to a physician/NPP-modified treatment plan if all payment requirements are met. The comment solicitation as to whether there should be a 90-day (or other) limit to the physician/NPP order extending from the order date to the first date of treatment/evaluation by the therapist did not result in a policy being adopted by CMS.

Dental and Oral Health Services

We are finalizing our proposal 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, or contemporaneously with, Medicare-covered dialysis services for the treatment of 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 the treatment of 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 also solicited 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 received many comments, which we considered and continue to engage with interested parties in clarifying definitions. We remain committed to exploring the inextricable link between dental and medical services associated with these chronic conditions.

CMS is also finalizing two policies related to billing of dental services inextricably linked to covered services. Effective July 1, 2025, we will require the submission of the KX modifier on claims for dental services that clinicians believe to be inextricably linked to covered medical services. We believe that the required usage of the KX modifier will support claims processing and program integrity efforts and that the delay provides time for any testing and education needed for implementation.

CMS is also finalizing our proposal to require the submission of a diagnosis code on the 837D dental claims format beginning July 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 finalizing that a diagnosis code will be required on claims for dental services inextricably linked to covered medical services submitted via the 837D dental claims format.

Drugs and Biological Products Paid Under Medicare Part B

Requiring Manufacturers of Certain Single-dose Container or

Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts

In rulemaking over the last few years, we finalized many policies to implement section 90004 of the Infrastructure Investment and Jobs Act, which established a refund for discarded amounts of certain single-dose container or single-use package drugs under Part B. We are finalizing clarifications to several policies implemented in the CY 2023 and CY 2024 PFS final rules, including: exclusions of drugs, for which payment has been made under Part B for fewer than 18 months, from the definition of refundable single-dose container or single-use package drug, and identifying single-dose containers. We are also finalizing a requirement that the JW modifier must be used if a billing supplier is not administering a drug, but there are amounts discarded during the preparation process before supplying the drug to the patient. Finally, we are finalizing that skin substitutes will not be included in the identification of refundable drugs for the calendar quarters in 2025.

Approach to Payment Limit Calculations when Negative or Zero Average Sales Price (ASP) Data Is Reported to CMS

CMS is finalizing an approach to how it will calculate payment limits when manufacturers report negative or zero ASP data to CMS. Generally, we are finalizing a policy that negative and zero ASP data is considered “not available” under section 1847A(c)(5)(B) of the Act and that positive ASP data is considered available. The finalized policies to determine a payment limit when ASP data is not available vary based on factors about the drug or biological, such as whether the drug is single source or multiple source; whether some, but not all National Drug Codes (NDCs) for a billing and payment code have a negative or zero ASP data, or all NDCs for a billing and payment code have a negative or zero ASP data; and whether relevant applications for all NDCs for a billing and payment code have a marketing status of discontinued.

Altogether, CMS is finalizing its policies for calculating the payment limit when a manufacturer reports negative or zero ASP data for a drug, with a modification relating to biosimilars, such that the finalized payment limit calculation will use the biosimilar's own, most recently available, positive manufacturer's ASP data.

Payment for Radiopharmaceuticals in the Physician Office Setting

In an effort to provide clarity on which methodologies are available to Medicare Administrative Contractors (MACs) for pricing of radiopharmaceuticals in the physician office setting, CMS is finalizing a clarification that, for radiopharmaceuticals furnished in a setting other than a hospital outpatient department, MACs shall determine payment limits for radiopharmaceuticals based on any methodology used to determine payment limits for radiopharmaceuticals in place on or prior to November 2003. Such methodology may include, but is not limited to, the use of invoice-based pricing.

Immunosuppressive Therapy

Because some people rely on compounded immunosuppressive drugs for maintenance therapy, we are finalizing revisions to regulations to include certain compounded formulations of FDA-approved drugs that have approved immunosuppressive indications in the immunosuppressive drug benefit, or for use in conjunction with immunosuppressive drugs, or that have been determined by a MAC to be reasonable and necessary to prevent or treat rejection of a transplanted organ or tissue. Specifically, we are finalizing inclusion of certain compounded formulations that are orally or enterally administered. In addition, we are finalizing two changes regarding supplies of immunosuppressive drugs to align with current standards of practice and reduce barriers to medication adherence: to allow payment of a supplying fee for a prescription of a supply of up to 90 days and to allow payment for refills of prescriptions for these immunosuppressive

drugs.

Blood Clotting Factors

Blood clotting factor treatments are covered under Medicare Part B, whether the treatment is self-infused or provided in the physician office setting. Clotting factor furnishing fees are paid when self-infused products are furnished to beneficiaries. In contrast, when clotting factor is administered in health care settings, administration fees are paid, reflecting the resources involved in administering the product.

Additionally, gene therapies have recently been FDA-approved for the treatment of hemophilia. These gene therapies for hemophilia are not administered by the patient in his or her home, but rather are typically administered via a one-time, single dose intravenous infusion in a setting where personnel and equipment are immediately available to treat infusion-related reactions. These gene therapies treating hemophilia are not clotting factors themselves; rather, they are genetic treatments that enable the body to produce its own clotting factors. Because gene therapies are not themselves clotting factors, they are not eligible for the clotting factor furnishing fee. We note that they are eligible for the administration fee. We also clarify this policy in this final rule.

Accordingly, we are finalizing an update to regulatory text to clarify existing CMS policy that blood clotting factors must be self-administered and must not be therapies that enable the body to produce clotting factors and do not directly integrate into coagulation cascade to be considered clotting factors for which the furnishing fee applies.

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

Care Coordination Services in RHCs and FQHCs

We are finalizing 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 similar care coordination. Specifically, we are finalizing with a modification to our proposal, a policy that, starting in 2025, RHCs and FQHCs will report the individual CPT and HCPCS codes that describe care coordination services instead of the single HCPCS code G0511. We are also allowing for a transition period of six-months, to at least until July 1, 2025, to enable those RHCs/FQHCs to be able to update their billing systems. We are also finalizing a policy that permits 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 adopting the coding and policies regarding APCM services for RHC and FQHC payments. Under these finalized rules, payments 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 payment rates. We would pay for these services in addition to the RHC All-Inclusive Rate (AIR) or FQHC prospective payment system (PPS). Payment rates would be updated annually based on the PFS amounts for these codes. RHCs and FQHCs, not eligible for MIPS, are not required to report the Value in Primary Care MVP to meet the performance measurement requirement.

We also sought 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, and we plan to evaluate the comments received for potential future rulemaking.

Telecommunication Services in RHCs and FQHCs

We are finalizing a policy clarification 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 also finalizing a policy to allow payment, on a temporary basis, for non-behavioral health visits furnished via telecommunication technology under the methodology that has been in place for these services during and after the COVID-19 PHE through December 31, 2024. Specifically, under our finalized policy, RHCs and FQHCs can continue to bill for RHC and FQHC services furnished using telecommunication technology by reporting HCPCS code G2025 on the claim, including services furnished using audio-only communications technology through December 31, 2025. For payment for non-behavioral health visits furnished via telecommunication technology in CY 2025, we will calculate the payment amount based on the average amount for all PFS telehealth services on the telehealth list, weighted by volume for those services reported under the PFS.

We are finalizing a continued policy 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 finalizing a new payment rate when four or more services per day in the RHC and FQHC setting, in addition to the current payment amount based on only three services. We are also aligning the four or more IOP services per day payment rate with the same payment rate for four or more IOP services in hospital outpatient departments, which will be updated annually.

Payment for Preventive Vaccine Costs in RHCs and FQHCs

We are allowing RHCs and FQHCs to bill and be paid for Part B preventive vaccines and their administration at the time of service. We are finalizing 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 are finalizing that RHCs and FQHCs begin billing for preventive vaccines and their administration at the time of service, effective for dates of service beginning on or after July 1, 2025. The intent of this policy 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

We are clarifying that when RHCs and FQHCs furnish dental services inextricably linked to other covered medical services we would consider those services to be RHC and FQHCs services and paid under the RHC AIR methodology and FQHC PPS, respectively. We are also aligning operational requirements, including the submission of the KX modifier effective July 1, 2025. Finally, we clarify that a dental service can be billed separately from a medical visit provided on the same day, provided the dental service is inextricably linked to other covered medical services.

RHC Productivity Standards

RHCs are currently subject to productivity standards that can impact the AIR, if the productivity standards are not met. Productivity standards were first established in 1978 and updated in 1982 to help determine the average cost per patient for Medicare payment in RHCs as a cost control mechanism. Section 130 of the CAA, 2021, restructured the payment limits for RHCs beginning April 1, 2021. We believe that the productivity standards are outdated and redundant with the CAA, 2021 provisions; therefore, we are finalizing to remove these standards effective for cost reporting periods beginning on or after January 1, 2025.

Rebasing and Revising of the FQHC Market Basket

Approximately every four years, CMS rebases and revises the FQHC market basket used to update FQHC PPS payments to

reflect more recent data on FQHC cost structures. CMS last rebased and revised the FQHC market basket in the CY 2021 PFS rule, where CMS adopted a 2017-based FQHC market basket. For CY 2025, CMS is finalizing to rebase and revise the FQHC market basket to reflect a 2022 base year and include changes to the market basket cost weights and price proxies. We are also finalizing to continue to apply a productivity adjustment to the 2022-based FQHC market basket percentage increase.

The final CY 2025 FQHC market basket update is 3.4%. This reflects a 4.0% increase in the 2022-based FQHC market basket, reduced by a 0.6 percentage point productivity adjustment.

RHC Conditions for Certification

CMS is finalizing changes to the RHC Conditions for Certification to increase flexibility and decrease provider burden, while also improving access to services for patients. Specifically, CMS is finalizing the proposal to explicitly require that RHCs must provide primary care services rather than being “primarily engaged” in furnishing these services, as indicated in the subregultory guidance. The revised language more closely aligns with the intent of the statute while also preserving access to primary care services in communities served by RHCs.

Additionally, CMS is finalizing the removal of “hemoglobin and hematocrit (H&H)” and “examination of stool specimens for occult blood” from the list of laboratory services that RHCs must perform directly in the regulatory text. By finalizing the removal of these requirements, CMS anticipates facilities will see a decrease in the burden associated with purchasing and maintaining the laboratory equipment and having qualified staff needed to process these tests. Alleviating these burdens will allow RHCs to focus their resources on the other services they provide, thereby, improving overall efficiency and patient care. Lastly, CMS is also finalizing updates to the regulations text for laboratory tests in RHCs to reflect modern lab techniques.

Ambulance Fee Schedule Reimbursement for Prehospital Blood Transfusion (PHBT)

For CY 2025, we are finalizing our proposal to modify the definition of ALS2 at §414.605 by adding the administration of PHBT, which now includes low titer O+ and O- whole blood transfusion therapy (WBT), packed red blood cells (PRBCs), plasma, or a combination of PRBCs and plasma. A ground ambulance transport that provides one of these PHBTs would itself constitute an ALS2 level transport.

Medicare Part B Payment for Preventive Services

For CY 2025, we are addressing two issues 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 final rule, we are expanding coverage of hepatitis B vaccinations to include individuals who have not previously received a completed hepatitis B vaccination series or whose vaccination history is unknown. This policy expansion 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.

In this rule, we clarify that a physician's order will no longer be required for the administration of a hepatitis B vaccine under Part B, which will facilitate roster billing by mass immunizers for hepatitis B vaccine administration. Additionally, we are finalizing a policy to set payment for hepatitis B vaccines and their administration 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 finalizing 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. CMS is finalizing policies that specify how a payment limit will be determined for DCAPS drugs. That is, we will set a payment limit according to the ASP methodology set forth in section 1847A of the Act when ASP data is available and will use alternative payment mechanisms for calculating payment limits for DCAPS drugs if ASP data is not available. We are also finalizing that we will set 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 will 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 will be paid at 100% of the Medicare payment amount and will be paid on a claim-by-claim basis.

On September 30, 2024, CMS released a national coverage determination(NCD) for Pre-Exposure Prophylaxis (PrEP) to Prevent Human Immunodeficiency Virus (HIV), which established coverage of HIV PrEP drugs under Part B as additional preventive services. PrEP for HIV drugs will therefore be paid under the DCAPS fee schedule effective January 1, 2025. More information can be found at https://www.cms.gov/medicare/coverage/prep.

Expand Colorectal Cancer Screening

We are finalizing an update and expansion of coverage of colorectal cancer (CRC) screening. We are removing coverage of barium enema as a method of screening because this service is rarely used in Medicare and is no longer recommended as an evidence-based screening method. We are also expanding coverage for CRC screening to include computed tomography colonography (CTC). Finally, we are adding Medicare covered blood-based biomarker CRC screening tests as part of the continuum of screening. Like stool-based CRC screening tests, which are already in the definition of a “complete CRC Screening,”

a blood-based biomarker test with a positive result will lead to a follow-on screening colonoscopy (with no beneficiary cost-sharing). We are also revising the regulation text to clarify that CRC screening frequency limitations do not apply to the follow-on screening colonoscopy in the context of "complete CRC screening." These actions 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 final rule, CMS is codifying 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 finalizing policies that include, but are not limited to, the following:

- 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.
- Establishing a civil money penalty process for when a manufacturer of a Part B rebatable drug or Part D rebatable drug fails to pay the rebate amount in full by the payment deadline for such drug, for such applicable calendar quarter or applicable period, respectively.
- 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.

CMS also stated in the final rule that it will explore establishing a Medicare Part D claims data repository to comply with the statutory obligation for removal of 340B units from Part D drug inflation rebate calculations, starting January 1, 2026. CMS plans to continue exploring the development of detailed policies and requirements related to any such repository for future rulemaking, related to this topic and the exclusion of 340B units, starting January 1, 2026.

Electronic Prescribing for Controlled Substances (EPCS) for a Covered Part D Drug Under a Prescription Drug Plan or a Medicare Advantage Prescription Drug Plan

We are finalizing our proposal to extend the date after which prescriptions written for a beneficiary in a long-term care (LTC) facility would be included in determining the CMS EPCS Program compliance, from January 1, 2025, to January 1, 2028, and that related non-compliance actions would commence on or after January 1, 2028. EPCS improves prescriber workflow, thus, it reduces prescriber burden and increases patient safety. We are aligning CMS EPCS Program compliance calculations to the date by which the new NCPDP SCRIPT standard version 2023011, which includes three-way communication functionality that improves communication between pharmacies and LTC facilities, is required for prescribers when electronically transmitting prescriptions and prescription-related information for covered Part D drugs for Part D eligible individuals.

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[1] Medicare Part B Drug Inflation Rebate Revised Guidance: *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-revised-guidance.pdf*; Medicare Part D Drug Inflation Rebate Revised Guidance: *https://www.cms.gov/files/document/medicare-part-d-*

inflation-rebate-program-revised-guidance.pdf collectively referred to as the "revised guidance." These revised guidance documents, published December 14, 2023, implemented policies relating to the Medicare Prescription Drug Inflation Rebate Program for 2022, 2023, and 2024. CMS also published guidance on the use of the 340B modifier to report separately payable Part B drugs and biologicals acquired under the 340B program (Revised Part B Inflation Rebate Guidance: Use of the 340B Modifier, *https://www.cms.gov/files/document/revised-part-b-inflation-rebate-340b-modifier-guidance.pdf*.

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