799 9th Street NW
Suite 210
Washington, DC 20001

T (202) 354-2600
vizientinc.com

Vizient Office of Public Policy and Government Relations

Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments

August 2, 2024

Background & Summary

On July 10, the Centers for Medicare & Medicaid Services (CMS) issued the annual proposed rule to update the Calendar Year (CY) 2025 Medicare payment and policies for the Physician Fee Schedule (PFS) (hereinafter, "Proposed Rule"). The Proposed Rule revises payment polices under the Medicare PFS and makes other policy changes, including changes related to telehealth services, certain evaluation and management (E/M) services, advanced primary care management services, and global surgery payments, in addition to implementation of certain provisions of the Inflation Reduction Act. The PFS Addenda, along with supporting documents and tables referenced in the Proposed Rule, are available on the CMS website. The Proposed Rule also includes changes to the Quality Payment Program (QPP) and the Medicare Shared Savings Program (MSSP).

Comments are due **September 9, 2024**, and most sections would go into effect January 1, 2025. Vizient looks forward to working with members to inform our comments to CMS.

Calculation of the Proposed CY 2025 PFS Conversion Factor

There are three components that must be considered to value each service under the PFS – work, practice expense (PE), and malpractice (MP) relative value units (RVUs). Each component is adjusted by geographic price cost indices (GPCIs), which reflect variations in the costs of furnishing services compared to the national average cost for each component. Then, the RVUs are converted to dollar amounts via the application of a conversion factor (CF), which is calculated by CMS's Office of the Actuary (OACT). Finally, the Medicare PFS payment amount (based on the below formula) for a given service and fee schedule area is calculated based on the previously discussed metrics.

PFS Payment = [(WorkRVU x WorkGPCI) + (PE RVU x PE GPCI) + (MP RVU x MP GPCI)] x CF

For CY 2025, the proposed CF is $32.3562, which is a decrease of approximately 2.80 percent from the 2024 CF. This decline is largely driven by the December 31, 2024 expiration of a 2.93 percent statutory boost to the CF, as shown in Table 1. The payment impact of the proposed policies by specialty is shown in Table 128 of the Proposed Rule (pg. 1561).

Calculation of the Proposed CY 2025 PFS Conversion Factor		
CY 2024 Conversion Factor		**33.2875**
Conversion Factor without CAA, 2024* (2.93 Percent Increase in CY 2024)		**32.3400**
CY 2025 Statutory Update Factor	0.00 percent (1.0000)	
CY 2025 RVU Budget Neutrality Adjustment	0.05 percent (1.0005)	
CY 2025 Conversion Factor		**32.3562**

Table 1. Calculation of the CY 2025 PFS Conversion Factor
* CAA, Consolidated Appropriations Act of 2024

Practice Expense Relative Value Units

The PE is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice (MP) expenses. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expenses, and all other expenses. PE RVUs are developed considering the direct and indirect practice resources involved in furnishing a service.

CMS allocates indirect costs at the code level based on the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. In addition, CMS incorporates survey data to determine indirect PEs incurred per hour worked (PE/HR) in developing the indirect portion of the PE RVUs.

Clinical Labor Pricing

In the CY 2022 PFS final rule, CMS finalized a four-year, phased-in policy to update clinical labor pricing for CYs 2022 – 2025. Table 5 (pg. 50) of the Proposed Rule provides the proposed CY 2025 clinical labor pricing information. **CMS welcomes additional feedback regarding clinical labor pricing, including any data that will continue to improve the accuracy of the agency's pricing.**

Development of Strategies for Updates to Practice Expense Data Collection and Methodology

In the CY 2024 PFS proposed rule, CMS solicited public comment on strategies to update the practice expense data collection and methodology. Among other sources, CMS uses the American Medical Association's (AMA's) Physician Practice Information Survey (PPIS) to inform PFS rates. In the Proposed Rule, CMS notes that AMA expects updated analysis, reporting and documentation related to the PPIS to be complete by the end of CY 2024. Despite updated information being available soon, CMS notes that it believes it is important for the agency to consider alternatives that improve the stability and accuracy of the agency's overall PE methodology. As such, CMS has started new work under contract with the RAND Corporation to analyze and develop alternative methods for measuring PE and related inputs for implementation of updates to payment under the PFS. **CMS seeks information regarding scheduled, recurring updates to PE inputs for supply and equipment costs in an effort to improve the stability and predictability of any future updates.**

Medicare Economic Index

The Medicare Economic Index (MEI) reflects the weighted-average annual price change for various inputs involved in furnishing physicians' services. The MEI is a fixed-weight input price index comprised of two broad categories: (1) physicians' own time (compensation); and (2) physicians' practice expense (PE). Additionally, it includes an adjustment for the change in economy-wide, total factor productivity (TFP) (which recently replaced the term multifactor productivity). While the MEI annual percentage change increase is not directly used to update the PFS CF, the MEI cost weights have historically been used to update the GPCI (e.g., weighting the four components of the practice expense GPCI (employee compensation, the office rent, purchased services, and medical equipment, supplies, and other miscellaneous expenses)) and to recalibrate the relativity adjustment to ensure that the total pool of aggregate PE RVUs remains stable relative to the pool of work and MP RVUs.

In CY 2023, CMS finalized a proposal to rebase and revise the MEI to reflect more current market conditions, but the agency delayed implementation of the rebased and revised MEI. In the Proposed Rule, CMS proposes to continue to delay implementation. CMS cites the ongoing data collection and updates to AMA's PPIS and the significant redistributive impacts that MEI updates would have on PFS payments. Consistent with the agency's position in the CY 2024 PFS final rule and given the agency's policy goal to balance PFS payment stability and predictability with incorporating new data through more routine updates to the MEI, CMS is not proposing to incorporate the 2017-based MEI in PFS ratesetting for CY 2025. **CMS invites comments on this approach, as well as any information on the timing of the AMA's practice cost data collection efforts and other sources of data CMS could consider for updating the MEI.**

Medicare Telehealth Services

Several conditions, such as patient eligibility, originating site, scope of distant site practitioners, and communications methods, must be considered before Medicare will make payments for telehealth services under the PFS. Other services involving communications technology (e.g., remote evaluation of recorded video and/or images submitted by an established patient, brief communication technology-based service (CTBS), online assessment and management) are also covered under the PFS, but are different from telehealth services. In the Proposed Rule, CMS proposes several changes related to telehealth services, as outlined below.

CMS maintains a Medicare telehealth services list, where services are assigned either a "permanent" or "provisional"[1] status. For CY 2025, CMS received several requests to permanently add services to the Medicare Telehealth Services List. Table 8 (pg. 93-96) of the Proposed Rule lists the services CMS proposes for addition to the Medicare Telehealth Services List for CY 2025.

Frequency Limitations on Medicare Telehealth Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations

When adding some services to the Medicare Telehealth Services List, CMS includes certain frequency restrictions on how often practitioners may furnish the service via Medicare telehealth (e.g., one subsequent hospital care service furnished through telehealth every 3 days; one subsequent nursing facility visit furnished through telehealth every 14 days; and one critical care consultation service furnished through telehealth per day). During the COVID-19 Public Health Emergency (PHE), CMS temporarily removed these frequency limitations. Although the frequency limitations resumed effect on May 12, 2023 (upon expiration of the PHE), through enforcement discretion, CMS suspended these limitations for certain codes (e.g., Subsequent Inpatient Visit CPT Codes 99231-99233, Subsequent Nursing Facility Visit CPT Codes 99307-99310 and Critical Care Consultation Services HCPCS Codes G0508-G0509) through CY 2024. For CY 2025, CMS proposes to remove the frequency limitations for these codes.

[1] A "provisional" status is assigned if there is not enough evidence to demonstrate that the service is of clinical benefit, but there is enough evidence to suggest that further study may demonstrate such benefit.

Audio-Only Communication Technology to Meet the Definition of "Telecommunications System"

Through regulation, CMS has defined "interactive telecommunications system" as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. During the COVID-19 PHE and through subsequent legislation, through December 31, 2024, audio-only communications technology could be used to furnish services described by the codes for audio-only telephone evaluation and management services and behavioral health counseling and educational services. In prior rulemaking, consistent with a legislative change (CAA, 2021[2]), CMS finalized policy to permit the use of audio-only telehealth when furnished to established patients in their homes for purposes of diagnosis, evaluation or treatment of a mental health disorder if patient is not capable of, or does not consent to, the use of video technology.

Given the various telehealth extensions, CMS now believes that it would be appropriate to allow interactive audio-only telecommunications technology for telehealth services more broadly than just certain mental health services. As such, CMS proposes to change the definition of "interactive telecommunications system" to state that an interactive telecommunications system may also 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[3]. Additionally, a modifier designated by CMS must be appended to the claim for services described in this paragraph to verify that these conditions have been met.

Distant Site Requirements

In the CY 2024 PFS final rule, CMS continued policy to permit a distant site practitioner to use their currently enrolled practice location instead of their home address when providing telehealth services from their home. CMS proposes to continue this policy through CY 2025.

Telehealth Originating Site Facility Fee Payment Amount Update

As required under statute, the telehealth originating site facility fee is increased by the percentage increase of the MEI. The proposed MEI increase for CY 2025 is 3.6 percent. Although more recent data may be used when the final rule is published, the proposed payment amount for CY 2025 for telehealth originating site facility fee (HCPCS code Q3014) is $31.04.

New CPT Codes: Telemedicine Evaluation and Management (E/M) Services[4]

In the Proposed Rule, CMS noted that it interprets the Medicare statute's telehealth section as expressly requiring payment to the distant site physician or practitioner of an amount equal to

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[2] The CAA, 2021 removed the geographic restrictions for Medicare telehealth services for the diagnosis, evaluation, or treatment of a mental health disorder and the addition of the patient's home as a permissible originating site for these services

[3] interactive telecommunications system as defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication, but the patient is not capable of, or does not consent to, the use of video technology.

[4] New CPT Codes for Telemedicine E/M Services are: CPT codes s 9X075, 9X076, 9X077, 9X078, 9X079, 9X080, 9X081, 9X082, 9X083, 9X084, 9X085, 9X086, 9X087, 9X088, 9X089, 9X090, and 9X091

the amount that such physician or practitioner would have been paid had such service been furnished without the use of a telecommunications system. CMS further provides that this means that CMS must pay an equal amount for a service furnished using a "telecommunications system" as for a service furnished in-person (without the use of a telecommunications system).

In February 2023, the CPT Editorial Panel added a new Evaluation and Management (E/M) subsection to the draft CPT codebook for Telemedicine Services. The Panel added 17 codes for reporting telemedicine E/M services as listed in the Proposed Rule (pg. 157-159). Based on the agency's review of these codes, CMS does not believe there is a programmatic need to recognize the new audio/video and audio-only telemedicine E/M codes for payment under Medicare since there are services already describing audio-video and audio-only telemedicine E/M codes on the Medicare telehealth services list.[5]

In addition, CMS notes that one of the new codes, CPT code 9X091[6] and HCPCS code G2012 (*Brief communication technology-based service*) are similar. As a result, CMS proposes to accept the RUC-recommended values for CPT code 9X091 and to delete HCPCS code G2012. For CPT code 9X091, CMS proposes to accept the RUC-recommended work RVU of 0.30 and is proposing the RUC-recommended direct PE inputs.

In the Proposed Rule, CMS seeks comments on how the agency might potentially mitigate negative impact from the expiring telehealth flexibilities, preserve some access, and assess the magnitude of potential reductions in access and utilization. CMS notes that it has developed proposed PFS payment rates for CY 2025, including the statutory budget neutrality adjustment, based on the presumption that changes in telehealth utilization will not affect overall service utilization. CMS also notes that historically it has not considered changes in the Medicare telehealth policies to result in significant impact on utilization such that a budget neutrality adjustment would be warranted. However, CMS is unsure of the continuing validity of that premise under the current circumstances where patients have grown accustomed over several years to broad access to services via telehealth. **CMS seeks comment on what impact, if any, the expiration of the current flexibilities would be expected to have on overall service utilization for CY 2025.**

[5] In the Proposed Rule, CMS also provides "There are services already describing audio-video and audio-only telemedicine E/M codes on the Medicare telehealth services list—the office/outpatient E/M code set—that can be furnished via synchronous two-way, audio/video communication technology generally and via audio-only communication technology under certain circumstances to furnish Medicare telehealth services in the patient's home for the purpose of diagnosis and treatment of a mental health disorder or SUD. Additionally, as stated above, section 1834(m)(2)(A) of the Act requires us to pay an equal amount for a service furnished using a "telecommunications system" as for a service furnished in person (without the use of a telecommunications system). Were we to accept the AMA's recommendations and add the telemedicine E/M codes to the Medicare telehealth services list, we would need to establish RVUs for the telemedicine E/M codes to equal the corresponding non-telehealth services to satisfy the requirements for payment under section 1834(m)(2)(A) of the Act." CMS also states, "As previously discussed, the introduction of new CPT coding to describe telemedicine E/M services does not change our authority to pay for visits furnished through interactive communications technology in accordance with section 1834(m) of the Act."

[6] CPT code 9X091 (Brief communication technology-based service (e.g., virtual check-in) by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related evaluation and management service provided within the previous 7 days nor leading to an evaluation and management service or procedure within the next 24 hours or soonest available appointment, 5-10 minutes of medical discussion)).

Other Non-Face-to-Face Services Involving Communications Technology under the PFS

Proposal to Extend Definition of "Direct Supervision" to Include Audio-Video Communications Technology through 2025

Since the PHE, CMS has permitted direct supervision to be provided virtually (e.g, via audio-video real-time communications technology). As noted in previous rulemaking, CMS is concerned that an abrupt transition to the agency's pre-PHE policy that defines direct supervision to require the physical presence of the supervising practitioner could be disruptive. However, CMS also expressed concerns about the appropriateness of virtual direct supervision, particularly the ability of the supervising practitioner to intervene if complications arise. Despite the concerns related to safety, the agency proposes to extend the virtual supervision option for direct supervision (and immediate availability) through December 31, 2025.

Proposal to Permanently Define "Direct Supervision" to Include Audio-Video Communications Technology for a Subset of Services

CMS proposes to adopt a definition of direct supervision that allows "immediate availability" of the supervising practitioner using audio/video real-time communications technology (excluding audio-only), but only for the following subset of incident-to services:

> (1) services furnished incident to a physician or other practitioner's service when provided by auxiliary personnel employed by the billing practitioner and working under their direct supervision, and for which the underlying HCPCS code has been assigned a PC/TC indicator of '5'; and
> (2) services described by CPT code 99211 (*Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional*).

For all other services required to be furnished under the direct supervision of the supervising physician or other practitioner, CMS proposes to continue to define "immediate availability" to include real-time audio and visual interactive telecommunications technology (excluding audio-only) through December 31, 2025.

Teaching Physician Billing for Services Involving Residents with Virtual Presence

As CMS continues to consider clinical scenarios where it may be appropriate to permit the virtual presence of the teaching physician, the agency proposes to continue the 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 when the service is furnished virtually (e.g., a 3-way telehealth visit, with the patient, resident, and teaching physician in separate locations). CMS clarifies that this would permit teaching physicians to have a virtual presence during the key portion of the Medicare telehealth service for which payment is sought in any residency training location through December 31, 2025.

New, Revised and Potentially Misvalued Codes

In the Proposed Rule, CMS reviews the work RVUs for new, revised and potentially misvalued codes. Table 13 (pg. 219-230) of the Proposed Rule includes the work RVUs for such codes and information related to CMS time refinements. In addition to the below and among other changes, CMS also proposes new codes related to Chimeric antigen receptor T-cell (CAR-T) therapy (HCPCS code 3X018-3X021) to replace four previously deleted temporary codes.

Hospital Inpatient or Observation (I/O) Evaluation and Management (E/M) Add-on for Infectious Disease[7]

In the Proposed Rule, CMS notes that it believes the timing is appropriate for CMS to establish a payment rate for infectious disease physician services since the COVID-19 PHE has led to more attention on infectious diseases. For CY 2025, CMS proposes a new HCPCS code to describe intensity and complexity inherent to hospital inpatient or observation care associated with a confirmed or suspected infectious disease performed by a physician with specialized training in infectious diseases. Specifically, CMS proposes HCPCS code GIDXX as an add-on code (ZZZ global period) separately reportable in addition to various other CPT codes (i.e., CPT codes 99221, 99222, 99231, 99232, 99233, 99234, 99235 and 99236).

CMS also indicates that HCPCS code GIDXX would include the following services elements, which are further detailed in the Proposed Rule (pg. 196-197): disease transmission risk assessment and mitigation; public health investigation, analysis and testing; and complex antimicrobial therapy counseling and treatment.

Payment for Caregiver Training Services (CTS)

CMS proposes to establish new coding and payment for caregiver training for direct care services and supports. **Specifically, CMS proposes three new HCPCS codes (GCTD1-GCTD3[8]) and seeks comment on supplies/equipment that would be typical for these codes.** CMS also notes these services would largely involve contact between the billing practitioner and the caregiver through in-person interactions, which could be conducted via telecommunications, as appropriate. Therefore, CMS proposes to add these codes to the Medicare Telehealth Services List to accommodate a scenario in which the practitioner completes the caregiver training service via telehealth.

CMS also proposes to establish new coding and payment for caregiver behavior management and modification training that could be furnished to the caregiver of an individual patient. Current CPT coding (CPT 96202 and 96203) allows for "multiple-family group behavior management/modification training services," meaning that this caregiver training service can only be furnished in a group setting with multiple sets of caregivers of multiple beneficiaries. CMS proposes to increase access to caregiver training by establishing two new HCPCS

[7] HCPCS Code GIDXX (Visit complexity inherent to hospital inpatient or observation care associated with a confirmed or suspected infectious disease by an infectious diseases consultant, including disease transmission risk assessment and mitigation, public health investigation, analysis, and testing, and complex antimicrobial therapy counseling and treatment. (add-on code, list separately in addition to hospital inpatient or observation evaluation and management visit, initial, same day discharge, or subsequent).

[8] GCTD1 (Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to-face; initial 30 minutes), GCTD2 (Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service) (Use GCTD2 in conjunction with GCTD1)), and GCTD3 (Group caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to-face with multiple sets of caregivers)).

codes (GCTB1 and GCTB2).[9] CMS also proposes adding these codes to the Medicare Telehealth Services List.

Non-chemotherapy Administration

In the Proposed Rule, CMS notes that it has received inquiries from several external parties with concerns that Medicare Administrative Contractors (MACs) have developed local coverage determinations (LCDs) and local coverage articles (LCAs) that down-code or restrict payment for complex and non-chemotherapeutic drug administration for CPT code series 96401-96549, when used for the administration of several biologic and infusion drugs. In response, CMS proposes an updated policy based largely on the Internet-Only Manual (IOM) Medicare Claims Processing Manual, Chapter 12, section 30.5, to include language currently consistent with CPT code definitions for the complex non-chemotherapy infusion code series. CMS states that the administration of infusion for particular kinds of drugs and biologics can be considered complex and may be appropriately reported using the chemotherapy administration CPT codes 96401-96549. Also, in the Proposed Rule, CMS notes that CPT guidance describes requirements for these non-chemotherapy complex drugs or biologic agents to include the need for staff with advanced practice training and competency, such as a physician or other qualified health care professional, to monitor the patient during these infusions due to the incidence of severe adverse reactions. There are also special considerations for preparation, dosage, or disposal of these infusion drugs. Based on this information, CMS proposes updating subregulatory guidance accordingly. **CMS welcomes comments on the proposal to revise the IOM as outlined, with the aim to better reflect how complex non-chemotherapeutic drug administration infusion services are furnished and billed.**

Request for Information for Services Addressing Health-Related Social Needs[10]

In the Proposed Rule, CMS provides a broad request for information (RFI) on the newly implemented Community Health Integration (CHI) (HPCCS codes G0019, G0022), Principal Illness Navigation (PIN) (HCPCS codes G0023, G0024), Principal Illness Navigation- Peer Support (PIN-PS) (HCPCS codes G0140, G0146), and Social Determinants of Health Risk Assessment (SDOH RA) (HCPCS code G0136) services to engage interested parties on additional policy refinements for CMS to consider in future rulemaking. **CMS requests information on if there are other types of auxiliary personnel, other certifications, and/or training requirements that are not adequately captured in current coding and payment for these services. CMS is also interested in hearing more about what types of auxiliary personnel are typically furnishing these services, including the certifications and/or licensure that they have. In addition, CMS requests feedback on whether there are nuances or considerations that CMS should understand related to auxiliary personnel and training, certifications or licensure barriers or requirements that are specifically experienced by practitioners serving underserved communities. Among**

[9] GCTB1 (Caregiver training in behavior management/modification for caregiver(s) of a patient with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; initial 30 minutes) and GCTB2 (Caregiver training in behavior management/modification for caregiver(s) of a patient with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service) (Use GCTB2 in conjunction with GCTB1))
[10]Services for addressing health-related social needs: Community Health Integration (G0019, G0022), Principal Illness Navigation (G0023, G0024), Principal Illness Navigation-Peer Support (G0140, G0146), and Social Determinants of Health Risk Assessment (G0136))

other questions related to community-based organizations (CBOs), CMS is seeking comment regarding the extent to which practitioners are contracting with CBOs (including current or planned contracting arrangements) for auxiliary personnel purposes, and if there is anything else CMS should do to clarify services where auxiliary personnel can be employed by the CBO, so long as they are under the general supervision of the billing practitioner. CMS also seeks feedback on more specific issues, such as those related to transitional care management (TCM) and a global post-operative add-on code (HCPCS code GPOC1).

Evaluation and Management Visits

Office/ Outpatient (O/O) Evaluation and Management (E/M) Visit Complexity Add-on

In the CY 2024 PFS final rule, CMS finalized separate payment for the O/O E/M visit complexity add-on code (HCPCS code G2211[11]). In the CY 2024 PFS final rule, CMS made clear that the O/O E/M visit complexity add-on code is not payable when the O/O E/M visit is reported with CPT Modifier -25, which denotes a significant, separately identifiable O/O E/M visit by the same physician or other qualified health care professional on the same day as a procedure or other service. CMS has been monitoring use of the O/O E/M add-on code and found that relatively few preventive services are being billed on the date preceding or following an O/O E/M visit. Also, in prior rulemaking, commenters raised concerns that denying payment of the add-on care when the O/O E/M base code is reporting on the same day as a Medicare preventive service is disruptive to the way care is usually furnished. In response, CMS proposes to the allow payment of the O/O E/M visit complexity add-on code when the O/O E/M base code 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 furnished in the office or outpatient setting. **CMS welcomes comments on this proposal.**

Enhanced Care Management

In the Proposed Rule, CMS outlines its proposal to recognize the "advanced primary care" delivery model[12] and related resources involved in furnishing services using an "advanced primary care" approach[13] to care under the PFS. Notably, building from elements of Innovation Center models related to primary care, CMS proposes to adopt coding and payment policies to recognize advanced primary care management (APCM) services (i.e., HCPCS codes GPCM1, GPCM2 and GPCM3), which are further described in the Proposed Rule (pg. 258-260). CMS notes these codes are for use by practitioners who are providing services under this specific model of advanced primary care when the practitioner is the continuing focal point for all needed health care services and responsible for all primary care services. CMS also proposes that the code descriptors would not be time-based, and that not all elements included in the APCM code descriptors must be furnished during any given calendar month for

[11] The full descriptor for the O/O E/M visit complexity add-on code, HCPCS code G2211, is (Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established).

[12] CMS proposes to define "advanced primary care" as propose to define using the 2021 National Academies of Sciences, Engineering, and Medicine (NASEM) report on Implementing High-Quality Care as: "whole-person, integrated, accessible, and equitable health care by interprofessional teams that are accountable for addressing the majority of an individual's health and wellness needs across settings and through sustained relationships with patients, families, and communities.

[13] Under this approach, the delivery of care is supported by a team-based care structure and involves a restructuring of the primary care team, which includes the billing practitioner and the auxiliary personnel under their general supervision, within practices.

which the service is billed. Also, Table 20 of the Proposed Rule (pg. 268) outlines patient-centered risk stratification for purposes of billing APCM codes.

Among other questions, CMS seeks feedback on these service descriptions, whether there are elements of other care management services that should be removed or altered for purposes of APCM services and ways to align with APCM services with other Medicare programs and initiatives, such as the Shared Savings Program, ACO REACH and advanced primary care models, and the Quality Payment Program.[14]

In the Proposed Rule, CMS addresses other aspects of APCM services such as beneficiary consent (pg. 278-280), initiating visit (pg. 280-282), 24/7 access and continuity of care (pg. 282-285), comprehensive care management (pg. 285-287), patient-centered comprehensive care plan (pg. 287-288), management of care transitions (pg. 288-290), practitioner, home-, and community-based care coordination (pg. 290-292), enhanced communications opportunities (pg. 292-294), patient population-level management (pg. 294-296), performance measurement (pg. 297-303), duplicative services and concurrent billing restrictions (pg. 304-308) and valuation of APCM services (pg. 308-315).

In the context of the proposal, CMS is also interested in feedback on other related policies for consideration in future rulemaking and has included an Advanced Primary Care Hybrid Payment Request for Information (RFI) in the Proposed Rule (pg. 315-327). CMS notes it is interested in building advanced primary care payment mechanisms that create pathways to recognize how primary care practice has moved away from an encounter-based orientation toward population-based care. Topics addressed in the RFI include streamlined value-based care opportunities, billing requirements, person-centered care, health equity, social and clinical risk, and quality improvement and accountability.

Strategies for Improving Global Surgery Payment Accuracy

As noted in the Proposed Rule, there are approximately 4,100 physicians' services that are coded and valued under the PFS as global surgical packages ("global packages"). Global packages are single codes that are valued to include all services provided during a specified period of days (0-day, 10-day, or 90-day global packages) by a physician (or another practitioner in the same group practice for a specific surgical procedure). Current policies require the use of transfer of care modifiers only where there is a formal documented agreement between practitioners to provide specific portions of the global package. However, in the Proposed Rule, CMS aims to address instances where there are informal, non-documented anticipated transfers of care.

Beginning for services furnished in CY 2025, CMS proposes to require the use of the transfer of care modifiers for the 90-day global packages in more circumstances. Specifically, CMS proposes to require the use of the appropriate transfer of care modifier (i.e., modifier -54[15], -

[14] For example, CMS notes that reporting of the "Value of Primary Care" MVP would be an APCM service element for MIPS eligible clinicians beginning in 2026.
[15] Modifier -54 Surgical Care Only: this modifier is appended to the relevant global package code to indicate that the proceduralist performed only the surgical procedure portion of the global package.

55[16], or -56[17]) for all 90-day global surgical packages in any case when a practitioner plans to furnish only a portion of a 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).[18]

CMS notes that practitioners billing for a global package procedure code with modifier -54 and other practitioners in the same group practice as that practitioner would still be able to bill during the global period for any separately identifiable E/M services they furnish to the patient that are unrelated to the global package procedure. To do so, the practitioner would append modifier -24 to the claim line for the E/M service. CMS notes that the proposal will prevent duplicative Medicare payment for post-operative care because the global surgical package payment would be adjusted based on the appended modifier, and payment for post-operative care would not be made both as part of a global surgical package and through separately billed E/M visits.

CMS seeks comment on the circumstances under which practitioners in separate group practices furnish different portions of the care included in global packages, and what that means for reporting the transfer of care modifiers. Also, while CMS is making proposals related to the 90-day global periods beginning for services furnished in 2025, the agency is also seeking comment on whether it should consider proposing these changes for the 10-day global packages in future rulemaking.

CMS also proposes a new HCPCS code[19], which would be reported by a physician or other practitioner who did not perform the surgical procedure for a global package and provides related post-operative visits during the global period despite the absence of a formal transfer of care. CMS proposes that this code could be billed only once during the 90-day global period for the global package because the agency believes the practitioner would only have additional resource costs upon the first visit following the procedure.

Advancing Access to Behavioral Health Services

In prior rulemaking, CMS sought comment on whether there is a need for potential separate coding and payment for interventions initiated or furnished in the emergency department (ED) or other crisis settings for patients with suicidality or at risk of suicide. As a result of feedback

[16] Modifier -55 Post-operative Management Only: this modifier is appended to the relevant global package code to indicate that the practitioner performed only the post-operative management portion of the global package.
[17] Modifier -56 Pre-operative Management Only: this modifier is appended to the relevant global package code to indicate that the practitioner performed only the pre-operative portion of the global package.
[18] CMS notes that practitioners billing for a global package procedure code with modifier -54 and other practitioners in the same group practice as that practitioner would still be able to bill during the global period for any separately identifiable E/M services they furnish to the patient that are unrelated to the global package procedure. To do so, the practitioner would append modifier -24 to the claim line for the E/M service.
[19] HCPCS code GPOC1 (Post-operative follow-up visit complexity inherent to evaluation and management services addressing surgical procedure(s), provided by a physician or qualified health care professional who is not the practitioner who performed the procedure (or in the same group practice), and is of a different specialty than the practitioner who performed the procedure, within the 090-day global period of the procedure(s), once per 090-day global period, when there has not been a formal transfer of care and requires the following required elements, when possible and applicable:

- Reading available surgical note to understand the relative success of the procedure, the anatomy that was affected, and potential complications that could have arisen due to the unique circumstances of the patient's operation.
- Research the procedure to determine expected post-operative course and potential complications (in the case of doing a post-op for a procedure outside the specialty).
- Evaluate and physically examine the patient to determine whether the post-operative course is progressing appropriately.
- Communicate with the practitioner who performed the procedure if any questions or concerns arise. (List separately in addition to office/outpatient evaluation and management visit, new or established))

received and survey data, CMS proposes new coding and payment for safety planning interventions (HCPCS code GSPI1[20]) and an additional monthly code for follow-up telephone calls after an emergency department discharge (HCPCS code GFC1I[21]).

In addition, CMS proposes three new G-codes related to digital mental health treatment (DMHT) devices. Specifically, CMS proposes that physicians and practitioners who are authorized to furnish services for the diagnosis and treatment of mental illness would be able to bill a new HCPCS code: GMBT1[22] for furnishing a DMHT device. In addition, CMS proposes GMBT2[23] and GMBT3[24], which should only be billed in cases where there is ongoing use of the DMHT device and should not be billed when the patient discontinues use of the DMHT device.

Also related to behavioral health, in the Proposed Rule, CMS addresses interprofessional consultations (pg. 384-389) and provides a comment solicitation regarding payment for services furnished in additional settings (pg. 389-392).

Proposals on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Services

In the Proposed Rule, CMS outlines various policies and changes related to payment for dental services inextricably linked to specific covered services (pg. 392-452), including a request for comment on dental services integral to specific covered services to treat systemic autoimmune diseases requiring immunosuppressive therapies (pg. 435-441).

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

The Infrastructure Investment and Jobs Act (Pub. L. 117-58, November 15, 2021) requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug ("refundable drug") for calendar quarters beginning January 1, 2023. In prior rulemaking, CMS finalized several policies to implement the law, such as the use of modifiers and the definition of "refundable single-dose container or single-use package drug".

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[20] HCPCS code GSPI1: Safety planning interventions, including assisting the patient in the identification of the following personalized elements of a safety plan: recognizing warning signs of an impending suicidal crisis; employing internal coping strategies; utilizing social contacts and social settings as a means of distraction from suicidal thoughts; utilizing family members, significant others, caregivers, and/or friends to help resolve the crisis; contacting mental health professionals or agencies; and making the environment safe; (List separately in addition to an E/M visit or psychotherapy).
[21] HCPCS code GFCI1: Post discharge telephonic follow-up contacts performed in conjunction with a discharge from the emergency department for behavioral health or other crisis encounter, per calendar month
[22] GMBT1: Supply of digital mental health treatment device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan)
[23] GMBT2: First 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing data generated from the DMHT device from patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month
[24] GMBT3: Each additional 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing data generated from the DMHT device from patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month

In the Proposed Rule, based on the agency's experience with the program and stakeholder feedback, the agency proposes revisions to the exclusions for drugs which payment has been made under Part B for fewer than 18 months. Specifically, CMS proposes to restructure the definition and add a fourth exclusion to address drugs for which the date of first sale does not adequately approximate the first date of payment under Part B due to an applicable NCD.

In addition, CMS proposes clarifications for identifying single-dose containers. Specifically, CMS proposes to include: (1) injectable drugs with a labeled volume of 2 mL or less and that lack the package type terms and explicit discard statements in their product labeling to be single-dose containers in the definition of refundable single-dose container or single-use package drugs; and (2) drugs contained in ampules and for which there is no discard statement in the definition of refundable single-dose container or single-use package drug.

Regarding modifier use, CMS proposes to require the JW modifier if a billing supplier is not administering a drug, but there are amounts discarded during the preparation process before supplying the drug to the patients. For example, if a billing supplier prepares a dose from a single-dose vial labeled as containing a total of 50 billing units such that 45 billing units of the drug are used in the prepared dose and 5 billing units are discarded during preparation, and then the drug is supplied to the patient (but not administered by the supplier), the claim should be submitted on two lines: 45 units (without a modifier) and 5 units with the JW modifier. CMS reiterates that suppliers who dispense a drug, but do not actually administer the drug, are not expected to monitor or bill for discarded amounts that are discarded after the drug is supplied. **CMS welcomes comments on this proposal.**

Payment Limit Calculation When Manufacturers Report Negative or Zero Average Sales Price (ASP) Data

CMS generally calculates the payment limits for drugs payable under Part B on a quarterly basis using the manufacturer's ASP. Manufacturers are required to calculate and report ASP to CMS. For each National Drug Code (NDC), in most cases, the manufacturer's ASP is a positive dollar value, along with a positive number of units sold (hereinafter referred to as "positive manufacturer's ASP data"). However, sometimes the reported data is not positive manufacturer's ASP data. For example, a manufacturer could report that an NDC has a negative or zero-dollar value for the manufacturer's ASP with a positive, negative, or zero number of units sold, or a positive dollar value for the manufacturer's ASP with a negative or zero number of units sold (each of these scenarios is hereinafter referred to as "negative or zero manufacturer's ASP data"). CMS indicates that such negative or zero manufacturer's ASP data could occur because of lagged discounts, units returned to the manufacturer, drug shortages, discontinuation of a drug, or other reasons that are not known to CMS.

In the Proposed Rule, CMS provides additional guidance regarding how the agency will handle payment for drugs separately payable under Part B when the reported manufacturer's ASP for at least one NDC within the billing or and payment codes of the drug is negative or zero. CMS proposes to consider ASP data to be not "available" for the purposes of calculating a payment limit in circumstances in which negative or zero manufacturer's ASP data is reported.

For single and multiple source drugs when negative or zero manufacturer's ASP data is reported for some, but not all, NDCs associated with a billing and payment code for that drug, CMS proposes to calculate a payment limit using only NDCs with positive manufacturer's ASP data (and omitting NDCs with negative or zero manufacturer's ASP data) for that drug. This policy would apply to single source drugs, including biosimilars, and multiple source drugs.

For multiple source drugs with only negative or zero manufacturer's ASP data, CMS proposes to carry over all positive manufacturer's ASP data for at least one NDC until at least one NDC for the drug has positive manufacturer's ASP data for a quarter.

In the case of a single source drug, excluding biosimilars, separately payable under Part B that has negative or zero manufacturer's ASP data reported for all NDCs associated with a billing and payment code for that drug (and at least one NDC for the drug is actively being marketed (that is, not discontinued)), CMS proposes to set the payment limit for the given quarter for the single source drug at the lesser of the following until at least one NDC for the drug has positive manufacturer's ASP data for a quarter:

- 106 percent of the volume-weighted average of the most recent available positive manufacturer's ASP data from a previous quarter in which at least one NDC for the drug has positive manufacturer's ASP data for a quarter. (If the payment limit from the quarter with the most recent available positive manufacturer's ASP data was based on 106 percent of the WAC, that payment limit would be carried over); or
- 106 percent of the WAC for the given quarter. If there is more than one WAC per billing unit for the drug, the payment limit would be set using the lowest WAC per billing unit.

In circumstances in which negative or zero manufacturer's ASP data is reported for all NDCs for a biosimilar for a given quarter (and at least one NDC for the biosimilar is actively being marketed (that is, not discontinued)), and positive manufacturer's ASP data is available for another biosimilar(s) with the same reference biological product for the given quarter, CMS is proposing to set the payment limit for the given quarter equal to the sum of the following until at least one NDC for the particular biosimilar for which all NDCs report negative or zero manufacturer's ASP data has positive manufacturer's ASP data for a quarter:

- The volume-weighted average of the positive manufacturer's ASP data from all other biosimilars with the same reference product, and
- 6 percent (or 8 percent for qualifying biosimilar biologicals as defined in § 414.902, as appropriate) of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in § 414.902) for the given quarter.

In circumstances in which negative or zero manufacturer's ASP data is reported for all NDCs for a biosimilar for a given quarter and either no other biosimilars have been approved for the same reference product or no other biosimilars with the same reference product report positive manufacturer's ASP data for the given quarter, CMS proposes to set the payment limit for the given quarter equal to the sum of the following until at least one NDC for the biosimilar has positive manufacturer's ASP data for a quarter:

- The volume-weighted average of the most recent available positive manufacturer's ASP data from a previous quarter, and
- 6 percent (or 8 percent for qualifying biosimilar biologicals, as appropriate) of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in § 414.902) for the given quarter.

CMS welcome feedback on these approaches. In addition, in the Proposed Rule, the agency outlines two alternatives considered (pg. 480-481) and welcomes comments on these approaches.

For discontinued drugs, CMS proposes that the drug be priced by MACs consistent with Chapter 17 of the Medicare Claims Processing Manual for developing payment limits for

covered drugs when CMS does not supply the payment allowance limit on the ASP drug pricing file.

Payment of Radiopharmaceuticals in the Physician Office

In the Proposed Rule, CMS indicates that MACs are uncertain of the payment methodologies available to determine payment of radiopharmaceuticals and that payment can vary by MAC. While CMS considers policies for future rulemaking, CMS proposes to clarify that any payment methodology that was being used by any MAC prior to the enactment of the Medicare Modernization Act (2003) can continue to be used by any MAC, including the use of invoice pricing. **CMS welcomes comment on this proposal.**

Immunosuppressive Therapy

After reviewing the agency's longstanding policies for the immunosuppressive drug benefit and engaging with interested parties about current practices and challenges, CMS proposes policies aimed to reduce barriers faced by beneficiaries receiving immunosuppressive drugs under this benefit.

CMS proposes to include orally and enterally administered compounded formulations with active ingredients derived only from FDA-approved drugs where approved labeling includes an indication for preventing or treating the rejection of a transplanted organ or tissue, or for use in conjunction with immunosuppressive drugs to prevent or treat rejection of a transplanted organ or tissue, or have been determined by a MAC, in processing a Medicare claim, to be reasonable and necessary for this specific purpose as outlined in the immunosuppressive drug benefit. CMS expects this proposal will improve adherence for patients who are not able to swallow capsules or tablets. Also, the agency does not believe there are access concerns with other types of formulations. As a result, CMS proposes to limit the included compounded formulations to those products with oral and enteral routes of administration (for example, oral suspensions or solutions).

In addition, CMS proposes changes regarding supplying fees and refills for immunosuppressive drugs. First, CMS proposes allowing payment of a supplying fee for a prescription of a supply of up to 90 days. In addition, CMS proposes to allow payment of refills for these immunosuppressive drugs. If finalized, CMS clarifies that the prescribing healthcare provider may adjust the days' supply up to 90 days and allow refills for an immunosuppressive drug based on the individual circumstance of the beneficiary in accordance with applicable state laws.

Blood Clotting Factors

CMS notes that it does not believe gene therapies for hemophilia meet the definition of clotting factors for purposes of Medicare payment. As such, CMS proposes to clarify that blood clotting factors must be self-administered to be considered clotting factors for which the furnishing fee applies. Additionally, CMS proposes to clarify that the furnishing fee is only available to entities that furnish blood clotting factors unless the costs associated with furnishing the clotting factor are paid through another payment system, including the PFS.

Medicare Diabetes Prevention Program

The Centers for Medicare & Medicaid Services' (CMS) Medicare Diabetes Prevention Program Expanded Model ("MDPP Expanded Model") is an evidence-based behavioral

intervention that aims to prevent or delay the onset of type 2 diabetes for eligible Medicare beneficiaries diagnosed with prediabetes. In the Proposed Rule, CMS notes that the Centers for Disease Control and Prevention (CDC) released the 2024 Diabetes Prevention Recognition Program (DPRP) Standards, which updates prior standards. As a result, CMS proposes various changes to the Conditions of Coverage to align with the 2024 DPRP Standards. CMS also clarifies that chat bots and AI forums do not count as live coach interaction.

Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) established a new Medicare Part B benefit for OUD treatment services furnished by OTPs during an episode of care beginning on or after January 1, 2020. Since then, CMS has provided various regulations to implement the law and subsequent changes, such as telecommunications flexibilities, such as allowing OTPs to furnish individual and group therapy and substance use counseling via two-way interactive audio-video telecommunications and via audio-only telephone calls when audio-video telecommunications are not available to the beneficiary, to the extent these technologies are authorized by the Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA).

In response to prior stakeholder feedback, CMS proposes to permanently allow OTPs to furnish periodic assessments using audio-only communications technology when video is not available on a permanent basis beginning January 1, 2025, so long as use of audio-only technology is permitted under SAMHSA and DEA requirements and all other applicable requirements are met.

In addition, CMS proposes to allow the OTP intake add-on code (HCPCS G2076) to be furnished via two-way audio-video communications technology when billed for the initiation of treatment with methadone, to the extent such technology is authorized by DEA and SAMHSA. CMS clarifies that it is not proposing to extend the flexibility to allow for audio-only telecommunications for intake activities for initiation of treatment with methadone, as these flexibilities are not currently permitted by SAMHSA and the DEA.

Proposals Related to Reforms to 42 CFR Part 8

Recently, SAMHSA issued a final rule which made major reforms to 42 CFR Part 8 and governs requirements for OTPs in providing medications for the treatment of OUD and many other services. CMS notes that refinements related to initial assessment requirements in SAMHSA's rulemaking likely necessitate additional resource costs for OTPs to comply with the opioid treatment standards for assessing various SDOHs and to identify a patient's goal for harm reduction interventions and recovery support service needs. As a result, CMS proposes to establish payment for SDOH risk assessments as part of intake activities within OUD treatment services, as long as these assessments are medically reasonable and necessary for the diagnosis or treatment of an OUD, and OTPs have a reason to believe unmet Health-Related Social Needs (HRSNs) or the need for harm reduction intervention or recovery support services identified during such an assessment could interfere with the OTP's ability to diagnose or treat the patient's OUD. Specifically, CMS proposes to update the payment rate for intake activities described by HCPCS code G2076 by adding in the value of

the non-facility rate for SDOH risk assessments described by HCPCS code G0136.[25] CMS clarifies that when OTPs bill the intake add-on code (G2076), CMS is not proposing to require that OTPs performed SDOH risk assessments in a specific manner, but rather that OTPs continued to perform initial assessment services consistent with SAMHSA certification requirements.

Establishing Payment for New FDA-approved Opioid Agonist and Antagonist Medications

Since the implementation of the Medicare OTP benefit, CMS has established bundled payments and/or add-on codes for several medications. In the Proposed Rule, CMS proposes new payment for injectable buprenorphine and nalmefene hydrochloride products furnished by OTPs.

Request for Information on Payment for Coordinated Care and Referrals to Community-Based Organizations that Address Unmet Health-Related Social Needs, Provide Harm Reduction Services, and/or Provide Recovery Support Services

In the Proposed Rule, CMS notes that it does not currently have specific coding for activities that OTPs may conduct to coordinate care and make referrals or "link" to community-based organizations (CBOs) that help facilitate a patient's needs and goals related to harm reduction and recovery support services, as well as to address unmet HRSNs. **CMS requests comment to understand how OTPs are currently coordinating care and making referrals to CBOs that address unmet HRSNs, provide harm reduction services, and/or provide recovery support services.** Additional information regarding this RFI is available in the Proposed Rule (pg. 640-644).

Medicare Part B Payment for Preventive Services

As required by statute, Medicare Part B covers both the vaccine and vaccine administration for specified preventive vaccines (pneumococcal, influenza, hepatitis B and COVID-19 vaccines). However, hepatitis B vaccines coverage is limited to those who are at high or intermediate risk of contracting hepatitis B. Also, per statute, payment for the vaccines is based on 95 percent of the Average Wholesale Price (AWP) for the vaccine product, except when furnished in settings for which payment is based on reasonable costs, such as a HOPD. In prior PFS rulemaking, CMS established policy where providers and suppliers could bill Medicare for one of the existing COVID-19 vaccine administration CPT codes along with HCPCS code M0201 (Administration of pneumococcal, influenza, hepatitis B, and/or covid-19 vaccine inside a patient's home; reported only once per individual home per date of service when such vaccine administration(s) are performed at the patient's home).

In 2024, FDA issued an Emergency Use Authorization (EUA) for Pemgarda (pemivibart) injection, which is indicated for use for pre-exposure prophylaxis to help prevent COVID-19 in adults and children 12 years of age and older who meet certain requirements. Since then, CMS used authority to cover the Part B preventive vaccine benefit, which CMS notes would be in remain even after the EUA is terminated (so long as the product still has market authorization). In the Proposed Rule, CMS notes it plans to propose long-term coding and payment rates for the administration of this product in the future.

[25] G0136: Administration of a standardized, evidence-based SDOH assessment, 5–15 minutes, not more often than every 6 months

In the Proposed Rule, CMS proposes to expand coverage of the hepatitis B vaccination series for an expanded range of Medicare enrollees. As proposed, CMS notes that an assessment of an individual's vaccination status could be made without the clinical expertise of a physician. As a result, if finalized, a doctor's order would no longer be necessary for the administration of a hepatitis B vaccine under Part B. CMS notes that if finalized, CMS would change the agency's procedures to allow mass immunizers to use the roster billing process to submit Medicare Part B claims for hepatitis B vaccines and their administration.

Tables 45 and 46 of the Proposed Rule (pg. 930) provide the CY 2025 projected payment rates for the vaccine administration services codes (HCPCS codes G0008, G0009, and G0010), at-home vaccine administration (HCPCS code M0201) and pricing for COVID-19 vaccine and monoclonal antibodies, including Pemgarda. Regarding the COVID-19 products, CMS notes that there is uncertainty surrounding the future of the Emergency Use Authorization declarations and, as a result, provides additional information. Specifically, Table 45 of the Proposed Rule (pg. 930) displays the CY 2025 Part B payment rates for preventive vaccine administration if the EUA declaration continues into CY 2026 and Table 46 of the Proposed Rule (pg. 930) displays the payment rates if the EUA declaration ends on or before December 31, 2024.

Payment for Drugs Covered as Additional Preventive Service

As required under statute, Medicare Part B covers "additional preventive services" that identify medical conditions or risk factors and that the Secretary determines are reasonable and necessary for: (A) the prevention or early detection of an illness or disability; (B) that are recommended with a grade of A or B by the United States Preventive Services Task Force; and (C) that are appropriate for individuals entitled to benefits under Part A or enrolled under Part B. In making such determinations, as noted in the statute, the Secretary should use the process for making National Coverage Determinations (NCDs) in the Medicare Program.

In the Proposed Rule, CMS notes that it has not yet covered or paid for any drugs or biologicals (hereinafter, referred to as drugs) under the benefit category of additional preventive services. Notably, in July 2023, CMS released a Proposed NCD for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention. As a result and in anticipation of a finalized NCD, CMS proposes a fee schedule for Drugs Covered as Additional Preventive Services ("DCAPS", however, CMS and this summary use "DCAPS drugs" for ease of reading) that uses existing Part B drug pricing mechanisms.[26] CMS proposes that the payment limit for a DCAPS drug be determined using ASP methodology, or if ASP data is not available for a particular drug[27], to use an alternative pricing mechanism. CMS also proposes to update the fee schedule quarterly, on the same schedule as the ASP pricing file. In addition, CMS proposes that the payment limit would be the amount described

[26] In addition, specific to PrEP for HIV, CMS propose national rates for HCPCS code G0012 (Injection of pre-exposure prophylaxis (PrEP) drug for HIV prevention, under skin or into muscle) that are crosswalked from CPT code 96372 (Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular).

[27] As noted in the Proposed Rule, manufacturers of DCAPS drugs are not required to report ASP data to CMS. If ASP data is not available for a DCAPS drug, CMS proposes to use the most recently published amount in the Medicaid's National Average Drug Acquisition Cost (NADAC) survey. When using NADAC data, CMS proposes to determine the payment limit per billing unit, which would be an average of NADAC pricing for all NDCs for the drug. If a drug is available in generic and brand formulations, CMS proposes all NDCs will be averaged together to determine the payment limit. If NADAC information is not available, CMS proposes to rely on the Federal Supply Schedule (FSS), are further detailed in the Proposed Rule (pg. 942) and if FSS pricing is not available, CMS proposes that MACs would determine the payment limit for the drug according to the invoice.

in statute[28], which is usually 106 percent of ASP. **CMS welcomes comment on the fee schedule for drugs paid as additional preventive services.**

As required under statute, the amount paid for the administration or supplying of the DCAPS drug will be the lesser of either the actual charge for the service or the payment limit.

- For drugs that are supplied by a pharmacy, CMS proposes that the fee schedule include a payment limit for a supplying fee that is similar to the supplying fee for other Part B-covered drugs dispensed from a pharmacy (e.g., immunosuppressives, oral anti-cancer and oral anti-emetic drugs), to allow for consistency among similar payments in Part B. CMS proposes that the agency will establish a payment limit of $24 to a pharmacy for the first DCAPS prescription that the pharmacy supplies to a beneficiary in a 30-day period, and a payment limit of $16 to a pharmacy for all subsequent DCAPS prescriptions that the pharmacy supplies to a beneficiary in that 30-day period. CMS proposes that the same fees would apply regardless of the number of days' supply that is dispensed.
- For drugs that are administered by a physician or a non-physician practitioner, CMS proposes that the fee schedule include a payment limit for such administration that aligns with the administration fee for other drugs provided as incident to physician services, as paid according to the PFS. To operationalize this, CMS proposes to determine the payment limit for administration of a DCAPS drug pricing incident to a physician service via a crosswalk to an existing, corresponding drug administration code under the PFS. The fee schedule would be published quarterly on the CMS website and implemented in the Medicare claims processing system.

Expand Hepatitis B Vaccine Coverage

The Social Security Act provides a benefit category under Part B for the hepatitis B vaccine and its administration, furnished to an individual who is at high or intermediate risk of contracting hepatitis. The statute expressly authorizes the Secretary to determine who is at high or intermediate risk of contracting hepatitis B for coverage of the hepatitis B vaccine. Based on research and updated information, CMS concludes that anyone who is not fully vaccinated to be at intermediate risk of contracting the hepatitis B virus as their risk would be above zero. As a result, CMS proposes to revise Intermediate Risk Groups to include individuals who have not previously received a completed hepatitis B vaccination series or whose vaccination history is unknown.

Expand Colorectal Cancer Screening

Medicare coverage for colorectal cancer (CRC) screening tests under Part B are described in statutes, regulation, and a National Coverage Determination (NCD) (i.e., Section 210.3 of the Medicare National Coverage Determinations Manual). CMS notes that the statute and regulations expressly authorize the addition of other tests and procedures (and modifications to tests and procedures) for colorectal cancer screening with such frequency and payment limits as appropriate based on consultation with appropriate organizations. In the Proposed Rule, CMS proposes to update and expand coverage for CRC screening by:

- Removing coverage for the barium enema procedure;
- Adding coverage for the computed tomography colonography (CTC) procedure; and

[28] Section 1847A(b) of the Social Security Act.

- Expanding a “complete colorectal cancer screening” to include follow-on screening colonoscopy after a Medicare covered blood-based biomarker CRC screening test.

Medicare Prescription Drug Inflation Rebate Program

The Inflation Reduction Act (IRA) established new requirements under which drug manufacturers must pay inflation rebates if they raise their prices for certain Part B and Part D drugs faster than the rate of inflation. For Part B drugs, CMS considers the rate of inflation for a calendar quarter, starting with the first quarter of 2023. For Part D drugs, CMS considers the rate of inflation over a 12-month period beginning with October 1, 2022. Given differences related to the inputs used to calculate the rebate amounts for Part B and Part D, CMS proposes to use different methodologies to calculate inflation rebates for Part B rebatable drugs and Part D rebatable drugs.

Figure 1 (pg. 956) of the Proposed Rule provides a summary of data timelines for Part B drug inflation rebate provisions for CY 2025 and Figure 2 (pg. 956) provides similar information for Part D drug inflation rebate provisions for CY 2025. In addition, Table 47 (pg. 957) of the Proposed Rule provides a summary of the Part B and Part D drug inflation rebate amount reports and deadlines.

Medicare Part B Drug Rebates for Single Source Drugs and Biological Products with Prices that Increase Faster than the Rate of Inflation

In the Proposed Rule, CMS largely proposes policy as provided in the revised Medicare Part B Drug Inflation Rebate Guidance. In addition, CMS proposes some new definitions and policies not addressed in the revised Medicare Part B Drug Inflation Rebate Guidance to implement the Medicare Part B Drug Rebate Program.

Determination of Part B Rebatable Drugs

In the Proposed Rule, CMS addresses the scope of Part B rebatable drugs.[29] CMS proposes policy consistent with the revised Medicare Part B Drug Inflation Rebate Guidance to identify Part B rebatable drugs by (1) identifying the applicable billing and payment code for each single source drug or biological product, including biosimilar biological products, for which payment is made under Part B and (2) excluding any billing and payment code corresponding to a drug or biological product in excluded product categories or that have average total allowed charges below an applicable threshold.

In the Proposed Rule, CMS further details excluded product categories, in addition to the agency’s process for excluding products with average total charges below the applicable threshold.

[29] Section 1847A(i)(2) of the Act defines a “Part B rebatable drug,” in part, as a single source drug or biological product (as defined in section 1847A(c)(6)(D)), including a biosimilar biological product (as defined in section 1847A(c)(6)(H)), but excluding a qualifying biosimilar biological product (as defined in section 1847A(b)(8)(B)(iii)), for which payment is made under 559 These data are referenced to 1982-84=100—that is, the average of pricing data for the 36 months from 1982 through 1984 serve as the basis for the index and are assigned a value of 100. These data are not seasonally adjusted. Part B. The definitions for a biosimilar biological product and a qualifying biosimilar biological product are codified in § 414.902.

Inflation-Adjusted Beneficiary Coinsurance Adjustment and Adjusted Medicare Payment for Part B Rebatable Drugs with Price Increases Faster than Inflation

For Part B rebatable drugs with price increases that rise faster than inflation, the IRA requires that the coinsurance be 20 percent of the inflation-adjustment payment amount for a given quarter. CMS proposes to use the payment amount in the quarterly pricing files to determine if a Part B rebatable drug should have an adjusted beneficiary coinsurance. Also, CMS notes that the calculation to determine the adjusted Medicare payment (if applicable) will not be adjusted for sequestration and drugs excluded from the identification of Part B rebatable drugs will not be subject to the inflation-adjusted beneficiary coinsurance.

Determination of the Rebate Amount for Part B Rebatable Drug

The IRA specifies the calculation of the rebate amount for a Part B rebatable drug assigned to a billing and payment code for an applicable calendar quarter for which a manufacturer must pay a rebate. Generally, CMS proposes to codify the rebate calculation, as established in revised Medicare Part B Drug Inflation Rebate Guidance, which considers the total number of billing units and the amount (if any) by which the specified amount exceeds the inflation-adjusted payment amount for the drug or biologic for an applicable calendar quarter. However, in the Proposed Rule, CMS provides that there are circumstances where a Part B rebatable drug could have more than one manufacturer (e.g., product produced by one or more manufacturers that is a repackager or relabeler), which was not addressed in the revised guidance. In the Proposed Rule, CMS also notes that there are several instances where there are multiple manufacturers in a billing and payment code and the ASP data, including the number of units sold, for all or some manufacturers' NDCs within a billing and payment code may be negative, zero, or missing. **To enable CMS to calculate the respective rebate amounts attributable to each manufacturer when the ASP units are negative, zero, or missing, CMS welcomes feedback on policy proposals, as further detailed in the Proposed Rule (pg. 973-976) that address the following scenarios:**

- **All NDCs within a billing and payment code that have negative, zero, or missing ASP units;**
- **Some (but not all) NDCs have negative, zero, or missing ASP units.**

As noted above, CMS proposes to codify the policy established in revised Medicare Part B Drug Inflation Rebate Guidance, including policy to calculate the Part B per unit rebate amount for the applicable calendar quarter by determining the amount by which the specified amount exceeds the inflation-adjusted payment amount. For example, CMS proposes policy for: identification of the specific amount for the applicable calendar quarter; identification of the payment amount benchmark quarter; identification of the payment amount in the payment amount benchmark quarter; identification of the benchmark period Consumer Price Index for All Urban Customers (CPI-U); and determination of the inflation adjusted payment amount. Additional information regarding the determination of the inflation-adjusted payment amount and circumstances where a product is in shortage or at risk of severe supply chain disruption is noted below.

Determination of the Inflation-Adjusted Payment Amount

The IRA specifies the determination of the inflation-adjusted payment amount and CMS has further detailed these requirements in the revised Medicare Part B Drug Inflation Rebate Guidance. To determine the inflation-adjusted payment amount, the total number of billing

units and exclusions, among other factors noted in the revised guidance, must be determined.[30]

In the Proposed Rule, CMS proposes codifying policy set forth in revised Medicare Part B Drug Inflation Rebate Guidance to exclude billing units under certain circumstances, including:

- **Units of Drugs Acquired Through the 340B Program:** CMS proposes to remove separately payable billing units in claim lines that are billed with the "JG" or "TB" modifiers from identified final action claim lines. CMS proposes to exclude separately payable billing units in claim lines for professional claims with dates of service during 2023 from suppliers that are covered entities listed by the HRSA 340B Office of Pharmacy Affairs Information System as participating in the 340B Program. CMS will use National Provider Identifier numbers and/or Medicare Provider Numbers to identify these suppliers and the claims submitted with such identifiers.
- **Units with a Rebate Amount under Section 1927 of the Social Security Act:** To determine unit counts for rebate calculations, at this time, CMS proposes excluding billing units from claims with dates of service during a month within a calendar quarter when the Medicare beneficiary has Medicaid coverage that may provide cost-sharing assistance.
- **Units that Are Packaged into the Payment Amount for an Item or Service and Are Not Separately Payable:** CMS proposes to only include claim lines with a Medicare allowed amount greater than zero.
- **Units When a Drug is No Longer a Part B Rebatable Drug:** CMS notes that a single source drug that is a Part B rebatable drug could become a multiple source drug at the start of or during a calendar quarter. In such cases, CMS proposes to exclude billing units of certain drugs furnished on and after the first day of the calendar month in which the therapeutically equivalent drug was first sold or marketed during the applicable calendar quarter.
- **Operational Considerations Related to the Inclusion of Units Furnished to Beneficiaries Who Are Enrolled in Medicare Advantage (MA) Plans:** In the Proposed Rule, CMS makes clear that, due to operational challenges, at this time it is not proposing to establish a policy on treatment of MA units in the calculation of Part B inflation rebates but may establish policy on this issue in future rulemaking. **CMS solicits comment on this approach.**
- **Units Subject to Discarded Drug Refund Amounts:** CMS proposes a policy addressing the interaction between Part B inflation rebates and billing units of discarded drugs. Although the IRA does not require that billing units of discarded drugs be excluded from Part B inflation rebates, CMS is proposing to exclude billing units of discarded drugs that are subject to discarded drug refunds from Part B inflation rebates. Notably, policy related to this issue was not established in the revised Medicare Part B Drug Inflation Rebate Guidance. In the Proposed Rule (pg. 993-994), CMS outlines an approach to exclude billing units of a refundable drug subject to discarded refunds from the calculation of the Part B inflation rebate amount during the reconciliation process, except for calendar quarters in CY 2023.

[30] The total number of billing units for each Part B rebatable drug include the number of billing units for the HCPCS code of the Part B rebatable drug furnished during the relevant calendar quarter minus billing units of drugs with respect to which the manufacturer provides a discount under the 340B Program, billing units with respect to which the manufacturer could have paid a Medicaid rebate, and billing units that are packaged into the payment amount for an item or service and are not separately payable.

Reducing the Rebate Amount for Part B Rebatable Drugs in Shortage and When there is a Severe Supply Chain Disruption

The IRA requires the Secretary to reduce or waive the rebate amount owed by a manufacturer for a Part B rebatable drug when either (1) a Part B rebatable drug is on the Food and Drug Administration's drug shortage list at any point during the applicable period or (2) CMS determines there is a severe supply chain disruption during the applicable quarter for a Part B rebatable drug (e.g., disruption caused by a natural disaster or other unique or unexpected event). Also, CMS notes that the statute does not address how CMS should reduce or waive the inflation rebates in each of these cases. Table 2, below, outlines the proposed determination of rebate reduction amounts of Part B rebatable drugs. Additional detail is included in the Proposed Rule (pg. 995-1005). **CMS welcomes comments on the proposed approach.**

	Drug Shortage		Severe Supply Chain Disruption
Duration of Reduction	Indefinite for as long as drug is "currently in shortage"		Four calendar quarters; manufacturer may request an extension for four additional quarters for up to eight calendar quarters total
Percent Reduction	Part B rebatable drug other than a plasma-derived product	Part B rebatable plasma-derived product	Part B rebatable biosimilar biological product
First four consecutive calendar quarters	25%	75%	75%
Second four consecutive calendar quarters	10%	50%	75%
Subsequent calendar quarters	2%	25%	Not applicable

Table 2. Determination of Rebate Reduction Amount for Part B Rebatable Drugs

Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments

The IRA requires the Secretary to provide a report to each manufacturer of a Part B rebatable drug certain information (e.g., total number of billing units for each Part B rebatable drug; the amount, if any, of the excess ASP increase, the rebate amount for the Part B rebatable drug) not later than 6 months after the end of an applicable calendar quarter. No later than 30 calendar days after receipt of this information, the manufacturer must provide a rebate for each Part B rebatable drug. To fulfill this statutory requirement, CMS proposes to provide a Preliminary Rebate Report followed by a Rebate Report to all manufacturers of a Part B rebatable drug, even if the amount due is $0. In the Proposed Rule, CMS also addresses reports of rebate amounts and suggestion of errors, reconciliation of the rebate amount which includes a preliminary reconciliation of the rebate amount and a reconciled rebate amount. For CYs 2023 and 2024, CMS proposes consolidating the Preliminary Rebate Reports into two reports: one report for the four applicable calendar quarters in CY 2023 and one report for the four applicable calendar quarters in CY 2024. For these combined reports, CMS proposes to provide an extended 30 calendar day Suggestion of Error period for the Preliminary Rebate Report.

CMS proposes that manufacturers that do not pay the Medicare Part B inflation rebate amount owed for a Part B rebatable drug within 30 calendar days of receiving a Rebate Report, including reports containing a reconciled rebate amount, may be subject to a civil money penalty of 125 percent of the rebate amount, as applicable, for such drug for the applicable calendar quarter. **CMS seeks comments on proposals related to the violations of payment deadlines and the issuance of a civil monetary penalty.**

Medicare Part D Drug Rebates for Drugs, Biologicals, and Sole Source Generic Drugs with Prices that Increase Faster than the Rate of Inflation

In the Proposed Rule, CMS proposes numerous policies that are provided in the revised Medicare Part D Drug Inflation Rebate Guidance. In addition, CMS proposes new definitions and policies not addressed in the revised Medicare Part D Drug Inflation Rebate Guidance to implement the Medicare Part D Drug Rebate Program.

Determination of Part D Rebatable Drug

In the Proposed Rule, CMS proposes to identify a Part D rebatable drug for each applicable period by determining which covered Part D drugs are brand name drugs approved under a New Drug Application, biologicals licensed under a biologics license application (BLA) or generic drug approved under an Abbreviated New Drug Application (ANDA). CMS also proposes to codify policy described in the revised Medicare Part D Drug Inflation Rebate Guidance, including policy to determine if a drug or biological is excluded from the definition of a Part D rebatable drug if the "average annual total cost" under Part D for such period per individual who uses the drug or biological product is less than $100 per year.

Determination of the Rebate Amount for Part D Rebatable Drugs

Under the IRA, the Part D drug inflation rebate for each Part D rebatable drug, subject to certain considerations, is the estimated amount that is equal to the product of: (1) the amount, if any, by which the annual manufacturer price (AnMP) for such Part D rebatable drug for the applicable period exceeds the inflation-adjusted payment amount for the Part D rebatable drug for the applicable period, and (2) the total number of units of the Part D rebatable drug dispensed under Part D and covered and paid by Part D plan sponsors during the applicable period. CMS proposes to codify the methodology used to determine the rebate amount for Part D rebatable drugs as outlined in the revised Medicare Part D Drug Inflation Rebate Guidance. More information regarding the exclusions from the determination of the total number of units dispensed under Part D is noted below.

Exclusions from Total Number of Units Dispensed Under Part D

CMS proposes to remove from the total number of units any units of a generic drug dispensed on or after the date that such generic drug no longer meets the definition of a Part D rebatable drug, as well as units acquired through the 340B Program. **CMS welcomes comments on additional units that should be excluded from the rebate amount calculation.**

Regarding the exclusion of 340B acquired units, CMS notes that the IRA requires that beginning with plan year 2026, CMS shall exclude from the total number of units for a Part D rebatable drug, with respect to an applicable period, those units for which a manufacturer provides a discount under the 340B Program. Based on this requirement, CMS would exclude 340B units starting on January 1, 2026. In the Proposed Rule, CMS acknowledges that the 340B status of a Part D drug is usually not known by the dispenser at the point-of-sale and

that 340B covered entities typically identify the 340B status of a Part D drug retrospectively. Because the covered entity and CMS do not exchange dispensed Part D drug information confirming the 340B status of a Part D rebatable drug, CMS believes it is unable to identify 340B units at the claim-level at this time. For these reasons, CMS proposes to establish an estimation methodology to remove 340B units from the total number of units for a Part D rebatable drug. CMS details this estimation methodology in the Proposed Rule (pg. 1056-1059) and notes various data sources it plans on relying on, including data from the Health Resources and Service Administration's (HRSA's) Prime Vendor Program (PVP) and manufacturer reporting under the Medicaid Drug Rebate Program (MDRP). Regarding the proposed methodology, CMS recognizes that the proposed estimation percentage represents the total number of 340B units dispensed as a proportion of total units dispensed, irrespective of insurance/payor type.

CMS solicits comments on whether the agency should further adjust the percentage of 340B units dispensed to the general population to estimate the percentage of 340B units dispensed to Part D beneficiaries for claims with dates of service on or after January 1, 2026, including comments on how the percentage of 340B units dispensed to the general population compares with the percentage of 340B units dispensed to Part D beneficiaries. CMS welcomes evidence that demonstrates how these percentages differ. CMS will consider this information in developing its final policies and may consider adjusting the estimation percentage to reflect variation between the percentage of 340B units dispensed to Part D beneficiaries and the percentage of 340B units dispensed to the general population.

In addition, CMS indicates that it considered using alternative data sources to calculate the estimation percentage (e.g., requiring other entities throughout the supply chain to report data to CMS) to better capture the limited 340B sales that the PVP data does not capture. However, at this time, CMS is not proposing this alternative because CMS would prefer to rely on data that are already reported to the PVP, as using these data would help to minimize reporting burdens and may result in cleaner and more accurate data due to the quality checks performed on the PVP data for purposes of compliance with the 340B Program.

Notably, in the Proposed Rule (pg. 1061-1065), CMS provides the following three comment solicitations: Comment Solicitation on a Medicare Part D Claims Data Repository; Comment Solicitation on Requiring Covered Entities to Submit 340B Claims Data to the Repository; and Comment Solicitation on Timing Requirements for Potential Submissions to a Medicare Part D Claims Data Repository.

Also, CMS notes that in the initial Medicare Part D Drug Inflation Rebate Guidance, CMS considered requiring that a 340B indicator be included on the Prescription Drug Event (PDE) record at the time of dispensing to identify drugs purchased under the 340B Program that were dispensed under Medicare Part D. After further consideration of comments received in response to the initial guidance and of the process through which a claim is determined to have 340B status, CMS indicates it is no longer pursuing this policy at this time but may consider it in future rulemaking.

Reducing the Rebate Amount for Part D Rebatable Drugs in Shortage and When There Is a Severe Supply Chain Disruption or Likely Shortage

The IRA requires the Secretary to reduce or waive the rebate amount owed by a manufacturer for a Part D rebatable drug with respect to an applicable period in three distinct cases: (1) when a Part D rebatable drug is on a shortage list in effect under section 506E of the FD&C

Act at any point during the applicable period; (2) when CMS determines there is a severe supply chain disruption during the applicable period for a generic Part D rebatable drug or biosimilar, such as a disruption caused by a natural disaster or other unique or unexpected event; and (3) when CMS determines that without such a reduction or waiver, a generic Part D rebatable drug is likely to be described as in shortage on FDA's shortage list during a subsequent applicable period. The statute does not describe how CMS should reduce or waive inflation rebates. Table 3, below, outlines the proposed determination of rebate reduction amounts of Part D rebatable drugs. Additional detail is included in the Proposed Rule (pg. 1067-1083). **CMS welcomes comments on the proposed approach.**

	Drug Shortage		Severe Supply Chain Disruption	Likely to be in Shortage
Duration of Reduction	Indefinite for as long as drug is "currently in shortage"		One applicable period; manufacturer may request an extension for an additional applicable period for up to two applicable periods total	
Percent Reduction	Part D rebatable drug other than a plasma-derived product or generic Part D rebatable drug	Part D rebatable plasma-derived product or generic Part D rebatable drug	Part D rebatable biosimilar or generic Part D rebatable drug	Generic Part D rebatable drug
First applicable period	25%	75%	75%	75%
Second applicable period	10%	50%	75%	75%
Subsequent applicable periods	2%	25%	Not applicable	Not applicable

Table 3. Determination of Rebate Reduction Amount for Part D Rebatable Drugs

Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments

The IRA requires the Secretary to provide a report to each manufacturer of a Part D rebatable drug with the certain information (e.g., amount, if any, of the excess AnMP increase for each Part D rebatable drug; the rebate amount for each Part D rebatable drug) not later than 9 months after the end of an applicable period. After no later than 30 calendar days of receipt of this information, the manufacturer must provide a rebate for each Part D rebatable drug.

To fulfill this statutory requirement, CMS proposes to provide a Preliminary Rebate Report[31] followed by a Rebate Report (the rebate amount is invoiced by the Rebate Report) to all

[31] CMS proposes that the Preliminary Rebate Report would include the following information: the NDC(s) for the Part D rebatable drug; the total number of units for the Part D rebatable drug for the applicable period (which would remove units when a generic drug is no longer a Part D rebatable drug and would exclude units acquired through the 340B Program; the benchmark period manufacturer price; the AnMP for the Part D rebatable drug for the applicable period; the applicable benchmark period and

manufacturers of a Part D rebatable drug, even if the amount due is $0. In the Proposed Rule, CMS acknowledges requests from interested parties to provide additional data elements including claims-level data such as days' supply, fill number, and prescription ID number on rebate reports. CMS considered these requests in development of the Proposed Rule but does not believe it is necessary to provide this further information to fulfill its statutory obligation and believes that the potential benefits to manufacturers of additional data are outweighed by the administrative burdens additional reporting would impose to the agency. In the Proposed Rule, CMS further details reports of rebate amounts, suggestion of errors, and reconciliation of the rebate amount.

CMS proposes to issue a Preliminary Rebate Report for each applicable period followed by issuance of the Rebate Report for each applicable period no later than December 31, 2025. For these reports, CMS proposes to provide an extended 30 calendar day Suggestion of Error period for these Preliminary Rebate Reports.

CMS proposes that manufacturers that do not pay the Medicare Part D inflation rebate amount owed for a Part D rebatable drug within 30 calendar days of receiving a Rebate Report, including reports containing a reconciled rebate amount, may be subject to a civil money penalty of 125 percent of the rebate amount, as applicable, for such drug for the applicable calendar quarter.

Medicare Parts A and B Overpayment Provisions of the Affordable Care Act

In the December 2022 Overpayment Proposed Rule, CMS proposed to change regulations regarding the standard for an "identified overpayment" under Medicare Parts A, B, C and D and to remove the existing "reasonable diligence" standard and adopt by reference the definition of "knowing" and "knowingly" as set forth in the False Claims Act.[32] CMS has not finalized the December 2022 Overpayment Proposed Rule, and in the Proposed Rule, makes additional proposals to revise existing regulations regarding the deadline for reporting and returning overpayments. Additional information regarding these proposals is available in the Proposed Rule (pg. 1169-1174).

Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan

The SUPPORT Act generally mandates that the prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D be done electronically in accordance with an electronic prescription drug program beginning January 1, 2021, subject to any exceptions, which HHS may specify. In the CY 2021-2024 PFS final rules, CMS finalized policies to implement this requirement and finalized proposals to limit compliance actions (i.e., non-compliance notices) through December 31, 2024.

In the Proposed Rule, CMS addresses prescriptions for beneficiaries in a long-term care (LTC) facility. Specifically, CMS proposes that prescriptions written for a beneficiary in a LTC facility would not be included in determining compliance until January 1, 2028, and that compliance actions against prescribers who do not meet the compliance threshold based on

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applicable period CPI-Us; the inflation-adjusted payment amount; the amount, if any, of the excess AnMP for the Part D rebatable drug for the applicable period; any applied reductions; and the rebate amount due.

[32] 31 U.S.C. 3729(b)(1)(A)

prescriptions written for a beneficiary in a LTC facility would commence on or after January 1, 2028 (a three three-year delay). **CMS seeks comment on the proposal to extend the date after which prescriptions for covered Part D drugs for Part D eligible individuals in LTC facilities would be included in our CMS EPCS Program compliance threshold calculation from January 1, 2025, to January 1, 2028, and that related non-compliance actions would commence on or after January 1, 2028.**

Shared Savings Program

Eligible groups of providers and suppliers, including physicians, hospitals, and other healthcare providers, may participate in the Shared Savings Program (SSP) by forming or joining an accountable care organization (ACO). Under the SSP, providers and suppliers that participate in an ACO continue to receive traditional Medicare FFS payments, and the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements, and in some instances, may be required to share in losses if it increases health care spending. Under the SSP, there are different participation tracks (i.e., BASIC[33] or ENHANCED[34]) that allow ACOs to assume various levels of risk.

Update to Shared Savings Program Eligibility Requirements and Application Procedures

CMS proposes two key modifications to the SSP eligibility and application procedures that will be implemented for performance years beginning on or after January 1, 2025.

First, CMS proposes to sunset the requirement that CMS must terminate the participation agreement and the ACO is not eligible to share in savings for that performance year if the ACO's assigned population is not at least 5,000 by the end of the performance year specified by CMS in its request for a corrective action plan (CAP). In the Proposed Rule, CMS notes that the population threshold was originally developed with the intent of protecting both CMS and the ACO from variability in expenditure calculations caused by a small, assigned beneficiary population. Given the minimum savings rate (MSR) and medical loss ratio (MLR) adjustments CMS finalized in 2018 rulemaking, the agency believes CMS is adequately protected from inappropriate over or under payments if the ACO has a reduction in assigned beneficiaries. However, CMS clarifies that the proposal does not modify the requirements that ACOs have 5,000 beneficiaries at critical points in CMS's determination of the ACO's eligibility to participate in the SSP, including: at the time of application in order to be eligible for the SSP, and at any point when an ACO elects to renew its participation in the program.

Second, CMS proposes removing the reference to the Antitrust Enforcement Policy Statement noted in regulations as related to eligibility requirements given that, in 2023, the Department of Justice and Federal Trade Commission withdrew the Antitrust Enforcement Policy Statement. CMS proposes that an ACO seeking to participate in the SSP, or entering into a new participation agreement, must agree that CMS can share a copy of their application with the Antitrust Agencies.

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[33] The BASIC track offers a glide path for eligible ACOs to transition from a one-sided shared savings-only model to progressively higher increments of financial risk and potential reward under two-sided shared savings (otherwise referred to as performance-based risk) and shared losses models within a single 5-year agreement period.
[34] The ENHANCED track offers ACOs the opportunity to accept greater financial risk for their assigned beneficiaries in exchange for potentially higher financial rewards.

Beneficiary Assignment Methodology

In the Proposed Rule, CMS outlines recent feedback from ACOs and its review of the HCPCS and CPT codes that are currently recognized for payment under the PFS or that CMS proposes to recognize for payment starting in CY 2025. As a result, CMS believes it would be appropriate to amend the definition of primary care services used in the SSP assignment methodology to include certain additional codes for the performance year starting on January 1, 2025, and subsequent performance years. For example, if finalized under Medicare FFS payment policy, CMS proposes to include Safety Planning Interventions (HCPCS code GSPI1) when the base code is also a primary care service code, Post-Discharge Telephonic Follow-up Contacts Intervention (HCPCS code GFCI1), Virtual Check-in Service (CPT code 9X091), and Advanced Primary Care Management Services (HCPCS GPCM1, GPCM2, and GPCM3), among others. More information regarding these changes to the assignment methodology is available in the Proposed Rule (pg. 689-712).

In addition, CMS proposes expanding upon current SSP regulations to broaden the existing exception to the program's voluntary alignment policy. Under this proposal, the exception to apply to beneficiaries assigned to entities in a CMS Innovation Center model under which claims-based assignment is based solely on (1) claims for primary care and/or other services related to treatment of one or more specific diseases or conditions targeted by the model, or (2) claims for services other than primary care services, and for which there has been a determination by the Secretary that waiver of certain requirements is necessary for purposes of testing the model. CMS clarifies that under this proposal a beneficiary's claims-based assignment to an entity participating in such a model would not supersede their voluntary alignment to a SSP ACO.

Quality Reporting Standard & Other Reporting Requirements

Proposal to Require Shared Savings Program ACOs to Report the APP Plus Quality Measure Set

In the CY 2021 PFS final rule, CMS finalized policy that required ACOs to report quality data via the Alternative Payment Model (APM) Performance Pathway (APP). In subsequent rulemaking, CMS built upon these requirements and in the CY 2024 PFS final rule, CMS established the Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs) as a new collection type for SSP ACOs reporting on the Medicare CQMs within the APP quality measure set for performance year 2024 and subsequent performance years. SSP ACOs have the option to report on Medicare CQMs and CMS notes this option is to support ACOs in the transition to digital quality measure reporting. In the 2024 PFS final rule, CMS also noted that it would evaluate the impact of aligning the APP quality measure set with the Universal Foundation measures, which are measures that CMS aims to utilize across quality programs and will be prioritized for stratification and digitization.

In the Proposed Rule, CMS proposes to create the APP Plus quality measure set to align with the Adult Universal Foundation measures. Under the proposed approach, the APP Plus quality measure set would incrementally grow to comprise eleven measures, consisting of the six measures in the existing APP quality measure set and five newly proposed measures from the Adult Universal Foundation measure set that would be incrementally incorporated into the APP Plus quality measure set over performance years 2025 through 2028. CMS proposes to make the APP Plus quality measure set optional for APP reporters. For performance year 2025 and subsequent performance years, CMS proposes to require SSP ACOs to report the

proposed APP Plus quality measure set. As a result, the APP quality measure set would no longer be available for reporting by SSP ACOs beginning in performance year 2025.

The proposed APP Plus quality measure sets for the SSP ACOs for performance years 2025-2028 are available in the Proposed Rule Tables 34-36 (pg. 755-757). CMS notes that it plans to update the APP Plus quality measure sets as new measures are added to or removed from the Adult Universal Foundation measure set in the future.

CMS proposes to focus the collection types available to Shared Savings Program ACOs for reporting the APP Plus quality measure set to eCQMs and Medicare CQMs.

Proposed Changes to the Methodology for Calculating the MIPS Quality Performance Category Score for Shared Savings Program ACOs Reporting the APP Plus Quality Measure Set

In the Proposed Rule, CMS proposed to establish the data submission criteria for the APP Plus quality measure set. Also, CMS proposes that the policies related to MIPS performance category scoring in the APP would apply to SSP ACOs that report the APP Plus quality measure set for the purpose of meeting the Safety Savings Program's quality performance standard. **CMS seeks feedback regarding these proposals, including the proposal to require the reporting of all measures within the APP Plus quality measure set**.

Also, CMS proposes to establish a Complex Organization Adjustment for virtual groups and APM Entities, including SSP ACOs, when reporting eCQMs. Under the Complex Organization Adjustment, beginning in the CY 2025 performance period/ 2027 MIPS payment year, a Virtual Group and an APM Entity would receive one measure achievement point for each submitted eCQM that meets the case minimum and data completeness requirement. The Complex Organization Adjustment for a Virtual Group or APM Entity may not exceed 10 percent of the total available measure achievement points in the quality performance category. The adjustment would be added for each measure submitted at the individual measure level.

CMS notes that the use of flat benchmarks helps ensure that ACOs with high quality performance on a measure are not penalized as low performers. For this, and other reasons, CMS proposes that beginning in the CY 2025 performance period/2027 MIPS payment year, measures of the Medicare CQM collection type would be scored using flat benchmarks for their first two performance periods in MIPS. Table 30 of the Proposed Rule (pg. 745) lists the Medicare CQMs eligible for flat benchmarks in performance year 2025-2029. **CMS seeks comment on the proposal to score ACOs reporting Medicare CQMs using flat benchmarks in performance year 2025 and subsequent performance years.**

Proposal to Extend the eCQM Reporting Incentive for Meeting the Shared Savings Program Quality Performance Standard

In the CY 2023 PFS final rule, CMS extended the incentive for reporting eCQMs/MIPS CQMs through performance year 2024 to align with the timeline for sunsetting of the CMS Web Interface reporting option and to allow ACOs an additional year to gauge their performance on the eCQMs/MIPS CQMs before full reporting of the measures is required beginning in performance year 2025.

In the Proposed Rule, CMS notes that SSP quality reporting data over the past two performance years indicates that ACOs have been slow to report eCQMs. As a result, CMS

proposes extending the eCQM reporting incentive to performance year 2025 and subsequent performance years to support ACOs in meeting the SSP quality performance standard.[35] Table 33 of the Proposed Rule (pg. 752) outlines the Proposed APP Plus Quality Measure Set Reporting Requirements and Quality Performance Standard for Shared Savings ACOs for Performance Year 2025 and subsequent performance years.

Advance Investment Payments

In the Proposed Rule, CMS describes previously finalized policy that made advance investment payments (AIPs) available to ACOs newly entering the SSP in their first agreement period. CMS proposes modest changes related to AIPs, such as opportunities for ACOs to voluntarily terminate receipt of AIPs while remaining in the SSP and recoupment of AIPs when CMS terminates the participation agreement of an ACO.

Providing the Option of Prepaid Shared Savings

While CMS is not expanding AIP eligibility, the agency does propose to provide additional prepaid shared savings to certain ACOs that meet certain eligibility criteria, as detailed in the Proposed Rule (pg. 766-769). The payments would be distributed on a quarterly basis and would be recouped from shared savings CMS determines the ACO to have earned during the annual financial reconciliation cycle. Table 37 of the Proposed Rule (pg. 791) provides the calculation of maximum quarterly prepaid shared savings payments.

CMS proposes that an ACO must submit to CMS supplemental application information sufficient for CMS to determine whether the ACO is eligible to receive prepaid shared savings. The application cycle for prepaid shared savings would be conducted as part of, and in conjunction with, the SSP application process, with instructions and timelines published on the SSP website. CMS proposes the initial application cycle to apply for prepaid shared savings would be for a January 1, 2026, start date. If finalized, CMS would provide additional information through subregulatory guidance. In the Proposed Rule, CMS specifies how an ACO may use prepaid shared savings (e.g., staffing, healthcare infrastructure and direct beneficiary services), prohibited uses (e.g., parent company profit, performance bonuses, cash payments to patients) and also notes different application and reporting requirements (e.g., a spend plan, actual use of prepaid shared savings, how services supported care of beneficiaries). CMS also indicates it may withhold and terminate payment in certain circumstances (e.g., if CMS predicts the ACO will not generate sufficient earned shared savings) and that it may recoup prepaid shared savings, such as the if ACO has an outstanding balance of prepaid shared savings of the final performance year of the agreement. **CMS welcomes comments on these proposals.**

[35] Specifically, CMS proposes that for performance year 2025 and subsequent performance years, an ACO will meet the quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable: If the ACO reports all of the eCQMs in the APP Plus quality measure set applicable for a performance year, meeting the data completeness requirement at § 414.1340 for all eCQMs, and; Achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP Plus quality measure set, and; Achieves a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining measures in the APP Plus quality measure set.

Financial Methodology

In the Proposed Rule, CMS proposes modifications to the financial methodologies under the SSP. Specifically, CMS proposes creating a health equity benchmark adjustment, to provide an upward adjustment to an ACO's historical benchmark based on the proportion of beneficiaries they serve who are dually eligible or enrolled in the Medicare Part D low-income subsidy (LIS). CMS proposes a health equity benchmark adjustment (HEBA) applicable to ACOs in agreement periods beginning on January 1, 2025 and in subsequent years.

In the Proposed Rule (pg. 815-816), CMS describes in greater detail how the HEBA would be calculated. To identify beneficiaries from underserved communities for purposes of the HEBA, CMS would identify those who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid. Only ACOs with a proportion of assigned beneficiaries enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid greater or equal to 20 percent would be eligible for the HEBA. Tables 38-40 of the Proposed Rule (pg. 818-820) present hypothetical examples to demonstrate how the HEBA would work in practice. **CMS seeks comment on the use of the Area Deprivation Index (ADI) to identify beneficiaries from underserved communities for purposes of determining eligibility for and the amount of any health equity benchmark adjustment.**

In addition, CMS proposes to establish a calculation methodology to account for the impact of improper payments in recalculating expenditures and payment amounts used in SSP financial calculations, upon reopening a payment determination. CMS also proposes a process for ACOs to request that CMS reopen a payment determination. Table 41 (pg. 853) of the Proposed Rule provides a hypothetical example of steps for recalculating ACO assigned beneficiary expenditures using proposed methodology to account for improper payments and Table 43 (pg. 858) provides a hypothetical example of how an ACO's financial performance may be recalculated after accounting for improper payments. CMS also proposes a process for ACO reopening requests for reopening of an initial determination or a final agency determination of shared savings or losses.

In the Proposed Rule, CMS proposes to establish an approach to identify significant, anomalous, and highly suspect ("SAHS") billing activity in CY 2024 or subsequent calendar years. CMS notes that current SSP regulations do not provide a basis for CMS to adjust program expenditure or revenue calculations to remove the impact of SAHS billing activity. CMS proposes to specify how the agency would exclude payment amounts from expenditure and revenue calculations for the relevant calendar year for which the SAHS billing activity is identified, as well as from historical benchmarks used to reconcile the ACO for a performance year corresponding to the calendar year for which the SAHS billing activity was identified, to mitigate the impact of SAHS billing activity. **CMS seeks comment on the proposal to apply the policy retroactively to performance year 2024, including how it would affect ACOs and their ability to participate in the SSP.** To clarify, the changes CMS proposes would address the impact of SAHS billing identify in CY 2024 and subsequent calendar years, and thus would apply to ACOs currently participating in performance year 2024.

CMS also proposes certain modifications for clarity and consistency in provisions of the SSP regulations on calculation of the ACO risk score growth cap in risk adjusting the benchmark each performance year and the regional risk score growth cap in calculating the regional component of the three-way blended benchmark update factor.

In addition, CMS proposes changes regarding when ACOs must communicate with beneficiaries. For example, CMS proposes to modify the requirements for when ACOs must provide the beneficiary information in follow-up communications.

Lastly, CMS seeks comment on establishing a higher risk under the ENHANCED track. CMS notes that a recent Congressional Budget Office report proposed that higher sharing rates might incentivize providers to decrease spending, as they would stand to gain a larger proportion of the savings generated. CMS notes that such an alternative participation option would replace the existing ENHANCED track in order to avoid the self-selection issues that would occur if a higher risk track were to be included alongside the ENHANCED track. **CMS seeks comments regarding the following potential features of a revised ENHANCED tracked, as further detailed in the Proposed Rule (pg. 902-908): benchmark discount rate; tapered sharing arrangements; symmetric MSR/MLR of 0 percent; cap on regional adjustment weight; and alternative payment mechanisms.** Also, CMS provides additional specific questions in the Proposed Rule (pg. 908-910).

Updates to the Quality Payment Program

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the QPP for eligible clinicians. Under the QPP, MIPS eligible clinicians can participate via one of two tracks – the MIPS (reporting via traditional MIPS or MIPS Value Pathways (MVPs)) and APMs. Generally, the Proposed Rule sets forth changes to the QPP starting January 1, 2025. CMS also provides several resources regarding the Proposed Rule on the Quality Payment Program website and a Fact Sheet and Policy Comparison Table for download. **Among several other highlights and proposals, CMS includes an RFI regarding MVP adoption and subgroup participation in the Proposed Rule. This RFI is particularly important, as CMS identifies the 2029 performance period as the potential timeline for completing the transition to MVPs and sunsetting traditional MIPS.**

Request for Information: Building upon the MIPS Value Pathways (MVPs) Framework to Improve Ambulatory Specialty Care

In the Proposed Rule, CMS provides a request for information on the design of a future ambulatory specialty model (pg. 1105-1127). Specifically, CMS is currently exploring developing a model for specialists in ambulatory settings that would leverage the MVPs framework. As currently envisioned, participants under this model would not receive a MIPS payment adjustment. Instead, a model participant would receive a payment adjustment based on (1) a set of clinically relevant MVP measures that they are required to report and (2) comparing the participant's final score against a limited pool of clinicians (other model participants of their same specialty type and clinical profile, who are also required to report on those same clinically relevant MVP measures). **CMS solicits comments on several parameters of a potential model, including considering mandatory participation of relevant specialty care providers to overcome challenges such as selection bias and participant attrition, and to ensure the model is reaching a representative group of providers and beneficiaries to facilitate scaling of the model test. In addition, the RFI poses questions related to: participant definition, MVP performance assessment; payment methodology, care delivery and incentives for partnerships with accountable care entities and integration with primary care; health information technology and data sharing; health equity; and multi-payer alignment.** Also, CMS notes that it would expect this ambulatory specialty model to be implemented no earlier than 2026.

What's Next?

CMS typically publishes the PFS final rule by early November, with effective dates of most policies being January 1, 2025. The comment period closes on September 9, 2024.

Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this proposed rule. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern. Please direct your feedback to Jenna Stern, Associate Vice President, Regulatory Affairs and Public Policy, in Vizient's Washington, D.C. office.