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Final Rule: 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

November 18, 2024

Background & Summary

On November 1, the Centers for Medicare & Medicaid Services (CMS) issued the annual final rule to update the Calendar Year (CY) 2025 Medicare payment and policies for the Physician Fee Schedule (PFS) (hereinafter, "Final Rule"). The Final 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 Final Rule, are available on the CMS website.

The Final Rule also includes changes to the Quality Payment Program (QPP) and the Medicare Shared Savings Program (MSSP). Additional Final Rule resources include CMS fact sheets on the PFS final policies, the Medicare Shared Savings Program final policies and the Quality Payment Program final policies.

The final regulations are effective January 1, 2025, with some exceptions.

Major Proposals Finalized and Key Changes from the Proposed Rule

Conversion Factor and Payment Update

CMS finalized their proposed conversion factor of $32.3465. The payment impact of the proposed policies by specialty is shown in Table 110 of the Final Rule (pgs. 2326-2327).

Table 1. Final PFS Conversion Factor for CY 2025

Calculation of the Final CY 2025 PFS Conversion Factor		
CY 2024 Conversion Factor		**33.2875**
Conversion Factor without CAA*, 2024 (2.93 Percent Increase for CY 2024)		**32.3400**
CY 2025 Statutory Update Factor	0.00 percent (1.0000)	
CY 2025 RVU Budget Neutrality Adjustment	0.02 percent (1.0002)	
CY 2025 Conversion Factor		**32.3465**

* CAA, Consolidated Appropriations Act

Medicare Telehealth Services

In the Final Rule, CMS indicated that without congressional action, several telehealth-related flexibilities that were established during the COVID-19 Public Health Emergency (PHE) will expire on December 31, 2024. However, other telehealth policies within the agency's authority are addressed in the Final Rule.

Medicare Telehealth Services List

In the Final Rule, CMS provided a comprehensive analysis of several codes where a request was made to add these services to the Medicare Telehealth Services List. Table 12 (pg. 132) of the Final Rule provides a list of services finalized for addition to the Medicare telehealth services list for CY 2025 on a permanent (e.g., PrEP for HIV; safety planning interventions) and provisional basis (e.g., caregiver training).

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

During the COVID-19 PHE, CMS temporarily removed frequency limitations on how often practitioners may furnish a service via Medicare telehealth. Although frequency limitations went back into effect on May 12, 2023 (upon expiration of the PHE), through enforcement discretion for CY 2024, CMS suspended these limitations for certain codes (e.g., Subsequent Inpatient Visit CPT Codes 99231-99233, Subsequent Nursing Facility Visit CPT Codes 99307-99310, Critical Care Consultation Services HCPCS Codes G0508-G0509). CMS finalized the proposal to remove the frequency limitations for these codes for CY 2025. CMS indicates that extending the flexibility related to the frequency limitations allows the agency to gather an additional year of data to determine future potential changes, including whether such changes should be made on a permanent basis.

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

CMS finalized the proposal to permanently change the definition of an "interactive telecommunications system" to 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[1]. Additionally, CMS proposed that a modifier must be appended to the claim for these services to verify that these conditions have been met. Also, in the Final Rule in response to stakeholder questions, CMS clarified that no additional documentation (other than the appropriate modifier) is required.

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 finalized the proposal to continue this policy through CY 2025.

In addition, CMS reminded stakeholders that the agency defers to state law regarding licensure requirements for distant site Medicare telehealth practitioners. Also, CMS noted that a separate Medicare enrollment is required for each state in which the practitioner furnishes and intends to bill for covered Medicare services.

[1] 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.

Telehealth Originating Site Facility Fee Payment Amount Update

For CY 2025, the telehealth originating site facility fee (HCPCS code Q3014) is $31.01, which was updated by applying 3.5 percent adjustment based on the Medicare Economic Index (MEI)

Also, while not specific to a proposal, in the Final Rule, CMS clarified that claims for telehealth services billed with POS 10 (telehealth provided in patient's home) will continue to be paid at the non-facility PFS rate for CY 2025 and subsequent years.

New CPT Codes: Telemedicine Evaluation and Management (E/M) Services[2]

In February 2023, the CPT® Editorial Panel, which is under the authority of the American Medical Association (AMA), added a new Evaluation and Management (E/M) subsection to the draft CPT codebook for Telemedicine Services. However, in the Final Rule, except for the service delivery modality, CMS found that the new telemedicine E/M codes appear to describe the same services that are provided in person and billed under the existing office/outpatient E/M codes. As a result, and consistent with the Proposed Rule, CMS reiterated that it will not recognize 16 E/M telehealth CPT® codes (CPT codes 98000-98015).

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

CMS finalized as proposed, to continue to define "direct supervision" to allow the presence and immediate availability of the supervising practitioner through real-time audio and visual interactive telecommunications (not audio-only) through December 31, 2025.

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

For certain services furnished after December 31, 2025, CMS finalized the proposal 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).

As noted above, for all other services required to be furnished under the direct supervision of the supervising physician or other practitioner, CMS finalized continuing to define "immediate availability" to include real-time audio and visual interactive telecommunications technology (excluding audio-only) only through December 31, 2025. However, CMS notes that it may

[2] 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

consider adding additional services for which direct supervision can include a virtual presence in future rulemaking.

Teaching Physician Billing for Services Involving Residents with Virtual Presence

CMS finalized policy, through December 31, 2025, to continue to allow teaching physicians to have a virtual presence for purposes of billing for services furnished involving residents in all teaching settings, but only when the service is furnished virtually (e.g., a 3-way telehealth visit, with the patient, resident, and teaching physician in separate locations).

New, Revised and Potentially Misvalued Codes

In the Final Rule, CMS finalized policy related to work RVUs for new, revised and potentially misvalued codes. Table 17 (pg. 344-362) of the Final Rule includes the work RVUs for such codes and information related to CMS time refinements.

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

For CY 2025, CMS finalized the creation of HCPCS code G0545 with some modifications to the proposed HCPCS code descriptor. The finalized full descriptor for the hospital I/O E/M visit complexity add-on code is: *Visit complexity inherent to hospital inpatient or observation care associated with a confirmed or suspected infectious disease by an infectious diseases specialist, including disease transmission risk assessment and mitigation, public health investigation, analysis, and testing, and/or 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, subsequent or discharge).* Also, in the Final Rule, CMS indicates that it expects that HCPCS code G0545 will be reported by practitioners who have the requisite specialized infectious disease training, including but not necessarily limited to physicians, nurse practitioners, physician assistants, and certified nurse specialists. CMS reiterated that the agency will consider using any newly available CPT coding to describe infectious disease services in future rulemaking.

Payment for Caregiver Training Services (CTS)

In the Final Rule, CMS established new coding (three new HCPCS codes (G0541-G0543[3]) and payment for caregiver training for direct care services and supports.

[3] G0541 (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 care, and infection control) (without the patient present), face-to-face; initial 30 minutes); G0542 (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 care, and infection control) (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service) (Use G0542 in conjunction with G0541)); and G0543 (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 care, and infection control) (without the patient present), face-to-face with multiple sets of caregivers)).

CMS also finalized HCPCS codes related to individual management / modification caregiver training services[4] to establish new coding and payment for caregiver behavior management and modification training that could be furnished to the caregiver of an individual patient.

Non-chemotherapy Administration

In response to ongoing requests related to downcoding and restrictions on payment for non-chemotherapy complex infusion services, CMS proposed to include language consistent with CPT code definitions to state 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. In the Final Rule, CMS also reiterated statements from the Proposed Rule that the "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 for these infusion drugs. These services do involve serious patient risk which requires frequent consults with a physician or other qualified healthcare professional." In the Final Rule, CMS indicated it is finalizing revisions to the Internet-Only Manuals (IOM) Medicare Claims Processing Manual, Chapter 12, Section 30.5 to update guidance on complex non-chemotherapeutic drug administration as proposed. CMS indicated that it believes these changes will provide complex clinical characteristics for the MACs to consider as criteria when determining payment of claims for these services.

Evaluation and Management Visits

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

In response to prior stakeholder concerns regarding the narrow applicability of the O/O E/M Visit Complexity Add-on Code (HCPCS code G2211) that was included in the CY 2024 PFS Final Rule, CMS finalized policy to allow payment of the O/O E/M visit complexity add-on code when the O/O E/M base code[5] 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.

Enhanced Care Management

In the Final Rule, as part of a multi-year strategy, CMS stated that their aim is to strengthen care management code sets with the goal of better recognizing the elements of advanced primary care. Building from elements of Innovation Center models related to primary care, CMS finalized the establishment and adoption of coding and payment policies to recognize advanced primary care management (APCM) services, including patient-center risk stratification for billing Advanced Primary Care Management (APCM) codes, without modification from the Proposed Rule (i.e., HCPCS codes G0556, G0557, and G0558) which

[4] G0539 (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 G0540 (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 G0540 in conjunction with G0539)).
[5] O/O E/M base codes would be CPT 99202-99205, 99211-99215

are further described in the Final Rule (pg. 397-400). The codes and descriptors reflect all elements of services furnished during a month without specifying the amount of time that must be spent furnishing the services during the month. All elements within the scope of APCM services are listed in Table 25 of the Final Rule (pg. 442-443). In addition, the codes do not include time-related billing restrictions for the elements of the services. Also, CMS noted that it anticipates that all the APCM scope of service elements (e.g., comprehensive care management and core coordination) will be routinely provided for each patient but that not all elements may be necessary for every patient during each month. Table 27 of the Final Rule (pg. 512) includes the Final APCM Bundled Codes and Valuation.

In addition, among other policies related to APCM services, CMS finalized the "Performance Measurement" requirement as proposed and clarified that to satisfy this practice-level requirement, practitioners who are MIPS eligible clinicians must register for and report the Value in Primary Care MVP for the performance year in which they bill for APCM services. Also, a practitioner who is part of a Tax Identification Number (TIN) that is participating in a Shared Savings Program ACO or a REACH ACO, or in a Primary Care First or Making Care Primary practice would meet these requirements by virtue of meeting requirements under the Shared Savings Program or CMS Innovation Center ACO REACH, Making Primary Care Primary, or Primary Care First models.[6]

Strategies for Improving Global Surgery Payment Accuracy

As noted in the Final 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). Prior to the Final Rule, policies required 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.

Beginning for services furnished in CY 2025, CMS finalized policies to broaden the applicability of transfer of care modifier -54[7] for 90-day global packages as proposed. More specifically, for CY 2025, modifier -54 is required for all 90-day global surgical packages in any case where a practitioner plans to furnish only the surgical procedure portion of the global package, and CMS clarifies that this includes both formal and other transfers of care. However, CMS did not finalize any changes regarding the use of modifier -55[8] and modifier -56[9] for CY 2025. Rather, CMS provided that modifiers -55 and -56 will continue to be billed only in cases where there is a documented, formal transfer of care.

[6] CMS also clarified in the Final Rule that the practice-level performance measurement element of APCM services does not apply for practitioners who are not MIPS eligible clinicians (e.g., because they are newly enrolled or bill a low volume of services under Medicare).
[7] 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.
[8] 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.
[9] 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.

CMS also finalized with some modifications a new HCPCS code (HCPCS code G0559)[10] for a post-operative visit follow-up. In the Final Rule, in relation to the policy for reporting transfer of care modifier -54, CMS clarified that the new HCPCS code (G0559) is a mechanism to account for practice patterns that are already happening where practitioners are spending time and resources with patients who are seen for a post-operative visit and to ensure those practice patterns are accurately reflected in coding and payment policy. CMS indicated that it expects the add-on code will be reported with an office or other outpatient E/M visit for the evaluation and management of a new or established patient. Also, CMS expects that the cost would be billed only once per practitioner during the 90-day global period for the global package.

Advancing Access to Behavioral Health Services

In recent proposed rules (e.g., CY 2024 and CY 2025 PFS proposed rules), CMS sought comment on whether there is a need for separate coding and payment for interventions initiated or furnished in the emergency department (ED) or other crisis settings for patients with suicidal tendencies or at risk of suicide. As a result of feedback received and survey data, CMS finalized, with some modifications from the Proposed Rule, new coding and payment for Safety Planning Interventions (SPI) (HCPCS code G0560[11]) and an additional monthly code for Post-Discharge Telephonic Follow-up Contact Intervention (FCI) (HCPCS code G0544[12]). In the Final Rule, CMS responds to various stakeholder questions regarding when these codes may be billed, clarifying that the services described by HCPCS code G0544 may be provided by auxiliary personnel incident to the services of the billing practitioner in accordance with certain requirements, and that as applicable, Part B cost sharing would apply for HCPCS code G0544 (consent could be obtained either prior to, or during the initial phone call).

In addition, CMS finalized three new G-codes related to digital mental health treatment (DMHT) devices which were modeled on coding for Remote Therapeutic Monitoring (RTM) services. Specifically, CMS finalized 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: G0552[13] for furnishing a DMHT device. In addition, CMS finalized, with

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[10] HCPCS code G0559 ((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 the same or of a different specialty than the practitioner who performed the procedure, within the 90-day global period of the procedure(s), once per 90-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)).

[11] HCPCS code G0560: Safety planning interventions, each 20 minutes personally performed by the billing practitioner, including assisting the patient in the identification of the following personalized elements of a safety plan: recognizing warning signs of an impending suicidal or substance use-related crisis; employing internal coping strategies; utilizing social contacts and social settings as a means of distraction from suicidal thoughts or risky substance use; utilizing family members, significant others, caregivers, and/or friends to help resolve the crisis; contacting mental health or substance use disorder professionals or agencies; and making the environment safe.

[12] HCPCS code G0544: 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

[13] HCPCS code G0552: Supply of digital mental health treatment device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan)

refinements from the Proposed Rule, payment for HCPCS code G0553[14] and G0554[15], which should only be billed in cases where there is ongoing use of the DHMT device and should not be billed when the patient discontinues use of the DHMT device.

Also, CMS finalized six new G-codes (G05446-G0551[16]) related to interprofessional consultations.

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

In the Final Rule (pgs. 616-704), CMS outlines various policies and changes related to payment for dental services inextricably linked to specific covered services. To add clinical scenarios where dental services may be inextricably linked to covered services, a request must be made by February 10, 2025, via email at MedicarePhysicianFeeSchedule@cms.hhs.gov. Interested parties should include the words "dental recommendations for CY 2026 review" in the subject line of their email submission to facilitate processing.

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, and in the Final Rule, the agency clarifies policy, including clarifications for identifying

[14] HCPCS code G0553: 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 information related to the use of the DMHT device, including 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)

[15] HCPCS code G0554: 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 information related to the use of the DMHT device, including 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. (List separately in addition to HCPCS code G0553))

[16] G0546 (Interprofessional telephone/Internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a verbal and written report to the patient's treating/requesting practitioner; 5-10 minutes of medical consultative discussion and review), G0547 (Interprofessional telephone/Internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a verbal and written report to the patient's treating/requesting practitioner; 11-20 minutes of medical consultative discussion and review), G0548 (Interprofessional telephone/Internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a verbal and written report to the patient's treating/requesting practitioner; 21-30 minutes of medical consultative discussion and review), G0549 (Interprofessional telephone/Internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a verbal and written report to the patient's treating/requesting practitioner; 31 or more minutes of medical consultative discussion and review), G0550 (Interprofessional telephone/Internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a written report to the patient's treating/requesting practitioner, 5 minutes or more of medical consultative time), and G0551 (Interprofessional telephone/Internet/electronic health record referral service(s) provided by a treating/requesting practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, 30 minutes).

single-dose containers by including “single-patient-use container” as a package type terms and adding three types of products that may be considered refundable single-dose containers or single-use package drugs.

Regarding modifier use, CMS finalized the proposal 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. Also, CMS finalized that the JZ modifier is required if no drug amounts are discarded during preparation.

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 but not all 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”). CMS finalized policy as proposed that for purposes of calculating a payment limit for Part B drugs, where the agency will view positive manufacturers’ ASP data as “available”, and “not available” data includes negative or zero manufacturers’ ASP data. As a result, negative or zero ASP data will not be used in calculations for reimbursement purposes.

In the Final Rule, CMS provides additional clarity regarding a range of circumstances including:

- Single and multiple source drugs when negative or zero manufacturer’s ASP data is reported for some, but not all NDCs
- Multiple source drugs with only negative or zero manufacturer’s ASP data
- Single source drugs with only negative or zero manufacturer’s ASP data, excluding biosimilar biological products
- Biosimilars with only negative or zero manufacturer’s ASP data
    - Notably, CMS finalized a policy different than proposed, opting for a second alternative policy described in the Proposed Rule. Also, CMS clarified that it will not consider the manufacturer’s ASP data of other biosimilars with the same reference product.
- Discontinued drugs

Payment of Radiopharmaceuticals in the Physician Office

CMS finalized policy that for radiopharmaceuticals furnished in a setting other than the hospital outpatient department that MACs shall determine payment limits for radiopharmaceuticals. MACs may base payment limits on any methodology (including invoice-based pricing) used to determine payment limits for radiopharmaceuticals in place on or prior to November 2003.

Immunosuppressive Therapy

CMS finalized as proposed policy 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.

Also, CMS finalized as proposed to allow payment of a supplying fee for a prescription of a supply of up to 90 days and to allow refills for an immunosuppressive drug based on the individual circumstance of the beneficiary in accordance with applicable State laws.

CMS also clarifies that stem cells are included in the meaning of a "tissue" as provided in regulation, and the individuals who receive stem cell transplants are eligible for the immunosuppressive therapy benefit.

Blood Clotting Factors

CMS finalized policy to clarify that blood clotting factors must be self-administered to be considered clotting factors for which the furnishing fee applies. Additionally, CMS clarifies that therapies that enable the body to produce clotting factors and do not directly integrate into the coagulation cascade are not themselves clotting factors for which the furnishing fee applies. Lastly, CMS clarifies 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 though another payment system, including the PFS.

Medicare Part B Payment for Preventive Services

Tables 51 and 52 of the Final Rule (pg. 1490-1491) include the CY 2025 payment rates for the vaccine administration services codes (HCPCS codes G0008, G0009, and G0010), at-home vaccine administration (HCPCS code M0201), hepatitis B vaccines, and pricing for COVID-19 vaccine and monoclonal antibodies.

CMS also finalized the proposal to expand the list of individuals who are determined to be at high or intermediate risk of contracting hepatitis B. As a result, hepatitis B vaccination coverage would be expanded to individuals who have not previously received a completed hepatitis B vaccination series and individuals whose previous vaccination history is unknown.

In addition, CMS finalized policy to expand coverage for colorectal cancer screening and added coverage for the computed tomography colonography procedure.

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 of the Department of Health and Human Services 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 Final Rule, CMS established a fee schedule to determine the payment limits for drugs covered as an additional preventive service (DCAPS) under Part B. The need to establish a fee schedule was prompted by a recent National Coverage Determination for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention where CMS would cover and pay for those drugs as an additional preventive service. The payment limits

for DCAPS drugs would depend on the following pricing mechanisms, which would be updated quarterly:

1. If ASP data is available for the DCAPS drug, the payment limit would be determined based on the methodology under section 1847A(b) of the Act (usually 106 percent of ASP);
2. If ASP data is not available, the payment limit would be calculated using NADAC prices for the drug;
3. If ASP data and NADAC prices are not available, the payment limit would be calculated using the FSS prices for the drug; and
4. If ASP data, NADAC prices, and FSS prices are not available, payment limit would be the invoice price determined by the MAC.

Also, CMS notes DCAPS drugs and the services to administer and supply them are paid at 100 percent of the Medicare payment amount, that is, the amounts on the DCAPS fee schedule.

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 proposed to use different methodologies to calculate inflation rebates for Part B rebatable drugs and Part D rebatable drugs.

While CMS finalized policy mostly as proposed, it is notable that the agency did not finalize a policy related to Part D to estimate the total number of products for which the manufacturer provides a discount under the 340B program. Instead, CMS will explore excluding from the total number of units for a Part D rebatable drug those units for which a manufacturer provides a discount under the 340B Program starting January 1, 2026, through the establishment of a Medicare Part D claims data repository.

In addition, CMS finalized policy to reduce the rebate amount when there is a severe supply chain disruption.

What's Next?

The PFS tables for this CY 2025 Final Rule are available on the CMS website. Most provisions in the Final Rule go into effect January 1, 2025.

Vizient's Office of Public Policy and Government Relations is happy to answer any questions you may have about provisions in this Final Rule. Please direct your feedback to Jenna Stern, Associate Vice President, Regulatory Affairs and Public Policy, in Vizient's Washington, D.C. office.