

UPDATES

CMS Issues Key Medicare Payment Policy Final Rules for Calendar Year 2025

November 7, 2024

On November 1, 2024, the Centers for Medicare & Medicaid Services (CMS) issued the Calendar Year (CY) 2025 Physician Fee Schedule (PFS) Final Rule (the “PFS Final Rule”) and the CY 2025 Hospital Outpatient Prospective Payment System (OPPS) Final Rule (the “OPPS Final Rule”). These rules contain a number of updates to payment policies that may significantly impact various stakeholders, including pharmaceutical manufacturers and telehealth providers.

For a look at a Sidley Update regarding the Inflation Reduction Act inflation rebates found in the PFS Final Rule, please visit our dedicated client alert [here](#).

Both the PFS Final Rule and the OPPS Final Rule are effective January 1, 2025. We address each rule in turn below.

PFS Final Rule

Overpayments Under Parts A and B

The PFS Final Rule includes revisions that implement an exception to the timeline for identifying and reporting overpayments. Under existing Medicare regulations, individuals who have received an overpayment must report and return it by the later of two dates: (i) 60 days after the overpayment is identified; or (ii) the due date of any corresponding cost report. As part of the PFS Final Rule, CMS finalized an exception to this deadline that affords greater flexibility in common place circumstances for recipients of overpayments where: (1) a person has identified an overpayment, but has not yet completed a good-faith investigation to determine the existence of related overpayments that may arise from the same or similar cause or reason as the initially identified overpayment, and (2) the person conducts a timely, good-faith investigation to determine whether related overpayments exist. In response to comments requesting CMS to define “good-faith” and “timely,” CMS stated that the commenters can rely upon the “plain meaning of those terms.”

If the finalized conditions for the exception are met, the obligation to return the initially identified overpayment and any related payments will be suspended until the earlier of: (i) the conclusion of the investigation into related overpayments and the calculation of the aggregate amount of the initially identified and related overpayments or (ii) 180 days after the date the overpayment was identified.

Digital Therapeutics

In a significant win for the digital therapeutics community, CMS finalized in the PFS Final Rule three new Healthcare Common Procedure Coding System (HCPCS) codes for digital mental health treatment (DMHT) devices furnished incident to the billing practitioner's professional services in association with ongoing behavioral health treatment under a plan of care by the billing practitioner:

- G0552 – Supply of DMHT device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan
- G0553 – First 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the DMHT device that augments a behavioral therapy plan, physician/other qualified healthcare 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
- G0554 – Each additional 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the DMHT device that augments a behavioral therapy plan, physician/other qualified healthcare 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

The DMHT devices available for reimbursement under these codes are required to have been cleared under section 510(k) of the Food, Drug, and Cosmetic Act (FD&C Act) or granted De Novo authorization by the Food and Drug Administration (FDA) and classified under FDA regulations for mental or behavioral health treatment. The DMHT devices may be used by the patient at home or in an office or other outpatient setting, if that is how the DMHT device has been classified by FDA for use under applicable regulations.

Physicians and practitioners authorized to furnish services for the diagnosis and treatment of mental illness may use HCPCS code G0552 for the supply of the DMHT device and initial education and onboarding. HCPCS codes G0553 and G0554 may be billed for monthly treatment management services related to the patient's use of the DMHT device. CMS also finalized its proposal for contractor pricing for G0552 and for valuing G0553 and G0554 based on a direct crosswalk to the CPT codes for remote therapeutic monitoring. This will provide a critical reimbursement pathway for applicable DMHT devices. However, many commenters sought a broader applicability of products that could be used with these codes, such as differing FDA approval status or applicability to any digital health product related to behavioral health.

Discarded Drug Refund Program

CMS finalized updates to the definition of "refundable single-dose container or single-use package drugs" under the Discarded Drug Refund Program. Under current regulations, the definition of "refundable single-dose container or single-use package drugs" excludes drugs for which payment has been made under Medicare Part B for fewer than 18 months, and CMS looks to the first date of sale to identify the beginning of the 18-month exclusion period. In the PFS Final Rule, CMS stated that it will instead use the date on which the drug is actually paid under Medicare Part B *if* the date of first sale as reported to CMS does not adequately approximate the first date of payment under Part B due to an

applicable National Coverage Determination.

CMS further finalized its proposal to amend the definition of “refundable single-dose container or single-use package drug” to include “single-patient-use container” as a package type term and to add the following three types of products to the scope of the definition:

- (1) products furnished from a single-dose container or single-use package based on FDA-approved labeling or product information;
- (2) products furnished from an ampule for which product labeling does not have a discard statement or language indicating the package type term, like “single-dose container,” “single-use package,” “multiple-dose container,” or “single-patient-use container”; and
- (3) products furnished from a container with a total labeled volume 2 ml or less for which product labeling does not have language indicating the package type term, like “single-dose container,” “single-use package,” “multiple-dose container,” or “single-patient-use container.”

Skin Substitutes

In the PFS Final Rule, CMS finalized its proposal to continue its policy of not considering skin substitutes refundable drugs under the Discarded Drug Refund Program “for calendar quarters in 2025.” CMS stated that the agency is “not establishing skin substitutes as exempt from the discarded drug refund policy for all future years, as [CMS] plan[s] to revisit the refund obligations for skin substitutes in future rulemaking.” CMS further stated that the agency continues “to consider making changes to the Medicare Part B payment policies for [skin substitute] products.”

Although CMS did not make any specific payment proposals for skin substitutes in the CY 2025 PFS Proposed Rule, the agency stated in the PFS Final Rule that it seeks to develop a “consistent payment mechanism” for skin substitutes and noted that it continues to examine ways that skin substitutes could be treated as “incident-to supplies” under the PFS rate-setting methodology. CMS also acknowledged input and comments received from stakeholders, stating that the agency “believe[s] continuing this dialogue with interested parties on payment for skin substitute products will help inform potential policy changes for future rulemaking.”

Blood Clotting Factors

CMS finalized an update to the regulations for the blood clotting factor furnishing fee to state that blood clotting factors, which are covered under Medicare Part B, must be self-administered in order to be eligible for the furnishing fee.

CMS explicitly stated its position that gene therapies used to treat patients with hemophilia do not constitute clotting factors because such therapies are not self-administered by the patient, but rather, typically administered via a one-time, single-dose intravenous infusion in a setting where personnel and equipment are immediately available to treat infusion-related reactions. Further, CMS noted that gene therapies function through a different mechanism of action than clotting factors. In particular, CMS stated that clotting factors are directly integrated into the coagulation cascade to restore the function of missing activated Factor VIII and infuse clotting factors into the body, whereas gene therapies enable the body to produce its own clotting factors.

Though there are statutory arguments to the contrary, CMS stated its belief that, even if gene therapies met the definition of a clotting factor, they still would not be eligible for the furnishing fee because the costs associated with furnishing such therapies are already reflected in the applicable administration codes paid under the PFS. Under the PFS Final Rule, CMS states that gene therapies used for the treatment of hemophilia are eligible for payment as drugs or biologicals under Part B, but are not considered clotting factors for which the furnishing fee applies.

Telehealth Flexibilities

As set forth in the Consolidated Appropriations Act of 2023, the geographic location and site of service restrictions on Medicare telehealth services that had previously been suspended as a result of the COVID-19 PHE will resume on January 1, 2025. As a result, most Medicare telehealth services will only be available for patients in rural areas and only when the patients are located in certain medical settings. In the PFS Final Rule, CMS acknowledged that the revocation of telehealth flexibilities raises access to care concerns and finalized proposals aimed at mitigating such concerns. These mitigation efforts include:

- *Review of Telehealth Services List.* CMS finalized its proposal to continue maintaining Medicare coverage for the following telehealth services on a provisional basis through 2025: caregiver training, cardiovascular and pulmonary rehabilitation, health and well-being coaching; psychological testing and developmental testing; and therapy/audiology/speech language pathology. CMS stated that it did not consider whether to recategorize these provisional codes as permanent because the agency will conduct a comprehensive analysis of all provisional codes in future rulemaking.

CMS further added preexposure Prophylaxis of HIV permanently to the list of Medicare-covered telehealth services, and also extended the suspension of telehealth frequency limits on subsequent inpatient and nursing facility visits and critical care consultations through 2025. CMS did not finalize proposals to include continuous glucose monitoring; or posterior tibial nerve stimulation for voiding dysfunction, radiation treatment monitoring, home International Normalized Ratio monitoring on the list of Medicare-covered telehealth services.

- *Permitting Audio-Only Telehealth Visits in Beneficiary's Homes.* CMS finalized its proposal to amend the definition of "interactive telecommunications system" to include audio-only communications for telehealth services furnished to beneficiaries in their homes if the provider is capable of providing video communication, but the beneficiary is not capable of, or does not consent to, the use of video. In these circumstances, providers will have to include a "93" or "FQ" modifier on claims.

Direct Supervision Requirements

Reimbursement for certain professional services, including diagnostic tests, pulmonary rehabilitation services, cardiac rehabilitation and intensive cardiac rehabilitation services, and certain hospital outpatient services and incident-to-services under Medicare Part B requires these services to be furnished under one of three levels of supervision: general, direct, or personal. Historically, "direct supervision" required the supervising physician to be physically present in the office suite and immediately available to assist throughout performance of the service. Since the COVID-19 PHE, CMS

has permitted “direct supervision” to be furnished through audio/video real-time communications technology if the supervising physician would still be “immediately available.”

In the PFS Final Rule, CMS extends this flexibility “only” through 2025. However, CMS also finalized its proposal to extend this flexibility permanently for certain “inherently lower risk” services. CMS defines “low risk” as “services that do not ordinarily require the presence of the billing practitioner, do not require direction by the supervising practitioner to the same degree as other services furnished under direct supervision, and are not services typically performed directly by the supervising practitioner.”

Payment Limit Calculations for Negative or Zero ASP Data Reported to CMS

In the PFS Final Rule, CMS finalized its approach to calculating payment limits when manufacturers report negative or zero Average Sales Price (ASP) data to CMS. CMS will consider negative and zero ASP as “not available” under section 1847A(c)(5)(B) of the Act and positive ASP data as available. When ASP data is not available, the payment limit will vary based on factors about the drug or biological, such as whether the drug is single source or multiple source; whether some, but not all National Drug Codes (NDCs) for a billing and payment code have a negative or zero ASP data, or all NDCs for a billing and payment code have a negative or zero ASP data; and whether relevant applications for all NDCs for a billing and payment code have a marketing status of discontinued.

For biosimilars, the payment limit calculation will be determined using the biosimilar’s own, most recently available positive manufacturer’s ASP data.

OPPS Final Rule

Radiopharmaceuticals

In the OPPS Final Rule, CMS finalized its proposal to establish separate payment for diagnostic radiopharmaceuticals with a per-day cost greater than \$630 beginning in 2025. Payment for such diagnostic radiopharmaceuticals will be based on the mean unit cost (MUC) of each product. CMS stated their position that MUC is an appropriate proxy for the ASP for a diagnostic radiopharmaceutical in a given year because MUC is calculated based on the average costs for a particular year and is directly reflective of the actual cost data that hospitals submit to CMS. CMS noted that the agency does not receive ASP for all diagnostic radiopharmaceuticals and expressed concerns about the accuracy of ASP where it does receive such reporting, and rejected requests from commenters that it use ASP data to determine the reimbursement rate where applicable. CMS encouraged manufacturers to submit ASP data for potential future use in diagnostic radiopharmaceutical reimbursement. CMS will continue to reimburse diagnostic radiopharmaceuticals with a per-day cost at or below \$630 under the current policy of packaging the cost into the payment for the nuclear medicine test.

CMS also finalized its proposal to establish an add-on payment of \$10 per dose for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99, beginning on January 1, 2026. In response to commenters’ suggestions for how to establish requirements to determine that a Tc-99m radiopharmaceutical is domestically produced and to concerns that manufacturers will use a mix of foreign and domestically produced Mo-99, CMS stated that the Department of Energy National Nuclear Security Administration is currently developing criteria to certify whether a Tc-99m dose is domestically produced and eligible for the add-on payment. CMS intends to consider in future rulemaking additional requirements for Medicare providers to document that the

Tc-99m radiopharmaceutical used in a procedure was domestically produced and therefore eligible for the add-on payment.

Skin Substitutes

In the OPPS Final Rule, CMS rejected a recommendation by the Advisory Panel on Hospital Outpatient Payment (the HOP Panel) that CMS end its policy of packaging graft skin substitute administration add-on codes, which essentially bundles the administration and product costs associated with graft skin substitutes.

In response to comments arguing that the packaging policy discourages providers from treating wounds in the outpatient hospital setting, does not promote payment accuracy, and does not fully compensate providers for the extra costs incurred in treating larger wounds, CMS stated that the packaged payment sufficiently accounts for the variation in product use, and that the policy is intended to “encourage[] efficiencies and cost-savings in the administration of health care.” CMS stated its belief that skin substitutes are no different from other procedures administered in the outpatient hospital setting with respect to “the need for cost efficiencies.”

Additionally, consistent with prior CMS policies addressing the classification of “high-cost” and “low-cost” skin substitute products, CMS finalized its proposal to continue assigning each skin substitute that exceeds either the MUC or the per-day cost (PDC) threshold to the high-cost group, and to assign any skin substitute that does not exceed either the MUC or the PDC threshold to the low-cost group, except that any skin substitute that was assigned to the high-cost group in CY 2024 is assigned to the high-cost group for CY 2025, regardless of whether it exceeds or falls below the CY 2025 MUC or PDC threshold. CMS also stated the following with respect to its determination of the applicable category for a skin substitute: (i) CMS assigns products with pass-through payment status to the high-cost group; (ii) CMS uses claims data to determine the cost of the relevant products; and (iii) for products with pricing information but without claims data, CMS determines cost using one of the following methodologies: ASP + 6%, wholesale acquisition cost (WAC) + 3% (if ASP is not available), or 95% of average wholesale price (if neither ASP nor WAC is available).

CMS also responded to a comment that advocated for allowing skin substitute products that have received FDA approval through either the Premarket Approval (PMA), Biologics License Application (BLA), or New Drug Application (NDA) process to be separately payable at a rate of ASP + 6%, instead of being packaged in the OPPS. CMS rejected that suggestion, stating its position that “skin substitute products that have either a PMA, BLA, or NDA are still considered to be supplies” under the agency’s policy that “unconditionally package[s] skin substitute products into their associated surgical procedures as part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure.”

Cell and Gene Therapies

In the OPPS Final Rule, CMS finalized its proposal to exclude various cell and gene therapies from Comprehensive APC (C-APC) packaging based on its stated belief that the cell and gene therapies are not “promoting a beneficial outcome for any of the primary C-APC services themselves,” but instead “serving as independent therapies” for CY 2025 and all subsequent years. This exclusion will allow for separate reimbursement of specified cell and gene therapies, recognizing their unique therapeutic value

and ensuring healthcare providers are appropriately compensated for their use.

CMS stated that it will continue to add product-specific HCPCS codes of “new cell and gene therapies that are not integral, ancillary, supportive, dependent, or adjunctive to a C-APC service” to the C-APC exclusion list.

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